CW+ ChemicalRiskManager
The hub for product safety resources

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

Global Service Providers Guide 2017

A guide to global chemicals management and control services

sponsored by

knoell
worldwide registration

Expert advice for your global markets

knoell worldwide registration

Are you in need of a clear picture about the global trends in chemical policies? Here comes a conference dedicated to bring you some relief!

We will provide an overview about chemical legislations and regulatory procedures in numerous important markets in the Americas and the Asia-Pacific region.

Topics include:

- Registration and evaluation of chemicals in Korea
- Management of chemicals in China and Taiwan
- Reform of the Toxic Substance Control Act (TSCA) in the USA
- New substance notification in Canada
- Chemical regulations in ASEAN countries
- Regulations in Central and South America
- Chemical Regulation in Turkey
- Update on the Japanese CSCL

Chemical Control Regulations in Asia and the Americas

Register now!
Cologne – June 27, 2017

Dr. Knoell Consult GmbH
Dr. Michael Cleuvers
Managing Director
Industrial Chemicals & Biocides
Tel. +49 214 20658-170
globalregistration@knoell.com

www.knoell.com

Foreword

Welcome to the 2017 Global Service Providers Guide, from Chemical Watch and Chemical Risk Manager.

It is ten years since the launch of Chemical Watch, and the seventh year of this guide – which combines our annual reader survey, with in depth research carried out by our team of journalists and articles contributed by a number of service providers.

With the final REACH registration deadline in 2018 looming in Europe, and reform of US TSCA, this year's guide includes two special articles, as well as the usual reports on market drivers, salaries and careers, and outlook. The first drills down into the latest approaches to testing chemicals; and the second looks in-depth at the US market.

In addition, we have included contributed articles on environmental management information systems, the latest approaches to identifying endocrine disrupting chemicals, advice for downstream users and, with a nod to the REACH 2018 deadline, how to avoid the use of animal testing.

It is clear from this year's guide, that professionals working in the chemicals management and controls field don't have it easy. There are constant challenges – from the assessment of a substance's hazards, uses and exposures, to its risk characterisation, through to the management of identified risks, across the workplace, in the supply chain, or at the consumer end.

With potential impacts on human health and environmental, as well as companies' liabilities and reputation, there is a huge pressure for people working in this area to get it right – often at minimal cost and under time pressure.

As mentioned earlier, Chemical Watch is celebrating its tenth anniversary – and it is the first anniversary of our new offering Chemical Risk Manager, which aims to provide practical information and tools to facilitate the work of professionals working in the field.

As such, Chemical Risk Manager should be a platform for service providers and those working in house on chemicals compliance, complementing the Service Providers Guide with real-time news and resources. I'd like to take this opportunity to invite readers to work with us to build CRM and create a proactive, dynamic community around the service provision industry.

This year's guide contains 416 companies, and almost 900 chemicals management and control professionals responded to our survey – all signs of a vibrant community, keen to interact.

Emma Chynoweth
Managing Editor

ACTA®

ASIA
EUROPE
THE AMERICAS

Global Chemical Product Innovation and Development®

A scientific and regulatory consulting firm providing strategic, comprehensive support for global chemical registration, regulation, and sustained compliance.

- **Global Chemical Notification and Regulatory Support**
  (North and South America, Europe, Asia)
- **Biocides, Pesticides, Antimicrobials, Nanomaterials, Food Contact, Cosmetics**
- **Hazard Communication, GHS Classification and Labelling, SDS**
- **Global Agent and Representative Services**
- **Testing Strategy and Co-ordination**
- **Toxicology & Ecotoxicology**
- **Transport of Dangerous Goods**
- **Dossier Preparation and Expert Review**
- **Data Compensation**

www.actagroup.com

Beijing, China
(86-10) 8453-4538

Manchester, U.K.
+44 (0) 330 223 0610

Washington, D.C.
+1 (202) 266-5020

Contents

Contents

ChemicalWatch

CW Research Ltd, trading as Chemical Watch, publishes news and intelligence to help companies achieve sound chemicals management that responds to the many non-regulatory drivers as well as meeting responsibilities under chemicals legislation worldwide, including regimes such as REACH, CLP, GHS and TSCA. We keep you abreast of policy and business trends across the EU, North America, Asia and the rest of the world. Because we are not tied to any trade associations, government or campaign group, we are able to offer objective news and analysis for all sectors.

CW Research Ltd, Talbot House, Market Street, Shrewsbury, SY1 1LG, UK
Tel: +44 (0)1743 818 101
Fax: +44 (0)1743 818 121
email: cw.enquiries@chemicalwatch.com
www.chemicalwatch.com
US office: +1 (202) 803 5869

Director & co-founder
Mamta Patel
mamta.patel@chemicalwatch.com

Director & co-founder
Julian Rose,
julian.rose@chemicalwatch.com

Operations director
Stuart Foxon,
stuart.foxon@chemicalwatch.com

Managing editor
Emma Chynoweth,
emma.chynoweth@chemicalwatch.com

Sales & marketing director
Richard Butterworth,
richard.butterworth@chemicalwatch.com

Publishing manager
Henry Tipping,
henry.tipping@chemicalwatch.com

Writers
Elaine Burridge, Catherine Cooney, Cynthia Challener and Keri Allen

Contributing editors
Sarah Thompson, Andrew Turley and Vanessa Zainzinger

Production
Nick Hazlewood,
nick.hazlewood@chemicalwatch.com

Marketing Manager
Sarah Scott,
sarah.scott@chemicalwatch.com

Account managers
Sonja Davidson,
sonja.davidson@chemicalwatch.com

Geraldine Gaffney,
geraldine.gaffney@chemicalwatch.com

Lotte Spencer,
lotte.spencer@chemicalwatch.com

Kerry Williamson,
kerry.williamson@chemicalwatch.com

Designer
Harrison Tanner,
harrison.tanner@chemicalwatch.com

Designed and typeset by Ministry of Design, Bath, UK
www.ministryofdesign.co.uk

Printed by Trident Printing, London.

Printed on 9 Lives 80 recycled stock.

First published 2017

All photos Fotolia.com (page) 7: © namming, 39: © stockphoto-graf, 43: © warloka79, 46: © torwaiphoto, 51: © kimtaro2008.

TRADE WIND

MORE THAN CHEMICAL SAFETY ONLY!

ARE YOU IN NEED OF:

- **Software to create your SDSs, Volume Tracking, Worker Exposures, Incident Management, or Maintenance?**
- **A solution to distribute your SDSs to your customers?**
- **A reliable partner to draft and translate your SDSs?**

With ExESS you can

- Create your SDSs and Labels according CLP and all worldwide GHS-dialects in over 40 languages. We just need your formulations, supplier SDS's and physical properties
- Draft Workplace Instruction Cards and any other document you may require
- Comply with the Detergent Directive (EC) 648/2004
- Distribute SDSs to your customers with full tracking and automatic distribution of updates
- Communicate with your ERP

DeDoks will

- Distribute your (multilingual) SDSs to your customers
- Send new versions automatically
- Publish your SDSs on your website with a multi-language interface
- Allow you to include other documents
- Enable your distributors to distribute your SDSs to their customers
- Interface with your ERP through FTP- or Webservice
- Work without any local installation (Webbased)

If you don't want to do the work yourself, we can

- Create your SDSs and Labels according CLP and all worldwide GHS-dialects in over 40 languages. We just need your formulations, supplier SDS's and physical properties
- Draft Workplace Instruction Cards and any other document you may require
- Comply with the Detergent Directive (EC) 648/2004
- Distribute SDSs to your customers with full tracking and automatic distribution of updates

Would you like more information? Please contact us:

Trade Wind B.V.
Haagsche Hof
Parkstraat 83
2514 JG The Hague
The Netherlands

T: +31 (0) 70 - 214 13 40
F: +31 (0) 84 - 747 24 99
M.: +31 6 5319 2758
E: info@twnl.com
W: www.twnl.com

Chemicals Management and Control

INTRODUCTION

Strong demand for chemical management and control activities shows no sign of abating, according to the seventh edition of our annual Service Providers Guide. Regulations in the EU, the US and Asia, and the UN Globally Harmonized System of classification and labelling, are all driving the work of in-house teams and external service providers.

What is striking in this year's guide is a big increase in the numbers of companies taking a profile (up 20% on 2016); and the numbers responding to the surveys. The high interest could reflect a buoyancy in the market; but whether that will continue in the long term – especially after the final REACH registration deadline next year – remains to be seen. Certainly, people responding to the survey are optimistic.

Overall, half of respondents plan to increase the number of staff working on chemical compliance in the next 12 months. And two thirds will do so over the next five years. Similar numbers will increase their use of external service providers over the two timeframes.

Unsurprisingly, the 2018 REACH deadline remains the number one driver of work, with 69% citing it.

The deadline, for low volume chemicals, is impacting more small- and medium-sized enterprises (SMEs). Many do not have the capacity to deal with issues like substance identity and data, and are seeking support from service providers. Laboratory capacity, both in-house and at contract research organisations (CROs), is also reported to be in short supply.

Uncertainty surrounding Brexit is an issue for UK REACH service providers. With a high proportion of 2010 and 2013 registrations coming from UK-based registrants, including only representatives, many companies will be affected by the decision to leave the EU.

In addition to registration, survey respondents say other provisions of REACH, such as those dealing with substances of very high concern, substance evaluation, and dossier updates will drive demand.

Opinion seems divided as to whether this work will significantly influence the market after the 2018. Some believe there will a backlog of poorly-prepared dossiers that will require updating after the deadline.

The EU's classification, labelling and packaging Regulation is also a significant factor, as is GHS implementation elsewhere.

Around half of people responding to the survey mention at least one US-based regulation. The US EPA Work Plan on Chemicals tops the list, followed by California's Safer Consumer Products regulation.

The survey was launched after the US presidential election and it seems the new administration is likely to follow a deregulatory agenda. However, the survey indicates respondents believe the work required under the Lautenberg Chemical Safety Act (LCSA) – the reformed TSCA – will continue to drive demand. If this turns out not to be the case, activity at state level in the US may well be stepped up to fill the void.

Consultants in the US report helping their clients track how TSCA reforms apply to specific substances, and are assisting in the development of strategies specific to companies' portfolios.

In Asia, China and South Korea remain the focus of activities, with a third and a quarter of respondents respectively saying regulations in these countries are the main drivers. Japan and Taiwan are next highest.

As well as overarching chemicals regulations – like REACH, LCSA and K-REACH – more specific controls and market pressures are fuelling demand for chemicals control. Legislation such as the EU's biocidal products Regulation (BPR) or the restriction of hazardous substances (RoHS) in electronic and electrical equipment – which has many variations globally – are cited.

Consumer-facing companies are also stepping up activities on chemicals management. Service providers note that a lot of work is strategic, with clients trying to ensure nothing happens to their brand's reputation. They also appear to be prepared to look deeper than just checking what chemicals are in a product; many are banning certain substances and working with suppliers on substitutes.

Off the back of this strong demand, more people responding to this year's survey expect to increase the numbers of staff employed in chemicals management and control over the next 12 months. Job security is at a similar level to last year, while the overall level of job satisfaction has increased. Average salary levels have declined slightly.

While two thirds of respondents are are satisfied with their experience of service providers, this figure is down slightly on last year. Nearly 60% say they may possibly change suppliers in 2017, a similar level to last year's survey.

Around a half of respondents say demand for external services and in-house staff will increase over the next 12 months; few say the demand will decrease.

Many companies interviewed say the future is not clear, partly because of the unstable business climate in many markets. However, they do believe that EU REACH – the biggest regulatory driver over the past decade – will have a knock-on effect globally. Already that is being seen in several Asian countries, but companies say it will not end there, as countries in the Middle East, Africa, Latin America, as well as more countries in Asia, follow suit.

Despite some uncertainty in the world at present, it appears that those working in the field of sound chemicals management see there is a job to be done, one that needs proper resources and skills. While the upcoming EU REACH deadline is at the forefront of activity, the survey results show just how global chemicals management is becoming, and how activities are spreading down the supply chain.

SHAPING YOUR **BUSINESS TO SUCCEED** BEYOND **2018**

OUR **SUPPORT**

REACHLaw's unique compliance solutions help us solve your most pressing chemical regulatory challenges. As a leading expert in the registration of chemical substances, we ensure that our clients fulfill all the EU REACH registration and authorisation requirements, as well as requirements for regulations outside the EU.

- **REACH** REGISTRATIONS
- **LEAD** REGISTRATIONS
- **AUTHORISATION** SERVICES
- **GLOBAL** NOTIFICATIONS
- **ADVOCACY** SERVICES

REACHLAW

FINLAND / BELGIUM / TURKEY / INDIA
REACHLaw Ltd. HQ: Vänrikinkuja 3 JK 21, FI-02600 Espoo, Finland
+358 (0)9 412 3055, sales@reachlaw.fi

www.reachlaw.fi

REACH still main driver, as 2018 deadline approaches

Given its dominance in previous years, it will come as no surprise that REACH remains the top regulatory driver in this latest Chemical Watch survey, with 85% of respondents citing it as the leading focus of attention **[Figure 1]**.

The second primary driver is the REACH 2018 registration deadline, which is the main concern for 69% of those that participated in the poll. Meeting the 31 May 2018 deadline – which covers substances produced in volumes of 1 to 100 tonnes/year – is posing significant challenges.

Zameer Qureshi, legal consultant with The Acta Group EU, the consulting affiliate of US law firm Bergeson & Campbell, says the deadline is presenting numerous problems for companies across the globe. "Many corporations have far more substances to register under the 2018 deadline than earlier REACH deadlines and must either address compliance in-house or engage suitable regulatory personnel," he says. "Both approaches can involve problematic levels of effort and expenditure, particularly for small- and medium-sized enterprises (SMEs)."

Manufacturers, importers, and only representatives (ORs) face challenges concerning substance identity, testing, legalities, substance information exchange forum (Sief) management and data sharing. According to Mr Qureshi, REACH registrants must spend time and money on evaluating supply chains to determine substances that must be registered, find appropriate Siefs for the relevant substances and prepare sufficiently robust and scientifically sound registration dossiers. "Limited laboratory capacity, both in-house and at contract research organisations (CROs), represents a notable challenge in terms of organising the testing needed to support registrations," he says.

To ensure legal certainty, he advises companies to task 'suitable' personnel with managing all legal aspects of REACH registration, including development and review of Siefs and cooperation agreements, and substantiation of letter of access (LoA) costs. He notes that this measure has been difficult for some registrants due to budget constraints, with lead registrants in particular facing significantly challenging Sief management obligations that include supporting transparency in developing LoA costs and communicating with registrants and potential registrants.

Costs and a lack of cooperation are a big issue for clients of German chemical compliance company KFT Chemieservice. Dr Karl-Franz Torges, KFT's managing partner, says the biggest difficulty for 2018 is a lack of cooperation or communication from lead registrants. He says there are cases where they do not supply prices for LoAs, which is hindering customers that want to register. "This means the new regulation concerning data sharing has not had any attention paid to it," says Dr Torges. Echa released a full revision of its guidance on data sharing in November 2016, one aspect of which was clarification on cost-sharing mechanisms.

Mr Qureshi notes that in addition to managing data sharing in a "fair, transparent and non-discriminatory" way, registrants must now also consider Commission Implementing Regulation (EU) 2016/9, which aims to support transparency and fairness. "Despite the European Commission's good intentions in enacting the Implementing Regulation, its detailed requirements are burdensome for many," he says.

Unlike the two previous REACH deadlines, the challenges this time around will be quite different in terms of both the number of registrations and the type of registrants, says Dr Michael Piber, managing director of German consultancy Arcerion. He expects that up to 70,000 registrations will be prepared for 2018, which is three times more than either of the prior deadlines. "Many of the registrants are expected to be inexperienced and located outside the chemical sector, and there will be more SMEs. The new Siefs will also be small or even consist of only a single company, while at the same time, there will be less information available on the substances to be registered," Dr Piber says.

UL Supply Chain & Sustainability offers

INNOVATIVE SOLUTIONS

TO HELP GLOBAL CHEMICAL COMPANIES WITH DIVERSE REGULATORY DEMANDS

UL offers right-sized, innovative solutions for chemical regulatory demands. From WERCS Studio automated or fully configurable software programs to global, personal regulatory assurance advice, UL has the services to satisfy your needs.

And now, UL is redefining REACH compliance with REACH Across, an in silico tool that combines the best aspects of QSAR and read-across approaches.

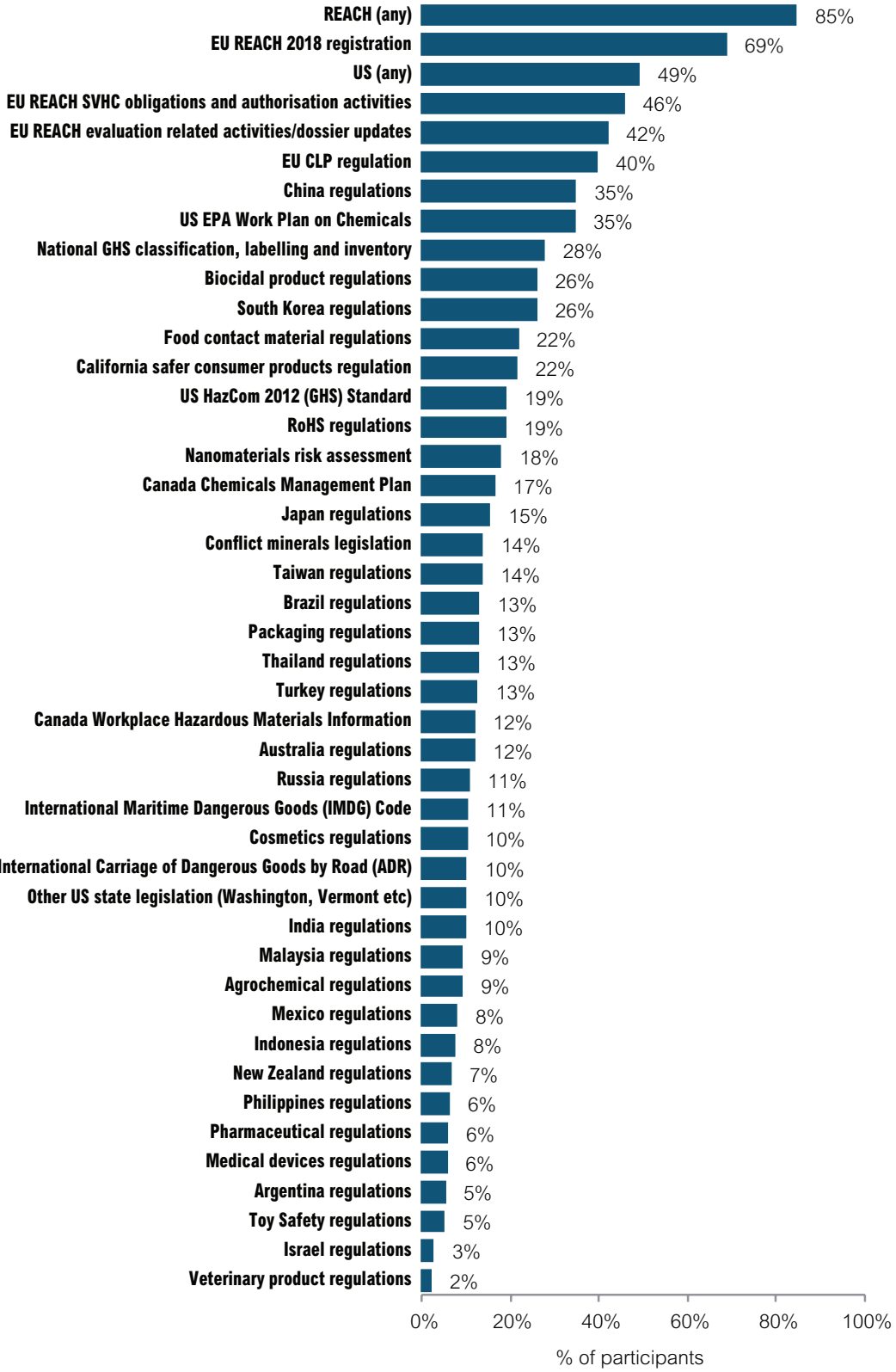
Featuring more than 100 million chemical structures, the tool will provide a new approach to REACH compliance to help companies meet regulatory deadlines.

LEARN MORE >>
ulscs.com/cwatch

SEE MORE >>
Chemical Watch Expo 2017
Stand 13 & 14
April 25-26 | Berlin

Figure 1

LEADING REGULATORY DRIVERS FOR SURVEY PARTICIPANTS



Dr Piber is urging companies to start preparations as early as possible, given that assessing all affected substances, comprehensively collecting the uses of the downstream users or obtaining analytical information on substances and preparations from suppliers can be quite time consuming and "bothersome".

He highlights two "potentially challenging" situations that need to be addressed by the deadline. Importers or manufacturers intending to submit a joint registration where the current dossier does not cover all uses of their downstream users, as well as registrants where no joint submission is available, need to be aware that they may need to create their own chemical safety report (for substances above ten tonnes a year).

Global environmental testing CRO, Smithers Viscient, says some of its clients, mostly SMEs, are generally unaware of their obligations under the REACH deadline. Besides, they lack a proper understanding of the tonnage

VERDANT

SUSTAINABILITY MATTERS

Verdant Law, PLLC is a boutique environmental law firm located in Washington, D.C. Although located in the United States capital, the firm has a global perspective, providing high-quality, personalized service to domestic and foreign clients on matters at the federal, state, and local levels, as well as those arising internationally. With its focus on the environmental regulation of products and its dedication to delivering value, Verdant distinguishes itself from other environmental law firms.

PRACTICE AREAS

- GREEN CHEMISTRY AND CHEMICALS MANAGEMENT
- RIGHT-TO-KNOW
- NANOTECHNOLOGY
- ENERGY EFFICIENCY AND CLIMATE
- ECOSYSTEM SERVICES
- GREEN MARKETING

INDUSTRIES SERVED

- Agriculture
- Chemicals
- Coatings
- Consumer Products
- Cosmetics & Personal Care Products
- Electronics
- Energy
- Food
- Fuels
- Glass
- Manmade Mineral Fibers
- Mining
- Pharmaceuticals
- Retail
- Rubber
- Trade Associations
- Transportation
- Voluntary Standards
- Wireless & Telecommunications

OUR TEAM

Philip A. Moffat
pmoffat@verdantlaw.com
Mr. Moffat founded Verdant Law to address the need for sustainability-related legal services and the demand for greater value in the delivery of legal services generally.

Kurt Blase
kblase@verdantlaw.com
In private practice since 1977, Mr. Blase has accumulated a wide range of experience under state and federal laws governing health, safety and the environment.

Catherine Lin
clin@verdantlaw.com
Ms. Lin focuses on complex, cross-border transactions, host country regulatory compliance, and product stewardship, including supply chain continuity and extended producer responsibility.

Sylvia Chi
schi@verdantlaw.com
Ms. Chi practices in the areas of green marketing law, TSCA, and EPCRA, as well as California regulations including the Safer Consumer Products program.

Irene Hantman
ihantman@verdantlaw.com
Ms. Hantman advises clients on legislation and regulations and provides auditing and enforcement defense services related to the domestic regulation of chemicals.

Danielle Schreiber
dschreiber@verdantlaw.com
Ms. Schreiber's practice includes compliance counseling and audits, enforcement defense, and litigation under TSCA, FIFRA, RCRA, CAA, and the FTCA.

EXPERIENCE

Advising manufacturers on state, federal, and international chemical bans and restrictions related to product manufacturing, marketing, and end-of-life management.

Managing global supply chains to achieve regulatory compliance and operational efficiency.

Directing EU REACH implementation for non-EU companies.

Advising consumer products companies and chemical manufacturers regarding their warning obligations under California's Proposition 65.

Counseling companies about the availability and requirements of the "treated articles" exemption from the provisions of FIFRA.

Defending companies facing prosecution for TSCA, FIFRA, RCRA, OSHA, and CAA violations.

Regulatory compliance counseling for companies subject to the FTC Green Guides.

Conducting TSCA, FIFRA, RCRA, OSHA, and CAA audits and implementing compliance management systems.

Advising manufacturers on labeling and risk assessment requirements under the Federal Hazardous Substances Act and other CPSC regulations.

VISIT US AT

verdantlaw.com

Read the latest about chemical and product law at our blog:
Green Chemistry Law Report

CONTACT VERDANT LAW

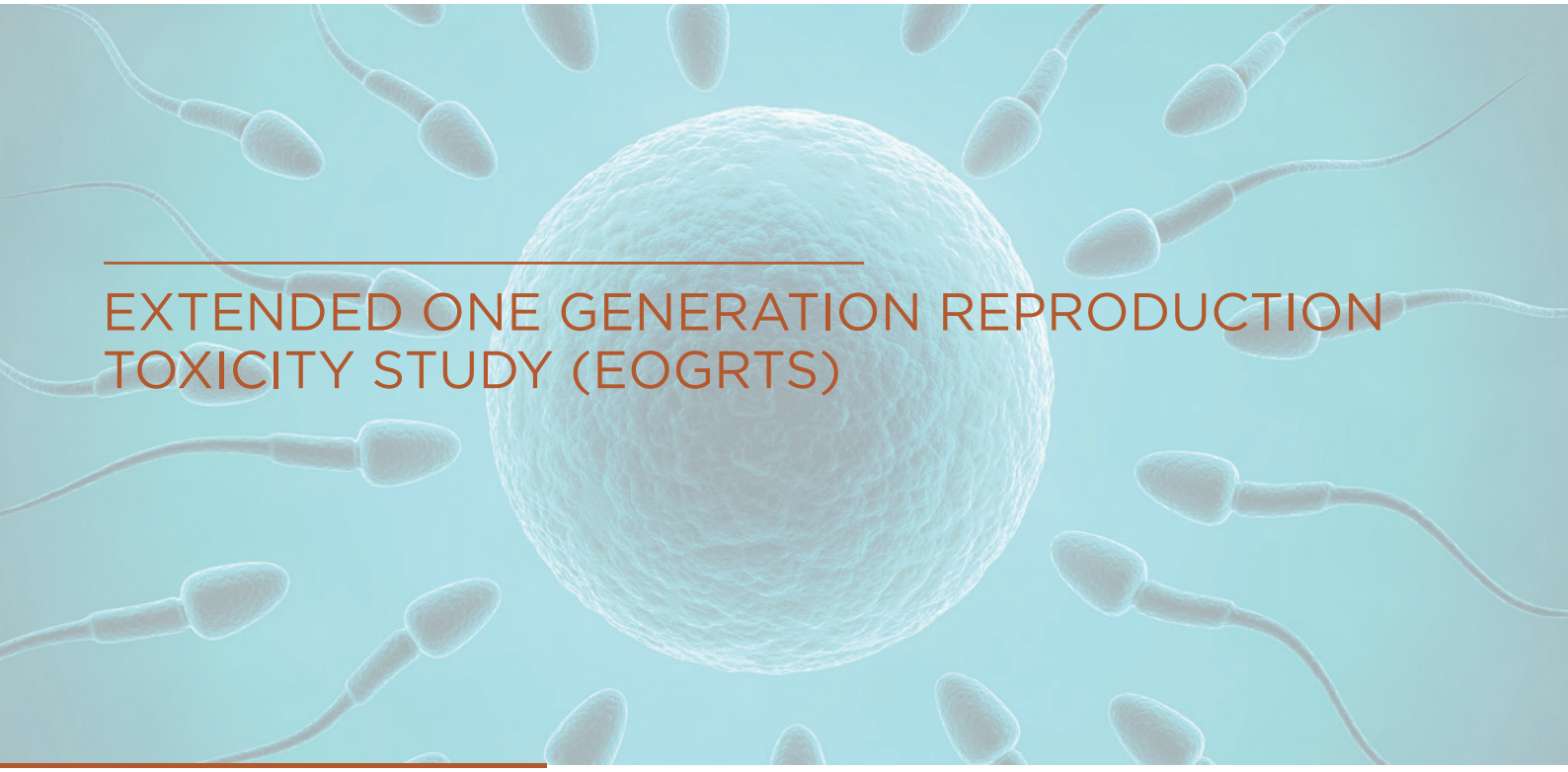
1025 Connecticut Avenue, NW
Suite 1000
Washington, DC 20036

inquiry@verdantlaw.com

+1 202 828 1233

TRISKELION
RESEARCH FOR BETTER LIVING

A TNO COMPANY



EXTENDED ONE GENERATION REPRODUCTION TOXICITY STUDY (EOGRTS)

OECD TEST GUIDELINE 443

TRISKELION POSITIONS ITSELF AS AN INNOVATIVE CONTRACT RESEARCH ORGANIZATION WITH ONE PRINCIPLE PURPOSE; TO HELP DEVELOP PRODUCTS THAT IMPROVE HEALTH AND WELL BEING OF YOUR CUSTOMERS. WE ARE SPECIALIZED IN MULTIDISCIPLINARY PROJECTS WHERE OUR CONSULTATIVE SKILLS, KNOWLEDGEABLE EXPERTISE AND PERSONAL CARE ALL CONTRIBUTE TO TAILOR MADE STUDY DESIGNS AND RELIABLE PROJECT MANAGEMENT. IT IS OUR PEOPLE THAT MAKE THE DIFFERENCE.

Extended One Generation Reproduction Toxicity Study (EOGRTS)-OECD Test Guideline 443

Selected or all cohorts:
- 1A/1B reproductive
- 2A/2B neurodevelopmental
- 3 immunodevelopmental

Planned or triggered F2 generation

All routes (diet, gavage, inhalation)

Highly qualified staff

Certified projectmanagement

TRISKELION B.V. A TNO COMPANY | Utrechtseweg 48, 3704 HE Zeist | P.O.Box 844, 3700 AV Zeist | The Netherlands | P +31 88 866 1628
chemistry@triskelion.nl | www.triskelion.nl

requirement and the one substance, one registration criteria. Dr Erick Nfon, regulatory scientist at Smithers Viscient, says: "In some cases, there are companies that have low tonnages and do not exactly know the composition of the substances in the portfolio and this is the first time they are having to prepare for registration." He adds that some firms are also part of an extensive supply chain, which can make it very difficult to establish the identity of the substance(s).

Founder of R.I.S.K. (Rebutting Industry Science with Knowledge) consultancy, Tony Tweedale, says because registrants of high production volume (HPV) chemicals failed to find and evaluate 80% of published toxicity findings, there is no hope that SMEs will perform any better on this all-important requirement. He feels strongly that this missing data is a massive opportunity if only stakeholders, including service providers, believed it. He says the industry attention that is focused on how to improve submitted studies is misplaced and SMEs should instead be concerned that the missing toxicity findings from academia are a problem.

And Dr Dietmar Kuhn, deputy managing director of German testing firm LAUS, is expecting a lot of problems with 'newcomers'; those companies that were not involved in the 2010 and 2013 registrations. He says most of the testing slots are already occupied before the newcomers start their registration process. While he says it is nice to have full order books, it does mean that the necessary capacity is not available to fulfil requirements in the necessary timescale. Some service providers will not invest in additional capacity because of uncertainty about demand after 2018, says Dr Kuhn, while noting that LAUS has invested in new technology to increase capacities and to achieve better detection limits.

This uncertainty about demand and the worries surrounding Brexit are the main issues for UK REACH service provider ReFaC. Managing director, Peter Newport, says the firm has increased staffing levels by 50% and provided appropriate training in anticipation of increased work volumes. "We consider there may be an acute shortage of competent staff for REACH 2018 if the anticipated demand for high volumes of substance registrations actually materialises. The upcoming 1-100tonne/year substances are relatively low volume and the margins generated may not support overall registration costs," says Mr Newport.

He says that in the 2010 and 2013 registrations, when substances were higher volume and typically commodities, REACH compliance was handled either in-house, or predominantly so, by chemical manufacturers acting as lead registrants or in consortia, sometimes with support from external service providers. Mr Newport, along with other service providers, believes that in-house experienced resource is unlikely to be available for 2018 deadline registrations. He anticipates that smaller companies will rely more heavily on contract service providers, provided the substance registration projects prove to be commercially viable.

For those companies that are affected by REACH for the first time, it will be challenging to face all the required negotiations in a Sief and to generate data where required, says Dr Thomas Berbner, regional director business development EMEA industrial chemicals at Dr. Knoell Consult. "With each passing month, it will become more difficult to find laboratories with free capacities. Furthermore, the collection and generation of exposure scenarios in the remaining time will also be challenging," he says.

Carsten Dietsche of Germany's pan-industry Materials Data Working Group for producers of discrete articles, says that as some industries are "rather late in the whole REACH project" companies that are just starting to implement the legislation will face enormous 'late-comer' costs compared to the 'early birds'. He believes many service providers will have already considered and taken action to remedy any disruptions in global supply chains post-2018 by finding alternative purchase options for their clients.

Mr Dietsche says, in his experience, many companies struggle to define their role under REACH. They question their obligations and reporting duties, or are unsure of how to deal with non-European suppliers. At minimum, companies have to report candidate list substances (SVHC) > 0.1 % weight by weight in articles to their customers or to interested consumers, according to the principle "Once an article, always an article" (O5A). He believes the global sourcing boom of late may backfire on some purchase cost-conscious companies as REACH may raise the price tags.

Scientific services company EAG Laboratories says short-term demand for laboratory services will spike, noting that the 2018 deadline could potentially require additional testing of some 25,000 substances. The San Diego, California-headquartered group also believes that short-term capacity constraints for analytical services in contract laboratories may make it difficult to meet the deadline, particularly for more complex test substances that need new method development and validation.

Amanda Halford, executive vice president of EAG Laboratories' Life Sciences Division, says some companies lack an understanding of the time required to perform testing, particularly when development of a new analytical method is required. "REACH customers may not understand they are competing for testing capacity with agrochemical, personal care products, pharmaceutical, veterinary medicines and other sectors that are performing similar studies," she says.

She adds that companies – particularly those with unique or higher risk substances – often need help with designing and executing the most efficient study programmes. While the required analyses may comprise a small portion of the overall dossier project, careful planning is critical to obtaining the right data and meeting timelines, according to EAG. "A focus on client communication and careful scheduling of these programmes is essential to meeting deadlines," Ms Halford says.

EAG, which operates 20 laboratories worldwide, has over the last 18 months expanded capacity for environmental testing in Ulm, Germany, and in the US at Easton, Maryland; Hercules, California; and Columbia, Missouri. It has also recently opened a new pollinator testing facility in Gainesville, Florida.

No doubt, the fact that many companies have far more substances to register under this deadline than earlier REACH ones is providing a boost and extra opportunities for service providers. As well as increased demand for testing and regulatory services, the UK's National Chemical Emergency Centre (NCEC), part of Ricardo Energy & Environment, regards this 2018 deadline as offering the opportunity to open a wider dialogue on poison centre compliance and emergency response.

With regard to emergency response, many companies find that their internal services or existing provider is not able to provide as professional a service as they would

like to manage the risk, says NCEC's practice director, Jon Gibbard. REACH-like regulations set up in other countries around the world can have more demanding views of the need for local language response and local phone numbers in an emergency.

Many companies are choosing to rely on mobile phones or a limited number of staff to be contacted by a switchboard, for example, which may only operate during the day. Furthermore, those relying on just EU poison centre numbers are also not managing the risk of wider incidents that do not include any chemical medical exposure.

NCEC has seen some examples of companies using a poison centre number on section 1.4 of their SDS for global distribution. Mr Gibbard says these were non-compliant and at risk of fines in half a dozen countries. In many cases a local language speaker would not have received any support as the centre in question was only providing it in English.

NCEC has found that in those companies with in-house solutions, employees often have little or no training in emergency response and the systems and processes have no backup or language capability. This creates significant risk, especially for those producing hazardous products and distributing them globally.

POST-2018 OPPORTUNITIES

ReFaC believes work will not stop once the May 2018 deadline hits. Mr Newport reckons there will be a rump of late registration work. This will comprise, he says, completion of dossier submissions as late or long-term testing data becomes available, ongoing changes to user profiles and long-term administrative notifications of annual tonnages and customers. ReFaC anticipates 2018 will be busy and says it will reevaluate market requirements during the course of the year as substance registration intentions and post registration work demands become clearer.

Mr Newport is not alone is preparing for post-2018. Smithers Viscient is looking at its equipment and the personnel available to make sure it is prepared for a potentially large volume of enquiries. Dr. Knoell Consult is also making preparations to cover for post-registration support, particularly since this 'last' deadline is also the final one for Echa. Dr Berbner says he is expecting increasing inquiries from Echa.

But, KFT's Dr Torges cautions that opportunities also come with risks. While demand for registration support is increasing significantly, the German consultancy is reluctant to increase its manpower because it is unsure how it will employ the extra staff after the deadline has passed.

Should demand slow, KFT has already made plans to transfer employees to other departments to work on, for example, SDS generation, exposure scenario generation and notifications according to article 45 of CLP. Dr Torges says he is seeing companies continue to need assistance with generating SDS and maintaining data. He adds there is also growing demand for information about global legislation and compliance, especially relating to legal texts but also for advice on processes.

Dr Knoell Consult says it has already prepared itself to cover and cope with post-registration support. "Since this 'last' registration deadline is also the last for Echa, we expect increasing inquiries from the agency," says Dr Berbner who is anticipating "all kinds of questions" concerning compliance issues, as well as an increase in statements of non-compliance (Soncs). Authorisation and substitution is expected to play a bigger role too, he notes.

Acta's Mr Qureshi believes the 2018 deadline is a unique opportunity for those service providers that can offer "comprehensive and well-informed" REACH consultancy, OR and third-party representation services. Companies able to display that they are fully aware of all considerations relating to REACH registration, and those able to produce compliant dossiers in a timely manner and follow closely global regulatory developments are likely to attract or build further a client base for a post-2018 environment, he states. He adds that the resulting uptick in demand for laboratories that can perform chemical testing of sufficient quality gives CROs the chance to demonstrate excellence and capitalise on the current scenario to support their continued business success.

OTHER DEMAND DRIVERS

Apart from REACH, other legislation spurring demand for service providers include GHS (for instance help with SDS, labelling), and CLP article 45, the Commission's requirement for EU countries to set up an appointed body – or poison centre – for receiving data on the health and physical hazards of mixtures. The biocidal product and the plant protection products Regulations (BPR and PPPR) were also mentioned, and the various global Restriction on Hazardous Substances (RoHS) rules for electrical and electronic devices were said to be presenting challenges for manufacturers.

"There are many European regulations that require attention on a daily basis like RoHS or the toy safety Directive. Further, chemicals in articles and the circular economy/sustainability together with ecolabels are also expected to play a pivotal role in the coming years. Moreover, there is an increasing demand in services for non-European legislations, particularly in Southeast Asia," says Dr Berbner.

For service providers, regulation in China and South Korea ranked 7th and 8th in terms of key drivers. For the chemicals and life sciences and 'other' manufacturers, China ranked in third and fourth place, respectively [see box overleaf].

The increasing efforts put into chemicals management in Asia prompted Dr. Knoell Consult to establish a presence in Shanghai, China, in 2010. Further growing demand in the region subsequently lead to the foundation of Knoell Thai in 2012, and Knoell Japan and Knoell Korea in 2016, all providing the same range of services that the consultancy offers in Europe.

Besides legislation, KFT's Dr Torges says chemical manufacturers often have general questions related to compliance in different countries. For instance, he says, clients want to know how to meet legal requirements for labelling and packaging, which rules apply to which product and whether they need to comply just with GHS or also have to follow biocide or consumer goods regulations.

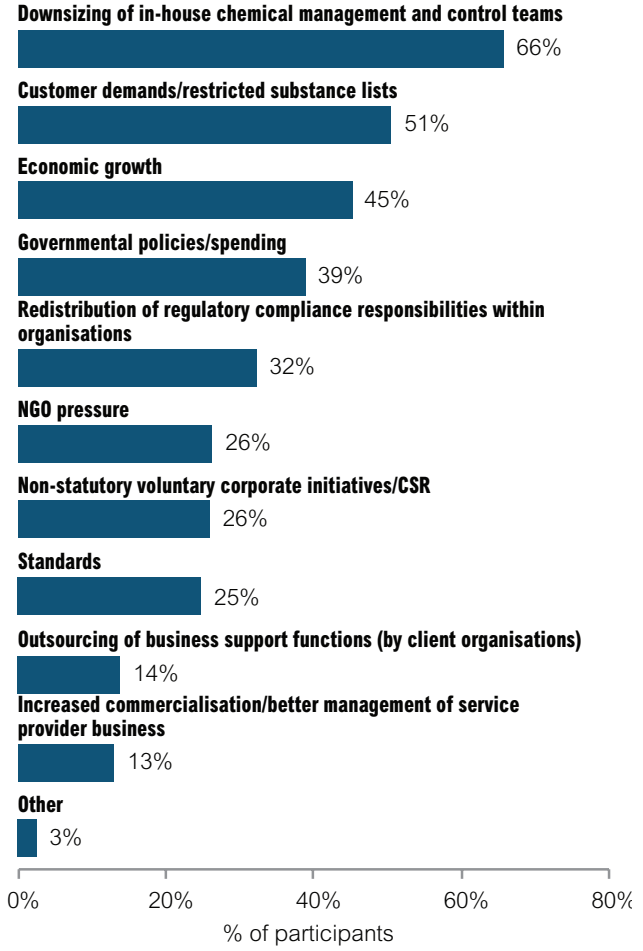
Chemical Watch survey respondents were also asked what their main non-regulatory drivers were **[Figure 2]**. In pole position with 66% of respondents was the downsizing of in-house chemical management and control teams. In second and third places were customer demands/ restricted substance lists and economic growth, accounting for 51% and 45%, respectively.

TOP EIGHT MAIN DRIVERS PER SECTOR

Chemicals, life sciences and similar	Consumer products, cosmetics and similar
EU REACH 2018 registration	EU REACH 2018 registration
EU REACH evaluation related activities/dossier updates	EU REACH SVHC obligations/ authorisation
EU CLP	California Safer Consumer Products Regulation
China regulations	EU CLP
EU REACH SVHC obligations/ authorisation	EU REACH evaluation related activities/dossier updates
US EPA Work Plan on Chemicals	US EPA Work plan on chemicals
South Korea regulations	China regulations
National GHS regulations	National GHS regulations
All other manufacturers	**Service providers**
EU REACH SVHC obligations/ authorisation	EU REACH 2018 registration
EU REACH 2018 registration	EU REACH SVHC obligations/ authorisation
China regulations	EU CLP
RoHS regulations	EU REACH evaluation related activities/dossier updates
US EPA Work plan on chemicals	US EPA Work plan on chemicals
Conflict minerals legislation	Biocidal products regulations
EU REACH evaluation related activities/dossier updates	China regulations
National GHS regulations	South Korea regulations

Figure 2

LEADING NON-REGULATORY DRIVERS FOR SURVEY PARTICIPANTS



IT SOLUTIONS

Investments in IT continue as technology improves. EAG's Ms Halford says IT to support Good Laboratory Practice (GLP) compliance remains an area of considerable investment. Mr Dietsche of the Materials Data Working Group says the present IT challenge is to integrate material data sheet solutions (databases for product compliance) into companies' enterprise resource planning (ERP) software packages, such as those supplied by the company SAP. Also, the use of product lifecycle management (PLM) software with the legally compliant tracking of product approvals and the substitution of non-compliant materials is a major challenge for manufacturers of discrete articles, he notes.

Dr Berbner is seeing big efforts being made to streamline and simplify communication within supply chains through IT, for instance by using software solutions for generating SDS. He says Qsar assessments are also increasing in several fields of chemicals management. And demand for the use of centralised global, or at least European, databases will increase as well.

The growing trend towards digitisation is also prompting companies to ask for exchange formats, which Dr Torges says is not available yet. Some firms, however, are now using cloud solutions. Dr Torges says KFT is moving from generating documents like SDS in its IT system to remote data maintenance and generation of documents in customers' own IT systems. This means, he says, we need a lot of knowledge in very different environmental, health and safety software systems. Service providers are increasingly offering knowledge systems/ wikis on regulatory compliance and there are a lot of new databases on monitoring of substance lists. As in past years, customers continue to prefer an off-the-shelf package that is then tailored to their needs, Dr Torges says.

Spanish consultancy KAELTIA Compliance Services has developed two new consortia IT systems to facilitate biocidal and plant protection product formulators/ distributors in the registration of their products and preparation of dossiers for authorisation. Elisa Capellan, regulatory affairs consultant at the company, says within its consortia systems, parties can express their interest in reaching an agreement to support similar products together by establishing a voluntary agreement with other companies. KAELTIA is in charge of coordinating the different forms of cooperations between the parties and informs all members of the 'registration group' of the steps that need to be followed. Ms Capellan says all information is managed by KAELTIA and treated as strictly confidential, with the members of each group/consortia not being made publicly available.

Targeted Science Solutions

ToxServices is a leading global provider of scientific consulting services designed to resolve complex human health, environmental health, and regulatory compliance issues. ToxServices excels at providing toxicology, sustainability, alternatives assessment, and risk assessment consulting services to private and public sector clients.

ToxServices assists a diverse range of clients located across the world. Our clients include multinational corporations with extensive portfolios, including manufacturers, suppliers, and distributors of personal care products, medical devices, electronics, textiles, and household and consumer products.

Key Areas of ToxServices Expertise Comprise:

- Cradle to Cradle Certified™
- GreenScreen® for Safer Chemicals
- Health Product Declaration™(HPD)
- U.S. EPA Safer Choice Program
- CleanGredients®
- Alternatives Assessments
- Full Materials Disclosure™ (FMD™)
- Study Design, Coordination, and Data Analysis
- Regulatory Compliance and Expert Witness Support

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

1367 Connecticut Avenue, N.W., Suite 300
Washington D.C. 20036
(202) 429-8791 • info@toxservices.com • www.toxservices.com

The safety of YOUR PRODUCT

How **the Business** sees it:

How **Competent Authorities** see it:

How **Downstream Users** see it:

How **NGOs** see it:

How **Consumers** see it:

How **your HSE team** sees it:

Put the future of your substance in the right hands

You, as an HSE manager, are under enormous pressure from all of these stakeholders to deliver **high-quality regulatory dossiers** - CEHTRA has a recognised track record of producing top-quality dossiers in a host of regulatory fields: come and talk to us about yours.

www.CEHTRA.com

in silico testing in partnership with www.KREATiS.eu

BREXIT EFFECT

The UK's vote to exit the EU will undoubtedly have significant repercussions, but these can only be the subject of speculation at the moment. ReFaC's estimates that 25% of OR service providers are UK-based, and anecdotal reports suggest 40% of OR registrations may have been by UK-based ORs.

Echa's director of cooperation, Andreas Herdina, reported at a UK Chemicals Stakeholder Forum meeting that roughly 25% of the agency's employees are British nationals. There is, therefore, currently great uncertainty for both UK-based OR service provision and UK nationals working in the Helsinki agency as a result of Brexit, says Mr Newport. The status of existing registered substances and maintenance of such substances by UK-based OR's is also yet to be negotiated.

Post-Brexit exporters from the UK to the EU market will be required to comply with REACH. But, asks Mr Newport, will they be able to use UK-based OR service providers, or will they be have to appoint ones based in the EU? This is yet to be negotiated.

According to ReFaC, many UK distributors have already registered as importers of substances into the EU under REACH (for example, 55% of existing 135 substance registrations is by members of UK trade organisation Chemical Business Association). However their status under the regulation, and hence the validity of their registrations, post-Brexit is unclear and still to be negotiated, says Mr Newport.

Other issues to be decided by the UK include the type of regulatory scheme that would be implemented for the domestic use and sale of chemicals and the agency that will act as the equivalent of Echa if a REACH-like scheme is pursued.

Mr Newport says ReFaC is actively exploring running its OR business through a new company registered in an ongoing member state of the EU.

CAREERS AND SALARY SURVEY

Career development in the chemicals management and control sector

Once again, chemicals management and control professionals benefited from a tight market in 2016 as conditions remained similar to those observed for the two previous years. There continues to be more jobs than people with the appropriate skills and abilities to fill them. Both companies hoping to retain experienced staff and those looking to entice people to switch from their existing positions had to be creative. Universities that offer toxicology and similar courses are relatively few. Nevertheless their graduates often have several choices for starting jobs and, in addition, employees seem willing to invest in training.

Here are the results of the fifth year of data collected by *Chemical Watch* regarding salaries, pay rises, bonus levels and career prospects in the chemicals management and control sector. We are grateful to everyone who participated in the survey and provided information about their organisations and positions.

With respect to participant demographics, nearly 80% are 30-60 years old and just over half (51.5%) are women. Most identify themselves as either project/team managers (32.8%) or specialists/technicians (31.4%), with the next largest group being senior managers (20.0%). The remainder includes directors or associate partners (9.3%), government officers (3.7%) and junior/graduate trainees (2.9%). Twenty nine percent are based in North America, while the majority (51.9%) are based in Europe, and 15% in the Asia-Pacific region – location being an important factor relevant to salaries and the general jobs market.

Staffing trends at the time of the survey at the end of 2016 and start of 2017 were positive compared to those a year earlier, with fewer companies decreasing their staff levels in the previous 12 months (10.4% in 2016 vs. 15.4% in 2015). Participants expect this trend to continue, with even fewer cuts in staff anticipated in coming year (6.0%, Figure 3). A slightly greater percentage of survey respondents also expect more hiring in the next 12 months compared to the previous period (38.5% vs. 34.2%).

CHEMSERVICE

GET EXPERTS ON YOUR SIDE

"You can do your business, we remove the regulatory roadblocks."

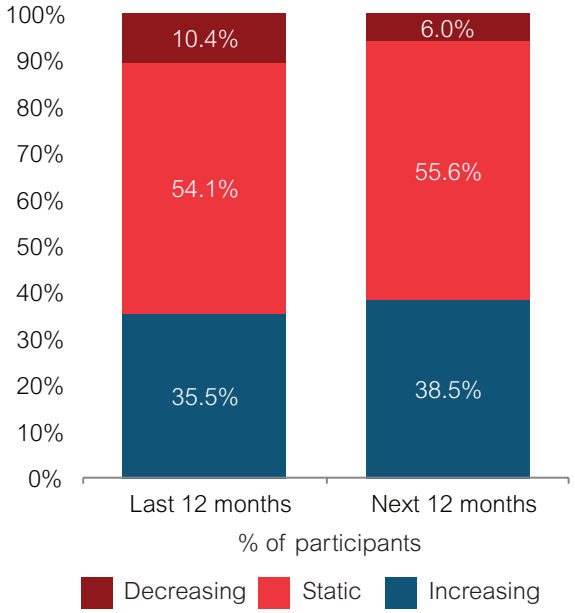
REACH-Code-Model
EU REACH
CLP
Regulatory Data Sheets
Food Contact
Only Representative
Korean REACH
International Chemical Control Legislation
Medical Devices
GLP & GMP Consulting
Exposure Scenarios
LoA Management
Regulatory Training
GHS
Biocides
Global Chemical Inventory Notifications
EH&S
Consortia Management
Supply Chain Compliance
Chemical Safety Assessment
Advocacy & Authorisation
Safety Data Sheets
Labels
Turkey REACH
Cosmetics

- Your strategic partner to comply with international & national chemical control legislation.
- Comprehensive expertise in global regulatory affairs, toxicology, risk assessment, environmental sciences & EHS issues.
- Joined efforts with CEHTRA: enlarging professional services to crop protection product & cosmetic legislation, besides existing service portfolio.
- One of the largest independent Regulatory Affairs service providers globally with resources of more than 100 people & offices in Belgium, Canada, France, Germany, India, Korea, Luxembourg, Switzerland and UK.

www.chemservice-group.com • info@chemservice-group.com

Figure 3

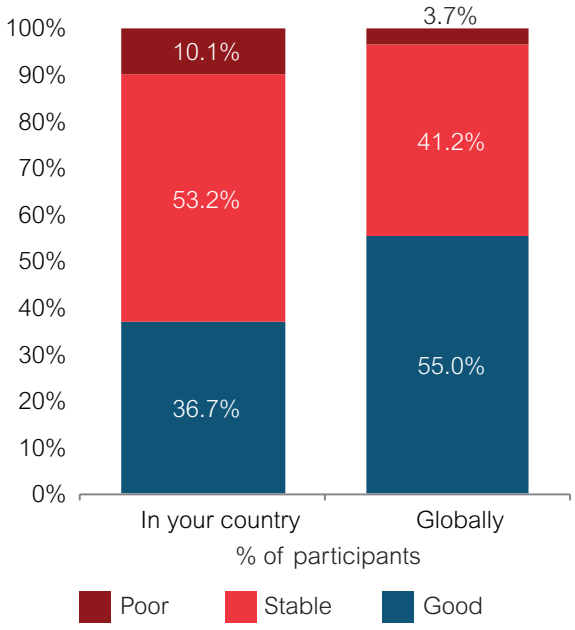
STAFFING TRENDS



Within their own countries, respondents' job expectations are slightly better in 2016 than in 2015. Nearly 90% of people answering the survey see at least a stable, if not good, situation **[Figure 4]**, compared with 86% the previous year. Respondents do, however, continue to see greater opportunities on a global level. In this case, over 96% of survey participants identified global job prospects as stable or good. It is also interesting to note that for the second year in a row, the percentage of respondents that see global job prospects as good has increased slightly, from 53.7% last year to 55.0% this year.

Figure 4

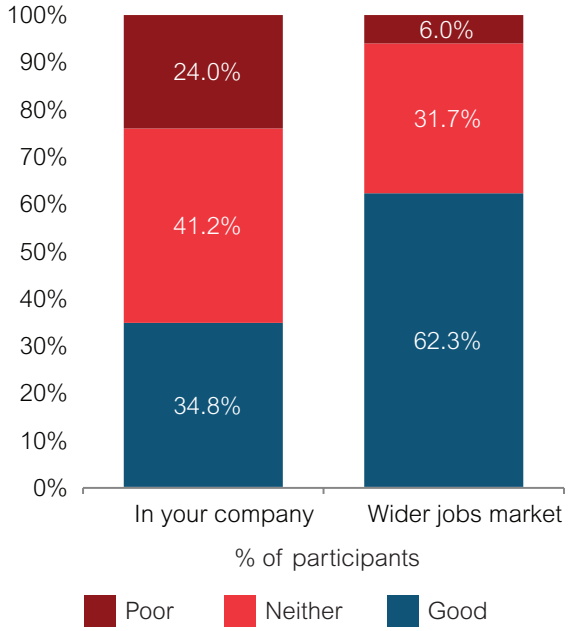
JOB PROSPECTS



Similar expectations exist with respect to career progression. Nearly twice as many survey participants believe that the opportunities are good in the wider jobs market than those that see them as good within their own companies **[Figure 5]**.

Figure 5

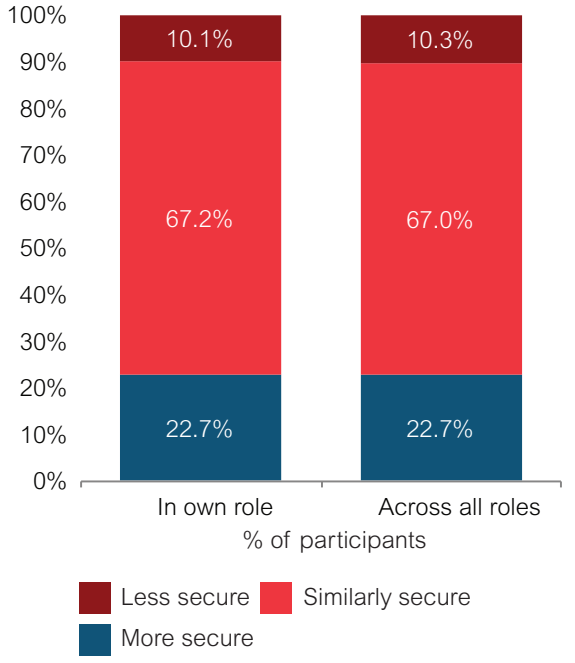
CAREER PROGRESSION OPPORTUNITIES



The number of participants that feel more or similarly secure in their current jobs compared to a year ago has been fairly static over the last few years, at 89.9% in 2016 **[Figure 6]**. Survey respondents also feel secure in their jobs across all roles (89.7%).

Figure 6

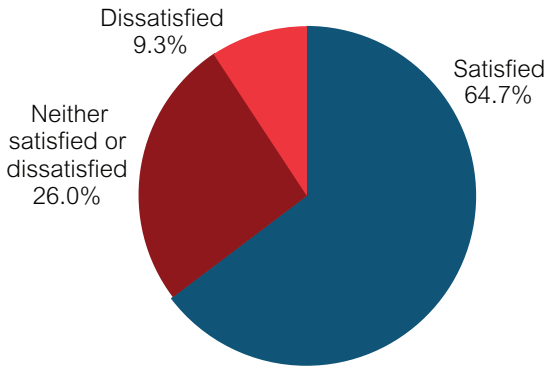
JOB SECURITY COMPARED WITH 12 MONTHS AGO



Another notable difference in the *Chemical Watch* survey results from 2014 and 2015 compared to those from 2016 is the level of job satisfaction felt by respondents. The percentage of participants satisfied with their jobs has increased from 55.9% and 58.0% in 2014 and 2015, respectively, to a much higher 64.7% in 2016. The number of dissatisfied respondents declined simultaneously from 12.6% and 11.3% in 2014 and 2015 to just 9.3% in 2016.

Figure 7

JOB SATISFACTION



On the other hand, although the gap was not as great, a wider distribution of average salaries by job title, which was first seen in 2015, was once again observed in 2016 **[Figure 8]**. Salaries of participants in the latest *Chemical Watch* survey ranged from €37,900 to €51,100 (the range was €37,400 to €56,700 in 2015). Notably, the average salary has declined over the last three years (€46,700, €47,200 and €49,700 in 2016, 2015 and 2014, respectively, calculated on a constant exchange rate basis). The highest average salaries were received by EHS management, regulatory personnel and product stewardship. Occupational hygienists received the lowest pay for the group of people responding to the survey.

Figure 8

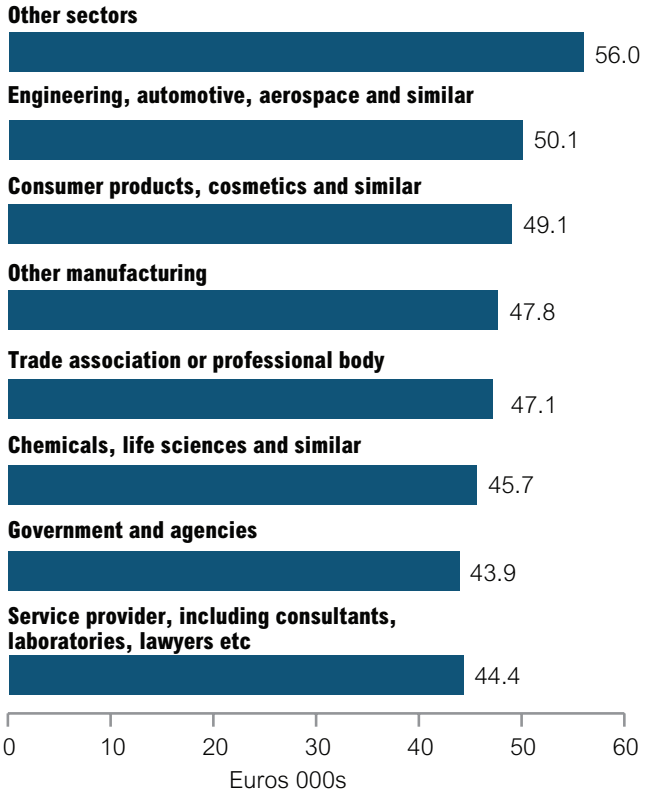
AVERAGE SALARY BY JOB TITLE

It is important to note that the values reported here are highly dependent on the pool of respondents, how each person identifies him/herself, and the mix of countries. Fluctuations may in part be attributed to variations in that pool from year to year. For instance, the industrial hygienist category can include both technicians and managerial positions held by people with advanced degrees, and salaries will depend on the educational backgrounds, experience and particular positions of the respondents. These are not singled out in the overall results.

Interestingly, the distribution of average salaries by organisation type is much smaller when looking at participants that hold defined positions (that is excluding the 'other sectors' category): €44,400 to €50,100 **[Figure 9]**. In this case, survey respondents working at engineering, automotive, aerospace and similar companies earned the highest basic pay, while those working at service providers took home the least.

Figure 9

AVERAGE SALARY BY ORGANISATION TYPE



On the other hand, company location continued to have a significant impact on earning potential **[Figure 10]**. Note that salaries are reported at a constant exchange rate basis (that is to say exchange rate fluctuations have been removed). Respondents in Europe continue to earn the highest average pay (€48,800), although the gap has decreased somewhat due to a decline in European salaries and an increase in North American pay for survey respondents. This was a trend the 2015 survey also observed.

EMERGENCY RESPONSE 24/7

KFT's partnership with the world's foremost emergency call center for information on hazardous materials and dangerous goods

KFT The **CHEMICAL COMPLIANCE** Company

KFT has been providing reliable and high quality service to support companies worldwide in the area of regulatory chemical compliance for over 20 years. One very important building block of chemical compliance is a quick and reliable emergency response to save lives and to avoid damage to the environment in the case of an accident with hazardous materials and/or dangerous goods. Our partner is linked to the largest network of chemical and hazardous material experts in the world, including chemical and response specialists, public emergency services, and private contractors

Communication
Safety Data Sheets
eSDS
Label
24/7 Emergency Number
Article Communication
Exposure Scenarios
Upstream Communication
Safety Data Sheet Portal

Compliance
REACH
REACH Turkey
Biocidal Products
Cosmetic Products
Risk Assessments
IUCLID Dossier
CSR-Generation
CLP Article 45 Reporting

Consulting
Global Chemical Regulations
GHS/CLP/HCS-2012
Hazardous Substances
Dangerous Goods
SIEF Management
Only Representative
Trustee
Marketability Check

TOP CONSULTANT Management-berater 2015

Im Leuschnerpark 3 • 64347 Griesheim • Fon +49 6155 86829 0 • mail@kft.de
www.kft.de • www.kft-academy.com • www.kft-chemdoc24.com • www.kft-ebook24.com

EBRC

Services for the Chemical Industries

REACH out for the market.

Agrochemicals

Biocides

Industrial Chemicals – REACH

Special Services

Classification and Labelling

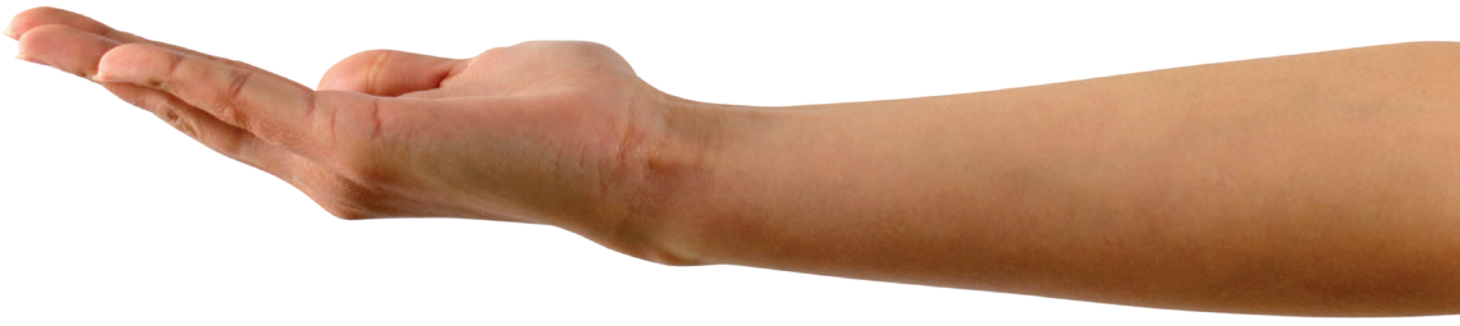
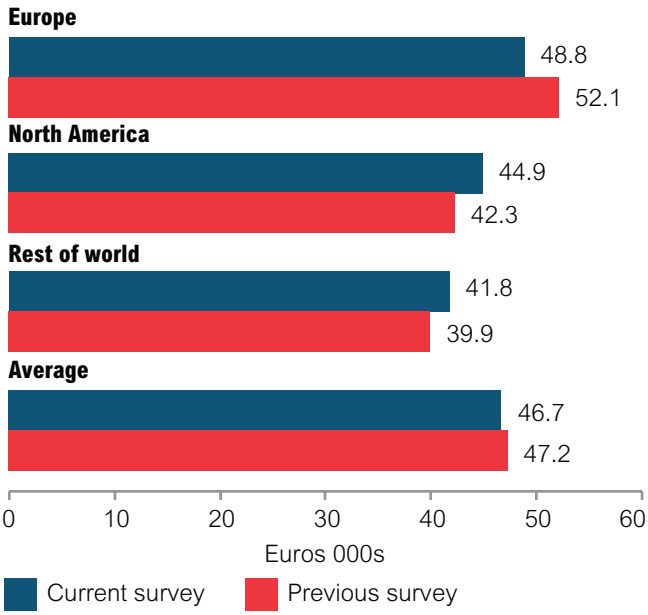


photo: dreamstime.com

EBRC Consulting GmbH
Raffaelstraße 4
D-30177 Hannover
Germany
Phone: +49 (0) 511 - 89 83 89 - 0
Fax: +49 (0) 511 - 89 83 89 - 10
E-mail: mail@ebrc.de
ebrc.de

Figure 10

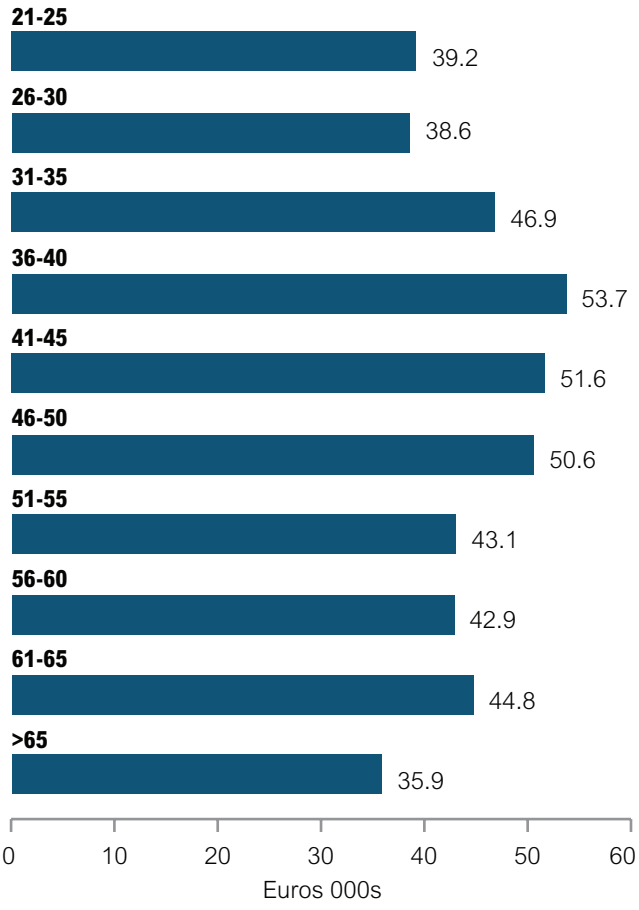
AVERAGE SALARY BY JOB REGION



Not surprisingly, survey participants aged 36-50 earn the highest average salaries (€50,600 to €53,700), followed by those that are 31-35 (€46,900) and interestingly 61-65 (€44,800) **[Figure 11]**.Those over 65 earned the least (€35,900). This last result may be due to the fact that people over 60 often enter semi-retirement and either work part time or as consultants.

Figure 11

AVERAGE SALARY BY AGE



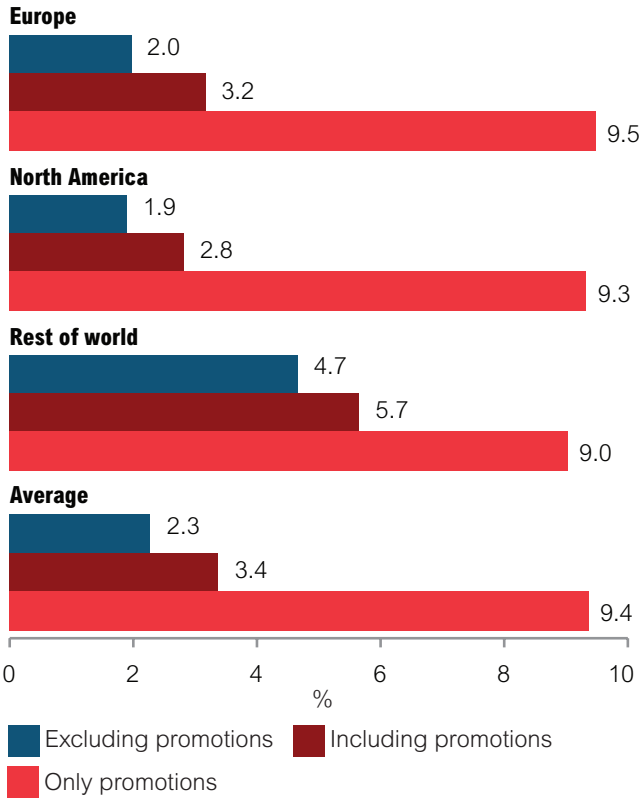
The average pay rise for survey respondents in 2016, excluding promotions, was 2.3% and ranged from 1.9% and 2.0% in North America and Europe, respectively, to 4.7% in the rest of the world (down from 5.6% a year ago) **[Figure 12]**. When promotions are included the average rises were 2.8%, 3.2% and 5.7%, respectively.

Once again, just over two thirds (68%) of *Chemical Watch* survey respondents were entitled to a bonus, the average value of which was 12.0% of salary. Participants in Europe and North America earned bonuses just below this level (10.7% and 10.2% respectively), while those located in other parts of the world received bonuses worth 21.3% of salary.

The increase in the number of Chemical Watch survey respondents who feel secure in their jobs, and are also satisfied with their current positions, is a reflection of the state of the jobs market for chemicals management and control professionals. "Demand remains high across all sectors, and I expect this situation to continue through 2017," says John Sherratt, RA Business Manager with recruitment firm VRS Regulatory. "The main issue is simple; the amount of work is outstripping the available experienced people," he says. Another factor is increasing regulatory complexity. "It takes time to fully understand the regulations and be able apply them at an expert level. The regulations appear to be getting more complex at a faster rate than a sufficient volume of people can develop deep expertise," Mr Sherratt notes.

Figure 12

AVERAGE PAY RISE



In fact, notable growth in global regulations in 2016 is driving demand for chemicals management and control professional. The emergence of K-REACH and REACH Taiwan, for instance, seems to have had a knock on effect on demand in countries like Singapore and Turkey, according one leading recruitment company. Abid Kanji, country manager for toxicology, ecotoxicology, regulatory

ARCHE CONSULTING

Not enough hands? Need help?

REACH Registration

How can we assist you in getting your products REACH registered by 2018?

REACH Authorisation

Safeguard your market access.

BIOCIDES-PPP

Have you already designed your game plan to keep your biocides and plant protection products compliant with the changing legislations?

CLP/GHS

Have you considered our MECLAS tool? The smartest way to fulfil your classification obligations for complex inorganic mixtures.

Medicinal Products

Let us support you in preparing your Environmental Risk assessment.

C2C

ARCHE is an accredited Material Health Assessor helping you to direct your innovation and leadership towards a positive footprint.

Liefkensstraat 35D ▼ B-9032 Gent (Wondelgem), Belgium ▼ Phone: +32 9 216 70 38
WWW.ARCHE-CONSULTING.BE ▼ INFO@ARCHE-CONSULTING.BE

affairs and REACH with European recruitment firm Nonstop Regulatory, says: “This news is encouraging for REACH professionals who have been worried about the 2018 deadline. Consultancies as a consequence seem to be investing more and channelling investments towards the Asia Pacific regions.”

With respect to specific positions, there continues to be demand for toxicologists and ecotoxicologists, but not at the high pre-2012 levels, says Mr Kanji. On the other hand, professionals with biocides experience are in high demand but short supply. “It is clear that companies are not training and developing enough in this area,” Mr Kanji says. He notes a similar situation exists for people with experience in plant metabolism and environmental fate; there has been a significant decline in candidate availability over the past two years.

For companies looking to hire experienced recruits, the biggest problem is finding the right people with experience to fit the job profiles who want to move at this time, according to Paul Thomas, senior ecotoxicologist and vice president of CEHTRA. “We’ve seen this in past phases for REACH; people in the middle of a project are less keen to seek challenges elsewhere than when they are between projects. I guess that’s just human nature, but in many ways it shows that people in the industry tend to want to get things done and don’t just shift jobs in the middle of a project!“ he says.

In addition, smaller organisations that have limited scope for progression for their chemical control people are having a harder time retaining them, according to Mr Sherratt. “These skilled people are often aware of the demand for their experience, so are keen to make the most of it and tend to move to larger departments or consultancies,” he says. Companies have to use several tactics to entice the best talent; relying solely on competitive salaries is no longer an option. For instance, the National Chemical Emergency Centre (NCEC) – part of global engineering and environmental consultancy, Ricardo – provides a significant level of internal development opportunities. This includes individually-tailored personal development programmes,with internal coaching supplemented by external courses, according to practice director of NCEC Jonathan Gibbard. Similarly, consultancy ReFaC offers a package of competitive starting terms and conditions linked to a learning environment both on the job and through suitable external courses that support the regulatory compliance service offerings of the business, according to managing director Peter Newport. He adds that remuneration is regularly reviewed and improved as key learning milestones are demonstrably reached.

Concerns about the aging of the workforce also remain in 2017, according to Terry Leyden, president of The Leyden Group. Fortunately, recruiting of entry level staff and new graduates has proven to be a little easier in the last 12 months, according to Mr Sherratt. “Chemical control seems to be better understood by new graduates, so more are showing interest – the career appears to be growing in prominence,” he says. Mr Leyden has also seen slightly increased activity with respect to the hiring of some younger people in the field, although not a dramatic change.

In 2016, FoBIG received many applications from graduate scientists when the company was looking for toxicologists, but typically found that while they had a good scientific education, they lacked experience in regulatory affairs and chemical management, says managing director Klaus Schneider. He does note that within its post-graduate education offerings, the German Society for Toxicology now offers courses on risk assessment and exposure sciences, which the company encourages its staff to attend.

CEHTRA’s Dr Thomas believes that universities are at last starting to meet the demands of the employment market. “In France there are now several universities dedicated to a master’s degree in toxicology and environment that includes a sprinkling of regulatory courses,” he says. He also notes that quite a few graduates today have lab experience picked up during their industrial training as part of their educational package. “But of course,” he says, “fresh out of university post grads do still need guidance and training before they have enough experience to be autonomous on a project.”

There is in fact a lot of on-the-job training required in this area, says Dr Schneider. Many companies also have established formal in-house training and use external programmes as well. Chemservice, for instance, sends people for training to maintain a high level of competence in areas of expertise that cannot be taught in-house, such as toxicology training to become registered toxicologists, according to managing director Dr Dieter Drohmann. CEHTRA also uses a mix of in-house and external training programmes, but Dr Thomas agrees that “nothing beats hands-on experience working on a project within a team,” and most of his company’s consultants acquire the majority of their experience via this mechanism.

Increasingly, some softer skills are becoming important for both new and experienced chemicals management and control professionals. As regulatory departments become more integrated in companies and more involved in new product development from an early stage, Mr Sherratt says that as well as understanding regulations and how to apply them, people need to be confident communicators and problem solvers.

Mr Newport adds: “Beyond holding a suitable chemical or chemical engineering degree and experiential employment, when recruiting ReFaC looks for the ability to be part of a team, a willingness to learn, recognition of customer service requirements and a degree of flexibility in developing the approach for each project.” He adds that ReFaC typically recruits either recent graduates or those with a few years of industry experience in relevant chemicals management and control roles, but mainly seeks candidates demonstrating the willingness to train, learn and develop their professional competence.

For NCEC the major recruitment challenge is ensuring that new hires have not just technical knowledge, but that they fit with the culture of the company, according to Mr Gibbard. The company looks for people with experience, a track record in delivery, and effective communications skills, but would also like to see more recruits arrive with the ability to effectively prioritise their work and manage their time effectively in order to deliver the best value to the organisation. In addition to needing a good background in the natural sciences, Dr Drohmann finds that many recruits lack knowledge of how to be team players and communicate effectively, as well as the ability to communicate complex scientific and regulatory issues in a readily understandable manner.

One issue that is not unique to the chemicals management and control sector, but must still be considered is the different perspectives brought by new generations of employees as they enter the workforce, according to Dr Drohmann. “In many cases, for younger people work-life balance is more important than some

aspects of a job, such as international travel or tackling significant challenges."

Career paths often depend on these types of perspectives, as well as the type of organisation for which a chemicals management and control professional works. Consultants in regulatory affairs, for instance, often initially work for a contact research organisation and ultimately obtain an interest in a regulatory affairs consultancy, while someone working in the chemical industry may follow a path to a marketing or product stewardship position, says Dr Drohmann.

Dr Thomas concludes: "There's no doubt that HSE is a fast developing area today where our understanding of environmental and health issues is advancing at an ever increasing rate. So typically, there may not be so much of a career jump from a hierarchical perspective, but personal development towards becoming a recognised expert in your field is highly prized and regulatory departments are starting, at long last, to be included by businesses as part of their company strategies."

SOFTWARE SOLUTIONS

Environmental management information systems: where is the market going?

The past decade has seen rapid change in product stewardship. This has come as a response to internal demands for business value and external scrutiny of the risks and impacts of products and processes. In addition to their core responsibilities, product stewards have evolved into sophisticated risk managers charged with protecting market access and delivering financial benefits. In this article, the consultancy Arcadis looks at how the environmental management information systems (Emis) market for product stewardship is also shifting, albeit more slowly, to reflect the changing paradigm and other market pressures.

EMIS SOFTWARE

The broader Emis market, which includes product stewardship solutions, has endured market uncertainty for the past decade. This is a result of high levels of business activity, including consolidation, rebranding, acquisitions and investments.

In 2010 SAP purchased Technidata and with it one of the more mature product stewardship solutions available.

A trend emerged of companies in the information business taking an interest in Emis:

- IHS began collecting environmental software companies in 2007 gathering EnvironMax, Dolphin and ESS for a total of $100m over a couple of years and then divesting its Emis portfolio into a standalone organisation, Sphera in 2016;
- Verisk Analytics acquired 3E Company in 2010 for $110m and;
- Most recently, Wolter Kluwers' purchased Enablon in 2016 for $275m.

There were large private equity investments in Intelex and Medgate. According to Crunchbase, Intelex CAD received a Can$160m investment in 2015 and a year later Norwest Venture Partners led a $100m investment in Medgate.

Battery Ventures acquired Enviance in 2015, and then added Remedy Interactive and Actio to the mix.

Several companies were impacted by the failure of Foresight in 2015 and therefore the discontinuation of the GEMS application.

While some of these transactions have been stressful for users, the outcomes have generally been positive from a consumer perspective. As investors have demanded growth, solution providers have been forced to up their game in a hotly competitive market. The result has seen important improvements to product stewardship and other environmental, health and safety applications.

These include:

- better integration of third party content and master data;
- more attention to and investment in the user experience; and

ARCADIS Design & Consultancy for natural and built assets

Solutions to enhance compliance and promote market access

Managing risk throughout your product's life cycle is one of the biggest challenges you face. We provide the expertise to help you implement flexible, efficient and scientifically rigorous product stewardship solutions that reduce liability, promote regulatory compliance, facilitate delivery, increase competitive advantage and add value to your bottom line.

For more information, visit www.arcadis.com/pss or contact us at pssinfo@arcadis.com.

Arcadis
Improving quality of life.

WWW.ARCADIS.COM

EXPLOREArcadis
DOWNLOAD OUR MOBILE APP
arcad.is/adv-Connect

Arcadis CONNECT

ECO ONLINE

ABOUT US
EcoOnline offers cloud services for authoring SDS, communicating in supply chains and managing chemical inventory. We facilitate safe handling of chemicals in a simple and effective way.

CONCEPT
We connect chemical suppliers, chemical buyers and chemical users together in a common database. They can share information and communicate directly with each other.

COURSE AND SEMINARS
We offer training courses as well as seminars focused on regulations and requirements, optimal use of our software & services, and other relevant topics. They are an important meeting place for exchange of experience and building new relationships.

SUPPORT
An investment in health, safety and environment should be profitable. Our focus is therefore on providing the best possible customer service through technical support and training.

- better standard options for access to information, such as user configurable dashboards and reports.

At the same time solution providers have tried to keep up with the changing nature of product stewardship by broadening out into:

- supply chain compliance, such as supplier communication and data collection;
- enhanced bill of materials (BOM) and bill of substances (BOS) management capabilities;
- extended producer responsibility features such as take-back scheme support; and
- mechanisms for risk assessment.

EMIS SERVICES

Another important trend impacting Emis solution providers and consumers is an emphasis on faster implementation. The appetite for traditional implementation approaches has waned for certain customers. Protracted deployments, including thorough user requirement discovery, followed by months of advanced configuration and customisation, along with integration with Enterprise Resource Planning (ERP) or other legacy systems had been the norm, with the expectation of a bespoke fit.

But often the final delivery did not meet user expectations – sometimes, because it had been so long the customer had forgot what they asked for. Sometimes the problem was a lack of understanding of system capabilities in the first place or because there was broad opportunity for interpretation of requirements.

As a result, consumers were increasingly demanding trials or pilots to test drive solutions to reduce the risk of making a bad decision or experiencing a failed implementation. The investment of time and money, and lost opportunity, are significant. No-one wants to be responsible for a system everyone hates or no-one uses.

However, these trial runs are not really feasible with solutions with very little standard out-of-the-box configuration and a dependency on complex master data and third party content to fuel the functionality.

In an effort to respond to this swelling demand, several solution providers are offering alternative deployment packages. There are different branded terms for the new methodologies depending on the solution, but they have common themes. Application-specific packages may feature tools that speed up implementation, such as:

- pre-configured software, sometimes tailored to a specific industry, sometimes not;
- standard functionality to address predefined business requirements;
- limited historical data migration using templates; and
- standard documentation templates with only very basic client specific detail captured.

Typically the idea is that the client deploys non-specific, standardised functionality that users then get to know before doing any major configuration, customisation or integration. This is normally on a go-forward basis without a major data migration beyond what is necessary to begin use, such as data on the organisation, products or personnel.

Complex workflows and rules are not modelled in the system. After a certain period customers can refine the configuration or implement more complex customisations based on a clear understanding of system capabilities and limitations.

The benefits of the accelerated deployment methodologies include:

- production-ready systems in weeks rather than months;
- lower cost of entry; and
- informed decision making with regard to required configuration and customisation.

But this approach is not going to be a fit for everyone and should not be assumed to be cheaper over the long term – just as you may buy a suit off the rack and then still have to have it tailored. The approach is loosely based on an agile development style and is assumed to be iterative. It is likely that customers will undertake follow-on projects to refine configuration, migrate historic data, create integrations or model unique processes and workflows. There is also an assumption that key players within the customer's organisation will be intimate with the process and game for the more intense commitment.

WHAT NEXT?

Software vendors indicate they will continue to invest in and improve their product stewardship capabilities, application delivery and access options. This will no doubt include a more erudite recognition of the data intensive nature of product stewardship and the need for product stewards to be able to apply interpretive analytics to enable them to let the data tell its story. In addition, the market is asking for better integration along the value chain to reflect the increasing influence of product stewardship in R&D, procurement and logistics.

Software users will start paying more attention to generating value post implementation. This includes executing formal governance infrastructure to:

- shepherd the asset and protect the investment;
- ensure the system is used to identify and enforce best practices;
- impose consistency and optimise data integrity to guarantee reliability of outputs;
- measure, improve and report performance; and
- utilise outputs to validate, enhance and communicate the contribution of the EHS function.

THINGS TO CONSIDER

When looking for technology to strengthen your product stewardship function, there are a lot of things to think about. Before you get started with a project ask the following:

- what can we do in-house and what do we need help with? Find a reliable partner early in the process. Make sure they have domain expertise as well as technology bench strength. Are they knowledgeable regarding best practices in your industry? Choose someone with good relationships with multiple vendors (software and content) and enlist them early to help you with the vetting process;
- what are your legacy systems and your strategic platform? It may make sense to explore what is offered by the vendors your company is already partnered with;
- what are your business drivers? Well articulated business drivers will help define priorities;
- what does 'product stewardship functionality' mean to your organisation? Create a checklist and make sure it aligns with the vendor's capabilities before considering them. For example:
  - Hazard communication
    - safety data sheet (SDS) authoring;
    - labelling; and
    - vendor sds management.
  - Dangerous goods
  - Product compliance and sustainability
  - Supply chain communication and compliance
    - Conflict minerals, material disclosures, declarations, surveys.
  - Extended producer responsibility
  - Risk evaluation

LISAM SYSTEMS

Global IT Solutions in Environment, Health & Safety

Chemical Compliance Solutions for All Actors in the Supply Chain

Basic & Advanced Trainings

Lisam provides the right training to optimize your day-to-day use of ExESS®, our flagship solution for SDS management.

Round-the-Clock Support

Benefit from the combined expertise of our regulatory experts and IT specialists through our helpdesk at all times!

Solutions for All Size Companies

Choose from our wide range of flexible modules to build the best solution at the most competitive price on the market.

www.lisam.com

- Chemical and hazardous materials (HazMat) management
- Global / multilingual

Make an honest assessment of the maturity of your product stewardship function. Are there well-defined processes in place? What data is needed? Are there key stakeholders within the organisation who are capable and willing?

An authentic awareness of programme maturity will allow you to responsibly allocate resources, secure appropriate levels of support, select a solution that is fit for purpose over the long term and capture an optimised ROI.

Types of data

Master data, is data that is relevant and consistent across the enterprise, such as product compositions, employee data, or supplier records. This data does not typically originate from product stewardship, but must be sourced from other systems, such as enterprise resource planning (ERP).

Third party content for product stewardship applications can mean chemical data, regulatory data, rules to calculate secondary data, templates, or phrases.

US REGULATIONS

Impacts of TSCA reform

For many in the chemical industry, passage of the Frank R Lautenberg Chemical Safety for the 21st Century Act (LCSA) offered the potential to bring certainty to the manufacturing and processing industry in the US.

Not only does the law modernise the 40-year-old Toxic Substances Control Act (TSCA), it also offers an alternative to the patchwork of emerging state-level chemicals legislation.

But as the US EPA begins to develop guidance and regulations, industry is facing new uncertainties.

The Service Providers Guide interviewed more than a dozen companies with work related to specialty chemicals to find out what might be the top challenges facing manufacturers, processors and downstream users as the EPA develops the nuts and bolts of TSCA reform implementation.

Companies by and large will have the most difficulty:

- generating scientific data and preparing risk assessments for pre-manufacture notifications (PMNs);
- managing confidential business information (CBI);
- responding to the TSCA inventory reset rules; and
- meeting quicker deadlines going forward.

MOUNTAINS OF DATA REQUIREMENTS

Every firm contacted said that the most significant change facing the specialty chemicals industry from the TSCA reform is that they must now deal with a lot more data. In the past companies seeking approval from the EPA to market or process with new chemicals provided the agency with the data they had in their control. Within 90 days, in almost every case, the company's PMN was approved. This is not the situation for companies now.

"EPA no longer has the ability to not have an opinion," notes James Eggenschwiler, director, global trade for The Redstone Group. During the PMN review process the EPA must make an affirmative finding that the chemical does – or does not – present an unreasonable risk to health or the environment under the conditions of use. This includes circumstances under which the substance is intended, known, or reasonably foreseen to be manufactured, processed or disposed of.

Requirements for more data are expected to increase activities in a number of areas, including laboratory services, chemical literature searches for chemical analogs, and expertise on read-across approaches. Companies expect to see growing demand for services such as mining existing chemical data and dossier development as they prepare dossiers that provide the information and assurances that the EPA is now looking for as a result of the new law.

BEGINNING TO TACKLE PMNS

Industry will have to do more to submit a PMN and it will be worth it in a lot of ways, says Mr Eggenschwiler. But in the short term the EPA is likely to do this through consent orders, because companies will not be presenting all of this

data to the agency right away. In these cases the agency will probably place restrictions on the chemical and request the information it needs to move forward on approval. The company will do the testing requested to get the consent order lifted. This can be done, but it might take longer for a company to receive approval. In the end this approach might be more expensive, Mr Eggenschwiler says.

"In the short term, companies that develop and use new chemicals are seeing significant delays in getting their new chemicals through the PMN process, and there is much uncertainty regarding how much data the EPA will require from companies in order to make hazard and risk determinations," says Jessie M Kneeland, senior environmental chemist with Gradient, which provides risk sciences consulting services.

"Companies that manufacture or use chemicals with known risks will need to make important decisions about whether to try to phase out those chemicals that are prioritised (or have the potential to be prioritised) for an EPA risk evaluation, or engage in what will likely be a resource-intensive risk assessment process with an uncertain outcome. Certain industries also use hazardous chemicals that can't easily be replaced with safer alternatives, so it will be profoundly important to ensure that risk assessments of such chemicals are scientifically robust," Ms Kneeland adds.

In general, companies should build into their business plans increased time for commercialisation of any new substances in order to account for the uncertainty around expectations and outcomes during the PMN process, notes Kindra Kirkeby, assistant counsel, NewMarket, the parent of leading manufacturing and support companies in the petroleum additives industry, including Afton Chemical. They can also anticipate increased time and costs for chemical testing because of the new requirement that the EPA make a definitive safety finding on all new chemicals, she says.

Redstone's Mr Eggenschwiler also suggests companies consider submitting new chemical PMNs now, as he predicts the fees will increase. The EPA is allowed to charge companies fees it incurs to assess and, if necessary, regulate their chemicals, capped at 25% of the agency's costs. Chemical manufacturers that request the EPA assess the risks of a chemical – as they can under the LCSA – would be required to pay the full cost of the evaluation and regulation.

LABORATORIES EXPECT TO SEE JOB GROWTH

"My sense is that industry is just now figuring out that they need to make a case to the EPA in their PMNs," says Stuart Cohen president, Environmental & Turf Services, a multi-disciplinary firm that specialises in water quality impacts. The discussions surrounding PMN submissions seems stuck on two extreme views, he adds: In one view people remember how PMNs were handled prior to TSCA reform. He says the other extreme is that companies are going to have to spend time and significant amounts of money to provide the EPA with chemical data that meets the TSCA requirements and protects the environment and human health.

"What I'm saying is there is a third point on this line which is an intelligent risk screening evaluation that can be done with a little more work and with data that can be dug up in the literature," Mr Cohen says. Quite a few consultants say they can help producers with this approach.

Manufacturers and processors can tap into the huge number of databases for information on hazard or environmental properties of substances. For chemicals that have little or no data, companies can use quantitative structure activity relationships (Qsar) to extrapolate information from similar substances for which data does exist.

People do not realise there are a lot of Qsars available, Mr Cohen says. "Let's put it all together in a risk screening evaluation and then focus on where the problems really are. It may be that all is needed is a couple of studies that combined would cost $30,000 and take one month."

Environmental & Turf Services is planning to develop a team with a toxicologist and a regulatory expert to complement its scientific test capability. The team will compile complete scientific packages, including data searches and comprehensive Tier 1 risk screening analysis and develop the paperwork for submission to the EPA.

Mr Cohen recommends that testing laboratories begin to build up capacity to do the type of shorter term tests that help a PMN move along in the new process. "They are the type of studies that can be done on a quick turnaround and won't break the bank," he says. For example, conducting a ready biodegradability study will tell the agency how quickly a chemical degrades in a wastewater treatment plant, which is a factor that is important to EPA's modelling.

There should also be an increase in the demand for scientists who can devise a strategy for which test should be done to come up with the specific data to satisfy the agency's approach, adds Mr Eggenschwiler. Decisions will also need to be made that determine the test methods that would be best to generate the required data.

This is not always clear, he says.There needs to be a dialogue with the laboratory because it needs to understand the substance and for this is relies on the manufacturer to select the test method, and what the second and third steps might be to provide the necessary information. "We do this a lot, in terms of discussion with the lab about what the procedures need to be and in what order, on a planned or contingent basis," Mr Eggenschwiler says.

REDUCING ANIMAL TESTING

Although the new legislation explicitly calls for reducing and replacing vertebrate animal testing, none of the proposed requirements provide a specific framework for meeting this objective. To address this, Gradient and the Humane Society of the US (HSUS) are working together to recommend evaluation strategies that promote the use of existing toxicity and exposure data as much as possible. This includes the use of robust read-across approaches that identify chemically-similar substitutes, consider high-throughput screening and Qsar data, and preferentially use studies that employ *in vitro* test methods, says Ari S Lewis, principal, Gradient. "We anticipate that these efforts will not only meet TSCA's animal welfare objectives, but will also [lead to] further innovations in toxicological analysis while being more time- and cost-effective than conducting animal studies," she adds.

Another option is to purchase access to the data that has already been generated, by buying membership in a US consortium, says Joshua Nevels, technical director of global chemical regulatory compliance with Global Safety Management (GSM).

The US consortia are similar to those set up in the EU as companies prepared for REACH. In them, companies that have a common interest in a substance gather the relevant substance identity, hazard and exposure data to perform the safety assessment. Data that is not in the public domain is valued, and members of the consortium calculate what

DEKRA Insight

Helping process industries improve performance and avoid major fire, explosion, and loss of containment events

www.dekra-insight.com
www.chilworth.co.uk

DEKRA Insight represents the collective expertise of our member companies, each an institution in safety.

BST Chilworth optimus seventh generation RCI Round the Clock Resources Russell Consulting

Sphera has been helping industry leaders achieve excellence in product compliance for over 25 years.

Where are **you** looking to drive improvements?

Comply with REACH and GHS

Automate the creation and distribution of Safety Data Sheets in 46 languages to global markets

Leverage global managed content:
- + 15,000 Regulatory Phrases and Translations
- + 7,500 Compliance Rules
- + 300,000 Chemicals & Properties Data

Simplify data management and production of SDS Documentation and labeling

Streamline chemical management from end-to-end

Improve insight for product classifications and regulatory impacts on your product portfolio

Access a team of Regulatory Experts to complement your in-house resources

spherasolutions.com | *Sphera Solutions, formerly the Operational Excellence & risk Management division of IHS, is now the largest global provider of software and information services in EHS*

companies should pay to reference the data in regulatory submissions. In this way, data costs can be shared, and the data owners are compensated.

For REACH, many of the EU consortia sorted out the data needs and costs for the substance information exchange fora (Siefs), which were responsible for submitting registrations.

In the US similar groups cooperate for submissions like premanufacture notices under TSCA, or registration under the Federal Insecticide, Fungicide, and Rodenticide Act (Fifra). "Even if you think you don't necessarily need access to say, the efficacy data, because perhaps you have no intention of registering your substance as a pesticide under Fifra, you may still wish to access the safety or exposure data that is also available through the consortium. Because consortia typically offer several tiers of access to their data, membership may still be of value. This can be especially true if the EPA finds during its risk evaluation or safety determination that your substance requires additional data to support a particular use under the revised TSCA," Mr Nevels says.

While the demand for REACH-type consortia in the US might increase, consultants can also help manufacturers and processors find the right consortia and the specific research with that consortia that could make a good case for approval from EPA.

WORK WILL GROW FOR REGULATORY CONSULTANTS

With the nuts and bolts of TSCA reform now under development, all of the companies and consultants interviewed advise that specialty chemical manufacturers and downstream users keep up on the regulatory changes as well as new guidance issued by the EPA. Consultants are helping their clients track TSCA reforms applicable to specific substances, and can help in the development of strategies specific to a company's portfolio.

Paul Brigandi with CGI, an IT and business process services and consulting firm says his company has seen an increase in people seeking advice about TSCA reform provisions. He expects this to increase because of the many nuances in new law that people may not fully understand.

Some clients may need education, for example, about the aspects of the reform they need to focus on. "I am telling them they need to be more strategic in how they look at their chemicals programme," says Mr Brigandi. "If you have data, you want to try and leverage as much of that as you can," he says.

In this new environment, the EPA is actively working toward using more read across, more no-animal testing, and more *in silico* methods. He adds that companies should put all of that data upfront, as much as they can, in order to support their substance and demonstrate it does not need more regulation, if the data suggest that.

"Obviously if your substance is hazardous, and if you need exposure controls ... if you want your submission to go faster, be upfront about it," he says. "This will make the EPA's decision easier. For example, if you think your substance is mildly hazardous and needs general ventilation, submit the data and your justification. If the data is not submitted, the EPA could determine that it does not know the level of hazard, and as a result, conclude that people should wear respirators."

BRAND REPUTATION

Patricia Beattie of SciVera works with cloud-based software tools and she also recommends chemical manufacturers and processors be more strategic in how they approach their products. SciVera counts as clients toy companies, and children's apparel or fabric manufacturers, with both small and very big companies. "A lot of our work is strategy focused, with companies that want to make sure nothing happens to their brand's reputation, and want to make sure they have information that is a little more comprehensive than what chemicals are on a list," Dr Beattie says.

Companies across the board are expected to see new challenges related to how the EPA handles CBI reforms, several consultants say. Redstone's Linda Curhan, senior regulatory specialist, says there is no doubt that it will become much more difficult to claim confidentiality under the EPA's new scrutiny, and companies need to prepare for these stricter requirements. Companies should take time to review their CBI now and only keep claims for those chemicals where they can substantiate the reason. Consulting companies can assist companies compose substantiation claims by helping them navigate through the agency's questions, Ms Curhan says.

INVENTORY RESET

While most companies should be aware of the larger TSCA reforms Bonita G Reynolds senior director, authoring services, 3E Company sees one exception: "Processors may be surprised to find that they, in addition to manufacturers, must respond to the TSCA inventory reset rule. For most TSCA regulations the focus is on manufacturers and importers while processors are exempt. This is an emerging development that will cause a shift in the way the industry responds. Some processors may be taken off guard to find this section of the regulation applies to them."

Several companies report that substantial uncertainty remains about how the agency will implement the chemical prioritisation process to initiate new risk evaluations. "EPA has also not clearly defined what using the 'best available science' means or detailed how to use the 'weight of evidence' in hazard assessments. Gradient scientists are very familiar with weight-of-evidence methodologies and, in fact, have published articles in peer-reviewed scientific journals on how to implement weight of evidence in risk assessments," Gradient's Ms Kneeland says.

Under reformed TSCA, importers are subject to the same obligations as manufacturers. Thus, complying with specific provisions under the LCSA as an importer also presents unique challenges. For example, under the Act, there will be a reset of the TSCA inventory 'active' chemical substances so that the EPA focuses risk evaluations for existing chemical substances in commerce. Each company must notify all chemicals that they manufacture, and in some cases import, to the EPA to place them on the active inventory in order to continue commercial activity, says Karen Lintz, regulatory affairs director with UL Supply Chain & Sustainability.

The EPA's inventory reset will affect every company that manufactures chemicals, or makes products using chemicals, as well as those that import from outside the US, says Irene Hantman, counsel with Verdant Law, a firm with a practice primarily focused on the environmental regulation of products. The inventory reset could present a challenge to importers as they will need to work with their upstream supplier if they import proprietary substances with confidential chemical identities. Importers of mixtures will need to ensure that all substances in the mixture are notified. Further, it is also essential that domestic formulators confirm that their suppliers comply with the inventory reset notification to ensure continued raw material supply, adds Ms Lintz.

Global chemical regulations are complicated.

Let us be your guide.

As a CRO with global regulatory expertise, we can help you put an effective plan in place to meet chemical notification requirements accurately and on time. We have the multidisciplinary experience and capabilities to support you from the first study to dossier submission and beyond. From individual line items to complete programs, trust us to assist you through chemical registration in any region.

Your full-service partner with:

- Proven success in achieving complete chemical registrations, including REACH
- Knowledge and experience in dealing with global regulatory authorities
- The ability to handle the entire registration process on your behalf
- An understanding of what is required for your substance identity
- Chemical safety assessment capabilities, exposure and risk assessment and risk refinement strategy
- The knowhow and ability to optimize testing for multiple markets and regions

Pressure on testing laboratories

In vitro skin sensitisation tests came to the fore in 2016, and as companies ramped up their activities for the 2018 REACH registration deadline, policy makers re-emphasised the importance of avoiding animal tests. Meanwhile, in the US, the regulation of chemicals changed significantly with the long-awaited revision of the Toxic Substances Control Act – the key legislative instrument.

Unsurprisingly, these events are all affecting the outlook for the chemical testing market.

According to Transparency Market Research (TMR), the global testing and analysis services market is expected to grow at a compound annual rate of 5.6% between 2015 and 2023, when it is forecast to reach $29.1bn.

This growth is being driven by a variety of regulatory requirements and updates alongside the expansion of testing services into new markets. According to TMR, North America is the largest market for such services, followed closely by Europe. But it is Asia Pacific that is expected to witness the fastest growth rate between 2015-2023, as European and American testing companies move into the region in response to expansion of the region's manufacturing capacity.

The 31 May 2018 REACH registration deadline for substances used in volumes of 1-100 tonnes/year is one of the biggest drivers of the testing market, but it is not the only one. Many companies have ongoing, increasing needs for laboratory or CRO services, in particular those in the pharmaceutical and agrochemical industries. Alongside this, there is continuing demand for testing of new products and substances and additional testing – in particular for reproductive toxicity – of many substances registered for REACH in 2010 and 2013.

THE PRESSURE ON LABS AND CROS

As deadlines get closer and demands continue to grow, laboratories and CROs look set to be especially busy throughout 2017 and into 2018. Companies are likely to turn to them for varying levels of help, depending on their experience, knowledge of substances and legislative requirements.

"Some CROs are saying that for some of the testing needed to meet the 2018 deadline they are already fully booked," says Laurence Hoffstadt, scientific officer at Echa. "This is not just down to REACH, but other commitments and regulatory requirements, too."

Arno Wess, expert consultant at Envigo CRS, agrees: "We have a significant workload because of the approaching deadlines. This is affecting almost all consultancies, and labs are struggling to perform the studies as early as required. It's a very demanding time."

Many are facing challenges from potential registrants encountering REACH for the first time and not realising the need to act now.

"Many still believe that testing for REACH 2018 is something available overnight and can wait until Q4 of 2017," says Frank Visser, European sales director, Charles River.

However, it is not only a matter of finding a laboratory that offers the required capacity. Companies must find one that can undertake the necessary tests in the right way.

"One of the challenges we have in the US and also in Europe is finding laboratories that have responded to and updated their services to be compliant with OECD guideline changes that occurred over the summer," says Jane Vergnes, senior toxicologist at Bergeson & Campbell and the Acta Group.

REGULATION UPDATES

On the regulation front, several changes took place in 2016 that have affected the sector. The REACH annexes have been revised with regard to:

- skin corrosion/irritation;
- serious eye damage/eye irritation;
- acute dermal toxicity; and
- skin sensitisation.

Registrants should only conduct an *in vivo* study if equivalent *in vitro* and *in chemico* test methods are not applicable, or if the test results are not adequate for risk assessment.

In the US, the then President, Barack Obama signed the Lautenberg Chemical Safety for the 21st Century Act in June last year, after a decade of discussions.

This amends TSCA, the US's primary chemicals management law. The EPA must now evaluate existing

chemicals to clear and enforceable deadlines. In addition, the revised law includes provisions for the development strategic plans around alternatives, the creation of a new risk-based safety standard and increased public transparency for chemical information.

"What this affirmative statement of safety will look like – how much and what kind of data will be required – is yet to be defined by the EPA," says Thomas Hartung, director of the Center for Alternatives to Animal Testing (CAAT). "At the moment this is what they're focusing on, by setting up advisory panels."

Professor Hartung also notes that potential harmonisation of approaches to chemicals assessment between Europe and America was investigated under the Transatlantic Trade and Investment Partnership (TTIP). However, "both sides agreed that harmonisation would not be easily possible and therefore would leave each other the right to regulate."

In the US the EPA's focus is on the Toxicology Testing in the 21st Century (Tox21) programme. This aims to use knowledge already gathered on chemical properties to improve risk assessment methodologies, enabling faster and more efficient evaluation of chemicals' effects on human health.

"The emphasis is going to be on how you collect data to address specific adverse outcome pathways (AOPs)," which describe the chains of molecular events in a body that lead to chemical-induced health effects, Dr Vergnes says.

She points out that the US is seeing a growth in the use of computational data as well as molecular biology techniques to undertake large-scale, high throughput screening of certain traits. This work lowers costs, time taken and the use of animal studies. The EPA's Toxicity Forecaster (ToxCast) project has already developed more than 700 plate-based tests to detect 300 cell-signalling pathways using a variety of approaches such as exposing human cells or cell receptors to chemicals.

"Not all are considered alternatives to animal testing, but they are *in vitro* and cell culture tests that are allowing them to profile substances," Professor Hartung notes.

"With Tox21, it's not a discussion about whether we need to change testing technologies, but only how and how fast. In the US this move isn't mainly animal welfare-driven, but actually technology-driven. They see that the current methods have limitations, they're too expensive and the throughput is not acceptable," he adds.

ALTERNATIVE TESTING: A REQUIREMENT, NOT A CHOICE

Regulations may often be slow to accept new tests. But current strategies are now taking into account that there is a growing availability of alternative test methods that reduce the use of animals and help to push businesses towards approaches that replace,or at least reduce, the use of *in vivo* methods.

Many of the alternative methods increasingly embraced by regulators deal with well-understood endpoints such as skin sensitisation and irritation, as well as eye irritation. Alternatives for acute toxicity testing are also becoming more popular, but things are further behind for more systemic endpoints, such as repeated dose toxicity and reproductive toxicity, notes Katy Taylor, director of science and regulatory affairs at Cruelty Free International.

Businesses must keep in mind that alternative testing options should always be their first port of call when preparing registration dossiers. With REACH, for example, they should only undertake tests on animals if no other options are available.

"Alternatives are no longer just a good idea," says Mr Wess. "According to my interpretation of the Echa guidance, to do an animal test when an alternative is available is an illegal infringement.

Testing strategies therefore need to consider the latest and imminent developments in alternative testing.

"While some legislation may reflect the availability of alternative tests, continuous developments may mean that acceptable alternatives are not always specified," says David Andrew, principal consultant at TSGE Consulting. "The availability of validated alternative methods therefore needs to be assessed and the regulatory acceptability of the methods considered."

Indeed, finding a laboratory or CRO that offers the necessary alternative tests can be an issue, as many are still considering whether they offer these tests now, due to demand, or hold off as the demand disappears post REACH.

"The REACH-compliant skin sensitisation *in vitro* and *in chemico* methods are relatively new and we don't entirely know how many labs can currently perform these tests," notes Kimmo Louekari, senior scientific officer at Echa. "We think the market is growing, but whether all companies will have their tests done in time is still a question. Hopefully labs are beginning to specialise in the *in vitro* tests, as we anticipate some opportunities for them there."

DEVELOPING EFFECTIVE TESTING STRATEGIES

With so many contingencies to plan for, an effective testing strategy will offer organisations a myriad of benefits. It will support successful clearance of regulatory hurdles, ensuring studies are done in a manner that maximises acceptability across as many jurisdictions as possible and result in more efficient, economical and timely testing.

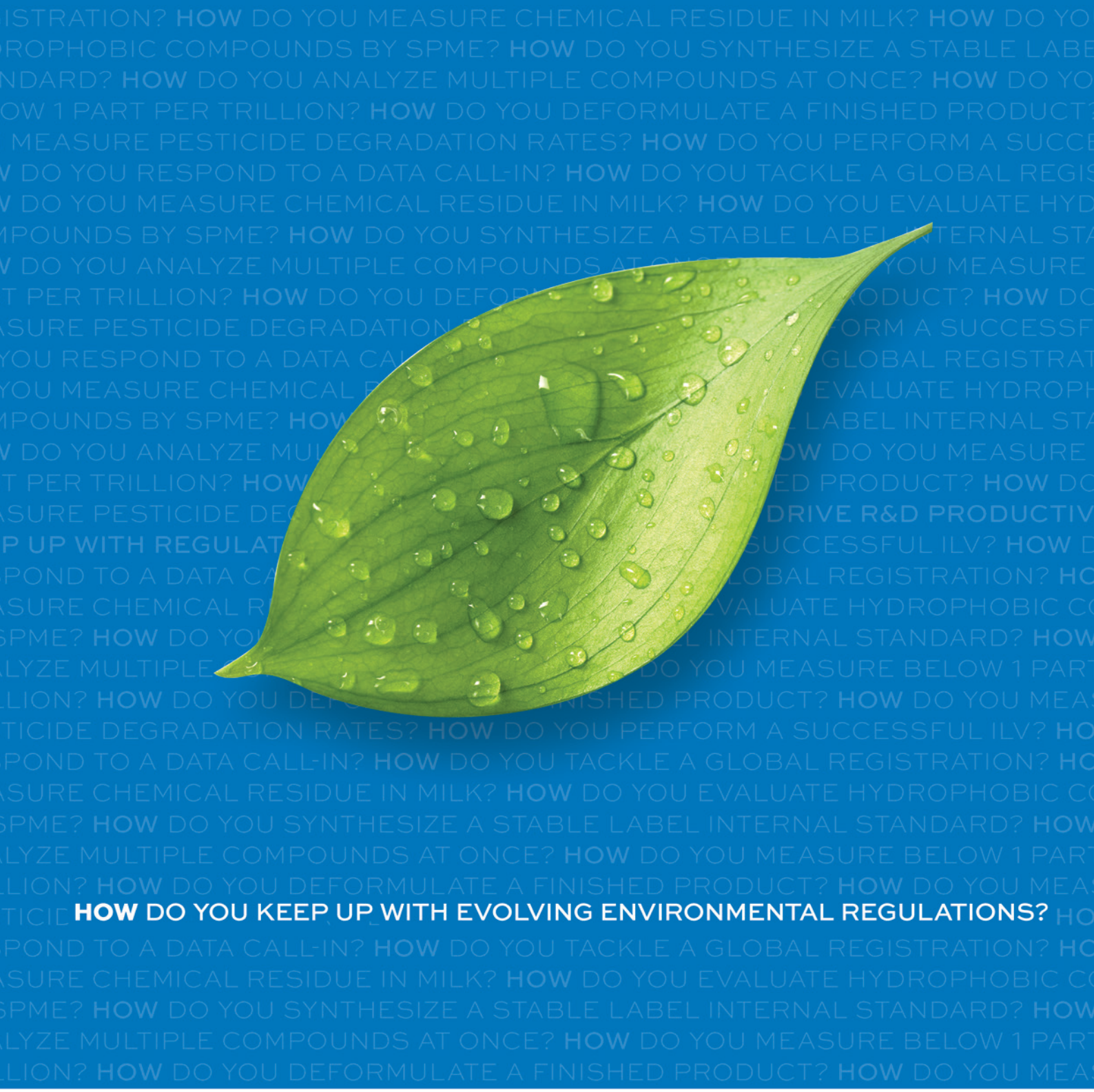
Integrated strategies, intelligent testing strategies (ITS), integrated approaches to testing and assessment (Iata): whatever you call them they are complex undertakings, and in most cases you will want to obtain the maximum quality information from as little as possible testing.

Behind the successful development and implementation of a testing strategy should be a basic set of steps, which Joyce Borkhoff, regulatory expert at Intertek, believes should be broken down to the following as a minimum:

- develop regulatory knowledge;
- understand your chemistry and your company's intended use and applications;
- define studies required by jurisdiction;
- undertake data gap analysis;
- develop your study selection; and
- begin placement and monitoring of studies.

"The first step requires research into the regulations and an understanding of the decision factors associated with the schemes of interest," she says. "There are many fundamental decisions that need to be made at this point, not only to understand the type of dossier that must be prepared, but also to provide necessary input for the prioritisation aspects of the plan."

Dr Andrew says: "The relevant regulation generally includes a simple list of the tests required. However detailed guidance on meeting the data requirements is published separately and may be far more extensive than the list of tests in the regulation. Familiarity with the details of the guidance is therefore essential in order to ensure an appropriate testing strategy."



How do you determine the environmental fate of a chemical substance? How do you measure below 1 part per trillion? How do you perform a study that has never been done? EAG knows how to translate guidelines into study designs to deliver the specific, reliable data regulators expect. **Ask EAG. We Know How.** EAG.COM

EAG Laboratories has brought together the most respected brands in environmental science to offer you a better choice for outsourced contract research services. With over 140 years of combined experience, EAG companies (formerly Wildlife International, PTRL West, PTRL Europe and ABC Laboratories) deliver aquatic, avian, and terrestrial toxicology services in AAALAC-accredited, GLP-compliant environments and the full range of environmental fate and metabolism testing required by the global agricultural, pharmaceutical, consumer product and chemical industries.

EAG LABORATORIES | WE KNOW HOW™

A GLOBAL SCIENTIFIC SERVICES COMPANY

MATERIALS SCIENCES • ENGINEERING SCIENCES • LIFE SCIENCES

EAG.COM • +1 800 538 5227

Royaltain Research
COMPANY

... Expands your horizons ...

French CRO specialised in environmental toxicology and ecotoxicology

ECOTOXICOLOGY

- Acute and chronic regulatory studies
- Aquatic/terrestrial organisms
- GLP guidelines, ISO standard, ASTM...

SUBSTANCES PROPERTIES AND ENVIRONMENTAL FATE

- Physical-Chemical properties
- Biodegradability and Bioaccumulation studies
- GLP guidelines, ISO standard, ASTM...

MESOCOSM STUDIES

- Dedicated climatic chambers/experimental hall
- Humidity, temperature and lighting controlled
- Biosafety level 2 or 3

ANALYTICAL AND BIOANALYTICAL CHEMISTRY

- Development and validation of analytical method
- Biomarker identification
- Organic substances monitoring

MALDI Imaging

- Macromolecule analysis
- Spatial repartition of targeted molecule in matrix
- Organ or plant tissue analysis

SCREENING AND OTHER ACTIVITIES

- Bibliographic studies
- Protocole custom made
- Efficiency tests

2 rue René Truhaut, 26300 Alixan, FRANCE - Phone: +33 77 66 33 805

royaltainresearch.com

Once the relevant information on the substance, its use and its regulatory requirements is gathered, the outcome should provide the necessary foundation to determine the full suite of endpoints and prescribed methodologies needed, which leads to one of the most important steps – the gap analysis.

"A comprehensive literature search may identify existing studies that would otherwise be expensive and time consuming to perform," says Dr Andrew. "Depending on the legislation, it may also be possible to read across to existing data for other closely related substances; this approach has the potential to significantly reduce the extent of testing required, but is associated with greater uncertainty and also requires a robust scientific justification."

Mr Visser says it is important to take a look at the bigger picture. Companies should assess where they plan to register their substances: only under REACH, or in other non-EU legislations that require data for registration? For REACH, *in vitro* alternatives, waiving statements and read-across are options to use as part of filling up the data gap, but this may not be accepted by authorities involved in the registrations or notifications in other regions in the world. This will influence decisions and direction for testing strategies and to what extent alternative approaches can be used, he says.

By identifying existing information gaps, it is possible to develop the necessary study selections to meet the business and regulatory requirements. Finally, it is time to get the studies underway, but companies should consider the need for a CRO, as well as a laboratory's capacity, speed and wait times. More than one CRO or laboratory may be required for an extensive testing programme, and it is also important to consider the sequence of testing.

According to the US EPA, testing is often based on sequential or tiered assessments, where a result at the initial tier is used to inform subsequent steps by identifying the importance and best approach for characterising specific endpoints in next tiers.

Generally, the tiered testing moves from basic physico-chemical properties testing to tests relating to the fate of the chemical in organisms or the environment. The results from these tests can determine what types of exposures may be expected and therefore what types of toxicity tests would be most relevant.

In all cases, however, it is essential to define the testing strategy as early as possible in order to allow for careful planning, time for the studies to be performed and contingency in case of unforeseen results.

With so many variables and pathways to consider, the development of a robust and efficient testing strategy can be extremely complicated. Help is on hand, however. Bodies such as Echa have plenty of resources available. For example, there are several REACH-focused webinars and practical guides available to download online. These cover information requirements, test methods and timescales, as well as practical examples.

Meanwhile, *Chemical Watch's* sister publication *Chemical Risk Manager* is developing a test database to bring together all the information in one place.

ENDOCRINE DISRUPTORS

Regulatory approaches for endocrine disruptors

Dr Martina Duft, ecotoxicology/regulatory affairs expert with Dr Knoell Consult reviews the different approaches taken to identifying EDCs in Europe, the US and Asia.

Endocrine disruptors, their definition and criteria as well as feasible options for testing and assessment, have been extensively worked on and discussed in science and regulatory panels. The debate has engaged the public and national and global political agendas.

Meanwhile, the WHO/IPCS definition of an endocrine disruptor is unanimously agreed upon:

"An exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in an intact organism, or its progeny, or (sub)populations."

Consequently, distinct adverse effects and their causal relationship to substance exposure, by a proven endocrine mode of action, need to be established.

By contrast, the scientific criteria for their identification have been the object of fierce and tedious detailed discussions. Finally, in June 2017, the European Commission

CGI

Experience the commitment®

For more information, contact **EHS@cgi.com** or **visit cgi.com/environment**

A leader in chemical regulatory compliance management

Providing end-to-end capabilities for global compliance and holistic product stewardship

Advisory Services

- EHS Compliance Audits
- Mergers, Acquisitions, and Divestitures
- Regulatory Consulting
  - GHS
  - REACH
  - TSCA
- IT Portfolio Optimization

ProSteward360®

- SDS / eSDS Authoring
- Exposure Scenario Management
- Vendor SDS Management
- Chemical Inventory and Workplace Management
- Reporting and ERP Integration

Outsourcing Services

- Hazard Communication
- Vendor SDS Management
- System Administration
- Hosting
- Application Implementation and Upgrade

CGI's EHS experience and expertise

- 20+ years experience in EHS information management
- Strategies and solutions that support compliance and reduce costs
- Business and technical expertise to help you tackle regulatory changes
- 200+ years of combined experience in product and regulatory compliance

presented its long-awaited draft scientific criteria to identify endocrine disruptors (EDCs) in the field of plant protection products and biocides.

This announcement was preceded by an expert meeting, organised by the Federal Institute for Risk Assessment (BfR) in Berlin in April. The meeting resulted in a consensus paper, essentially suggesting the presented criteria.

Mid-March 2017, the proposed criteria are still not adopted. Until final scientific criteria are agreed on and adopted, interim criteria for toxicology still apply for plant protection products and biocides: carcinogenic category 2 and toxic for reproduction category 2 – shall be considered as EDC, or toxic for reproduction category 2 and specific effects on endocrine organs – may be considered as EDC. However, no interim criteria are available for wildlife.

Current regulatory approaches to identify EDCs differ around the world.

EUROPEAN UNION

A community strategy for EDCs was developed by the Commission in 1999. It involves regular updates on implementation, including a priority list of substances for further evaluation. In 2014, the roadmap on "Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products Regulation and biocidal products Regulation" was presented.

It included a public consultation (report published in July 2015) and an impact assessment (IA) (published in June 2016), to evaluate health, socio-economic and environmental impacts of the different options for the criteria and their implementation in the respective legislations.

The IA was supported by two studies, which selected substances and screened them for their potential to be identified as EDCs according to the options, and an assessment of the potential impacts on health, environment, trade, agriculture and socio-economics was made. The screening was guided by a methodology developed by the Commission's Joint Research Centre (JRC).

Several pieces of legislation are relevant with regard to EDCs in the European Union.

In addition to the plant protection products and the biocidal products Regulations, REACH and the cosmetics Regulation are highly important.

Under REACH Article 57f, EDCs are eligible as SVHCs with an equivalent level of concern as for PBT or CMR substances. Thus, generally they might be subject to authorisation, including a socio-economic analysis.

By January 2016, Echa had selected about 300 chemicals for additional manual screening by the national authorities, for further regulatory action. An important focus was on substances with endocrine-disrupting potential. Substances were selected by an automated IT screening of any data available, meaning the complete REACH registration database, existing lists and other databases, publications, Qsar model data, and data on exposure and uses.

To this end, a related "screening definition" document was issued in January 2016, specifying the scenarios for identifying potential endocrine disrupting substances. It is emphasised that no single scenario is considered sufficiently robust for selecting a substance for manual screening. Thus the scenarios should be considered in a weight-of-evidence approach. In a nutshell, the following scenario categories were applied:

- check if the substance itself, or a constituent, impurity or additive can be found in published/external lists of suspected EDCs (Commission, WHO, TEDX or SIN) or are structurally similar to substances in these lists;
- use of models to predict if the molecular structure of the substance itself, and its constituents, impurities or additives trigger specific structural EDC alerts, such as those based on the Danish Qsar models, developed by the Technical University of Denmark;
- check the self and harmonised classification, suggesting suspected endocrine disrupting effects, such as the presence of specific target organ toxicity classifications for endocrine organs;
- analyse information in the registration dossiers and chemical safety reports, by screening text patterns typically associated with evidence for/indications of endocrine disrupting properties (for example, repeated dose toxicity, toxicity to reproduction, fertility and developmental toxicity, long-term aquatic toxicity); and
- positive findings in external experimental data generated with assays, for example, ToxCast *in vitro* data (see further below).

Application of these scenarios led to the selection of more than 100 substances. These were ranked according to total tonnage for full registrations, which resulted in the selection of 75 of them.

The cosmetics Regulation is currently still under review, and so far EDCs are not restricted in any way. Once that the criteria for the identification of EDCs are adopted, a review will be completed.

No precise data requirements are foreseen for any European regulation, but studies can be requested at any time and at any level of the assessment. Requested studies are mostly based on the OECD Conceptual Framework for Testing and Assessment of Endocrine Disruptors, and detailed guidance for the assessment is provided in the comprehensive OECD guidance document No 150: Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption.

In parallel to the process of defining the scientific criteria, individual proposals have been put forward by different European nations. These vary considerably, not least in that some are more risk-based and some are strictly hazard-based. However, in general, European proposals mostly focus on a hazard-based assessment, proposing endocrine disrupting properties as cut-off criterion with few exceptions.

Currently, assessment is mostly conducted on a case-by-case basis.

AMERICAS

In the US, the EPA takes an opposite approach with its comprehensive, two-tiered screening programme, which is still followed by regular risk-based assessment. The Endocrine Disruptor Screening Program (EDSP) intends to cover oestrogen, androgen and thyroid hormonal systems with respect to human safety and wildlife*.

Tier 1 aims at the identification and classification of potential EDCs by *in vitro* and *in vivo* assays (series 890, EDSP Test Guidelines). Tier 2 focuses on the establishment of concentration- or dose-response relationships, with several test guidelines finalised in August 2015.

The initial tier 1 list of 67 chemicals to be screened was issued in 2009, followed by list 2 in 2014. This is made up of 107 substances. It is strongly emphasised that the lists are not intended to be lists of suspected chemicals, but instead are based on a potentially high level of exposure (pesticide active ingredients and HPV chemicals, used as pesticide inert ingredients).

Results of tier 1 assays are reviewed together with other scientifically relevant information (Osri), leading to a decision on eventual further tier 2 testing. A review of tier 2 data will, in turn, directly support risk assessments for registration and actions.

In July 2015, the EPA published the first results from screening 52 chemicals from the tier 1 list. This identified a potential for interaction with endocrine pathways (EAT) for 32 of the chemicals, and further required actions on tier 2 testing for 18 chemicals.

It has been recommended that more modern, alternative approaches replace some of the EDSP tier 1 screening assays. Therefore, an efficient and robust screening programme is under development, applying high throughput *in vitro* screening assays and computational and *in silico* model alternatives, for example, ToxCast models, especially envisaged to be applied to a third draft list of chemicals.

ASIA

In China, an agro-industrial standard, Evaluation Method of the Endocrine Disruption Effects of Pesticides, became available in late 2014. It was reviewed by the Ministry of Agriculture, and has been implemented from 1 April 2016. The guidance includes two tiers and seven toxicological study types, and intends to screen for probable endocrine disrupting properties of pesticides, applying methods similar to the ones developed by the US EPA.

An action plan for water pollution prevention by the State Council was implemented in 2015, including a national survey on production and uses of environmental endocrine disruptors before the end of 2017. The aim is to eliminate, restrict or substitute EDCs.

In Japan, the Ministry of Environment has, for a long time, been promoting research on the mechanisms of endocrine disruption, environmental monitoring, as well as the development of test methods, hazard and risk assessment, risk management, information sharing and risk communication on the substances.

Several projects have been launched in the country, such as SPEED'98 and ExTEND (Extended Tasks on Endocrine Disruption). The ministry updated this in 2016. If results suggest that a substance has endocrine disrupting properties, it will be regulated under Japan's Chemical Substance Control Law (CSCL) and can be subject to restrictions or even banned.

In recent years, Japan has been actively collaborating with the US on the development of test guidelines for the US EDSP. Like the US, Japan advocates risk-based assessment.

IMPLICATIONS AND RECOMMENDATIONS FOR GLOBAL REGISTRATIONS

The foreseen EU criteria for EDCs will most certainly affect global trade, as they will apply to products imported into the EU, which in turn trigger a WTO notification.

Although their implementation in the respective EU legislations is not directly linked to other global regulatory programmes, this will influence the overall discussion on the assessment and regulation of EDCs, as part of a larger global policy debate.

In conclusion, weight-of-evidence and expert assessments, tailored for respective regulatory programmes, are still required for the evaluation of endocrine disrupting properties of a substance.

It is strongly recommended that studies are conducted carefully in order to meet global requirements and avoid redundant testing, not least with regard to animal welfare. Results obtained by studies for one regulatory programme will be considered and dealt with like any other.

**At press time, President Trump had issued a budget proposal suggesting the funding to the EDSP be cut.*

QSARS AND READ-ACROSS

Using Qsars and read-across for REACH 2018

REACH requires that chemical companies identify and manage the risks associated with substances they manufacture and market in the European Union. To register a substance, companies need to provide information to characterise its physico-chemical properties, human health and environmental effects.

REACH is explicit that tests on vertebrates should be conducted as a last resort and offers considerable scope

Your last chance to make it for REACH 2018

Let us be your guide

- Complete REACH solutions (tests / IUCLID / CSR)
- Global integrated registration services
- SIEF and consortia management
- OR and trustee support

SCC Scientific Consulting Company
Chemisch-Wissenschaftliche Beratung GmbH
Am Grenzgraben 11 • 55545 Bad Kreuznach • Germany
info@scc-hq.de • www.scc-gmbh.de

SCC
WE CARE FOR YOUR SUCCESS

CHEMTREC®

The right information at the right time

ARE YOU COMPLIANT?

www.chemtrec.com

sales@chemtrec.com

to avoid such testing under Annex XI. Alternative methods such as (quantitative) structure-activity relationships, or Qsars, grouping approaches (analogue and category) and *in vitro* tests may be used as part of an endpoint-specific integrated testing strategy (ITS).

When applying non-testing approaches, such as Qsars and read-across under REACH, a number of factors needs to be considered.

The underlying basis of a Qsar is that the activity of a substance is related to one or more physico-chemical properties or descriptors, derived from a chemical structure. A Sar represents a qualitative association between a chemical substructure and a biological effect, whereas a Qsar statistically relates the activity of chemicals to their physico-chemical properties and/or structural descriptors. Under REACH, Qsars may provide estimates for endpoints in lieu of testing when certain conditions are met. In particular, the scientific validity of the Qsar and its applicability to the substance of interest must be assured.

The following factors need to be considered:

- scientific validity of a Qsar makes reference to the OECD Principles for Qsar Validation (OECD, 2004, 2007). A Qsar should be associated with a well-defined endpoint, an unambiguous algorithm, a defined applicability domain, appropriate measures of goodness-of-fit, robustness and predictivity, and a mechanistic interpretation, if possible. The Qsar Model Reporting Format provides a convenient template to sumarise the key information that characterises these principles;
- the applicability domain needs to be assessed to provide a pragmatic means of demonstrating the relevance of a Qsar to a substance of interest. There are many ways in which an applicability domain may be extracted from a Qsar, for example, using numerical descriptors, structural features, metabolic transformations or mechanistic information. Software tools such as AMBIT Discovery and LMC Domain Manager are helpful to assess applicability domains. Substances that lie within the applicability domain of a given Qsar are more likely to give rise to an accurate prediction. This and the evaluation of its relevance with respect to the applicability domain can be documented in a Qsar Prediction Reporting Format.

Use of Qsars is most promising for fulfilling data gaps for physico-chemical, ecotoxicity and environmental fate properties. Significant progress has also been made for *in vitro* genotoxicity endpoints, skin sensitisation and skin/eye irritation. Qsars for repeated dose toxicity endpoints are not sufficiently evolved to be used to provide estimates in lieu of testing but may be useful in supporting read-across within grouping approaches.

Chemical grouping comprises both analogue and category approaches. An analogue approach refers to a grouping based on a very limited number of substances, whereas a category refers to a more extensive range of analogues. A chemical category is defined as a group of chemicals whose physico-chemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity. Read-across describes one of the methods for filling data gaps in either the analogue or category approach.

To derive a category/analogue approach, one must first identify and evaluate the relevance of analogue(s) and then evaluate the scope of the category/analogue – whether it should be restricted to certain endpoints and how a read-across might be substantiated for each endpoint. Other considerations include the classification and labelling of the category members as well as their impurities.

For grouping the following factors need to be considered:

- existing categories should be evaluated. A number of categories have been developed in the past under other regulatory frameworks, such as the OECD high production volume (HPV) programme. Checking whether a substance is a member of such a category is an important first step in the REACH workflow. The OECD Toolbox can help identify whether a substance is a member of, or falls within the scope of, an existing category. In either case, the registrant is responsible for reviewing the available information to determine whether the data and supporting information are sufficient to address REACH requirements;
- identify and evaluate analogues, if no existing category is available. This step gathers information for the substance of interest to help inform the evaluation of any "similar" analogues, identified following a structural similarity search. Similarity may be characterised by what is known about the substance and how the related analogues compare in terms of their physico-chemical properties, reactivity potential and metabolism. Tools such as the OECD Toolbox or Toxtree can be helpful in this evaluation;
- if a change in chemical properties corresponds to a trend in toxicity, use interpolation within a category to predict values for the target substance from experimental values for neighbouring category members on either side, or use extrapolation for cases where only one analogue is identified. Confidence in a read-across prediction depends on the amount and quality of data available for each category member, the robustness of the trend underpinning the category and, to an extent, size. Echa appears to have a preference for data to be interpolated; however, extrapolation has been accepted as a scientifically valid method. Registrants should refer to the illustrative example, published by Echa, and the agency's read-across assessment framework (RAAF). Some of the practical pitfalls of read-across are also discussed in Ball et al, (2014);
- Evaluate the scope of the category/analogue so that a read-across can be adequately justified for each endpoint. Reference to structural similarity alone is typically insufficient. A category (analogue) reporting format document is a helpful framework to document, in a systematic manner, all the considerations and assumptions made in reasoning the grouping and associated read-across.

Read-across can be enhanced with mechanistic information from Adverse Outcome Pathways (AOPs). They provide a framework to relate chemical structure to an adverse outcome through a series of key events. Several AOPs are in development under the auspices of an OECD programme. The first to be published are for skin sensitisation.

KEY MESSAGES

Although the 2018 REACH deadline represents the significant task of compiling the information requirements for Annexes VII and VIII, Annex XI provides opportunities for using adaptations prior to any experimental testing. To maximise the validity of non-testing methods to fill data

BLUE FROG SCIENTIFIC

BLUEFROGSCIENTIFIC.COM

BLUE FROG CHEMICALS

BLUE FROG SCIENTIFIC HAS RECOGNISED EXPERTISE SUPPORTING REGULATORY PROGRAMMES FOR CHEMICALS.

gaps, registrants should consider the types of endpoints for which these exist, assess the applicability domain of available Qsars, use the templates provided and favour a weight-of-evidence approach consistent with the relevant ITS described in the technical guidance, making use of AOPs where possible. It is the responsibility of the registrant to adequately define and justify the use of any method, used to waive new animal tests.

This article has been adapted from material presented in a series of webinars on alternative approaches to animal testing organised by Chemical Watch and Peta International Science Consortium Ltd. Collaborators include: Dr Mark Cronin is a Professor of Predictive Toxicology at the School of Pharmacy and Chemistry at Liverpool John Moores University, UK; Dr Grace Patlewicz (then with DuPont's Haskell Global Centers for Health and Environmental Sciences, now with the National Center for Computational Toxicology, US EPA and Julia Baines with Peta.

REACH & SUPPLIERS

What does REACH mean for suppliers?

The announcement, earlier this year, that Echa expects to receive approximately 60,000 registration dossiers for 25,000 substances by the 2018 REACH registration deadline, brought the nature of the final phase-in into focus for many registrants.

Importantly, the deadline will have a large impact on the downstream user, something they must be aware of well in advance. So what are their obligations when a supplier completes a REACH registration?

SUPPLIER REGISTRATIONS

REACH Article 6 (1) sets registration requirements for "any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year..."

While Article 3 (13) defines a downstream user as "any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities ...".

If a supply chain actor is downstream of the original substance manufacturer or importer, the registration burden lies with the latter. Although there are remaining REACH obligations for the downstream user to consider and manage, it benefits from the supplier's REACH registration.

The downstream user avoids the upfront and deferred costs, associated with registration. For example, those to obtain a letter of access or the shared costs of further studies. Ongoing savings may also arise from reduced regulatory affairs resourcing.

For the registering supplier, completing a registration is often mandatory due to cumulative manufacture/import tonnage. Extending the scope of their registration can contribute to the maintenance and/or growth of their market share. An existing registration can incentivise the use of the suppliers' product.

If a supply chain actor is downstream of the original substance manufacturer or importer, the registration burden lies with the latter.

DOWNSTREAM USER OBLIGATIONS

Downstream users may view supplier registration(s) as the answer to all their REACH obligations. In reality this is not the case. Being a downstream user in a supply chain will reduce the regulatory burden but not eliminate it.

Title V of REACH deals exclusively with downstream users, imposing two significant obligations. They must operate within the scope of a chemical safety assessment (CSA) that has been either prepared by themselves or the registered supplier (Article 37). Additionally they must report information to Echa under certain circumstances (Article 38). Both obligations have legally prescribed timelines, which must be addressed within 12 months (Article 37) or six months (Article 38), following receipt of the supplier's REACH registration number.

As a minimum, any potential downstream user should be aware of the following:

- Article 37 (2): They have the "right to make a use ... known in writing ... to the manufacturer, importer, downstream user or distributor who supplies him with

a substance or mixture with the aim of making this an identified use". The downstream user has the right to provide "sufficient information" to allow preparation of an exposure scenario. They may relay any use information from further down the supply chain to the next upstream actor.

- Article 37 (3): Upon receipt of use information from a downstream user, the party responsible for preparation of the chemical safety report (CSR) is required to assess the new identified use within a defined period, depending on the substance's phase-in status. Should it not be possible to include a new identified use in the CSR (for example, unacceptable risk), the supplier must inform both the downstream user and Echa in writing, without delay, detailing the reason(s) for non-inclusion.

If the supplier's CSA can accommodate their downstream user's use, the latter is obliged to operate within the scope of it. Failure to operate within the prescribed use(s), emission limits and/or risk management measures, set by the supplier, will mean the downstream user falls outside the CSA.

If a downstream user is outside the scope of a CSA, there are two options. They can attempt to find an alternative supplier who can provide the required substance/mixture and accommodate their required use(s). Or they are obliged to submit a downstream user CSR. Article 37 (4) states that "a downstream user of a substance, on its own or in a mixture, shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against." This requirement is independent of the ten tonne trigger set out in Article 14 (1) and the CSR shall be reported to Echa (Article 38 (1)). Article 37 (4) also incorporates a number of exemptions to these requirements if the downstream user is above the one tonne per use threshold prescribed by Article 38 (5).

FURTHER OBLIGATIONS

Additionally, the downstream user may have further REACH obligations under:

- Article 31 – requirements for the SDS;
- Article 32 – communication of information down the supply chain (SDS not required);
- Article 33 – communication of information on substances in articles;
- Article 34 – communication of information on substances and mixtures up the supply chain;
- Article 35 – workers' access to information; and
- Article 36 – retention of information.

It should be apparent that REACH obligations for downstream users are a potential regulatory quagmire. Assessing these is a repetitive process, required for each substance covered by a supplier registration. Key considerations include:

- type of product supplied (substance or mixture);
- registration status (pre-registration or full registration);
- existing identified uses;
- hazard classification;
- mass used per year by the downstream user;
- concentration limits (substances in mixtures); and
- product and process-orientated research and development (PPORD) applications.

SUPPLY-CHAIN SPECIFICITY

It is often forgotten that a REACH registration is supply-chain specific. A downstream user for a substance or mixture, is only such for that supply chain. But if they have multiple suppliers of a substance/mixture, supplier registrations for each substance in each supply chain are required. These registrations must therefore be considered in terms of both procurement and regulatory strategy.

DOWNSTREAM USER RECEIVING A MIXTURE

If a downstream user receives a substance from their supplier, the challenge of meeting their obligations is not comparatively straight forward. The registrant is obliged to disclose substance identity, either via the SDS or by communicating their REACH registration number. Once the substance identity is known, determining the associated requirements is relatively straightforward.

However, a downstream user will often receive a hazardous mixture, containing one or more classified substances from their supplier. In such circumstances, meeting their obligations, particularly if operating outside of the registrant's CSA(s), may be complicated by the lack of clear substance identity and compositional information. Depending on hazard classification or registration status, the supplier may disclose substance identity for certain components but it is only obliged to disclose concentration ranges (REACH Annex II (Part A, 3.2)). A lack of reliable identity and/or compositional information will hinder the downstream user from accurately assessing and identifying their REACH obligations.

EUROPEAN SUPPLIERS

Sourcing substances/mixtures within Europe has potential advantages. A prospective downstream user can expect a supplier to be well informed about REACH, able to directly monitor their capacity to accommodate customer consumption within their registration tonnage band(s), and should also be well equipped to support them on an ongoing basis (for example, accommodation of new uses).

NON-EUROPEAN SUPPLIERS

In this case, cooperation between the non-European supplier, their only representative (OR) and the downstream user is essential. REACH Article 8 (1) requires the OR in the supply chain to fulfil the obligations of an importer for registration. For the downstream user, the OR is the REACH registrant and is usually the point of contact for related concerns. The non-European supplier acts as the point of contact for procurement. Communication throughout the supply chain is essential from all parties, to ensure that the OR can fulfil its obligation as the registrant for a substance.

DOWNSTREAM USER OF A NON-EUROPEAN FORMULATOR UTILISING PROPRIETARY MATERIALS

Suppose a non-European formulator sources part of their mixture from another non-European manufacturer.

Under the local regulatory regime, the manufacturer is not obliged to disclose the identity or composition of their material (substance/mixture) to the formulator and may only disclose a trade name along with certain properties of their proprietary material.

The non-European formulator may incorporate this proprietary material into a mixture, which is exported to their downstream user based in Europe.

If the manufacturer does not disclose the chemical composition of the material to the formulator's OR, the OR is powerless to register the relevant substance(s) and assume regulatory liability

If the manufacturer does not disclose the chemical composition of their material to the formulator's OR, the OR is powerless to register the relevant substance(s) and assume regulatory liability. Regulatory liability would therefore lie on the party responsible for introducing a non-REACH compliant substance to Europe, the recipient of the material, that is, the downstream user. Ideally an arrangement should be in place before European exports commence, which ensures that either the manufacturer (via an OR) or the formulator's OR completes the necessary registration(s) and risk assessments.

It is essential that the downstream user understands the chain of regulatory responsibility and engages consistently with parties further up the supply chain, to ensure REACH compliance is achieved and maintained.

Downstream users under REACH experience many benefits compared to a registrant. However, this is not a reason for complacency. Although operating under a reduced regulatory burden, they must identify their obligations and be prepared to engage with often complex challenges.

The role of the downstream user is not a silver bullet for REACH obligations. Ongoing regulatory stewardship is essential before and after a supplier registers their substances.

This article has been adapted from a feature in the Global Business Briefing contributed by Dominic Byrne, regulatory affairs manager, Blue Frog Scientific. The views expressed in contributed articles are those of the expert authors and are not necessarily shared by Chemical Watch.

SERVICE PROVIDERS

Outlook generally positive despite global uncertainties

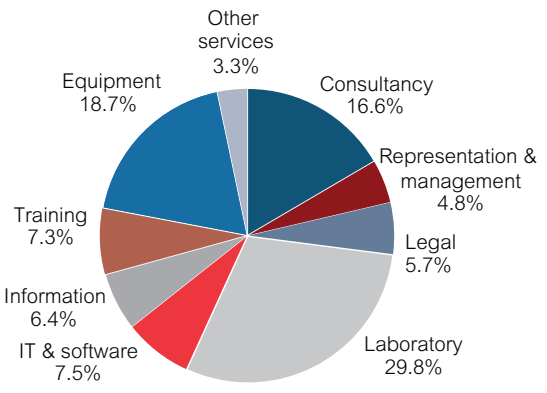
Looking forwards, the only certainty for service providers is the prevailing uncertainty about the business environment and the subsequent level of demand for their services. Big question marks hover over the outcome of Brexit negotiations between the EU and the UK, and the regulatory landscape in the US under newly-elected President Donald Trump.

Nevertheless, CEO and head of pest innovations at research company ICB Pharma, Pawel Swietoslawski, believes service providers will continue to be busy with REACH after 2018. "Many companies are still not in full compliance, even in the area of REACH's main requirement – registration – and they will not succeed until the last registration deadline. Both consultancy and laboratory services will be in high demand for many years forward for substances already on the market and for new ones," he says.

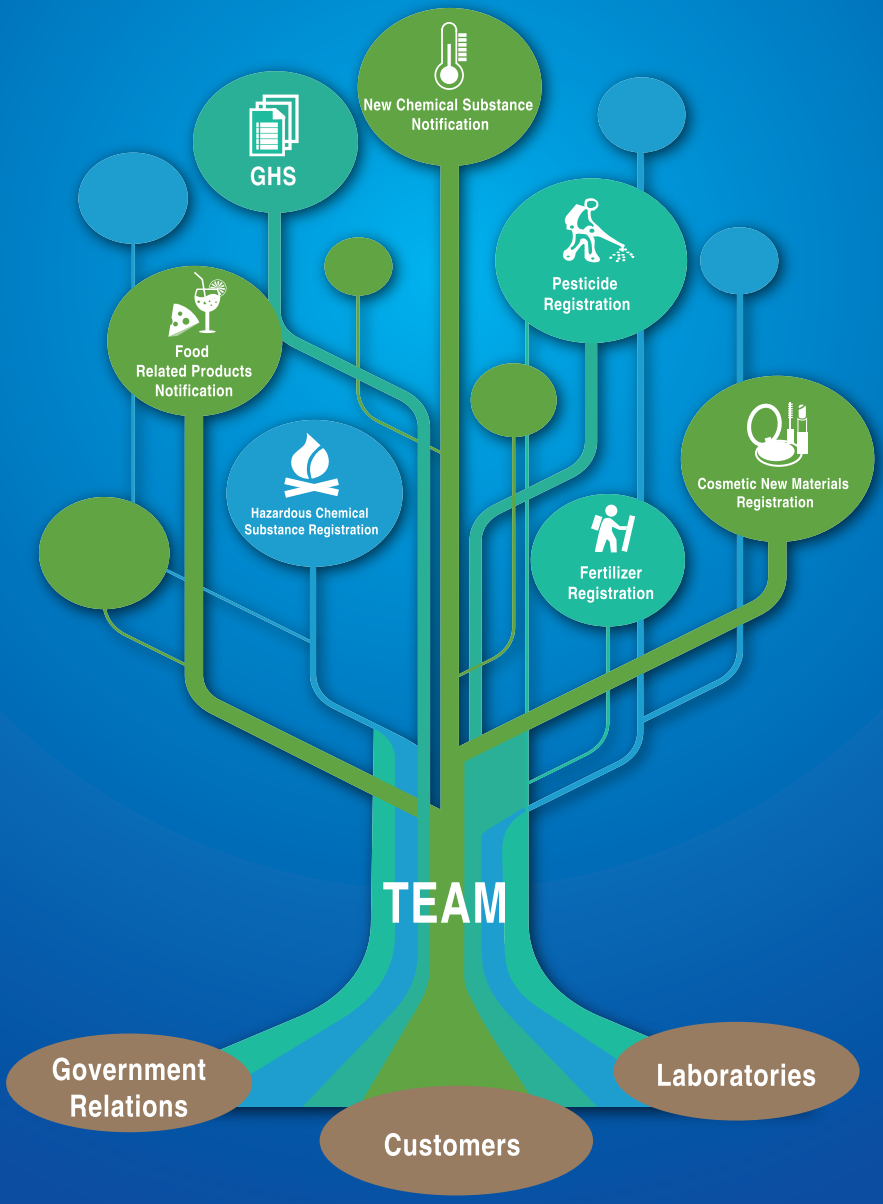
In this latest Chemical Watch survey, laboratory services were most in demand by participants in 2016, accounting for nearly 30% of their total spend **[Figure 13]**. This was followed by equipment with almost 19%, and consultancy services third at 16.5%.

Figure 13

SERVICES RETAINED BY PARTICIPANTS



CLEAN OFF YOUR COMPLIANCE OBSTACLES IN CHINA



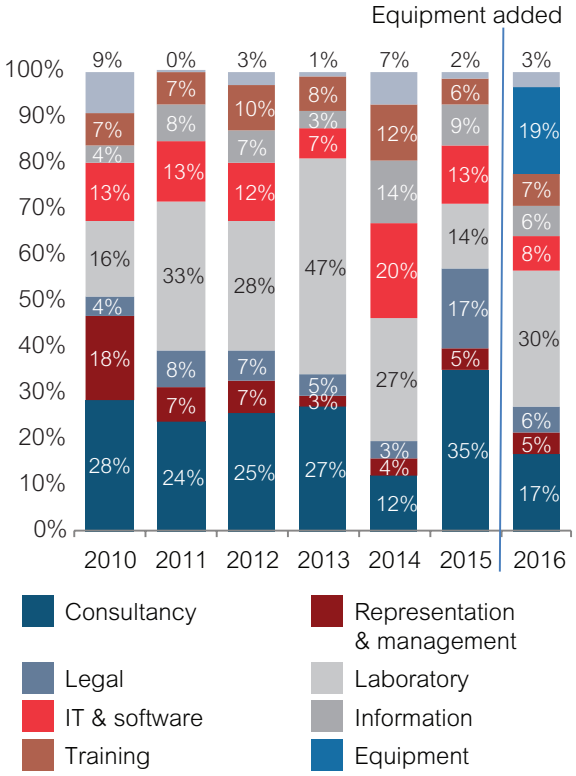
Facebook

Twitter

Contact Info: Product Registration and Compliance Services, China National Chemical Information Center
Address: No. 53 Xiaoguan Str. Anding menwai, Beijing, 100029 China Tel: +86 10 64434938、64421139 Email: regulation@hse.cncic.cn

Figure 14

CHANGES IN THE PROPORTION OF SPENDING ON PROVIDER SERVICE TYPES



In fact, demand for laboratory services more than doubled in 2016 **[Figure 14]** while that for consultancy support dropped by over a half. Interestingly, equipment featured in participants' responses for the first time since 2010, taking up nearly a fifth of their spending last year.

Unsure of demand until the May 2018 REACH deadline, Peter Newport, managing director of UK REACH service provider ReFaC, says this uncertainty will continue to apply for UK providers in the medium term, although the necessary options and strategies may be put in place once the Brexit negotiated outcomes become clearer.

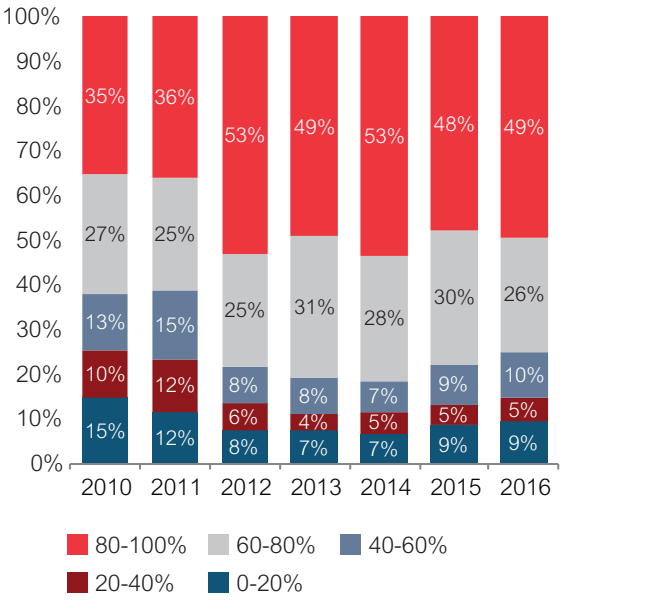
For the UK's National Chemical Emergency Centre (NCEC), part of Ricardo Energy & Environment, Brexit is at the top of its agenda. Practice director, Jon Gibbard, says the following three topics are key considerations for NCEC at the moment: Brexit and the "great reform act" and how this will impact existing REACH registrations and whether UK companies will suddenly need an only representative (OR) in Europe; implementation of REACH-like regulations in other countries around the world; and the "special" relationship between the UK and USA. "We will see demand increase on REACH if there is a need to re-submit dossiers or for UK companies to have European HQ ORs," comments Mr Gibbard.

He is very positive on the outlook over the next 12 months and indeed in the longer-term. With regards to emergency response, NCEC says more companies are looking at their existing systems and processes with a new light due to poison centre regulations, or problems with existing internal processes or service providers. As a result, notes Mr Gibbard, these firms want to explore how NCEC can support them with a premium service. "Furthermore, we are getting lots of interest from the US and the GBP/US dollar rate has made our premium service more accessible to many who use cheaper service providers," he says.

Mr Gibbard says that REACH-like regulations often create new legislation for emergency response and so NCEC is seeing the number of in-country regulations grow. This makes it even harder for companies to handle compliance in-house.

Figure 15

PERCENT OF CHEMICAL MANAGEMENT WORK PERFORMED BY IN-HOUSE TEAMS

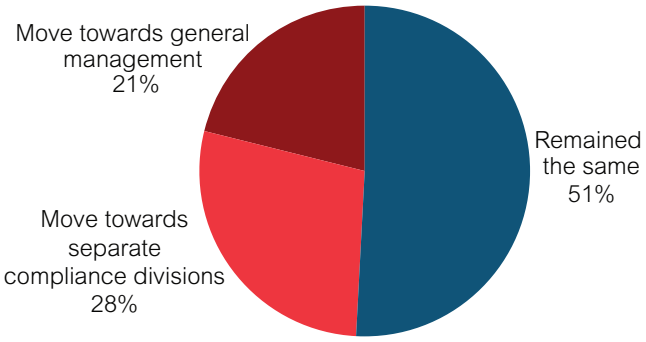


The amount of work completed on average by in-house teams in 2016 has not changed significantly from the year before **[Figure 15]**.

Results of the survey suggest there has also been little change in the approaches of companies to in-house chemicals management and control over the last five years **[Figure 16]**. Of the respondents, 21% say their companies increasingly integrated compliance management with other activities and 28% – the same percentage as last year – saw a switch to separate compliance divisions. The number reporting no change in their company's management approach was 51%, down 1% from 2015.

Figure 16

INTEGRATION CHANGES AT SURVEY RESPONDENTS OVER THE LAST FIVE YEARS



With respect to the frequency of use of chemicals management and control services, most Chemical Watch survey respondents use outside assistance on an

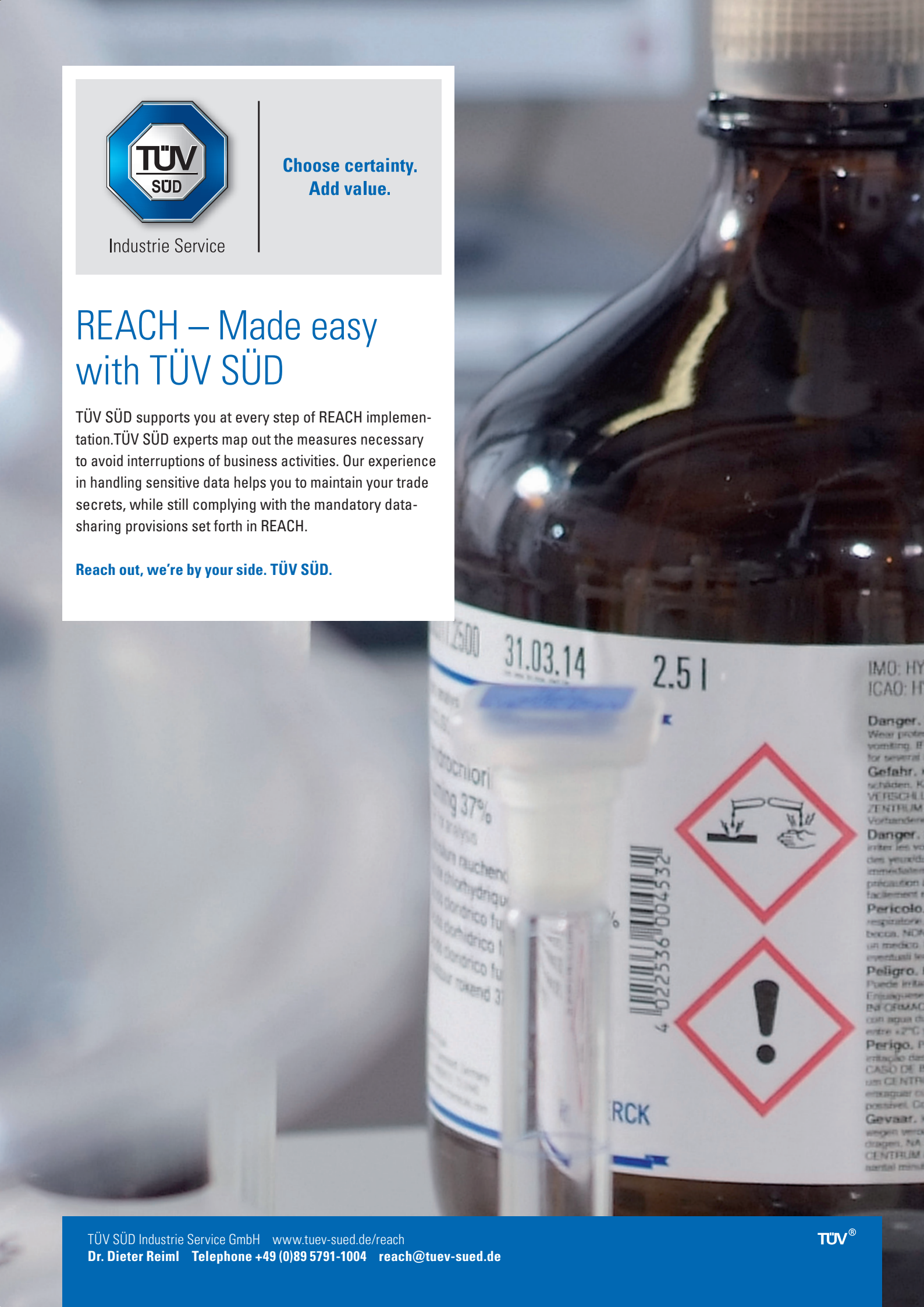
Industrie Service

Choose certainty.
Add value.

REACH – Made easy with TÜV SÜD

TÜV SÜD supports you at every step of REACH implementation.TÜV SÜD experts map out the measures necessary to avoid interruptions of business activities. Our experience in handling sensitive data helps you to maintain your trade secrets, while still complying with the mandatory data-sharing provisions set forth in REACH.

Reach out, we're by your side. TÜV SÜD.



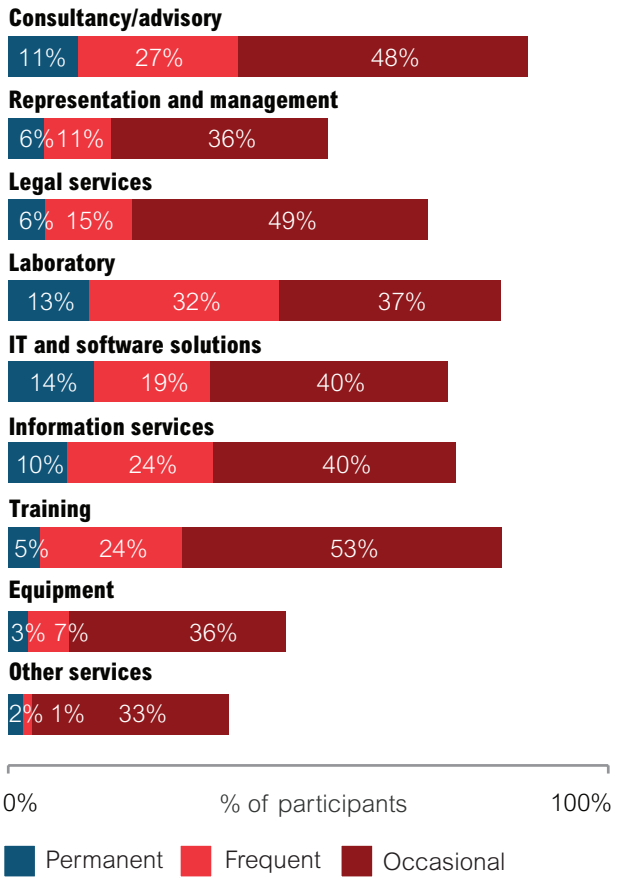
TÜV SÜD Industrie Service GmbH www.tuev-sued.de/reach
Dr. Dieter Reiml Telephone +49 (0)89 5791-1004 reach@tuev-sued.de

TÜV®

occasional basis (55%), rather than on a frequent (31%) or a permanent (14%) basis.

Figure 17

FREQUENCY OF SERVICE RETENTION BY SURVEY PARTICIPANTS



DRIVING MANAGEMENT AGENDAS

Mr Newport says global and regional economic factors top ReFaC's present management agenda, followed by regulatory controls, especially post-Brexit. While the potential economic impacts are not yet clear, Mr Newport believes it will take the rest of this year and 2018 for the EU to complete work for the final REACH deadline. After that, planned reviews of REACH and its scope, for example polymers, nanomaterials, concerns over endocrine disruptors and cumulative effects of chemicals, could all drive ongoing demand for services in the EU.

Outside Europe, demand will continue to be driven by countries such as China, which is actively reviewing and revising its suite of chemicals legislation. The US is revising its Toxic Substances Control Act (TSCA), and GHS adoption and implementation is a process being pursued by many countries, says Mr Newport.

Carsten Dietsche of Germany's Materials Data Working Group for discrete articles has a fairly pessimistic outlook and says there will be some "panic reactions" from companies to the 2018 deadline as well as missed chances to secure future markets. He says: "In the long run, all affected sectors will face shortages in the supply chain at certain times, in a rather narrow range of products with just a few alternative suppliers". Citing the global antimony trade as an example, he says many mixtures and compounds are not registered yet as the critical mass is not there to form a Sief. Thus, for very special applications, for example in electronics, there are predictable shortages to be faced.

Despite an unstable and difficult business climate in many markets, there are better commercial opportunities than ever in countries such as Iran, Cuba, North Africa, Brazil, India, Singapore, Malaysia, Australia, and Japan, according to Mr Dietsche. Africa will be a future hotspot, he says, and the industry needs more "chemically trained, culturally diverse and open-minded service providers", both for production sites and dismantling/recycling facilities. The REACH/CLP legislation's impact on selling recyclates or on occupational health and safety issues, and even on existing administrative decisions concerning companies' handling of dangerous substances, is being underestimated, he says.

Over the next 12 months, Thomas Berbner, regional director business development EMEA industrial chemicals at Dr. Knoell Consult, expects to spend a great deal of time on the approaching REACH registration deadline. Once May 2018 has passed, he anticipates there will be an increase in demand for post-registration support concerning dossier and substance evaluations as well as for growing lists of restrictions and candidate substances. Dr Berbner also expects that Annex XIV of REACH (authorisations) will be extended by several substances, leading to a rise in the number of questions related to the authorisation and substitution of substances. "The awareness of chemicals in products by consumers will also increase and lead to more communication between the consumer and the retailer. Brands will request an increasing amount of information on the substances used in their sourced products," he says, adding that there will be a growing move towards global compliance requirements. In response the German consultancy intends to expand its global presence as many countries continue to implement chemical management regulations or reform existing legislation.

Dr Berbner believes that clients currently asking for support in fulfilling their European obligations will start asking for support in other countries of the world. "Due to the numerous regulations and directives in Europe and the reform of TSCA in the US, we expect to still have a great amount of demand. The changes in Asia, such as K-REACH [South Korea] and in Thailand will also trigger an increase in demand for support by service providers."

For Karl-Franz Torges, managing partner of KFT Chemieservice, the outlook differs according to region. Like his industry peers, Dr Torges sees huge demand in REACH-related matters over the next 18 months, which will decline after 1 June, 2018. Beyond that date, Dr Torges believes he will only have to support late-comers and provide help with updating dossiers, chemical safety reports (CSRs) and registrations.

However, in the area of global regulatory chemical compliance, KFT is forecasting rising demand in the next three years, that will continue after 2020. Dr Torges says: "We see currently a very strong growing demand for managed services because of outsourcing and out-tasking activities. Industry has learned that data search, data maintenance and generation of SDS are not core tasks of a chemical company or a formulator. In addition and outside this sector, for example consumer goods, the need for support is growing."

Europe will be still the most demanding market in the next five years, according to KFT, followed by Asia. In the Middle East, where there has been no demand in the past,

RGS
REACH
Global Services

Your regulatory compliance partner

EU REACH REGULATION

EU Only Representative Services
Consultancy and Trainings

EU COSMETICS REGULATION

Responsible Person Services & PIF Preparation Assistance

TURKISH REACH (KKDIK) COMPLIANCE

Turkish Only Representative Services
Market Access and (Pre)-registration
Compliance Strategy Consultancy

COMPLIANCE WITH TURKISH CHEMICALS REGULATIONS

Representative and Notification Services For CICR (TURKISH Inventory) and SEA (Turkish CLP)

CHEMICAL COMPLIANCE SERVICES FOR ASIA, KOREA, CHINA, JAPAN

EUROPEAN UNION • TURKEY • JAPAN • CHINA • KOREA

RGS - Belgium Headquarter
+ 32 (2) 234 77 77

RGS - Turkey Branch
+ 90 (212) 454 09 93

info@reach-gs.eu

www.reach-gs.eu

HELPING TO MEET YOUR GLOBAL CHALLENGES

ReachCentrum is a market leader for consortia management related to EU REACH. We provide legal, data, financial, project management and consulting services to more than 100 consortia, in addition to regulatory support.

The team assists companies for authorisation under Biocidal Products Regulation and clients with respect to K-REACH and other global REACH-like legislation.

ReachCentrum trainers develop, design and deliver courses for REACH, CLP, K-REACH and BPR.

Our specialist areas include:

REACH
- ▷ Registration 2018
- ▷ Evaluation
- ▷ Authorisation

CLP

BPR

K-REACH
- ▷ Registration
- ▷ Data Sharing

reachcentrum
T: +32 2 676 74 00
E: info@reachcentrum.eu
W: reachcentrum.eu
@reachcentrum

Dr Torges sees no sign that this will change. Demand for services in the US, meanwhile, is "unforeseeable" because of recent political changes and uncertainty on the country's regulatory landscape under newly elected President Donald Trump. At the time of writing, President Trump had embarked on what was reported as "the most aggressive campaign against government regulation in a generation", repealing rules already in place, such those governing coal mining, healthcare and anti-corruption.

DISSATISFACTION RISING

The number of respondents dissatisfied with their service providers stayed unchanged last year at 3%, although the number of satisfied companies fell to its lowest level in six years, at just 67%. This compares with 78% in 2010 **[Figure 18]**.

Figure 19 shows a comparison of the satisfaction levels of Chemical Watch survey participants in 2016 and 2015 for specific performance areas. Satisfaction levels rose in the areas of local country experience and knowledge, service flexibility, value for money, pricing and meeting the brief. Companies fared slightly worse on availability, personal relationships, technical knowledge and delivering on schedule.

With regards to pricing, satisfaction levels soared to 67% in the latest Chemical Watch survey, compared to just 25% in 2015 **[Figure 20]**. A big drop is also noted in dissatisfaction levels, which were recorded at just 3% this year versus 14% the previous year.

Figure 18

CHANGE IN OVERALL SATISFACTION LEVELS FOR SURVEY RESPONDENTS

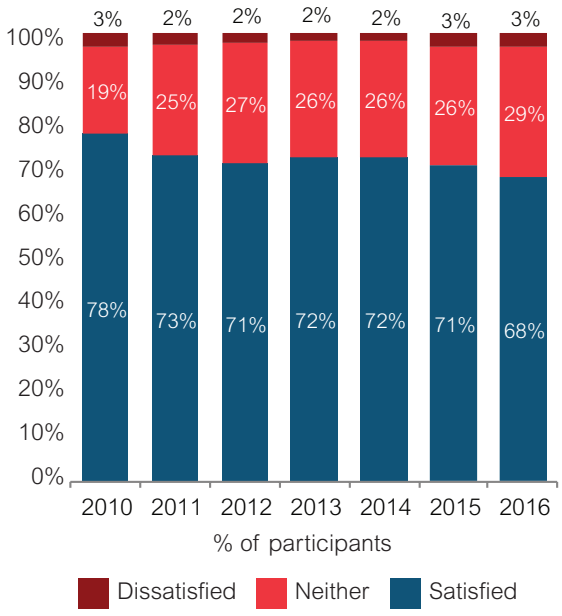


Figure 19

SATISFACTION LEVELS IN 2016 AND 2015

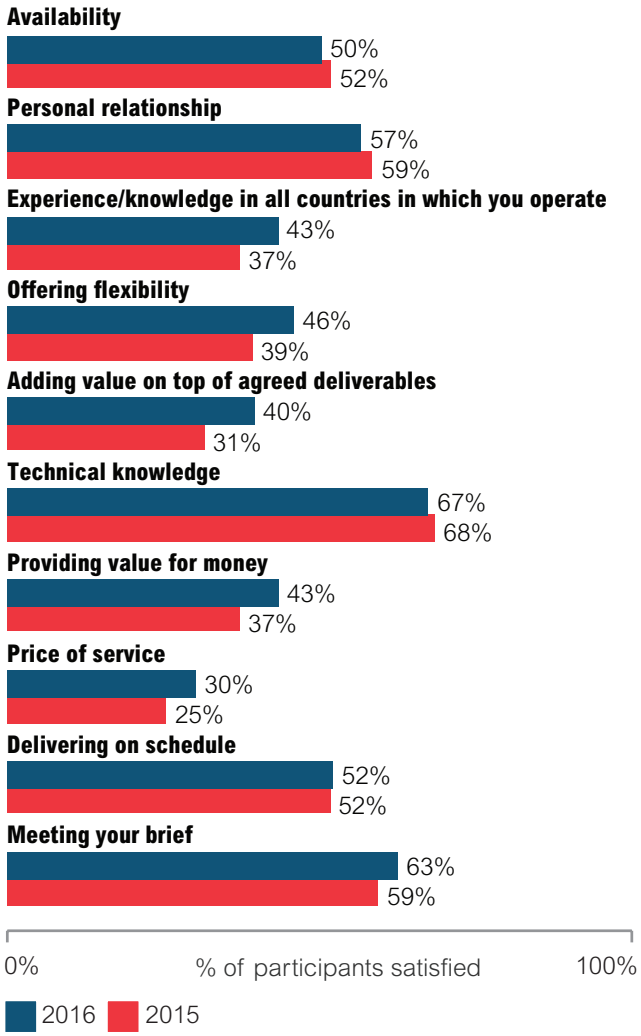
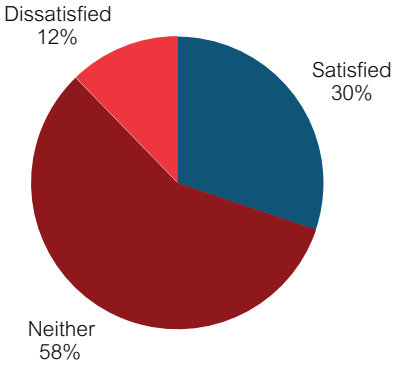


Figure 20

SATISFACTION LEVELS OF SURVEY PARTICIPANTS WITH PRICES CHARGED FOR SERVICES



CRAD

Çevre Risk Analiz Denetim

Your window for compliance..
Your key for the Turkish Market

- Regulatory Compliance Check-Up
- KKDIK Registrations (Turkish REACh)
- Only Representative Services
- Notification to Turkish C&L Inventory
- Notification for C.I.C. Regulation
- Turkish Compliant SDS Authoring
- Biocidal Product Registration
- Acting as Registrant
- Detergent Notification
- Bespoke Regulatory training
- Outsourced Regulatory Services
- Notification for C.I.C. Regulation

CRAD REGULATORY COMPLIANCE SERVICES

Istanbul / Türkiye

www.crad.com.tr info@crad.com.tr

BEST POSITION FOR FUTURE OPPORTUNITIES

The best opportunities for service providers in the future, Mr Dietsche believes, would come from dividing REACH into working packages that could be dealt with under any ISO management system, and to advocate the use of the EU's Eco-Management and Audit Scheme (EMAS) III environmental management system that focuses more on legal compliance than on legal compliance "promises".

The biggest opportunities, according to Dr Torges, are the increasing complexity of legal frameworks and the increasing expansion of the industry into new areas, segments and regions. He says companies need to be flexible and fit, while adding that digitalisation can help the mature managed services market to transfer this knowledge to clients in a cost-efficient manner.

A "thorough" provision of cost-effective compliance services and building a positive brand reputation in the marketplace will be a prime differentiator for successful service providers in the future, believes ReFaC's Mr Newport. NCEC adds that those service providers that have a clear idea of their core strategy, invest appropriately in people, knowledge, systems, tools and processes, and have great information to support the chemical industry, will be best placed to position and differentiate themselves in various regulatory areas.

Given the fall in overall satisfaction, it is somewhat surprising that the number of respondents indicating they may change their current service providers is only 1% higher than in 2015 **[Figure 21]**, while the number that are not interested in moving to a different supplier rose to 42% from 40% last year.

Strong relationships may be the key to keeping suppliers, with expertise and proven experience the top factors at 85% and 78%, respectively **[Figure 22]**, followed in third place with in-depth knowledge of country specific regulations. This reflects the trend of rising demand for regulatory supports overseas. A strict adherence to project protocols and building long-term relationships were the most important parts of a relationship, while paying more and using penalty clauses were the least significant **[Figure 23]**.

Figure 21

INTEREST LEVEL OF SURVEY RESPONDENTS IN CHANGING SUPPLIERS

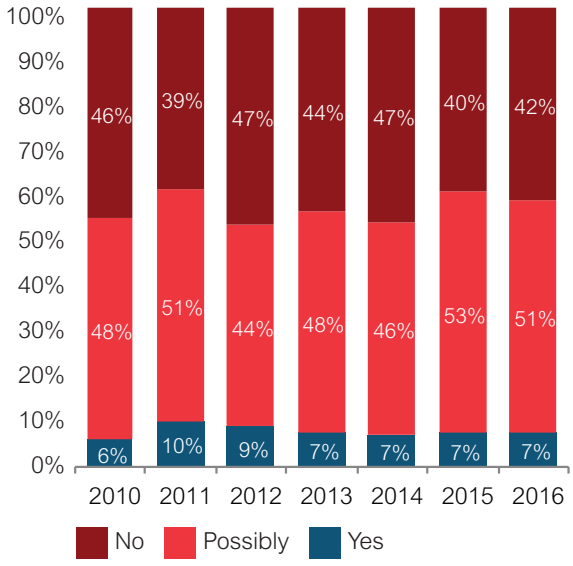


Figure 22

STRONG RELATIONSHIP MOST IMPORTANT FACTOR FOR SURVEY PARTICIPANTS

ChemSafe®

REACH & CLP/GHS (Dossier preparation, CSA/CSR, MSDS)

Agrochemical and Biocides

Cosmetic

Pharmaceutical Services (OEL, PDE)

Project Management

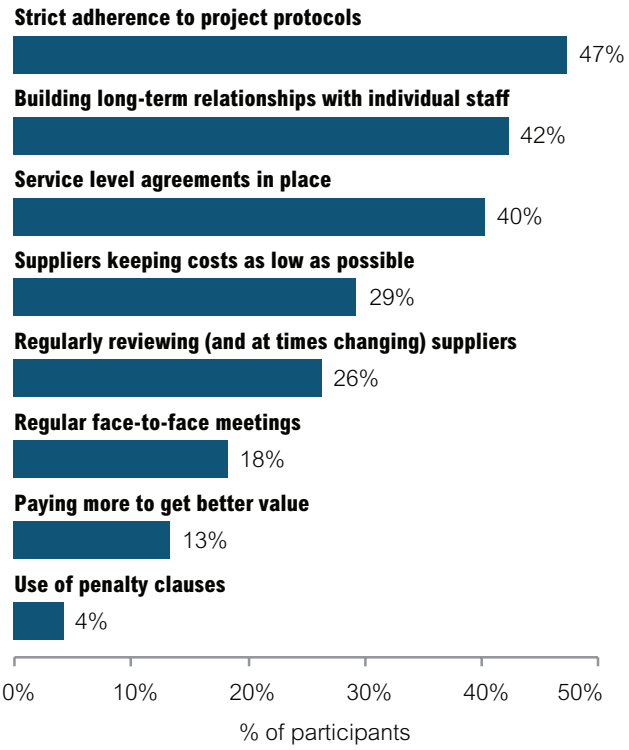
Legal advice & Consortia Management

Only Representative (OR)

www.chemsafe-consulting.com

Figure 23

MOST IMPORTANT RELATIONSHIP FACTORS FOR SURVEY PARTICIPANTS



CHALLENGES AHEAD

Where there are opportunities, there are always challenges. The biggest future challenges – after the REACH 2018 deadline – revolve around the provision of replacement and/or alternative services to maintain income and growth, for example the development of new services and new markets, says Mr Newport. He suggests that challenges may arise around providing services in regions and countries where demand is high, such as Asia, if the service provider resides elsewhere.

Other potential challenges relate to matching the availability of services with ever-fluctuating demand for consultancy support, keeping up-to-date with constantly changing legislation on a global scale and educating staff on an ongoing basis.

"While larger companies commonly have trained and experienced staff dealing with chemicals management, lots of smaller companies do not have the personnel and financial capacities. These companies are required to get external support," says Dr Berbner, noting that the diversity and quantity of questions from clients can be "challenging".

More participants to this year's Chemical Watch survey expect to use in-house staff compared with a year ago – 50% versus 47% in 2015, with the same number (45%) expecting no change **[Figure 24]**. The outlook for the longer term is even more positive, with 62% expecting to recruit more in-house staff.

Outsourcing of chemicals management and control activities continues to expand at a higher rate than internal expenditures. More respondents expect their need for external services to increase both over the next 12 months and the next five years **[Figure 25]**. In the short term, 54% of participants anticipate greater use of external services, increasing to 62% for the longer term – replicating last year's survey result.

Figure 24

ANTICIPATED FUTURE NEED FOR IN-HOUSE STAFF

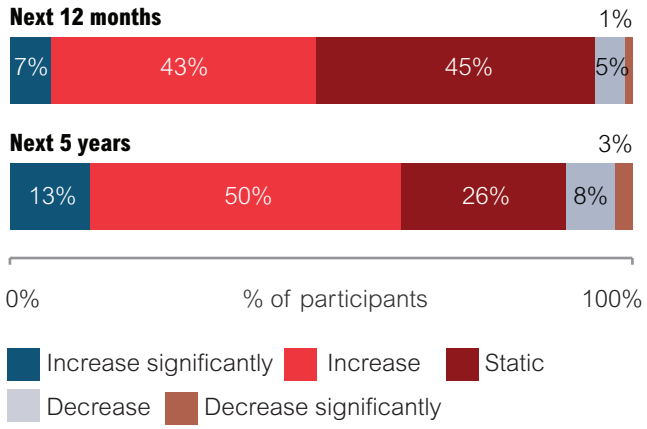
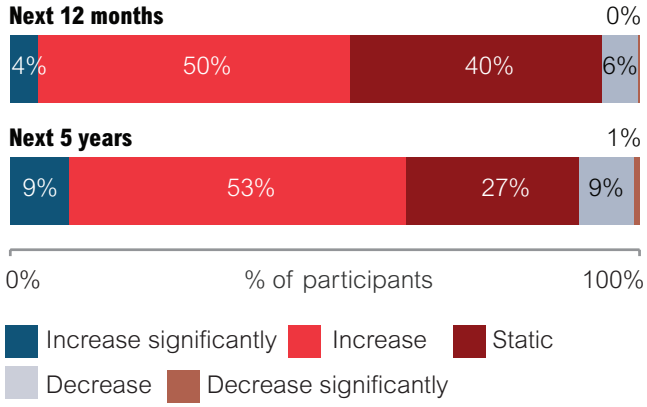


Figure 25

ANTICIPATED FUTURE NEED FOR EXTERNAL SERVICES



EXTERNAL SERVICES SUPPORT

Survey respondents that intend to use external services over the next 12 months are interested in various types of support **[Figure 26]**. Information and training were the top two areas requiring assistance (66% and 60% of responses, respectively), followed by IT and software (54%), consultancy/advisory services (53%) and laboratory (52%). These same four service categories will experience the greatest increases in demand over the next five years as well **[Figure 27]**.

A look at the specific types of services in demand within each category provides further information about the future shape of the market **[Figure 28]**. In the information services category, respondents expect to need the most additional support with the tracking of regulatory developments (62%). In IT and software solutions, demand will increase the most for consortia management (45%) and supply chain communication (43%), which is not surprising given the looming 2018 REACH deadline and the concerns voiced about Siefs and communication downstream. With respect to training assistance, respondents expect to have the greatest increase in need for training courses and webinars (53%). Consultancy and advisory services that

are expected to increase the most include interpretation of regulations (65%) and chemical safety assessments (60%).

Figure 26

ANTICIPATED NEED FOR EXTERNAL SECTOR SERVICES BY SURVEY PARTICIPANTS IN THE NEXT 12 MONTHS

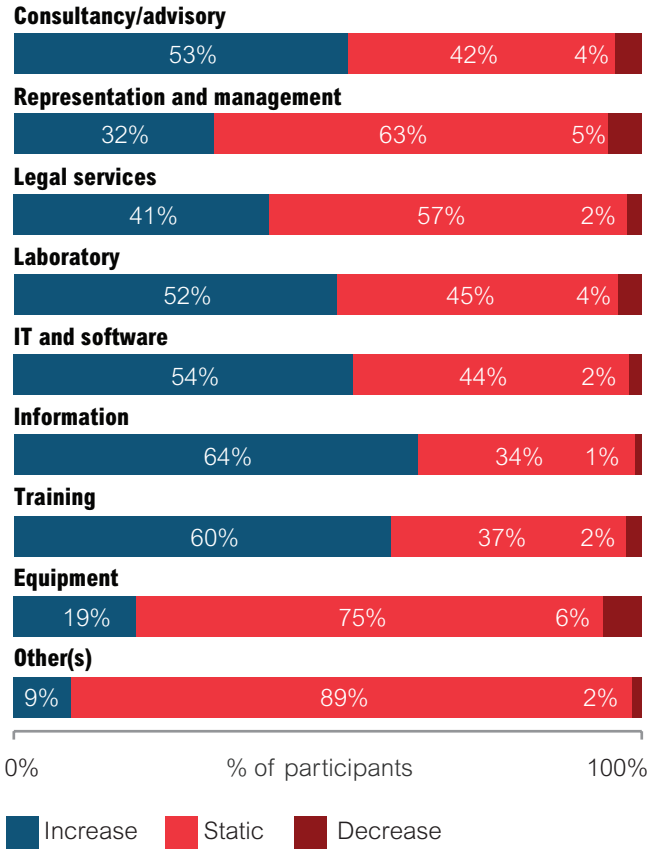
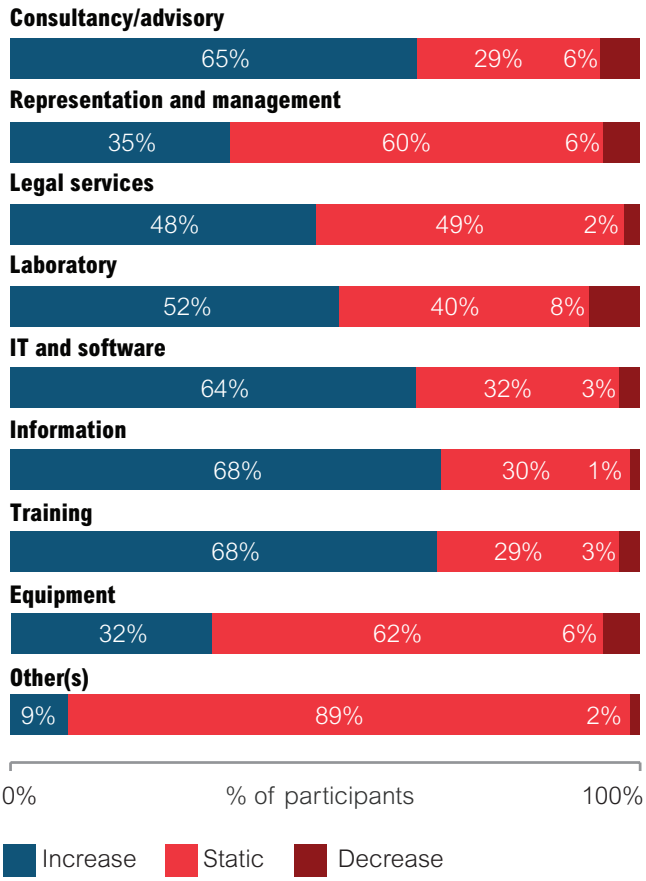


Figure 27

ANTICIPATED NEED FOR EXTERNAL SECTOR SERVICES BY SURVEY PARTICIPANTS IN THE NEXT FIVE YEARS



Co-funded by the Erasmus+ Programme of the European Union

Challenged by Chemical Regulations?

The Erasmus Mundus MSc in Chemical Innovation and Regulation can make it clear

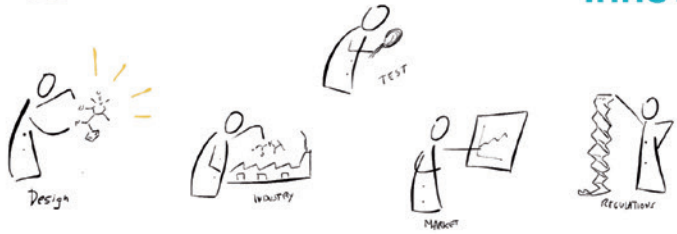
The Erasmus Mundus MSc in Chemical Innovation and Regulation

Your company needs qualified staff with the knowledge of **international regulations**, strong background on **toxicological and environmental assessment**, and the ability to **design alternative, safer solutions**? The **ChIR - Erasmus Mundus MSc in Chemical Innovation and Regulation** prepares highly qualified professionals to deal with all aspects of the chemical safety management.

Innovative

Flexible

Prestigious



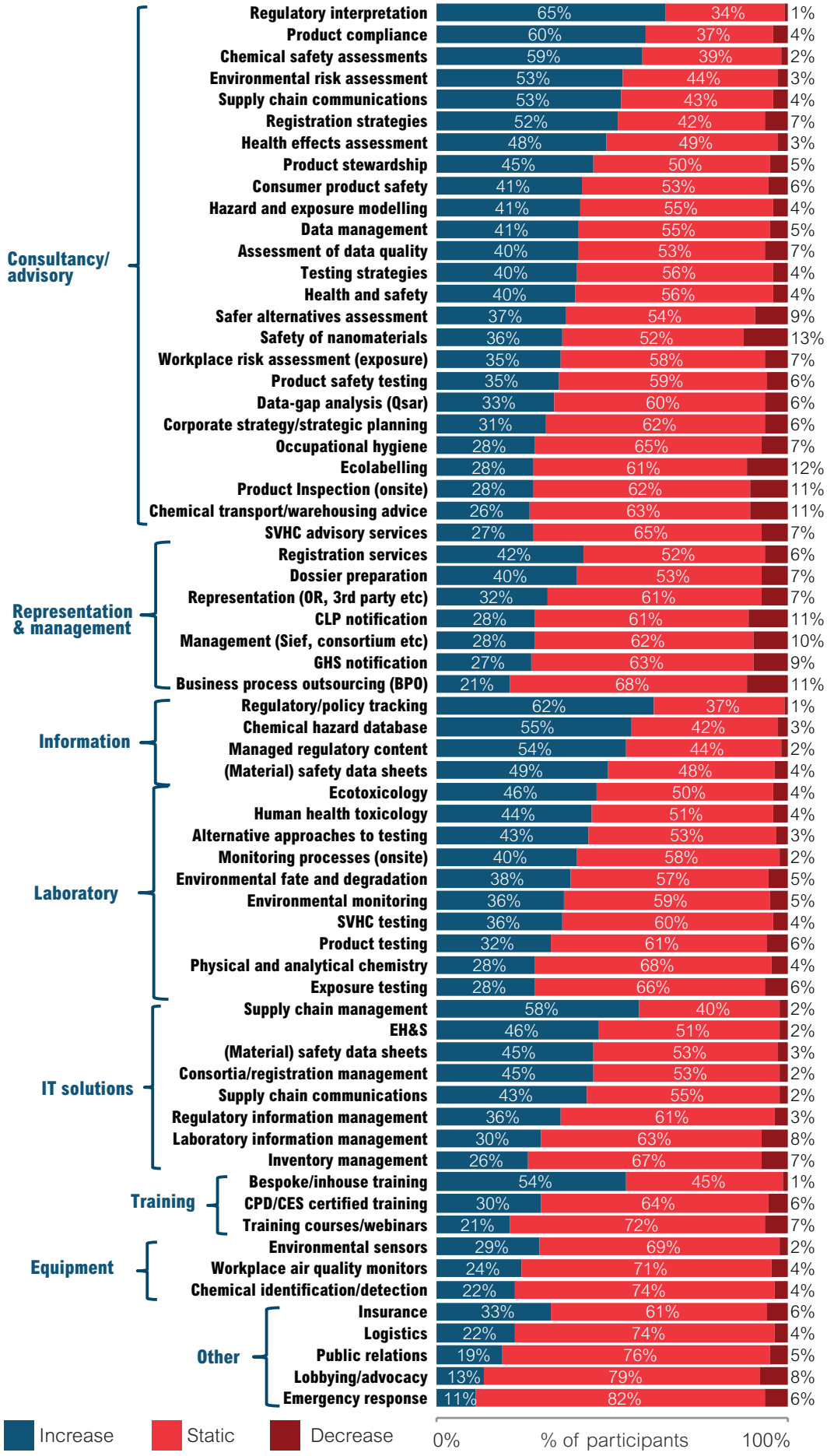
UAlg Universidade do Algarve · Universitat de Barcelona · Alma Mater Studiorum Università di Bologna · Heriot Watt University

ChIR Chemical Innovation & Regulation

www.emmcchir.org

Figure 28

ANTICIPATED NEED FOR SPECIFIC EXTERNAL SECTOR SERVICES BY SURVEY PARTICIPANTS OVER THE NEXT FIVE YEARS



Contact ReFaC's team now to find out how our Regulatory Professionals can assist your company in complete confidence with a wide range of cost-effective regulatory compliance solutions including…

- Consortium & SIEF management
- Toxicology consultancy
- SDS and eSDS development
- Re-classification of mixtures
- CLP compliance management
- Supply chain management
- SVHC tracking
- Exposure assessment

ReFaC

www.refac.eu
+44 (0)1270 258530

A Chemical Business Association Company

CONSOLIDATION CONTINUES

M&A activity in the chemical industry is set to continue as companies shift their strategic focus and target higher growth markets to enhance their financial returns.

This will undoubtedly impact the service providers sector. On the positive side, Mr Gibbard of NCEC believes industry mergers and acquisitions will deliver opportunities to provide support to new organisations where often a relationship already exists.

Mr Newport believes that although M&A activity in the chemical industry will continue, its drivers may change, for instance from growth through acquiring market share and coverage to gaining cost-economies of scale.

The service providers' sector will also see a lot of future M&A activity, predicts Dr Torges. He says in recent years, big international consultancies that were focused on business processes, tax and the environment, for example, discovered regulatory chemical compliance is a good income stream and wanted to act as a globally organised full service provider. "But, we think that a lot of them will fail because the legal support and services for substances is very different from their current business," he says.

SURVIVAL OF THE SINGLE OPERATOR

The pool of small service providers or 'one-man bands' is likely to shrink in the future, partly because of retirement (at the one-person consultancy), or from their incapacity to deal with the wide range of services, expertise and knowledge that will be required to deal with complex and changing regulations around the world, particularly once work for the last REACH deadline passes its peak.

"REACH compliance services were perhaps seen as an easy service provision opportunity both in the early years of REACH and for a few years after, but in our view the level of support and service now being demanded, particularly by smaller client businesses, makes it less attractive unless there is a high level of competence, experience and support resources," says Mr Newport. "We anticipate ongoing shrinkage and consolidation towards offering more expert service provision."

REACH, and legislation generally can create artificial peaks and troughs in demand, and hence resource requirements and profits, owing to its deadline-driven nature. This impacts both on smaller service providers like ReFaC, but even larger, multi-service strand providers such as, test houses providing REACH dossier management services. In response, says Mr Newport, service providers will need to be agile in response to the vagaries of demand and in the flexibility of their service provision.

NCEC also believes the pool of small service providers is shrinking and Mr Gibbard says this will create a great opportunity for those with a few years of experience to start stepping into roles and looking at safety and risk as well as compliance in new ways, pushing up standards further, using technology to support compliance and improving supply chain safety.

When asked his view, Dr Berbner says he expects that very small service providers will specialise on specific topics. However, he cautions they may lack the capability to provide a full service from a single source. "Customers are looking for the 'all-inclusive' package," he comments.

KFT's Dr Torges notes that it is becoming more difficult for small service providers to survive. In agreement with his industry colleagues, he says clients want to have a broad coverage, which a single-person consultant or even a small company cannot deliver.

Large-sized clients also want to partner with a reliable organisation that can guarantee it can still deliver the required and necessary services in five years' time, states Dr Torges. He says a partnership with a consultant needs a lot of investment, which will become obsolete if the service provider fails. In addition, he says, these big organisations are looking for quality certification, something a small provider cannot deliver.

The potential impact of this diminishing pool of small operators on the service providers' sector has yet to be felt. But for those older, outsourced employees of big companies that have made their fortune by supplying 'special' REACH services, Dr Torges is quite sure of their outlook "They never built up specialised legal and substance knowledge, he says. "Their time is over."

Chemical Inspection & Regulation Service

- Chemical Regulatory Compliance Service
- Medical Device Regulatory Compliance Service
- Cosmetics and ingredients Regulatory Compliance Service
- Regulatory Compliance Testing Service
- Food and Food Contact Material Regulatory Compliance Service

CIRS China
11F Building 1, Dongguan Hi-Tech Park, 288 Qiuyi Road, Binjiang District, Hangzhou 310052, China
Tel: 0086 571 8720 6574 Fax: 0086 571 8720 6533 Email: service@cirs-reach.com

CIRS Europe
Unit 1 Ardee Business Park, Hale Street, Ardee,Co. Louth, Ireland
Tel : +353 41 9806 916 Fax: +353 41 9806 999 Email: service@cirs-reach.com

3E Company is a Verisk Analytics business

CONTACTS

Website	www.3ecompany.com
E-mail	info@3ecompany.com
Head office	3207 Grey Hawk Court, Carlsbad, CA 92010, USA
Tel	North America (US): +1 760 602 8700; Europe (Denmark): +45-69918473; APAC (Japan): +81-363880381
Directors	Edmund Webecke, President Matthew Johnston, VP, Global Business Development Alex Ortiz, VP, Global Regulatory Content Leo Oves, Chief Information Officer Marie Shannon, SVP, Finance Clark VanScoder, SVP, Authoring Software & Services Andrea Verspay, VP, EMEA Business Development Tamie Webber, VP, Supplier Data Management Christina Widodo, AVP, Regulatory Consulting
Ownership	Owned by public company, Verisk Analytics
Locations	US, Canada, Europe, Asia
Founded	1988

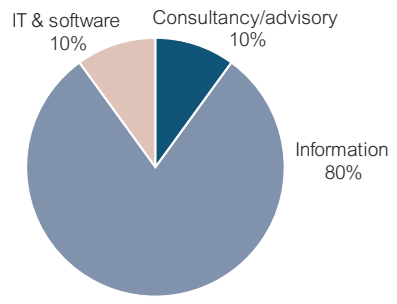
OVERVIEW

3E Company is a global provider of EH&S and supply chain compliance information services. By combining our extensive data assets with rigorous industry-leading analytics and deep domain expertise, we provide unique insights that enable our customers to improve compliance through the entire lifecycle of a chemical product. As an industry leader with more than 5,000 customers in 35 countries, we support companies in almost every industry. Leveraging our expertise in the obtainment, management and distribution of compliance information, we provide solutions that reduce risk, achieve regulatory compliance and improve disclosure management in relation to supply chain activities.

VITAL STATISTICS 2016/17

Turnover, group	-
Turnover, chemical service provision	-
No of offices	7
No of countries represented	Global
Staff, group	300+
Staff, chemical service provision	80%

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Carlsbad, CA, US: 3E Company's headquarters and the world-renowned EH&S call centre.
Copenhagen, Denmark: European headquarters and SDS authoring and related regulatory services centre-of-excellence.
Montreal, QC, Canada: SDS management products and services operations.
Bethesda, MD, US: global regulatory data development and operations.
Kingsport, TN, US: SDS authoring centre-of-excellence.
Canton, OH, US: authoring software development, operations and support centre.
Tokyo Japan: The Tokyo office serves as the company's sales presence in the Asia-Pacific region.

SERVICES PROVIDED

Product safety and stewardship tools and decision support

Regulatory research and monitoring – subscription-based online reference tool for researching and tracking how chemicals and substances are regulated around the globe. Content coverage is global in scope and includes chemicals, cosmetics, personal care, food contact, and flavours, food and beverages.
System-integrated data, rules, phrases and templates – integrated chemical, regulatory, toxicity and ecotoxicity data, vendor SDS data, expert rules, multilingual phrases, document and label templates and data loading tools for managing EH&S compliance activities in other corporate systems.

SDS authoring and distribution

MSDgen® SDS Authoring Software – an enterprise software solution suite designed for companies' in-house EH&S staff.
SDS Authoring Services – provides outsourced or co-sourced assistance with authoring SDSs via 3E's own fully-dedicated, in-house staff of highly qualified, multilingual authors.
SDS Distribution – facilitates the dissemination of SDSs to all stakeholders.

Chemical and workplace safety

SDS and chemical management – a variety of products and services for the management of vendor supplier SDSs.
Risk assessment / green chemistry – analyse the toxicity of chemicals used in the workplace to determine risk profile.
Dangerous goods transportation – 24-7-365 global hotline access for guidance and classification of shipping hazardous materials for any mode.
Emergency response – 24-7-365 emergency response to spills, ingestions or exposures, or for dispatching emergency responders to an incident.
Disclosures, permits and reports – outsourced services for researching, identifying, analysing, tracking, completing and submitting required disclosures, permits and reports.
Hazardous waste management and classification services – supports customers' hazardous waste management obligations, including proper storage and disposal.

Supply chain stewardship

Supply chain compliance solutions – products and services to facilitate compliance with regulatory and market driven requirements for detailed information about the source and origin of products. Service areas include conflict minerals, RoHS, REACH, California Prop 65 and more.

Consulting services

REACH – 3E can work collaboratively with a company to produce exposure scenarios for eSDSs.
GHS – classification services and consulting to companies who need assistance with understanding the implications that GHS has on their business.
TSCA – services range from fully outsourcing TSCA compliance to project-based, function-specific areas.
C&L Notification – assists manufacturers and importers with CLP classification and subsequent Echa notification under the European Union's CLP Regulation.
European product registration – 3E can determine which products need to be registered, perform the registration process, the maintenance of the registration and any necessary updates to SDSs and labels.
DGSA (dangerous goods safety adviser) – 3E can serve as a company's DGSA.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1998	Company founded.
2004	Acquisition: Ariel Research Corporation; international expansion.
2007	Acquisitions: HSE Systems and MSDS Solutions.
2008	REACH and GHS initiatives.
2010	Acquired by Verisk Analytics.
2013	Launched 3ESC Supply Chain platform and services.
2014	Expand global presence with new Tokyo office.
2002 -17	Long-time and frequent industry award recipient: http://3ecompany.com/about-3e/awards-recognition.

ACCREDITATIONS

CHMM, CSP, DGSA, CPEA, CSBA, REA, IATA, more.

PARTNERS

Airsweb, ASD, BIOVIA, DGM (Dangerous Goods Management Group), Dotmatics, Enablon, Intelex, Kelaroo, Logic1, Logical Data Solutions, RGB Chemicals Co, Ltd., SciQuest, The Chemical Daily, more.

CLIENTS

More than 5,000 clients across 35 countries span multiple industries including chemicals; cosmetics; food contact; food; flavours and fragrances; personal care and consumer products; electronics and medical devices; healthcare; industrial, automotive and heavy equipment manufacturers; oil, gas and petrochemicals; pharmaceuticals; retail; utilities.

CASE STUDY 1: Vigon International manufactures compliant SDSs for flavour and fragrance industry

Industry: flavours and fragrances.
Challenge: burdened with providing accurate and comprehensive safety data sheets and labels in each of the markets it serves.
Solution: MSDgen SDS and label authoring software.
Results: since deploying MSDgen, Vigon has realised increased quality of SDSs and more efficient change management. "With the automation, robust classification and automated authoring provided through MSDgen's Rules, the quality of the SDSs that we are producing has significantly improved."

CASE STUDY 2: Linde AG modernising SAP EH&S for global results

Industry: gases and engineering.
Challenge: Linde AG needed to modernise its SAP EH&S environment in order to more efficiently meet compliance requirements.
Solution: SAP EH&S populated with 3E's content.
Results: improved delivery of REACH/CLP-compliant SDSs to customers; increased efficiency as a result of automated workflows for once-manual processes; ensures all transport-related documents are created according to European legal requirements. In addition, the platform and content are scalable and can be extended to serve global needs.

STAFF SELECTION

Adrienne Black, Senior Regulatory Analyst

Adrienne Black holds a PhD in toxicology from Rutgers University/ UMDNJ and is board-certified by the American Board of Toxicology. Dr Black provides toxicology expertise for the range of global regulatory and chemical management services offered by 3E Company to both 3E personnel and clients. As both an internal and client resource, Dr Black supplies expert knowledge, enabling the completion of global and country-specific GHS-compliant classifications and regulatory guidance documents for the US, EU and throughout Asia.
Her previous experience includes global product stewardship for consumer, cosmetic and food products as well as research work using *in vitro* models for assessing toxicological and chemical hazards. She has also evaluated the potential toxicological hazards from exposure to nanomaterials in the occupational setting and worked with industrial hygienists to determine the appropriate equipment and control methods necessary to ensure worker safety.
She has been an adjunct faculty member with the University of Maryland and New York Medical College, providing online undergraduate and graduate-level instruction in toxicology fundamentals and applications.

Zeina Attar, Senior Regulatory Analyst

Zeina Attar specialises in the Middle East and Africa regions. Ms Attar provides regulatory research, analysis and customer support for clients in the chemical, cosmetics and food safety arenas. She maintains an extensive database of EH&S related regulations and oversees the regulatory content for food in support of 3E's ArielLogic product. Her areas of expertise include chemical and biocide regulatory management frameworks in the Middle East and Africa. She also has extensive knowledge of global food regulations. In addition to her duties as a regulatory expert, Ms Attar is in charge of conducting product trainings of 3E's reference products, Ariel WebInsight and ArielLogic, for internal staff as well as external clients.
Ms Attar received a Bachelor of Arts in sociology from Columbia University. She is a native speaker of Arabic. Prior to joining 3E Company, Ms Attar worked as a global media analyst at Brightwire Company.

Nursulu Davrenova, Manager, SDS Authoring Software and Services

Nursulu Davrenova is an experienced global safety data sheet (SDS) and exposure scenario (ES) author. She is also an MSDgen user support specialist for 3E's global outsourced authoring team. Nursulu also leads the analysis and design of the ES/SUMI authoring service and MSDgen authoring software updates.
Nursulu has a BS in chemistry and an academy profession (AP) degree in chemical and biotechnical science, is a certified Dangerous Goods Safety Adviser, and is also a authoring project manager. She has a background in chemical and biological laboratories, and hence has knowledge of theoretical and practical chemistry. She is fluent in Russian, English, proficient in Danish, Uzbek, and Kazakh.

ACTA ASIA EUROPE THE AMERICAS
Global Chemical Product Innovation and Development™

CONTACTS

Website	www.actagroup.com
E-mail	lbergeson@actagroup.com
Head Office	The Acta Group EU, Ltd, Brook House Suite 2B, 64-72 Spring Gardens, Manchester M2 2BQ, UK
Tel	+44 (0) 330 223 0610
Contact	lbergeson@actagroup.com
Directors	Lynn L Bergeson and Lisa M Campbell
Ownership	Private company, affiliated with: Bergeson & Campbell, PC B&C® Consortia Management, LLC
Locations	US, UK, and China
Founded	2004

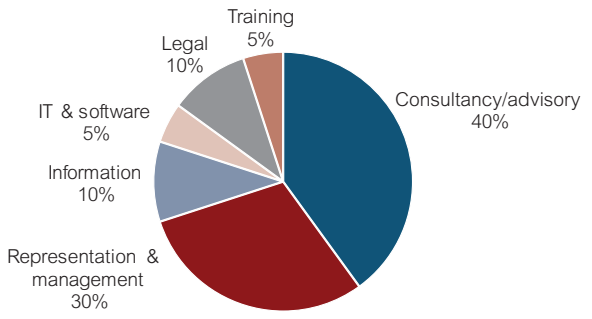
OVERVIEW

The Acta Group (Acta) is a leading international specialist in chemical product approval, compliance support, business strategy, and regulatory defence, providing a full-range of support for the process of developing, commercialising, and sustaining industrial and specialty chemicals, biocides, cosmetics, metals, food contact chemicals, products of biotechnology, nanotechnology and medical devices. Acta professionals are scientists and business and regulatory consultants. This combination and our wealth of experience in and out of laboratories, global chemical companies and government agencies makes Acta an exceptional resource for companies in the chemical space. Acta maintains offices in the US, Europe, and China, and offers expertise with regulatory programmes and chemical product approvals in North America, the European Union (EU), South and Central America, Asia, and the Pacific Rim.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No. of offices	4
No. of countries represented	>25
Staff, group	30+
Staff, chemical service provision	30+

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

The Acta Group EU, Ltd, Brook House Suite 2B, 64-72 Spring Gardens, Manchester M2 2BQ, UK.
The Acta Group, LLC, 2200 Pennsylvania Avenue, NW, Suite 100W, Washington, DC 20037-1701, US Tel: +1 (202) 266-5020.
The Acta Group China, LLC, 1009 Tongguang Tower, No 12 Nongzhanguan Nanli, Beijing, China 100125.
The Acta Group China, LLC, has affiliates in Shanghai, Nanjing, and Xi'an.

SERVICES PROVIDED

General consulting services

We represent and counsel individuals, business entities, trade associations, and industry associations. Our fundamental goals are to solve our clients' existing problems and to minimise future difficulties. We take a multi-disciplinary approach in assisting our clients. Attention must be paid to the interplay of all branches of government and interest groups. Our capabilities, borne of site and issue-specific experience, combined with our national and international view on policy and regulatory developments, position us to handle all these tasks with judgment, creativity, and efficiency.

Global product registration and agent services (only representative services)

Regulatory chemical product notification, registration, and technical defence under the framework of global chemical programmes, including REACH, biocidal products Regulation (BPR), globally harmonised system of classification and labelling of chemicals (GHS), Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Korean REACH (K-REACH), the Canadian Environmental Protection Act (Cepa), China Order No 7, and California Safer Consumer Products Regulations. Acta concentrates on obtaining, maintaining, and supporting product approvals and efficiently overcoming commercial or regulatory impediments to the successful and profitable marketing of approved products. Jurisdictions we are active in are: North and South America, EU, Switzerland, Turkey, Australia and New Zealand, Malaysia, China, Japan, South Korea, Taiwan, Philippines, Singapore, and Indonesia.

Data compensation support services and trade infringement/ competition issues

Acta is engaged in numerous data compensation and competition-related issues at the global level. Activities range from supporting, evaluating, preparing, and managing data cost on behalf of the data owner as well as for those entities seeking data access. As a result of recent activities in association with the REACH legislation, many clients continue to evaluate and pursue competition-related issues. We are actively engaged in data compensation and competition-related disputes.

Technical document preparation activities – hazard, exposure and risk assessment

Undertaking the appropriate document preparation and coordination to support registration and post-registration activities (ie chemical substance dossier preparation, exposure assessments, hazard assessments, specific effect analysis and assessments, petitions, response to comment documents, inquiries, and safety data sheet (SDS) preparation).

GHS, classification, labelling and packaging (CLP) services

Acta offers comprehensive global services, including substance classification, SDS preparation/review, label formulation/review, and guidance on strategic approaches to GHS adaptations. Tailored training programmes are also available.

ACCREDITATIONS

Occupational Health and Safety Assessment Series 18001; International Organisation for Standardisation (ISO) 9001; ISO 14000

PARTNERS

B&C® Consortia Management, LLC
Bergeson & Campbell, PC

CLIENTS

Acta EU's clients are involved in many businesses, including basic, specialty, agricultural, and antimicrobial chemicals; biotechnology, nanotechnology, and emerging transformative technologies; medical devices and diagnostic products; fibres; paints and coatings; plastic products; and chemical manufacturing, formulation, distribution and consumer product sectors.

TESTIMONIALS

Our client list is maintained on a confidential basis. We do not publish client names/testimonials.

CASE STUDY 1: Successful European Chemicals Agency (Echa) appeal

Provided strategic technical support to our European legal counsel, Field Fisher Waterhouse, in the first successful appeal under the REACH legislation. It is important to note that at the time of the appeal, the technical completeness check (TCC) tool was not available. Echa rejected the dossier based on the premise of incompleteness. A successful appeal was performed without the need to petition Echa further. The substance was granted registration, a registration number assigned and appeal fees returned.

CASE STUDY 2: Data compensation issue

Prepared strategic counselling and documentation to support and submit data compensation dispute/appeal under the REACH legislation. Reviewed and issued response to Echa's position on the data-sharing dispute. Initiated documentation to support a petition for competition law infringement in association with conduct under the framework of REACH. Our work in this area builds upon our significant and extensive data compensation work in the US under FIFRA. In other roles, we perform analysis of data valuation in association with the data rights to be granted.

CASE STUDY 3: Import tolerance

Provided strategic regulatory counselling on the development of import tolerances/exemption from tolerances for raw and/or processed agricultural goods exported from Europe into the US that have been treated with pesticides that are not registered in the US under FIFRA, and can be expected to have residues. Worked extensively with the US Environmental Protection Agency (EPA) and the US Food and Drug Administration (FDA) staff to bring cases to successful resolution. In addition, worked extensively with enforcement personnel in cases where commodities have been inadvertently imported bearing residues of unregistered pesticides and resolved matters successfully.

STAFF SELECTION

Lynn L Bergeson – President

Ms Bergeson has for over two decades assisted individual companies and a wide range of trade groups and ad hoc consortia on chemical-specific legislative and regulatory matters. Ms Bergeson's practice areas include TSCA, FIFRA, REACH, and related international chemical notification, registration, and strategic product defence and product approval litigation matters.

Jane S Vergnes, PhD, DABT –Vice President, Scientific Affairs

An esteemed toxicologist with an impressive track record of success directing global product stewardship for Fortune 500-listed chemical companies before joining Acta, Dr Vergnes has particular expertise in toxicological testing within the regulatory framework of REACH and TSCA, including study design, laboratory practices, and data requirements for new chemical introductions.

Karin F Baron, MSPH – Senior Regulatory Consultant

Ms Baron has more than 15 years of experience leading hazard communication, industrial hygiene, and EHS programmes for multi-national chemical companies. Her primary areas of practice include hazard and risk assessment and communication, industrial hygiene and EHS programmes, US FDA regulations pertaining to food contact materials, GHS and SDS, and the transport of dangerous goods. She is a certified by the Dangerous Goods Advisory Council.

J Brian Xu, MD, PhD, DABT – Toxicologist

Dr Xu is a board-certified toxicologist, an MD in pathology, holds a PhD in pharmacology and toxicology, and has over 15 years of industry experience as a senior toxicologist and scientist at companies such as Ashland, Inc, Schering-Plough, and Merck. Dr Xu designs safety testing, risk assessment, product safety, and regulatory compliance programmes and works with clients to place, manage, and monitor toxicological and clinical tests ensuring Good Laboratory Practices (GLP) at laboratories in the US, EU, and China.

Amy C Jackson – Regulatory Specialist

Ms Jackson offer clients particular expertise in the fields of organic chemistry and physico-chemical properties testing, and has substantial practical experience with industrial chemicals, pharmaceuticals, and pesticides and biocides. Within REACH she concentrates on the full spectrum of support services for co-registrants or lead registrants, including compiling and submitting Iuclid dossiers, preparing chemical safety reports (CSR) documentation, engaging in supply chain interactions, developing exposure scenarios, and CLP notifications.

Emma Louise Jackson, CBIOL, MSB – Regulatory Specialist

Ms Jackson has more than a decade of experience in testing and regulatory environments, assisting clients to achieve regulatory compliance in the EU, the Americas, and Asia. She offers particular expertise in worldwide chemical notifications, data analysis, preparing test plans, and managing to completion large and complex compliance projects quickly, cost-effectively, and harmoniously across multiple jurisdictions.

Zameer Qureshi – Legal Consultant to Acta EU

Mr Qureshi is a chemical regulatory and international business lawyer based in the UK. Mr Qureshi has an in-depth understanding of UK and European Union (EU) laws related to Acta EU's practice areas, and he deploys this knowledge to assist Acta clients in achieving and maintaining compliance across multiple global regulatory frameworks. A native English/Urdu bilingual, Mr Qureshi is also conversant in Hindi and can read Arabic.

Michael S Wenk, M.S. – Senior Regulatory Associate

Mr Wenk is an internationally-recognised expert in chemical registration and regulation in Central and South America, and the Middle East. Mr Wenk offers clients particular expertise in categories including food contact substances, biocides and pesticides, fertilisers, oil and mining chemicals, and pulp and paper products, and in regulatory due diligence for chemical companies involved in mergers and acquisitions.

Louise C Boardall – Regulatory Associate

Ms Boardall assist clients with registration and sustained compliance of industrial, plant protection, biocidal, and other chemical products in the EU. Ms Boardall is proficient in dossier preparation and submission, Substance Information Exchange Forum (Sief) communication, supply chain analysis, downstream user communications, tonnage tracking, data assessment, statistics packages, and utilisation of national authority websites and databases, including REACH Iuclid-6.

APC
Global solutions, local focus

CONTACTS

Website	www.apc.eu.com
E-mail	enquiries@apc.eu.com
Head office	Unit 4, Cromwell Business Park, York Road, Wetherby, LS22 7SU, UK
Tel	+44 (0)1937 587962
Contact	Chris O'Hara
Directors	Steve Shires, Saul Shires, Daniel Shires, Tom Smith
Ownership	Private
Locations	UK (Wetherby and Ringwood), France (Maubec and Lyon), Poland, Czech Republic, Hungary, Australia and Brazil
Founded	2001

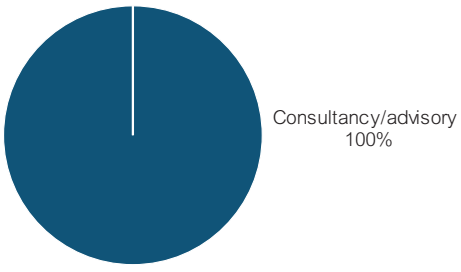
OVERVIEW

Established in 2001 by Dr Steve Shires to satisfy a market need for a co-ordinated network of scientific consultants. APC has steadily grown to have offices in the UK, France, Poland, Czech Republic, Hungary, Australia and Brazil, as well as a global network of consultants covering more than 40 countries.
APC's experienced team of chemists, agronomists, toxicologists and environmental experts can address a broad range of regulatory challenges. Working together with our network of local experts, whose knowledge and contacts within various ministries around the world enable APC to design bespoke regulatory solutions for our clients' needs.
Due to the global reach of the APC network, APC can provide sound regulatory and technical support for biocides (Regulation 528/2012), plant protection products (Regulation 1107/2009) and general chemicals (REACH – Regulation 1907/2006).
Dedicated APC project managers are assigned to each client from the beginning. They become the focal point for communications, providing the client with valuable strategic advice and timely support throughout each project, to submission and during evaluation, to approval.

VITAL STATISTICS 2015/16

Turnover, group	€4m
Turnover, chemical service provision	€4m
No of offices	9
No of countries represented	>40
Staff, group	28
Staff, chemical service provision	23

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Offices in the EU, Brazil and Australia. Agents in Japan, plus a consultant network covering Europe, South America, Africa, Asia, Australasia.

SERVICES PROVIDED

Regulatory dossier services

Data gap analysis, drafting of data waivers, data extrapolation, risk assessments, dossier preparation, placement and monitoring of studies, including efficacy development programmes.

Plant protection products

Staff at APC have extensive experience in the preparation and submission of dRR's in the support of zonal authorisations. APC has provided support to clients for many different regulatory projects, including data matching, technical equivalence, comparative analysis, CLP, CLH, literature reviews, active substance approval, product renewal under Article 43, Annex I renewal (AIR) and dRR Zonal dossiers. Many of these projects required an innovative and bespoke approach to the preparation of higher tier risk assessments.
APC has considerable experience in obtaining international registrations outside the EU including Africa, Asia and CIS countries.
We have successfully managed >10 active substance data matching programmes for protected study dossiers and gained approval for both conventional and novel active substances.
We have supported numerous actives through the EU review process, including four biopesticides and managed and submitted >200 product dossiers, with another 50 applications for mutual recognitions.
APC's particular strength is in the use of our local consultant network to provide regulatory support for our customers, from the drafting of MSDS and labels in the local language, through to in-person negotiation with the regulatory authorities.

Biocides

APC's team of experts have experience in the submission and support of active substance and biocidal product dossiers for various PT groups, including the conduct of higher tier environmental and non-dietary human risk assessments. In addition, APC's network of consultants can complete, submit and follow-up applications for our clients' products during the transitional period before the approval of the active substance.

Biopesticides

APC has expertise in the submission of four Annex I dossiers in support of biopesticides.

REACH and GHS

APC provides a range of services from third party/only representation to dossier preparation and risk assessment for CSR's. Our experts have experience of various exposure modelling tools required for CSR's, including ART, Stoffenmanager, EUSES, ConsExpo, BEAT etc.
APC can prepare CLP/GHS proposals for MSDS's and dossiers.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2001	Company registered in England
2005	French office opened
2008	UK Wetherby office opened
2009	Polish office opened
2010	UK Ringwood office opened
2012	APC Brazil and APC Australia opened
2015	Lyon (France) and Prague (Czech Republic) office opened
2016	Lyon office expands. Hungary office opens and APC celebrates 15 years

CLIENTS

Our current client data base has more than 100 clients from various industry sectors and disciplines.

CASE STUDY 1: European plant protection product support at product renewal

APC prepared a dRR for the renewal of the authorisation of a product in different member states across the EU. This product was used on a wide range of crops, which involved a complex environmental risk assessment. As a first step, APC's environmental and efficacy experts reviewed the application dates and timings (BBCH stages) across the different crops to identify the critical risks. The efficacy and residue trials programme was then tailored to support the revised rates and timings in order to support the maximum number of crops at the renewal of the authorisations. In the environmental fate and ecotoxicity section problems were identified in surface water and groundwater, including the relevance of metabolites in groundwater. Strategies used for solving the problems included the performance of new environmental fate studies, correcting the application parameters according to the application type for specific crops, and higher tier modelling. These solutions were successful and the product was approved by the zonal Rapporteur Member State.

CASE STUDY 2: Technical equivalence and data matching

One of the active substance data matching programmes for protected study dossiers that APC managed was for an insecticide with many complex metabolites and some very challenging environmental issues. In this project we were able to save our client >€1m of studies by drafting skilful waiver arguments and having detailed negotiations with the EU RMS. APC led the successful negotiations for access to protected vertebrate studies with the primary data holder. Our client was therefore able to maintain all their existing national registrations at a cost well below what was initially expected.

CASE STUDY 3: Out of season trials

Using our large network of consultants, APC was able to organise out of season trials in South Africa, Australia and New Zealand in order to speed up the acquisition of data needed to confirm the performance of a new formulation. Our field efficacy experts were then able to justify the inclusion of this data as supporting evidence showing comparability with EU conditions where appropriate. This initiative resulted in a registration being obtained one year earlier than first anticipated.

CASE STUDY 4: REACH registration non-phase-in substance

APC have assisted a PPP manufacturer with their REACH preparations by undertaking a full analysis of their marketed products and undertaking REACH registration procedures for the relevant substances. Within this, APC identified the requirement to register non-phase-in substances with Echa, and took the relevant action to achieve this, filing enquiry dossiers with Echa, and then using the results of this, and our in-house expertise, to undertake a data gap analysis. We then oversaw the completion of any data gaps by reviewing data access agreements with previous registrants, or by constructing expert data waiving arguments for submission to Echa. This led to a full REACH registration for the substances in question.

STAFF SELECTION

Steve Shires – Managing Director

Steve Shires started his career in the plant protection business at Shell Research in 1977, where he was a founder member of the environmental biology group. Following seven years leading ecotoxicology projects on pesticides, he spent a further four years with Shell, managing development and registration in the Far East and Australia.
In 1988 Steve moved to FMC as the registration manager for Europe Middle East and Africa (EMEA) and then moved to become director of development and regulatory affairs.
In 2001 he started Agchem Project Consulting Ltd (APC), with a vision of making it a truly international consultancy offering a full range of services at national as well as central EU level. In his current role as managing director of APC Steve is responsible for providing overall company management, plus guidance in both technical and business strategic issues.

Andrew Murray – Director of Development and International Business

Andrew's career started in 1978 with Shell Research where he was involved in both field R&D and ecotoxicology roles. In 1985 he joined Rohm and Haas where he was the UK and Ireland R&D Manager. In 1996 Andrew moved to Inveresk Research International Limited where he helped co-ordinate a field trials department as part of the CRO's services. Andrew joined Hockley International Limited in 2001 where he was the registration and technical manager registering agricultural, public health and veterinary products with distributors and consultants worldwide together with the provision of appropriate technical support to allow the market development of the products. In 2011 he joined APC as a project manager with responsibilities including management and development of APC's international business, together with field study development and biocidal projects support. Andrew is now APC's Director of Development and International Business, responsible for management of APC offices in Australia, Brazil, Poland, Czech Republic and Hungary, together with the running of the network of local country consultants.

Chris O'Hara – Director of Regulatory Affairs

Chris has over 20 years of regulatory experience with plant protection products, biocides and REACH gained from working at a contract research organisation and at a major consultancy. He has a comprehensive working knowledge of EU regulatory evaluation procedures and risk assessment methods, including relevant guidelines and EC regulations as they pertain to existing and new active substances. Chris has been a project manager for numerous biocide and pesticide projects. These projects included the conduct of completeness checks, preliminary risk assessments, dossier compilation and the provision of regulatory strategic support.
In addition to his general regulatory project management skills, he specialises in the conduct of human health exposure and risk assessments for pesticides, biocides and chemicals, and has made expert presentations at conferences on the subject. Prior to joining APC, Chris was the Head of the Human Health Group at a major consultancy co-ordinating the preparation of dossiers/risk assessments and the management of resource allocation.

Kati Pikulik – Manager, APC Poland

Kati is a Regulatory Manager, and Manager of the APC Poland office. Her registration career began in 2000 in both sales and consultancy and she represents APC for all regulatory, development and technical activities and advice in Poland. Kati has experience in the provision of regulatory advice and registration procedures in Poland according to EU requirements as well as changes in registration procedures following Poland joining the European Union. Kati also has excellent contacts with Polish registration and evaluation authorities.

François Walker – Manager, APC France

François is a Senior Regulatory Manager and Manager of the APC France office. François has experience in agrochemicals (including biopesticides) and biocides, gained from both industry and consultancy. François has experience in all areas of managing and making regulatory submissions. He is also one of APC's residue experts. Working across many EU member states, François is experienced in the provision of regulatory advice and has developed cost effective regulatory strategies for a range of clients. He has placed and monitored a wide range of regulatory studies especially in the areas of residues, toxicology and ecotoxicology. François has been involved in the preparation and management of national/zonal product dossiers, and also active substance dossiers in compliance with current directives.

CONTACTS

Web site	www.apeiron-team.eu
E-mail	info@apeiron-team.eu
Head office	Berten Pilstraat 4, 2640 Mortsel, Belgium
Tel	+32 3 808 20 67
Contact	Elke Van Asbroeck
Directors	Elke Van Asbroeck and Hiram Moerman
Ownership	Private company
Locations	Mortsel (Antwerp), Belgium
Founded	2009

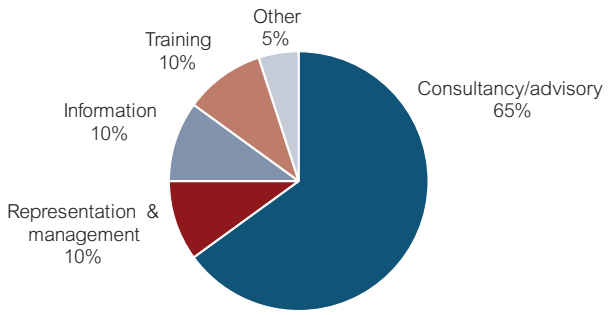
OVERVIEW

Our mission is to support industry with cost efficient implementation of complex chemical related regulations. We provide a high level of expertise in chemicals management in the entire supply chain for the relevant regulations as well as for internal responsible care objectives. We are a highly motivated team of doctors in toxicology and chemistry and engineers with industrial experience. As a company of over ten people and a limited number of sub-contractors with niche knowledge, we provide specific expertise, while being able to act flexibly and maintain our client focus.

VITAL STATISTICS 2016/17

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	> 10
Staff, chemical service provision	> 10

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

Regulatory services

We assist in the interpretation of legal texts: REACH, REACH-like legislations, CLP, biocidal product Regulation (BPR), cosmetics Regulation, EU andnational nano legislations, food contact, RoHS, developments in circular economy.

Scientific services

A selection of our services:

- REACH registration dossiers from A to Z: substance identification, hazard assessment, study monitoring, exposure and risk assessment, PBT assessments;
- REACH authorisation dossiers: strategy development, chemical safety assessment, analysis of alternatives, socio-economic analysis, supply chain communication;
- other REACH related topics: support during evaluation, support during BoA, eSDS compliance training, company specific eSDS support, DU-CSR generation, mixture classification, Annex XV dossier generation, representation of clients in consortia; and
- biocide dossiers: biocidal product dossier generation, biocidal product family concept integration.

Strategic support and industrial services

Apeiron-Team provides tailor-made advice for a cost efficient implementation of regulations, taking into account the global business strategy and required flexibility of the client. We provide assistance in the development of chemicals management systems and product stewardship programmes. Examples of our services:

- several audit programmes (eg compliance; system; supply chain; project; due diligence and SCC audit);
- set up of monitoring programmes (occupational hygiene);
- engineering support for the implementation and documentation of strictly controlled conditions for intermediates;
- advice on import/export strategy to ensure business continuity;
- position papers and communication with authorities;
- scientific advocacy in the pre-authorisation process;
- strategy for comments during evaluation and/or during pre-authorisation process;
- strategy deployment for authorisation dossiers; and
- integrating chemical legislation in circular economy business models

Training

Apeiron organises workshops on various aspects of the REACH and biocides implementation process. Examples: in-house workshop on REACH (pre)-authorisation, course on eSDS compliance, understanding REACH and its business impacts, luclid for REACH and for biocides, PNECs and DNELs, SVHC in articles, etc.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2009	Apeiron-Team NV was founded
2010	Successful REACH registration of >100 substances.
2011	Expansion of services and experience in REACH-like legislations, global SDS requirements, eSDS related products eg DU-CSRs.
2012	Expansion of our services with the “E” of evaluation and “A” of authorisation within REACH. Scientific advocacy for several projects (related to restrictions, SVHC status, authorisation and evaluation). China REACH notifications (in collaboration with Chinese experts).
2013	Generation of three authorisation dossiers. Organisation of workshops on the (pre-) authorisation process. Addition of biocides- and cosmetics-related services to our portfolio.
2014	Submission of two authorisation dossiers for trichloroethylene. Preparation of REACH Registration dossiers (new substances or 2018). In function of substance evaluation, commenting on the basis of scientific and regulatory arguments. Defence of substance under scrutiny for PBT.
2015	The two TCE authorisation dossiers received a 12 year review period. Preparation of several chromate authorisation dossiers. Submission of a Union authorisation under the BPR.
2016	Submission of 2 EDC and 2 chromate authorisation dossiers. Generation of Union authorisations. Implementation of circular economy business models.

ACCREDITATIONS

- European registered toxicologists (ERT)
- Environmental advisor (Milieu Coordinator)
- Strategic advisor SME

PARTNERS

Burgess Regulatory Services Ltd, eftec, Jongerius Consult

CLIENTS

Our references are situated in several industries and cover the entire supply chain from manufacturing to recycling:

- petrochemical industry, fine chemicals, toll manufacturing, food industry, polymer industry, refinery, tyre industry, pharma industry, textile industry retail.

TESTIMONIALS

"Apeiron-Team are professional and experienced, driven and engaged. With their expertise they translate the tangle of the REACH legislation into practical, concrete guidelines and actions" – BP Chembel

"Apeiron-Team is a no-nonsense company delivering their services on time, in full and in budget" – Monument Chemical

"For us, Apeiron-team distinguish themselves from other excellent consultants because they are able to think further in the benefit of the company together with us. We consider them as one of us" – Christeyns

"During the long process of authorisation (approx. two yrs) Apeiron confirmed numerous times that our choice for them as partner was right: The work delivered exceeded our expectations. Not only have I never experienced such a pro-active consultancy so far in my business life, but they deliver excellent and high-quality work. They are approachable at any time and pick things up even before we realised it is needed. In addition, Apeiron has an almost unrivalled network of contacts to almost every import person in this line of business." – Vlisco.

CASE STUDY 1: REACH authorisation application: from strategic support to dossier generation

The REACH authorisation process is complex and business critical. Vlisco (textile industry) requested our support for the authorisation of trichloroethylene, a non-threshold substance. In a first step, the dossier strategy was developed by means of in-house workshops with the company's management. In a second step, an authorisation application was generated. A company specific exposure scenario was prepared, demonstrating minimisation of emissions. This was supported by the (bio)monitoring data generated during the course of the project. In the analysis of alternatives a long list of potential alternatives was assessed, followed by a short list, demonstrating that the potential alternatives are not technically feasible, not economically feasible and not resulting in a risk reduction. Several non-use scenarios were discussed and the most plausible one was identified. This formed the input for the socio-economic analysis. A review period of 12 years was requested. On the basis of the arguments and research plan that was provided, Rac and Seac confirmed this review period was considered justified. In a final step, the Commission also granted 12 years.

CASE STUDY 2: REACH registration and evaluation for a multi-constituent

To support the registration of a high volume rubber chemical, we built the complete REACH registration dossier in the context of a consortium. The multi-constituent substance was analysed for all relevant physico-chemical and toxicological aspects related to both human health and the environment. Exposure was assessed for all stages of the lifecycle including the waste stage. Scaling equations were generated allowing the downstream users to evaluate their compliance.

Within the consortium we developed the cost-sharing model and performed the cost evaluation of the studies based on their scientific validity.

The multi-constituent was selected for substance evaluation by the MSCA based on its potential PBT properties. During this evaluation process we assisted the lead registrant in determining the most suitable test strategy and in writing the comments to the MSCAs, and were involved in discussion/communication with the relevant authorities. We are currently supporting this client during its Board of Appeal procedure.

CASE STUDY 3: Development of downstream user chemical safety report model for about 500 chemicals

A formulator dealing with about 500 incoming chemicals found that performing an eSDS compliance check and the associated communication was too cumbersome to allow for an efficient follow-up of the safe use of their chemicals. Apeiron-Team developed a user-friendly DU-CSR model tailored to their specific process. The model does an automatic safe use check of each incoming chemical based on limited input by the user. In case safe use cannot be demonstrated, operational conditions and risk management measures can be adapted in the model to determine which changes in use are required for a specific chemical. The model ultimately created a huge efficiency gain compared to the work required for a traditional eSDS compliance check. Moreover, new incoming chemicals are easily added to the model and the formulator is no longer dependent on his supplier for eSDS or any updates thereof.

CASE STUDY 4: Union authorisation of a biocidal product family

A Union authorisation dossier for a biocidal product application was prepared based on the biocidal product family (BPF) concept. This within product type 4. The composed biocidal product family, and its meta-SPCs, was evaluated in detail together with the client to ensure the different criteria of a BPF were fulfilled. Furthermore, a detailed data gap analysis was performed taking into account the data that was available and previously submitted under the BPD and the new data requirements stipulated in the BPR. All available information was integrated into luclid. In a final step, a draft risk assessment covering the complete BPF was generated. Both the BPF composition, data gap analysis and risk assessment were discussed with the evaluating CA before submission, and are currently under evaluation.

STAFF SELECTION

Elke Van Asbroeck – ir (Bio-)chemical engineer

- Polymer chemistry/ waste and recycle
- Cost-efficient regulation implementation, import/export strategy
- Authorisation process, generation of authorisation dossiers
- Supply chain communication
- Circular economy

Hiram Moerman – ir Chemical engineer

- Specialised in process chemistry
- Product stewardship/GPS
- Authorisation process, generation of authorisation dossiers
- Auditing
- Consortium/ project management

Dr Katrien Monsieurs – PhD Organic Chemistry

- Specialised in organic synthesis
- REACH dossiers: registration and authorisation
- Substance identification & human toxicology
- Read-across
- PBT assessments

Dr Tine Vandenbrouck – PhD Ecotoxicology

- Specialised in mixture effects
- REACH dossiers: registration and authorisation
- eSDS generation/scaling tools
- Biocidal product dossiers
- ERT certified toxicologist

ARCADIS Design & Consultancy for natural and built assets

CONTACTS

Website	www.arcadis.com
E-mail	PSSinfo@arcadis.com
Head office	Gustav Mahlerplein 97-103, 1082 MS Amsterdam PO Box 7895, 1008 AB Amsterdam, the Netherlands
Contact	Europe: alain.vassart@arcadis.com +32 492 972 330 Switzerland/Laboratory Services: andreas.haener@arcadis.com +41 44 732 92 52 North America: tina.armstrong@arcadis.com +1 410 279 8637 APAC: grant.sprick@arcadis.com +86 136 6174 0762
Directors	Barbara Hudec (EU Director Environment), Tim Strongman (Global Proposition Lead, Strategic Environmental Consultancy)
Ownership	Public company
Locations	400+
Founded	1888

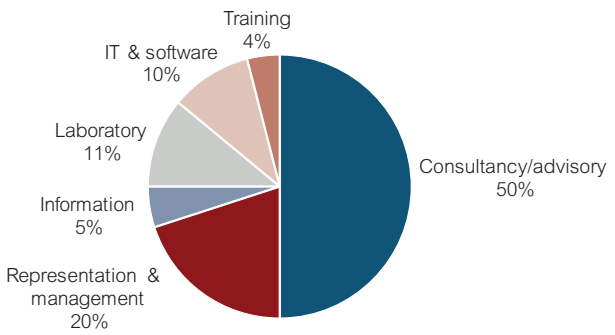
OVERVIEW

Arcadis is the leading global natural and built asset design and consultancy firm working in partnership with our clients to deliver exceptional and sustainable outcomes through the application of design, consultancy, engineering, project and management services. Arcadis differentiates through its talented and passionate people and its unique combination of capabilities covering the whole asset life cycle, its deep market sector insights, and its ability to integrate health and safety and sustainability into the design and delivery of solutions across the globe.

VITAL STATISTICS

VITAL STATISTICS	2015/16
Turnover, group	€3.4bn
Turnover, chemical service provision	€13m
No of countries represented	38
Staff, group	27,000+
Staff, chemical service provision	300+

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Centres of excellence for our product stewardship services are in both Europe (Belgium and Switzerland) and North America, with additional staff located across 300 global offices providing our clients with a local presence in growing markets such as Asia-Pacific and South America.

SERVICES PROVIDED

We help our clients to identify and manage their business risks, enabling them to market their products in a safe, responsible, and globally-compliant manner covering the whole life cycle from production and use through the waste stage. Our practice focuses on the following services:

Product stewardship programmes and audit services

Includes compliance programme development and implementation, auditing, due diligence, and post-merger integration assistance.

Worldwide regulatory surveillance

Includes continuous regulatory monitoring for emerging and existing chemical and product regulations including batteries, WEEE, RoHS, and waste, and impact assessments for individual products, product lines and product portfolios.

Implementation of global product compliance and stewardship information management systems

Includes implementation of global environmental, health, and safety (EHS) information management systems supporting product stewardship and product compliance, sustainability, EHS compliance and operational risk management.

Chemicals and biocides regulatory management

Includes registration and authorisation support for REACH and REACH-like regulations, country-specific chemical licensing/permitting, classification, labelling, and packaging for GHS and national variants, hazard communication support, biocides authorisation, plant protection product authorisation, and US FIFRA, TSCA, and California Proposition 65 assistance.

Agrochemical fate and exposure

Includes conduct of environmental fate and consumer safety field studies, aquatic and terrestrial modelling, risk assessment, and registration support for plant protection products.

Strategic scientific solutions

Includes in-house ecotoxicology, biodegradation, and environmental fate testing in compliance with OECD's Good Laboratory Practice (GLP), laboratory support services, and toxicology and risk assessment.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1888	Parent company, Heidemij, formed in the Netherlands
1998	Global company becomes Arcadis
2002	Establishment of a product stewardship Centre of Excellence in North America
2006	Arcadis Belgium becomes a product stewardship Centre of Excellence
2012	Arcadis acquires BMG Engineering Ltd in Switzerland, a leader in product stewardship, ecotoxicology (including GLP compliant laboratories) and REACH

ACCREDITATIONS

European registered toxicologists (EuroTox); European registered chemists; Diplomates of the American Board of Toxicology (DABT). The ecotoxicology laboratory of Arcadis Switzerland is GLP certified and accredited according to ISO/IEC 17025. The Arcadis team is GLP certified to conduct environmental fate and consumer safety field studies to support the registration of agrochemicals.

PARTNERS

Arcadis has a broad network of partners with whom we work together on an ad hoc basis (CROs, legal advisors, other consulting companies).

TESTIMONIALS

References can be provided upon request.

CASE STUDY 1: Groundwater monitoring for agrochemical re-registration activities

Arcadis recently completed a groundwater monitoring study at 125 real-world farming locations in the key maize-growing regions of 11 European countries. An international team used a web-based application to conduct more than 5.000 telephone screening interviews with potential farmers. Following completion of the telephone interview phase, the project team conducted more than 360 site assessments which involved the collection of detailed historical pesticide use information, characterisation of shallow soil profile, and determining the depth to groundwater at each monitoring location. A network of 375 high-quality, standardised, shallow groundwater monitoring wells were installed using Arcadis's own environmental drilling equipment. Groundwater sampling was conducted by local Arcadis staff on a quarterly basis with more than 700 groundwater samples collected. This study provided an unprecedented magnitude of data regarding the environmental fate of the agrochemical being studied.

CASE STUDY 2: Application for authorisation within REACH

Arcadis assisted an international pharmaceutical company to quickly and successfully compile the authorisation dossier for a processing aid. Support for the dossier preparation included comprehensive data gathering within the company and assistance with the preparation of analysis of alternatives, socio-economic analysis and the chemical safety report. Arcadis further provided support answering questions from the RAC and SEAC and participated in the trialogue.

CASE STUDY 3: Project management and study monitoring support for a pharmaceutical company

Arcadis is considered a strategic partner for a pharmaceutical company in its REACH registration project for over 100 substances by the 2018 deadline. Arcadis provides full-service support for this client's product stewardship team, reducing their internal workload associated with REACH registration requirements and allowing them to focus on other business-critical issues. Arcadis also assists senior management by tracking budget and progress status, overall and per substance. We highlight which processes need more attention and solve critical issues to promote business continuity. As study monitor, we support our client's subject matter experts by managing the project through continuous status follow-up and communication with the CRO, review of study plans, evaluation of draft results, and final reports.

CASE STUDY 4: Global implementation of a product compliance information management system

A global article manufacturer exporting products worldwide requested an integrated information management platform to support product compliance and enable efficient chemical management. The global product compliance information management system developed by Arcadis enables our client to:

- easily determine the impacts of new or changing regulations on raw materials and products
- determine whether chemicals purchased from suppliers contain ingredients harmful to the environment, or to the health and safety of workers and consumers
- access product-level and substance-level content and information, including physico-chemical properties and classifications
- create compliant safety data sheets (SDSs) and labels for diverse countries and in diverse languages in an automated fashion
- identify all the chemicals present at each facility, and verify that SDSs are available for each chemical at each facility.

CASE STUDY 5: APAC chemical and product compliance assistance

Using in-country resources, Arcadis is currently assisting an international chemical product manufacturer with compliance under China's State Council Decree 591 – Regulations on the Safe Management of Hazardous Chemicals in China, Taiwan's Toxic Chemical Substance Control Act, and Japan's Poisonous and Deleterious Substances Control Law. In addition, we are assisting this client with customising labelling solutions to meet requirements under GHS in China and Japan as well as country-specific requirements. Arcadis staff have also provided local-language chemical emergency response measures training in preparation for potential facility inspections associated with product permitting.

STAFF SELECTION

Sam Temara, European EHS Information Driven Performance Lead

With more than 20 years of experience in IT and EHS-IT, Sam leads Arcadis' EHS information driven performance practice in Europe. Sam has been implementing product compliance information management systems using various tools and platforms (including SAP, Enablon, 3E Company, ChemAdvisor, and Lisam) for global industries primarily in the chemical, consumer, pharmaceutical, and manufacturing sectors.

Andy Newcombe, Agrochemical Product Stewardship

Andy has more than 26 years of experience in the design, conduct, and management of complex, higher tier agrochemical fate and transport studies including studies conducted at the field, regional, national, and continental-scales. He has successfully negotiated with European member state and United States federal and state regulators on behalf of agrochemical industry clients on environmental fate issues associated with their products and has considerable experience in providing clients with litigation support.

Kathy Zesses, Chemical Regulatory Affairs Expert

Kathy has more than 15 years of regulatory and product stewardship experience with multi-national automotive, chemicals and coatings, and pharmaceutical companies. She has supported product compliance under a wide variety of North American federal and state regulations including US TSCA, California Proposition 65, Osha's Hazard Communication Standard, and US Food and Drug regulations.

Alain Vassart, Sr REACH / Batteries / Recycling and Waste Expert

Alain has more than 20 years of experience in the chemical and recycling industry. He was an active member of the EU Copper Task Force (plant protection), participated in the VRA on copper and was past chairman of the copper compounds REACH consortium. Alain has actively contributed to the development of EBRA (European Battery Recycling Association – www.ebra-recycling.org), currently taking the role of secretary general. He is managing several REACH consortia (eg, MoZo, rare earth) including the administrative and financial side.

Beatrice Verdickt, Agrochemical Registration Expert

Beatrice has more than 25 years of experience in agrochemical registrations. She provides consulting services to agrochemical companies and organisations on various aspects of plant protection product registration – the regulatory context as well as technical and scientific matters – with special expertise in data analysis for registration packages and submissions, management of issues related to compliance with EU registration requirements, and technical support for risk assessments.

Andreas Häner, Microbiologist / Ecotoxicologist

Andreas heads the Product Stewardship Solutions (PSS) department and Ecotoxicology Laboratory at Arcadis Switzerland. Over the last 20 years, he has specialised in the fields of chemical safety (such as global product stewardship, legal compliance, REACH, GHS) and environmental risk assessment and has supervised non-clinical GLP studies (aquatic toxicology, biodegradability and environmental fate).

ARCHE CONSULTING

CONTACTS

Website	www.arche-consulting.be
E-mail	info@arche-consulting.be
Head office	Liefkensstraat 35d, 9032 Gent-Wondelgem, Belgium
Tel	+32 9 216 70 38
Contact	Marnix Vangheluwe
Directors	Marnix Vangheluwe Patrick Van Sprang
Ownership	Private company
Locations	Gent and Leuven, Belgium
Founded	2009

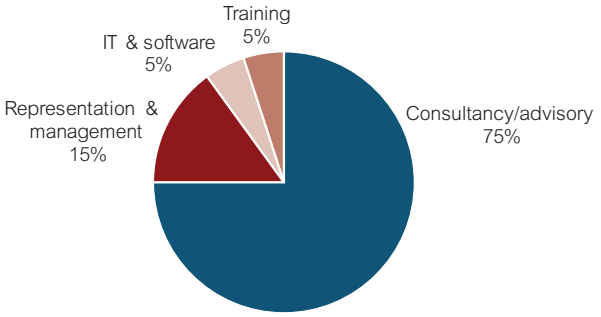
OVERVIEW

One of the key areas of expertise is the preparation of REACH-related risk assessments and full dossiers for inorganic substances such as metals, alloys, slags, etc and, as such, the ARCHE experts have been involved in the preparation of many guidance documents (eg Echa) on these topics. Other key services include the assessment (environment and human health) and development of registration dossiers for biocidal products and plant protection products classification of substances and complex mixtures (GHS/CLP), and setting and/or evaluation of (site-specific) environmental quality standards and performing environmental risk assessments of medicinal products for human use. In addition, ARCHE is also a certified material health assessor, assisting companies towards certifying their products in line with the Cradle Certified Products Programme CM (cradle-to-cradle).

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	2
No of countries represented	1
Staff, group	26
Staff, chemical service provision	26

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

PJ Van Benedenstraat 4, box 203
3000 Leuven, Belgium
Tel: +32 16 28 49 00

SERVICES PROVIDED

REACH

The REACH Regulation is the biggest piece of chemical legislation ever. ARCHE is well placed to help you set up a REACH implementation plan and assist you with the fulfilment of your obligations as producer, importer, distributor and/or downstream user of phase 2 and 3 substances under REACH. We can assist in (a) literature search and data evaluation; (b) Iuclid; (c) exposure scenarios; (d) CSA/CSR; (e) read-across and data waiving; (f) Qsar; (g) REACH dossier submission, updating and follow-up and h) reach compliance. For the latter, ARCHE developed an unique one-to-one assistance programme called RESCUE to help downstream users to ensure REACH/CLP compliance for their substances and mixtures, as these elements will be the primary focus of enforcement authorities across the EU as embedded in the REACH-EN-FORCE programmes.

Join our REACH 2018 Orphan Substances Consortium (ROSC)!

Orphan substances are those substances that have no or limited data and no existing organisation working on them. ARCHE acts as a technical partner to the ROSC consortium, which is an initiative together with two other renowned and experienced service providers. For more information visit our dedicated website www.rosconsortium.eu

Biocides and plant protection products (PPPs)

ARCHE offers a one-stop-shop for the registration of your biocides and ppp products or active substances. We furthermore generate and manage consortia for biocidal products or active substances. ARCHE has extensive expertise and a proven track record in delivering solutions to problems at all stages in the registration/review of biocides and PPPs. Offered services include: (a) consortia management for biocidal product; (b) effect and exposure assessment for active substances and products; (c) data gap identification and designing higher-tier studies; (d) exposure modelling (FOCUS suite of models, Euses, Consexpo, EASE); (e) higher-tier exposure scenario development; (f) CLP; (g) dossier preparation, submission and follow-up; (h) client representation in meetings with regulatory authorities; (i) product stewardship; and (i) training Iuclid for biocides.

Cradle to Cradle certification®

As an authorised Cradle to Cradle material assessor, ARCHE assesses healthy and sustainable products under the Cradle to Cradle certifiedCM Products Programme. The Cradle to Cradle product standard addresses five quality categories relating to human and environmental health: (a) material health, (b) material reutilisation, (c) renewable energy and carbon management, (d) water stewardship, and (e) social fairness. The ultimate goal of the Cradle to Cradle CertifiedCM Products Programme is to encourage continuous improvement, innovation, and formulation of products that benefit humans and the environment.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2009	Foundation of ARCHE (staff: five people).
2010-2012	Expansion of the team to 16 people, with offices in Ghent and Leuven.
2013-2017	Further expansion to more than 25 people, and further development of the services on biocides, plant protection products and cosmetics.

PARTNERS

EBRC Consulting GmbH, Hannover
PietConsulting
ECTX-Consulting
ROSC
Toxicological Consulting

CLIENTS

Industrial clients and consortia related to the following chemical substances:

- metals including: Cu, Ni, Mo, Pb, Zn, Hg, V, Co, Fe, Se, Sb, Sr, Mg, Bi, Te, Ti, etc;
- organic compounds: chlorinated flame retardants, organic acids, plasticisers, amines, biocides, plant protection products;
- complex materials: Cu slags, Ti slags; and
- other inorganic substances: Ca, B, NaOH, KOH, sulphur dioxide-related substances (SO2, sulphites, thiosulphates, dithionites), lime, nitric acid, phosphoric acid.

TESTIMONIALS

"ARCHE Consulting played a key role in helping us to achieve our approval by ECHA as an art 95 listed supplier for Geraniol in PT 18 and PT19. They were always available, knowledgeable, thorough and were instrumental in guiding our responses and submissions to help insure the successful outcome. We look forward to maintaining an ongoing relationship for our future regulatory requirements with ARCHE Consulting." – Antoine Birron, Director, TerpeneTech Ltd.

"IMOA has worked for the last decade with the environmental scientists working at ARCHE, and they have proved for IMOA/MoCon to be a very wise investment. We can therefore highly recommend ARCHE with regard to their technical expertise and knowledge on environmental issues (aquatic and terrestrial), organisation of research projects, and data interpretation." – Sandra Carey, International Molybdenum Association (IMOA)

"ARCHE has proven to be a very valuable consultancy partner for DeLaval over the past few years. DeLaval was able to benefit from the in-depth knowledge of the ARCHE scientists on the European biocidal Regulations (BPD/BPR) and we can only recommend to others the training we received on several aspects of risk assessments (both human and environmental)." Adelheid De Ketelaere, Regulatory Affairs Manager EMEA, SEA PPMQ&AH DeLaval NV

more testimonials can be found at www.arche-consulting.be

CASE STUDY 1: Active substance renewal and product registrations for plant protection products (PPPs)

ARCHE Consulting collaborated with a task force to obtain renewal of their active substance for use in PPPs. Upon submission and evaluation of the dossier, ARCHE entered into discussion in 2016 with the regulatory bodies, mainly on topics related to environmental fate and ecotoxicology, aiming to successfully complete the active substance renewal. These activities, as well as addressing questions of regulators to preparing zonal core registration dossiers and national addenda, were part of the services provided to clients in the crop protection industry, and have led to multiple product authorisations across the EU.

CASE STUDY 2: REACH registration dossiers for low-tonnage substances (2018 deadline)

ARCHE as technical partner of the ROSC (the REACH Orphans Substances Consortium) will prepare the REACH registration dossier for strontium and barium by the 2018 deadline.

CASE STUDY 3: Consortia for biocidal products

Since 2015, ARCHE is generating several consortia to jointly prepare biocidal product family dossiers. The main goal is to share the burden of costs for fees, testing and dossier preparation between all members. Our first dossier will be submitted early 2016. ARCHE is responsible for the consortium management, testing coordination and dossier preparation including risk assessment, whereas FieldFisher has been acting as our legal partner for these projects.

STAFF SELECTION

Patrick Van Sprang – Managing Director ARCHE

Patrick Van Sprang graduated as master of science in engineering (environmental technology) at Ghent University (1988). At Ghent University (1994-2000) he was responsible for the research group aquatic ecotoxicology. He was co-founder of EURAS, a consultancy company specialising in environmental risk assessment. Patrick Van Sprang is the main author of the environmental part of several risk assessments (eg Cu, Ni, Pb) and contributed to the metal risk assessment guidance document (Merag).

Marnix Vangheluwe – Managing Director ARCHE

Marnix Vangheluwe graduated as master of science in engineering (biochemistry) at Hogeschool Gent (1989). In 1991 he obtained a master in environmental sanitation (Ghent University). At Ghent University (1992-2000) he was responsible for the research group sediment ecotoxicology. He is the main author of the metal risk assessment guidance documents (Merag) and the official REACH Appendix R.7.13-2.

Frederik Verdonck – Senior Science Project Manager

Dr Frederik Verdonck obtained his PhD degree in bio-engineering on probabilistic risk assessment at Ghent University (Belgium). At ARCHE his main expertise area comprises the implementation and application of statistical and modelling approaches in exposure, effects and risk/safety assessment. Currently, Dr Frederik Verdonck is the leading expert in developing and implementing new tools in the field of exposure assessment. As a certified trainer, he also deals with training programmes on various REACH and BPR risk assessment topics.

An Ghekiere – Senior Science Project Manager

An Ghekiere graduated as Master of Biochemistry in 2001 and obtained her PhD in Bio-engineering on endocrine disruption in invertebrates at Ghent University (Belgium) in 2006. From 2002 until 2010 she worked on projects (ENDIS-RISKS and INRAM; risk assessment of micropollutants in estuarine and marine environments. At ARCHE she is responsible for the biocides and ppp services. As a ERT certified toxicologist she also deals with human and environmental risk assessments..

bibra
toxicology advice
& consulting

CONTACTS

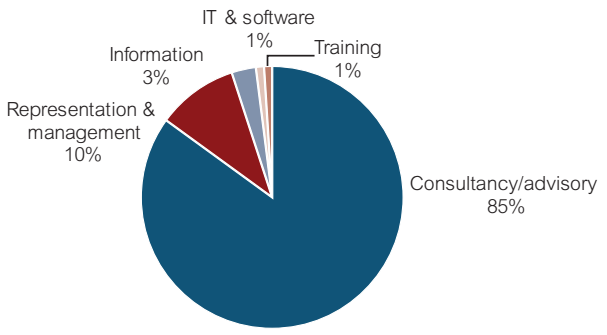
Website	www.bibra-information.co.uk
E-mail	info@bibratoxadvice.co.uk
Head office	Cantium House, Railway Approach, Wallington, Surrey, SM6 0DZ, UK
Tel	+44 (0)20 8619 0770
Contact	Peter Watts
Directors	James Hopkins, Managing Director Peter Watts, Director of Toxicology Richard Young, Principal Toxicologist and Director Ashleigh Ace, Commercial Director
Ownership	Private company
Locations	UK
Founded	1961, acquired by current management 2005

OVERVIEW

Bibra toxicology advice & consulting Ltd is one of the most experienced and successful chemical hazard and risk assessment organisations in Europe. We combine the skills and expertise of a large team of highly experienced and outstandingly qualified toxicologists with the finest, independently owned toxicological databank in the world. This unique combination of world-class expertise and consulting skills with an outstanding information system means we can provide superior quality solutions to virtually all the problems faced, both by toxicologists and related company managers, in a highly-efficient and cost-effective manner. Bibra toxicology advice & consulting has been working successfully with government departments and industry for many years across a broad range of sectors, for example industrial chemicals, agrochemicals, biocides, cosmetics, pharmaceuticals, medical devices, e-cigarettes, and food/drink. We have built an enviable reputation for our ability to handle large, as well as small projects, and to deliver high quality consulting and information services to tight deadlines. We are a leading supplier of REACH compliance services, assisting chemical manufacturers, importers and downstream users with all their REACH responsibilities.

VITAL STATISTICS	2016/17
Turnover, group	£2m
Turnover, chemical service provision	£2m
No of offices	1
No of countries represented	1
Staff, group	23
Staff, chemical service provision	20

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Surrey (Greater London)

SERVICES PROVIDED

Dossier preparation, including CSA/CSRs (DNEL/DMEL derivation)

Highly skilled in working directly into Iuclid preparing technical dossiers required under REACH and the biocidal products Regulation, and in describing toxicological data in a robust but efficient way. Very experienced in interpreting/evaluating toxicity studies and working with appropriate assessment factors to derive risk-based levels of tolerable exposure (DNELs/DMELs). Accurate input of information into Iuclid facilitates the overall chemical safety assessment and production of the final chemical safety report for submission to Echa. We can also advise on relevant classification/labelling, and PBT/vPvB status. Working with partners, we cover all aspects of REACH. We also provide a Iuclid 6 web-hosting service to our clients.

Human health hazard and risk assessment

The bibra toxicology advice & consulting team of toxicologists has worked together over many years (<30 years in some instances), providing robust human health hazard and risk assessments for a diverse range of clients. Tailoring our output to suit the specific requirements of the client, we have worked with companies from the industrial chemicals, agrochemicals, biocides, food and food contact, consumer products, pharmaceutical and medical device sectors, as well as a number of governments (eg, UK DoH and EA), international organisations (eg, OECD and WHO) and respected NGOs. Our skill sets are very well matched to current requirements for toxicological hazard and risk assessment under REACH and other regulatory chemical control activities.

Data searching, gap analysis and development of testing strategies

We perform data searches as required under REACH (including in our ECHA-approved TRACE database). Retrieved information can be quickly assessed for relevance and reliability to satisfy tonnage-relevant data requirements. Additional laboratory testing can be minimised by expertly exploring opportunities for data waiving, read-across, and use of Qsar to create weight-of-evidence approaches to fill data gaps. If further testing is necessary we can advise on testing strategies to minimise both the use of animals/overall costs to the client, while maintaining scientific integrity. We assess the impact of the results of new tests conducted and provide ongoing expert guidance on what is really needed.

Extensive in-house toxicological database and databank

For 55 years, bibra toxicology advice & consulting has been scrutinising emerging toxicological literature, expert reviews or pronouncements, and indexing them systematically (by endpoint and chemical). Much of this scientific literature is held in-house in our technical library and quickly accessed using its associated database, TRACE. This unrivalled resource (listed as a valuable data source in Echa guidance) allows instant access to relevant documents and is critical in helping us produce the finest hazard and risk assessment work for our clients, in the most timely and cost-effective manner.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1961	Formation of BIBRA
1961	Establishment of Toxicology Information and Advisory Department
1961	Began to build the technical library
1987	TRACE, a database designed to source data, from the tech library (databank), was developed
2000	TRACE, and associated databank, independently assessed as the finest toxicological data source of its type, worldwide
2003/5	Toxicology Advice & Consulting Ltd and Bibra Information Services Ltd established as vehicles to facilitate management buyout of Information and Advisory Department, including TRACE and its associated databank
2005	The new combined entity began to trade as bibra toxicology advice & consulting from Sutton, Surrey offices
2010	Relocated to new, larger offices in Wallington, Surrey

ACCREDITATIONS

Our senior toxicologists are all Royal Society of Biology/British Toxicology Society and European Registered Toxicologists. We are a REACHReady approved supplier.

PARTNERS

Enviresearch Ltd, wca environment Ltd, REACHWise, Linmark Consulting Gmbh, ReFaC

CLIENTS

Many of our clients have a need for confidentiality so those listed below are just a small sample of the types of organisations that we work with:

- Infineum UK Ltd
- INEOS Group
- Innospec Active Chemicals
- Johnson Matthey plc
- CSL Behring Biotherapies for Life
- Groupe Danone
- Environment Agency (UK)
- Health Canada
- World Health Organization (WHO)

TESTIMONIALS

"James Hopkins and his team have always delivered toxicity reviews of high quality, have always met deadlines and are very flexible in terms of adapting to changes in Environment Agency research priorities. In view of this I have no hesitation in recommending them for other work related to the derivation of human health criteria values for environmental contaminants" The Environment Agency

"We involved bibra from conception to completion of a REACH dossier (with a short deadline and little data). We have been very impressed with their efficiency, professional manners, knowledge of the subject and their ongoing suggestions to help us to find solutions to meet our deadline. The dossier was ready on-time and of an impeccable quality" Product Stewardship / Reach Manager at INEOS Oligomers

"We acknowledge that bibra toxicology and consulting provide services that are highly regarded among the international scientific community" Efsa

"Reliable, responsive and adept at applying their toxicological expertise to REACH, our experience of working with bibra has been very positive" Infineum UK

"We have worked with Bibra on a number of occasions and have always received a thorough and professional service. A number of the reports compiled by Bibra have been used to successfully support global regulatory submissions" Development Manager at Advanced Medical Solutions

CASE STUDY 1: Complex REACH submission involving a large category of substances

Bibra toxicology advice & consulting has been working on a number of REACH submissions that involve large categories of substances. In one case, we are supporting a consortium of companies with all the mammalian toxicology aspects of their regulatory obligations for a group of >70 related metal compounds. The work has involved the evaluation of a large number of proprietary studies and published literature, drafting of endpoint study records (ESRs) in Iuclid, assessment of Annex III compliance, complex data-gap analyses and advice on possibilities for read-across and weight-of-evidence approaches, and the development of an appropriate integrated testing strategy, to minimise the amount of animal testing required.

CASE STUDY 2: Urgent request for help with chemical safety report

We are very happy to take on smaller projects and have been working with a number of clients to help out with specific areas of their REACH registration dossiers.

In one case we were asked at short notice to help improve an existing Iuclid dossier on a petrochemical additive manufactured in the EU at greater than 1,000tpa. This urgent request involved the peer-review (and significant improvement) of previously drafted ESRs and associated endpoint summaries, and the compilation of a chemical safety report (CSR), which included calculation of DNELs and PNECs, a PBT/vPvB and exposure assessment, risk characterisation step, and documentation of the necessary risk management measures and operational conditions (RMMs/OCs). The size and capabilities of our team meant that, despite the late notice and tight deadline, we could incorporate this project into our work schedule and the client was able to successfully submit their registration dossier in time.

CASE STUDY 3: Provision of alerting service to keep industry up-to-date on emerging issues

Bibra toxicology advice & consulting was asked by an industry sector group to provide an ongoing service to track the emerging toxicological literature on a range of chemicals of particular interest to their members. Using a range of carefully tailored search and alerting strategies (SDI – selective dissemination of information), the bibra team receives daily notification of newly published or pre-published papers, abstracts or comment, and alerts the sector group members to keep them abreast of the scientific literature and developing areas of possible concern. The service allows the industry to successfully foresee and manage arising issues in a co-ordinated and proactive way.

STAFF SELECTION

James Hopkins – Managing Director

James has worked at bibra for 41 years; he is a principal toxicologist and chemical health risk assessor of high repute, and led the management buyout in 2003. The new company, bibra toxicology advice & consulting, has performed impressively under James' guidance. James has wide experience in reviewing/evaluating toxicological data for a range of chemicals in a cross-section of industries. He has also compiled numerous critical reviews of chemicals and several strategy documents for national governments (including the UK Environment Agency and Health Canada).

Peter Watts – Director of Toxicology

Peter is our Director of Toxicology and is a bibra veteran of 40 years. His vast experience includes reviewing and critically evaluating toxicological data and providing health risk assessments on numerous chemicals for government departments and industrial organisations. He helped in the preparation of the REACH Guidance on Information Requirements, has authored WHO-IPCS CICADS and Environment Agency CLEA reports, acted as a temporary adviser to the WHO, and has provided peer-review services for OECD SIAMs (and CoCams).

Richard Young – Principal Toxicologist and Director

Richard has 15 years' experience at bibra, reviewing and critically evaluating toxicological data on a wide range of chemicals. He has worked with clients from a diverse range of industry sectors, international government departments and most recently has been very involved with a collaboration within the electronic cigarette industry to help meet their TPD requirements. He is intimately involved in REACH, leading the bibra toxicology advice & consulting team of toxicologists to support a number of client companies and consortia with their registration submissions (including the REACH registration of >70 related metal compounds).

The rest of the team

We have another 16 highly-competent and experienced toxicologists. All of the seniors are professionally qualified (RSB/BTS and European Registered Toxicologists) and, barring our graduate trainees, range in practical experience from 15 to 41 years. All are extremely skilled in chemical hazard and risk assessment and have been heavily involved in REACH-related work during the past decade.

BLUE FROG SCIENTIFIC

CONTACTS

Website	www.bluefrogscientific.com
E-mail	info@bluefrogscientific.com
Head office	Quantum House, 91 George Street, Edinburgh, EH2 3ES, UK
Tel	+44 (0) 131 523 1412
Contact	Damien Carson
Directors	Damien Carson Tom Hargreaves
Ownership	Private limited company
Locations	UK (Edinburgh and Cardiff)
Founded	2006

OVERVIEW

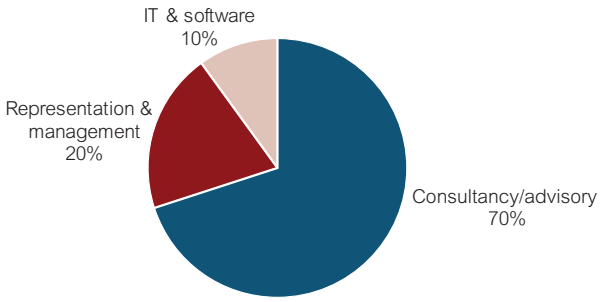
Blue Frog Scientific is an independent regulatory consultancy, providing scientific and regulatory affairs solutions to companies in all sectors of the chemical industry. Blue Frog's philosophy is achieving regulatory compliance through the application of good science, innovative thinking and clarity; ensuring that all submissions are prepared efficiently and to a high standard.

We offer scientific and regulatory affairs services with particular experience in chemicals, human pharmaceuticals, veterinary medicines, agrochemicals and consumer products.

Based in the UK, our core team of consultants coordinate operations and our comprehensive network of associates (including contract laboratories, legal support and financial accounting) ensures that we can assist our clients in all areas of regulatory compliance. We have particular in-house strengths in chemistry, toxicology, ecotoxicology, environmental fate, and regulatory affairs. We utilise our network of associates when we need leaders in specialised fields (eg reproductive toxicology) to address issues requiring an expert opinion, statement or report.

VITAL STATISTICS	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	2
No of countries represented	2
Staff, group	12
Staff, chemical service provision	12

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Edinburgh, Scotland, UK
Cardiff, Wales, UK

SERVICES PROVIDED

Scientific consultancy

- regulatory testing design and study monitoring
- intelligent testing strategies
- ecotoxicology and environmental fate
- environmental hazard and risk assessment
- toxicology
- human health hazard and risk assessment
- compilation of dossiers and expert reports

Regulatory affairs

- regulatory affairs for chemicals, human medicinal products, veterinary medicinal products, agrochemicals and consumer products
- project management
- product defence
- consortium and task force management
- only representation of non-EU chemical companies under REACH

Chemicals (REACH and CLP)

Blue Frog Scientific provides a full technical and administrative registration service for chemical substances under Regulation (EC) No 1907/2006 (REACH). Our team is highly qualified and experienced in preparing registration dossiers, chemical safety assessments, coordinating with Siefs and consortia, and liaising with regulatory authorities during and post dossier submission.

Key sectors of experience include:

- monomers, process chemicals, coatings and catalysts;
- oilfield chemicals and petroleum products;
- fragrances;
- pharmaceutical intermediates;
- substances of unknown or variable composition, complex reaction products or biological origin (UVCB);
- transported isolated intermediates (Article 18).

We also provide supply only representative services in accordance with Article 8 of REACH for non-EU companies that manufacture or formulate chemical substances and mixtures.

Consortium/Sief management

Blue Frog Scientific has developed a model for managing the financial and administrative challenges of consortia and task forces. We are currently managing consortia and Siefs under REACH as well as other groups of companies collectively working on research and development projects.

Our services include:

- provision of a consortium bank account;
- accounts payable and accounts receivable;
- VAT and tax accounting;
- purchase contract management;
- teleconferencing facilities;
- data storage and management via the secure Blue Frog Scientific extranet.

Environmental risk assessment of human medicinal products (HMPs) and veterinary medicinal products (VMPs)

Blue Frog Scientific has extensive experience in assessing the potential environmental risk posed by human pharmaceuticals and veterinary medicines.

Environmental risk assessment:

- authoring expert reports for inclusion in European marketing authorisation applications and FDA filings;
- planning and coordinating the necessary activities required in the preparation of risk assessments for regulatory submission;
- expert evaluation of laboratory studies;

- protocol development and environmental testing requirements to GLP, and following international guidelines;
- preparing literature based weight-of-evidence risk assessments for specialist products;
- multimedia mathematical modelling of the fate of pharmaceuticals in soil, freshwater, sediment and marine compartments;
- deterministic and higher tier probabilistic assessment of effects on biota and exposure concentrations;
- preparation of conclusions of risk, with relevance to the "real world" and mitigation solutions;
- use of mammalian ADME data to refine models and aid conclusions regarding bioaccumulation and secondary poisoning.

Key sectors of experience:

- HMPs: AIDS, chronic kidney disease, ataxia, an.-inflammatory, hypertension, diabetes;
- VMPs: antibiotics, parasiticides, coccidiostats, antipyretics;
- all classes of cattle, swine, sheep, poultry;
- oral drenches, injectables, pour-ons, in feed, in drinking water;
- product defence, particularly for two "priority list" substances.

Agrochemicals

Blue Frog Scientific and associates offer a full dossier service for registering plant protection products throughout Europe.
Our range of services provides cost effective solutions to support placing your products on the European market.
Data gap analysis:

- overview of quality of existing studies and identification of any data gaps for re-submission of dossiers according to EC 1107/2009;
- preparation of updating statements.

Study management:

- regulatory testing design;
- testing strategies and study design (GLP/GEP);
- study monitoring;
- preparation of study summaries.

Dossier preparation and regulatory affairs:

- OECD and dRR sections 1 to 7 prepared to a high standard;
- communication with regulatory authorities within EU 27 to support submissions.

Key sectors of experience include:

- insecticides: pyrethroid, neonicotinoid, organophosphate and carbamate;
- herbicides: organophosphorus, phenylpyrazole;
- benzoylcyclohexanedione, chloroacetanilide;
- fungicides: triazole, anilinopyrimidine, amide, pyrazole;
- other: semiochemicals and biopesticides.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2006	Formation of chemical regulatory services team within BMT Cordah Limited, part of the BMT group of companies.
2007	Development of REACH technical consulting services supporting a global client base.
2008	Development of human pharmaceutical and veterinary medicine consulting services supporting a global client base.
2010	Management buy-out of Chemical Regulatory Services business by D Carson and T Hargreaves, forming Blue Frog Scientific Limited.
2010	Development of agrochemical consulting services.
2012-2017	Sustained growth leads to major expansion of company with new staff and offices to support growing client base.

ACCREDITATIONS

European Partner: Society of Environmental Toxicology and Chemistry (SETAC).
REACH Ready Approved Service Provider.
Member of the Only Representatives Organisation (ORO).
Associate Member of the European Oilfield Speciality Chemicals Association (EOSCA)

CLIENTS

Blue Frog Scientific supports a global client base of chemical, pharmaceutical, veterinary, agrochemical and consumer product companies, ranging from SMEs to large multinational corporations. We take our clients' confidentiality very seriously and will not disclose their identity.

CASE STUDY 1: REACH advisor to a European Defence Agency

Provided long-term support to a European Defence Agency in defining the parameters of the defence exemption, training staff on the fundamental aspects of REACH, and developing internal procedures for assessing exempt/non-exempt chemical substances and complying with REACH.

CASE STUDY 2: Assessment of the environmental fate and effects of the PPARgamma receptor agonist, pioglitazone

The environmental fate and effects of pioglitazone prescribed for the treatment of type 2 diabetes were evaluated in an environmental risk assessment. A predicted environmental concentration (PEC) for surface water was estimated at 0.023µg L-1, triggering a comprehensive battery of laboratory evaluations. Pioglitazone and its major metabolites were determined not to significantly adsorb to sewage solids, were not persistent in the aquatic environment, did not bioaccumulate and were non-toxic to aquatic organisms. Pioglitazone does not pose an unacceptable risk to groundwater supplies, with concentrations not anticipated to be a risk to aquatic organisms or human drinking water supplies. Pioglitazone does not pose a risk of secondary poisoning.

STAFF SELECTION

Damien Carson BSc PhD – Director

An expert in chemical hazard and risk assessment with more than 15 years' experience across a wide range of sectors in the industrial and fine chemical industry. Expert in good laboratory practice (GLP) and testing strategies.

Tom Hargreaves BSc (Hons) – Director

An expert in environmental hazard and risk assessment, with more than 20 years experience in veterinary medicinal products, human pharmaceuticals, agrochemicals and chemicals. Expert in good laboratory practice (GLP) and testing strategies.

Nigel Halsall BSc PhD – Associate Director

An expert in environmental hazard and risk assessment with more than 25 years experience in the agrochemical industry. Expert in good laboratory practice (GLP) and testing strategies.

bluesign®

CONTACTS

Website	www.bluesign.com
E-mail	info@bluesign.com
Head office	bluesign technologies ag, Moevenstrasse 18, Switzerland
Tel	+41 71 272 29 90
Fax	+41 71 272 29 99
Contact	Mr Christian Dreszig, Head Marketing
Directors	Mrs Jill Dumain, CEO
Ownership	Ag, main shareholder SGS
Locations	Switzerland / global
Founded	2000

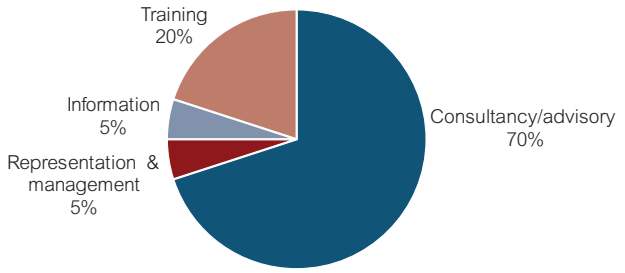
OVERVIEW

bluesign technologies ag was founded in Switzerland in 2000. The unique combination of expertise in key segments of the textile production as chemistry, textile technology, environment technology and supply chain management characterizes our company. We not only further develop the independent bluesign® system but also ensure its implementation and maintenance. Cultivating our interdisciplinary network, our essential aim is to act as a solution provider for the entire textile industry.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	9
No of countries represented	Global
Staff, group	75
Staff, chemical service provision	20

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

bluesign technologies ag
Moevenstrasse 18
9015 St.Gallen
Schweiz
Telefon: +41 71 272 29 90
info@bluesign.com

bluesign technologies germany gmbh
Am Mittleren Moos 48
86167 Augsburg
Deutschland
Telefon: +49 (0)821 74 77 544

bluesign technologies china limited
Room 1105, 11/F, Manhattan Centre
8 Kwai Cheong Road, Kwai Chung, N.T.,Hong Kong
Telefon: +852 2425 1600

SERVICES PROVIDED

Product stewardship services

Any chemical company should have a fully functioning product stewardship programme in place. In some instances this is not fully implemented and bluesign technologies can provide a tailored service for the textile chemistry industry to improve this.
Gap analysis, implementation and training of holistic product stewardship systems for chemical companies. The main focus is on in-put stream management, process management & quality control and hazard assessment and communication.

Risk assessment of chemical product

Full hazard and exposure assessment for chemical products regarding environment, occupational health & safety and consumer safety

bluesign® certification of chemical products

Certification of chemical products according the criteria of the bluesign® system.

bluesign® audits for chemical companies

Audits of chemical companies according the criteria of the bluesign® system with the target of a bluesign® system partnership

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

bluesign® system	Holistic chemicals management system to monitor hazardous chemicals within the entire supply chain
bluesign® approved	Certification based on unique risk assessment including harzard and exposure scenario assessments

STAFF SELECTION

Senior product stewards

Long term experience in implementation and management of product stewardship

Senior chemical assessors

Special experience on risk assessments of chemical products for textile and relevant industries

Senior chemical auditors

Experienced company auditors for textile chemistry industry

C.S.B. GmbH

Chemie - Sicherheit - Beratung

CONTACTS

Website	www.csb-online.de
E-mail	info@csb-online.de
Head office	Düsseldorfer Str 113, 47809 Krefeld, Germany
Tel	+49 2151 652086 0
Fax	+49 2151 652086 9
Contact	Lars Dobbertin
Directors	Heinz Dobbertin
Ownership	Privately owned company
Locations	Germany
Founded	1996

OVERVIEW

Coming from a chemical trading background, CSB is a family operated company that was founded back in 1993 as Büro für Umweltservice in the legal form of a personal company, with the focus on providing services for the preparation of safety data sheets (SDS) for its clients in the chemical traders' and formulators sector. Very soon companies from Japan and the US became the main group of customers, which they are still today.

As business grew the legal form was changed to the form of a German GmbH in 1996 and the name was changed to C.S.B.

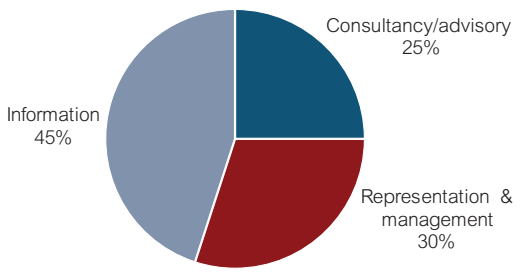
Gradually, we built an interdisciplinary team with experts ranging from EHS specialists over human and ecotoxicologists to technical advisors for CLP/GHS. Our employees worked in many different companies and have experience in the chemical trading and industry sector, but also on the authority side, with several ex-employees of the German competent authority (Baua).

With this strong team, we nowadays offer a large range of services with regards to European Legislations, *inter alia* REACH, BPR and CLP/GHS.

VITAL STATISTICS

	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	20
Staff, chemical service provision	15

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

REACH

We actively support our clients since 2007 in all questions and services with regard to the requirements of the REACH Regulation. Our wide expertise and diverse skills enable us to provide expert services for all requirements and challenges companies are facing.

Our fields of expertise include

- **Only representative services**

Serving as OR for a wide variety of worldwide customers since the introduction of REACH, we are able to use our knowledge and experience as OR to support companies in efficient supply chain management. With our interdisciplinary team we fully comply with the legal requirements for ORs.

- **Administrative services**

We actively manage Siefs and consortia for our clients. We are representing our clients in several consortia, eg in the Iodine REACH Consortium, where we take part in the Steering and Technical Committee. Furthermore, we manage several Sief, respectively data sharing, agreements according to the new implementing regulation (EU) No 2016/9.

- **Management and organisational services**

Together with our clients we develop strategies for their product portfolios and analyse their products to be able to determine the actual needs. This already helped several clients to better understand their portfolios and enabled them to set up action plans and prepare strategies to achieve compliance for their products.

In a second step, we manage, according to the actual needs of our clients, the complete registration process for all types of registrations. We have so far performed a two-digit number of lead registrations in all relevant tonnage bands and a three-digit number of joint-registrations including intermediates. In most those projects we have managed the complete registration process (from an administrative and scientific point of view) in house, effectively reducing the burden of costs for our clients.

- **Scientific expert services**

We offer a relatively wide variety of scientific services and experience with regard to REACH registrations. In the context of the data gap analysis at the beginning of each project we develop an individual testing strategy – together with our client – including alternative methods, read-across or Qsar, we act as study monitor for tests which are prepared new and evaluate study reports for all relevant endpoints (phys-chem, toxicology or ecotoxicology). Based on these results, we prepare the complete Iuclid 6 dossier and, where needed, perform the chemical safety assessment (CSA) and prepare the chemical safety report (CSR).

- **Follow up services**

After initial submission of registrations, we offer support to update dossiers and manage requests by authorities in the context of dossier and substance evaluations.

Besides support in registration processes we offer several other services, *inter alia*:

- management of authorisation processes including alternative and socio-economic analysis
- downstream-user consulting; and
- preparation of downstream-user CSR.

CLP/GHS

Employing one of the most experienced and largest teams in terms of manpower for a mid-sized consulting company we offer:

- **Safety data sheets (including labels)**

We are able to prepare SDSs for all European and EEA countries, Canada, Australia, most South-American countries, most Asian countries (including Japan) and South Africa. For the European market, we also prepare extended safety data sheets (eSDS).
Since the foundation of the company we have prepared SDSs for 40,000+ individual products and are currently actively managing 8,000+ products within our maintenance service for chemical traders, manufacturers and formulators including advice on compositions to minimise classification.

- **Notifications to the European C&L-Inventory**

We submit and manage C&L-notifications. In the past we already submitted notifications for several thousand substances.

- **Notifications according to Article 45 of CLP**

We prepare and where needed, manage dangerous substance notifications currently in a number of European countries. We are also well prepared to switch to the soon expected revised notification system on a complete European level.

BPR

With the long-time involvement of our staff in the biocides legislation we offer several services to fulfil the requirements of the BPR:

- approval of active substances;
- application for national authorisation and/or mutual recognition of biocidal products;
- application for Union authorisation of biocidal products;
- application according to Article 95;
- application for technical equivalence; and
- chemical similarity service.

Besides the listed services, we also offer all relevant organisational and scientific expert services mentioned in the REACH description also in the field of biocides.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1993	Company founded by Heinz Dobbertin
2001-2006	Active Involvement in the development of REACH.
2007-2008	Hiring three experienced regulatory experts from the German CA (Baua) expanding the capacity for REACH services.
2009-2010	• First representation of a client in a REACH consortium. • First submissions of lead and joint dossiers.
2015	Two of our key REACH staff members successfully finish their toxicology education.
2000-2016	Due to constant growth and careful human resource management, CSB now holds one of the largest and most experienced teams dedicated to SDS creation, REACH and BPR services in the field of mid-sized consulting companies
2016	First application for product authorisation under BPR

ACCREDITATIONS

Member of the German VCH (Chemical Distributors Association)
Active in FECC working groups

PARTNERS

- LAUS GmbH (GLP certified test laboratory), Kirrweiler, Germany
- LLR (specialised lawyers) Cologne, Germany
- GGSB (Dangerous Goods Safety Advisor), Mönchengladbach, Germany
- ChemSolutions, Philadelphia, US

CLIENTS

We serve clients varying from small to large sized chemical manufacturers, formulators and traders worldwide. Our clients are active in most industry sectors, *inter alia* specialty chemicals, detergents, pharmaceuticals, biocides, veterinary products, food additives etc.

CASE STUDY 1: Biocide product application

We successfully applied for listing according to Art 95 and technical equivalence in connection with the application for authorisation of a product in a major EU member state. We prepared a full product dossier including the necessary studies within a very short timeframe.

CASE STUDY 2: Dossier evaluation process

For one of our clients we are currently managing the Corap/substance evaluation process for one of his major substances, which faces the threat of inclusion into Annex XIV of REACH. On behalf of the client we lead the communication with the authorities and together with him we set up a strategic approach to defend the substance and are currently collaborating with key industry players to generate necessary data. This process is currently ongoing.

CASE STUDY 3: Safety data sheet management

Insecurity about the compliance of their SDS is an emerging issue for many companies due to gradually increasing regulatory requirements. Within our SDS maintenance service we actively manage product portfolios of our clients ranging from ten to 2,000+ products. We make sure that all SDS stay up to date to the latest regulatory requirements. Furthermore, we support our clients in managing their suppliers and customers, communicating directly or through our client with those parties. Due to our flexibility we can offer holistic approaches to SDS management or work out tailor made solutions according to the clients' needs.

CEHTRA

Consultancy for Environmental & Human Toxicology and Risk Assessment

CONTACTS

Website	www.cehtra.com
E-mail	cehtra@cehtra.fr
Head office	43 rue Laroque, 33560 Sainte-Eulalie, France
Tel	+33 557775610
Fax	+33 557775620
Contact	Paul Thomas
Directors	Xavier Dennery Philippe Adrian, Belgium Laurence Gasnot Dr Peter Jenkinson, France and UK Dr Nathalie Ledirac Jason Nugent, Canada Dr Paul Thomas
Ownership	Private company
Locations	France: Bordeaux, Lyon, Paris; Belgium: Brussels; UK: Nottingham; India: Trivandrum: Canada: Toronto
Founded	2001

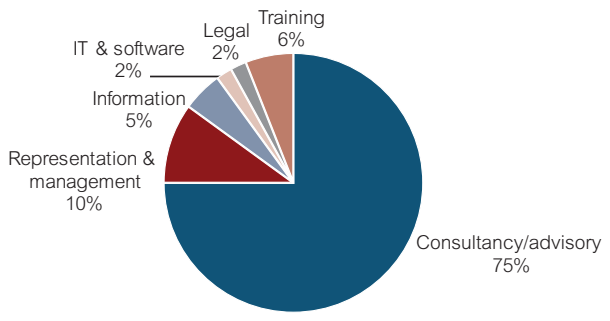
OVERVIEW

CEHTRA offers scientific and innovative solutions ensuring regulatory compliance of chemicals to international obligations: from portfolio strategy to the notification of chemicals, from human exposure to site audits. CEHTRA provides high quality regulatory services, to companies committed to the safety of their products, at optimal cost.

VITAL STATISTICS 2015/16

Turnover, group	€5.5m
Turnover, chemical service provision	-
No of offices	7
No of countries represented	5
Staff, group	70
Staff, chemical service provision	59

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

CEHTRA Bordeaux – 43 rue Laroque, 33560 Sainte-Eulalie, France
CEHTRA Lyon – 23 rue du Creuzat, 38080 L'Isle d'Abeau, France
CEHTRA Paris – 4 avenue Laurent Cély, 92600 Asnières sur Seine, France
CEHTRA Europe – 134 rue Saint Germain, 1410 Waterloo, Belgium
CEHTRA UK – First Floor, Wellington House, 190 Derby Road, Wellington Square, Nottingham, NG7 1NF, UK
CEHTRA India – TC15/1764, Forest Office Line (B51), Vazhuthacaud, Trivandrum, Kerala, Pin-695014, India
CEHTRA North America – 24 Ivy Lea Crescent, Toronto, ON M8Y 2B6, Canada

SERVICES PROVIDED

Regulatory dossier services

CEHTRA provides clients with bespoke services for the production of regulatory dossiers worldwide or together with our partners, be that in the field of general chemicals, cosmetics, biocides, pesticides or pharmaceuticals. We have all the competencies in-house to do all or any part of a project. We have contributed to, or realised over 2,000 projects since CEHTRA was founded and we have produced over 250 REACH dossiers, all of which were successfully submitted on time. We use, verify and validate the algorithms of software such as Ecetoc TRA, FOCUS (for pesticides and biocides) and ART and improve on existing tools (eg by adding a module to allow speedy formatting of final dossiers or work on Consexpo). CEHTRA is able to realise dossiers in PPP Regulation from dta gap assessment to physical submission with CADDY, including study monitoring and risk assessments.

Industrial hygiene and worker exposure studies

With more than 15 years of culture and experience in different industrial sectors, from pesticides to general chemicals, and a complete understanding of the tools used in risk-data interpretation, including generation of exposure limits, CEHTRA is able to bring you answers and support in industrial hygiene adapted to your specific needs.

Consortium and Sief management

We offer a complete service that can either be used as a stand-alone or may be combined with the technical services provided by CEHTRA. We make sure that the milestones and deadlines of your project are met while ensuring the spirit of fairness and transparency, at the same time maintaining strict confidentiality for those areas that matter for your business. We can help you with the preparation of consortium agreements, maintaining contact lists, archiving, billing and all the aspects required for effectively running consortia and Siefs.

Expert services

Our experts have been successful in proposing and supporting complex issues for CMR classifications, modifying acceptable exposure limits and other critical substance-related end-points at member state or EU level. We have also successfully used our knowledge in clinical toxicology and epidemiology to support several of our clients in court cases.

REACH OR Services

CEHTRA provides a REACH only representative (OR) service.

Authorisation services

CEHTRA is one of three companies in a joint venture, ChemAdvocacy, providing a full service in the field of authorisation including socio-economic analysis and the company has already provided SEAs for specific biocidal substances.

Modelling services

In January 2014 CEHTRA opened a subsidiary company, KREATiS SAS, which specialises in *in silico* predictions (High-Accuracy Qsars), which can be used to replace laboratory studies in many regulatory dossiers such as REACH (more info on www.kreatis.eu).

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2001	Company established.
2004	Opening of UK office.
2008	Opening of Brussels office.
2008	Opening of Lyon office.
2009	Start of the Indian Joint venture.
2011	Opening of North America offices.

2012	Opening of ChemAdvocacy.
2014	Opening of KREATiS.
2016	Integration into H2B Group

ACCREDITATIONS

Almost all our consultants have either an MSc and/or PhD or equivalent. Senior members of our team hold recognised accreditations such as Eurotox registered toxicologists and ecotoxicologists (British Toxicology Society or Société Française de Toxicologie), or similar such as Dangerous Goods Safety Advisor (DGSA), Certified Industrial Hygienist (CIH).

PARTNERS

KREATiS, LTS REACH OR, ChemService GmbH, ECOonline, Global Regulatory Communications, Microeconomix

CLIENTS

Chemical companies, flavours and fragrances, petrochemicals, cosmetic companies, plant protection industry, biocides, veterinary products, pharmaceuticals.

TESTIMONIALS

"CEHTRA helped us to submit ten 2010 REACH dossiers as lead registrant. We greatly appreciated their expertise in toxicology and ecotoxicology in particular in cases where the protocols of standard studies needed to be adapted to the test substances. In fact many of our substances turned out to be 'difficult to test' due to their physico-chemical properties. We have decided to use them again and are once more confident of success for our 2013 dossiers." – signed DRT, loyal client for 2010, 2013 and 2018 dossiers.

CASE STUDY 1: *in silico* predictions a priority

In silico methodologies to replace experimental studies are becoming a hot topic, especially with the 2018 REACH deadline approaching. CEHTRA has heavily invested in an *IN silico* toolbox we call i-SAFERAT on the basis of high quality predictions based on best quality experimental data where necessary coupled with a read-across and weight-of-evidence approach. Our aim is to cut the cost of REACH substance submissions for lower tonnage substances without compromising data quality.

CASE STUDY 2: Biocidal dossier

Facing the review programme of active substances, the formulator of a biocidal product asked CEHTRA to consolidate a vulnerable dossier submitted five years before. After designing a strategy based on a strength/weakness analysis, CEHTRA completed the missing data and provided the formulator with the key resources that were absent in the initial dossier: an in-depth risk assessment and a scientific expertise focused on environment and ecotoxicology with a positive RCR. As a result, the client met his objectives and received from CEHTRA a biocidal active substance dossier passing the completeness check and all required use scenarios.

CASE STUDY 3: Authorisation dossier

The biocides products Regulation requires a socio-economic analysis of substances which may be subject to substitution (CMR, PBT endocrine disruptors, etc). ChemAdvocacy has been awarded a study on a national authorisation dossier for a wood protection product (PT8), classified CMR, PBT. We are developing a methodology, the first of its kind for biocide products, inspired by the available guidance (REACH, etc), and we have presented our proposal to the French competent authorities, with expected finalisation of preparation for submission in early summer 2013.

STAFF SELECTION

Peter Jenkinson – PhD, GT – CEO CEHTRA SAS and Manager of UK Office

Peter Jenkinson has a PhD in reproductive toxicology and over 30 years' experience in the CRO industry specialising in genetic toxicology. Latterly he was the director of the Chemical Business Unit at Harlan Laboratories with a primary role of developing the REACH services of the company. In March 2010 he joined CEHTRA to open the UK office and has provided expert toxicology advice, particularly for study monitoring and data interpretation.

Paul Thomas PhD, ERT – Marketing Director CEHTRA, Manager of Lyon Office and CEO KREATiS

Paul Thomas has a PhD in aquatic ecotoxicology and over 20 years' experience with industrial chemicals, agrochemicals and biocides gained at CIT, ATOFINA and AkzoNobel. He joined CEHTRA in 2008 as director of CEHTRA Lyon specialising in REACH-related services and is manager of the CEHTRA ecotoxicology team. Paul has contributed strongly to numerous successful registrations. He is also leading the KREATiS venture and has contributed to the development of several innovative new Qsar models

Philippe Adrian PhD –Manager of Brussels Office

Philippe Adrian has a PhD in soil science and over 20 years' experience with agrochemicals and biocides. Prior to his current position he worked as research scientist in Germany. Later he worked at CNRS in France and then Rhone-Poulenc Agrochimie and FMC. In 2001 he created CEHTRA with Pierre-Gerard Pontal and manages the environmental fate team. He has developed modelling expertise for pesticides according to current models, as well as biocides using relevant TGDs.

Nathalie Ledirac PhD, ERT – R&D Director and Manager of CEHTRA Bordeaux

Nathalie has a PhD in cellular and molecular aspect of biology and 16 years' experience with agrochemicals. She worked as a research scientist at INRA in France on pesticide toxicity and has also participated in private research on drugs for pharmaceutical industries (HMR, Galderma).
She joined CEHTRA in 2006 as a regulatory toxicologist and provides expert toxicology advice in study monitoring and data interpretation. She develops close partnerships with private and academic research by increasing the scientific participation of CEHTRA experts in research projects (research programmes, publications, model development for pesticides, accreditation, etc).

Laurence Gasnot PhD – Manager of Paris Office

Laurence has a PhD in material sciences. She has worked for 20 years in the industry where she has gained profound experience in polymer science as well as in food contact regulations and health products. She joined CEHTRA in 2008 developing the food and food contact market and proposing a pragmatic approach for cosmetic packaging assessment to our customers. For the last few years she has worked on several successful European authorisation dossiers on food contact, drinking water and food additives.

Charles Alarcon PhD, CIH – Industrial Hygienist

Charles has a PhD in geochemistry and over 15 years' experience as an industrial hygienist, and was one of the first in France to obtain the prestigious CIH certification (still one of only ten in France). He joined CEHTRA in 2009 developing exposure scenario in REACH dossiers and e-SDS. Through audits and other site studies, and using currents models in risk assessment, he has gained a large experience in many industrial sector activities and acquired a unique understanding of health and safety industrial culture.

Jason Nugent MSc – Manager of CEHTRA NA

Jason is a highly experienced chemical registration specialist who has worked within the North American chemical industry for more than 18 years. Over the course of his career, Jason has managed and participated in the preparation of more than 400 chemical registrations in Canada, USA, the EU, China, Australia, and Japan. In recent years he has been heavily involved in assisting North American companies to prepare for and comply with REACH.

CGI

CONTACTS

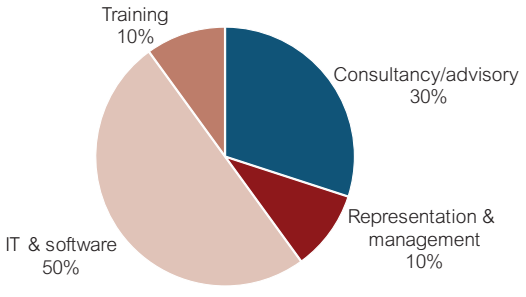
Website	www.cgi.com www.cgi.com/environment
E-mail	ehs@cgi.com
Head office	CGI
	1350 Rene-Levesque Boulevard West, 15th Floor, Montreal, Quebec, H3G 1T4, Canada
Tel	+1 514-841-3200
Fax	+1 514-841-3299
Contact	Larry McEntee Larry.McEntee@cgi.com +1 703-267-7305
Directors	Serge Godin, Founder and Executive Chairman George D. Schindler, President and CEO Dave Henderson, President, US
Ownership	Publicly traded company (NYSE: GIB; TSX: GIB.A)
Locations	The Americas, Africa, Asia, Europe
Founded	1976

OVERVIEW

CGI is one of the largest IT and business process services providers in the world, delivering high-quality business consulting, systems integration and managed services. With a deep commitment to providing innovative services and solutions, CGI has an industry-leading track record of delivering 95% of projects on time and within budget, aligning our teams with clients' business strategies to achieve top-to-bottom line results. CGI has 20+ years of experience partnering with leading commercial and public sector organisations to implement effective EHS information management strategies and solutions that improve our clients' compliance postures and reduce costs. We have extensive experience helping companies tackle the business and technical challenges associated with regulatory changes including REACH and GHS around the globe.

VITAL STATISTICS	2015/16
Turnover, group	$10bn CAD
Turnover, chemical service provision	-
No of offices	400
No of countries represented	40
Staff, group	68,000+
Staff, chemical service provision	100+

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

CGI has over 400 offices in 40 countries around the world
US Headquarters: CGI Technologies and Solutions, Inc, 11325 Random Hills Road, Fairfax, VA 22030 (+1 703-267-8000)

SERVICES PROVIDED

Advisory services

Expertise across the complete spectrum of product stewardship and chemical regulatory compliance

EHS compliance audits
Identify risk areas before they are identified by the local regulatory authority, reducing exposure and improving workplace safety.

Mergers, acquisitions, and divestitures
Get an independent assessment of products portfolios and compliance programs for acquisition targets as part of due diligence to avoid costly surprises. Benefit from portfolio and business integration services once the acquisition is complete.

Regulatory consulting
Tap our team's 200+ years of combined experience in product and regulatory compliance to help position your company for success. Strategically leverage our experts to support your global distribution of goods.

IT portfolio optimisation
Maximise your existing investment in IT solutions through our combined IT and product stewardship domain expertise. Exploit our experience to architect cost-effective and scalable operations necessary to keep pace in today's global regulatory climate.

PROSTEWARD360®

A state-of-the-art hazard communication and chemical management software platform fully aligned with GHS and REACH

SDS/eSDS authoring
Manage regulatory information with rules-based chemical data management and SDS authoring in accordance with regulations in 100+ countries and 40+ languages.

Exposure scenario management
Efficiently store and manage the use, exposure scenario and risk management measure information for REACH and CLP compliance.

Vendor SDS management
Store and maintain a central repository of vendor and company-authored SDSs for employee access aligned with local requirements.

Chemical inventory and workplace safety
Get one-stop access to critical information regarding RTK, site-level authorised material use lists, and chemical inventory used to generate ready-for-submission reports such as SARA 311/312.

Reporting and ERP integration
Flexible integration engine to flow data to third party systems or support business requirements such as volume tracking, chemical safety assessments, EHS data access, and report generation.

Ongoing BPS

Highly trained resources providing fully managed or supplemental IT and business process services for flexible, demand-based support.

Hazard communication
Benefit from certified SDS/eSDS authors and dangerous goods specialists trained in ProSteward360 or other in-house authoring systems.

Vendor SDS management
Get a tailored approach to vendor SDS acquisition, review and data capture using a blended resource model providing high-quality expert services at low per-request prices.

System administration
Choose from CGI administration services for ProSteward360 and third-party IT systems, including routine maintenance, upgrades, configuration changes and help desk services.

Hosting
Scale your infrastructure via world-class CGI data centres or the public cloud, providing full housing and integrated IT management services.
Application implementation and upgrade
Leverage CGI IT and subject matter resources for initial deployment, configuration, integration and upgrade services for ProSteward360 and third-party EHS IT software.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1976	CGI founded.
1996	ProSteward released: supports global hazard communication compliance.
2004	Acquired American Management Systems (AMS): expanded IP product offerings.
2007	Global GHS compliance supported. REACH compliance supported; customers submit >200 REACH registrations. Acquired Stanley: expanded services to US government.
2011	Echa cites a CGI customer's SDS as a best practice example.
2012	Acquired Logica: expanded global presence.
2013	Launch SDS Authoring services.
2014	ProSteward360 released: fully configurable web-based platform.
Ongoing	CGI is frequently recognised as an outstanding service provider across a myriad of industries and outlets – www.cgi.com/en/overview/awards.

ACCREDITATIONS

ISO 9001, Run SAP® methodology

PARTNERS – Corporate

Global SAP Alliance partner

CLIENTS

CGI supports a wide range of companies, from Fortune 100s to SMEs, that manufacture, distribute, and/or import chemicals across a variety of industry sectors including oil and gas, specialty chemicals, consumer goods, pharmaceuticals, medical devices, energy, and government.

CASE STUDY 1: Outsourcing – hazard communication solutions

CGI has been the sole provider to a major international technology company with customers in graphic arts, commercial print, publishing, packaging, electronic displays, specialty chemicals, entertainment, and commercial films, and consumer products markets for over three years, providing global hazard communication support, complex product assessments, safety data sheets / labelling and dangerous goods classifications for 1,000s of materials in over 45 countries and 36 languages. Successfully implemented all phases of global GHS, along with HSE consultation services and chemical tracking solutions.

CASE STUDY 2: Global requirements in support of joint venture activities

A Fortune 50 energy company engaged CGI to identify the chemical control, labelling and poison control centre requirements for 14 Asia Pacific countries in support of a new joint venture (JV) with a major heavy equipment manufacturer. The first stage included a gap analysis reflecting the status of the substances to be a part of the new products, and subsequent reports have clarified the regulatory landscape, paving the way for a successful launch.

STAFF SELECTION

Paul Brigandi – Director, Consulting

Mr Brigandi is a recognised expert in US and international hazard communication regulations. Mr Brigandi spent the first part of his career with Mobil Oil Corporation, where he represented industry during the development of the Globally Harmonized System for the classification and labelling of chemicals (GHS) and chaired the ACC's Global Harmonization Task Force. He was also a member of the OECD Expert Group on the Classification of Mixtures, which developed the GHS mixtures classification criteria. Since joining CGI, Mr Brigandi has been the senior regulatory compliance subject matter expert for CGI Technologies and Solutions Inc where he has led the requirements, design, and implementation phases of multiple projects that delivered commercial software supporting global GHS and REACH regulatory compliance programmes. Mr Brigandi also provided subject matter expertise to EPA in support of the design and development of the new electronic reporting web tools supporting TSCA reporting (eTSCA).

Bruce Crowder – Director, Consulting Services

With more than twenty-one years of experience as an EHS IT professional, Mr Crowder has focused on the design, development, and delivery of EHS information management solutions to private and public sector entities. Mr Crowder has managed project execution for numerous EHS consulting, and system development, modernisation, and integration efforts to provide quality delivery within schedule and budget. Mr Crowder currently manages delivery of projects primarily associated with the ProSteward360 product suite and related managed services.

Jennifer Mahoney – Senior Consultant, Regulatory Advisory Services Lead

Ms Mahoney pulls from 12+ years of experience to provide global regulatory compliance assistance for clients across all chemical industries. She deploys her knowledge to assist clients in achieving and maintaining compliance across global regulatory frameworks. She provides clients thoughtful guidance enabling companies to make well-informed strategic decisions about their compliance activities.

Kamal Singh, PhD – Senior Consultant

Ms Singh has more than 20 years varied experience in chemical regulations, regulatory toxicology, hazard communication, and experienced in selection and implementation of authoring software solutions. She has a PhD in chemistry and postdoctoral research and regulatory training in toxicology and a MS in management. She provides expert advice on global compliance of chemicals and hazard communication such as CLP, GHS and process optimisation to deliver compliance in the most cost effective manner.

Paul Manno – Senior Regulatory Consultant

Mr Manno has more than 30 years' experience in manufacturing operations, hazard/risk assessment communications, safety data sheet/label outsourcing, dangerous goods transportation, logistics and regulatory compliance, sustainable product development and marketing. He has extensive experience in leading diverse, inclusive teams worldwide with complex regulatory compliance issues in manufacturing and marketing. Mr Manno brings a solid track record in process improvement for all corporate EHS functions (manufacturing support, product development and strategic planning).

Stephen Zakowicz – Director, Consulting Services

Mr Zakowicz has more than 15 years' experience helping global organisations leverage information technology to meet chemical regulatory compliance obligations. Currently CGI's Regulatory Solutions Group Practice Lead, Mr Zakowicz is responsible for aligning CGI's global capabilities in chemical data management and reporting with current and emerging regulatory and business requirements.

charles river

CONTACTS

Website	www.criver.com
E-mail	askcharlesriver@crl.com
Head office	251 Ballardvale Street, Wilmington, MA, US 01887
Tel	+44 1875 614545 (UK) /1-877-CRIVER-1 (US)
Fax	+44 1875 614555
Contact	Karen McCusker
Directors	James Foster
Ownership	Public limited company
Locations	Global locations and offices
Founded	1947

OVERVIEW

Charles River is the market-leading provider of contract testing services to the pharmaceutical, chemical and agrochemical industry and has been providing high-quality research models and laboratory animal support expertise since 1947.

Our unique safety assessment portfolio spans the entire research and development process, allowing for flexible, customised approaches to support both single-study and broad-based programmes.

With facilities in Europe, North America and Asia, we are well-positioned to help optimise the discovery and development of our clients' drugs, chemicals, agrochemicals, medical devices and therapies. Our customer base includes major pharmaceutical and biotechnology companies, as well as leading companies in the chemical and agrochemical sectors, academic institutions and government research centres.

Always leading with science, our exceptional team of toxicologists, pathologists, veterinary surgeons, regulatory specialists and support personnel designs and conducts safety studies ranging from acute to chronic toxicity and carcinogenicity studies.

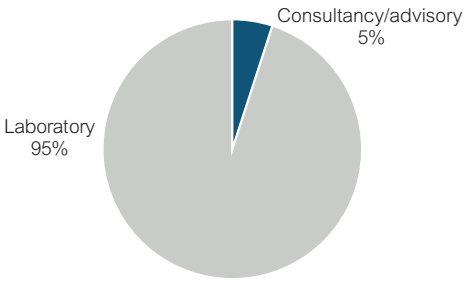
Charles River is also at the forefront of the industry in the fields of developmental and reproductive toxicology, inhalation toxicology and other specialty toxicological assessments. We offer an expanding portfolio of *in vitro* methods to replace traditional *in vivo* studies where possible.

All of our studies are conducted to GLP and are supported by the highest quality analytical services, including bioanalysis, central laboratories, immunology, drug metabolism and pharmacokinetics and formulation development.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No. of offices	-
No. of countries represented	17
Staff, group	10,000
Staff, chemical service provision	-

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

251 Ballardvale Street
Wilmington, MA 01887
United States

SERVICES PROVIDED

Services to meet global registration requirements

Charles River has supported the chemical industry for over 40 years. Drawing on this extensive experience, we offer a full range of studies to meet the requirements of REACH and other global notification and registration requirements.

Regulatory support

Charles River can advise and assist in many ways, including designing a registration strategy for REACH that suits the needs of a substance and/or portfolio. We partner with clients across the whole process, from helping to assess data requirements and evaluating data, to helping with dossier preparation. For non-EU manufacturers we can also perform the role of only representative.

We can also advise on the cost-effectiveness of taking a more global approach to design a suitable testing strategy by including endpoints and studies to fulfil a wider range of regulatory study requirements.

We provide human and environmental hazard, exposure, and risk assessments to meet the requirements of all major global regulatory authorities, including determining testing strategies for the use(s) of substance(s).

Physico-chemical testing

Our service includes all the characterisation and physico-chemical studies necessary to support worldwide registrations for both active ingredients and formulated products.

We offer a full range of testing services that meet REACH requirements, either as packaged or stand-alone studies conducted to the appropriate guidelines.

Acute toxicology

A full spectrum of regulatory-compliant studies is offered to evaluate oral, dermal and inhalation toxicity, dermal and ocular irritation, and skin sensitisation. *In vitro* models are available to assess dermal irritation or corrosivity and ocular irritation. An *in chemico* assay is available to assign skin corrosion classifications, while *in silico* models are also offered to identify corrosive or irritation potential.

Repeat, reproductive and chronic toxicology

We routinely perform repeat dose studies from short term to chronic, including carcinogenicity possible via oral/dermal/inhalation exposure. Reproductive toxicology screening to OECD 421 and 422 is available, as well as developmental toxicology in rats and rabbits. Our portfolio of multigenerational studies also includes the Extended One-Generation Reproductive Toxicity Study, required to satisfy OECD Guideline 443.

Genetic toxicology

Studies typically follow a tiered approach beginning with an *in vitro* Ames test and progressing to short-term *in vitro* assays, including mouse lymphoma and chromosomal aberrations assays, and *in vivo* assays such as rodent micronucleus test and/or comet assay. In addition to standard study designs, we are also able to offer customised protocols for the rapid screening of candidate molecules for toxicity profiles.

Ecotoxicology

Charles River offers a comprehensive range of aquatic and terrestrial ecotoxicology testing services to assess the environmental risk of chemical, biocide and agrochemical products.
We design studies to meet specific data requirements that take into account the properties of the test item and its potential routes of environmental exposure. Our scientists are skilled in the handling of difficult test items (eg, volatile, unstable, complex and poorly soluble mixtures), and our facilities are specifically equipped to support complex test situations. Most ecotoxicology tests can be conducted with a radiolabelled test item if necessary.

Environmental fate studies

Charles River has over 25 years' experience conducting environmental fate studies to meet European, US and Japanese regulatory requirements.
We perform the in-life phases of environmental fate studies in environmentally controlled incubation rooms or incubators. Self-contained flow-through incubation systems (aerobic and anaerobic), with the flexibility to accommodate different trapping systems for collection of volatile products, are available for radiolabeled degradation studies; a similar flow-through apparatus is used in photolysis studies. Sealed systems are available for investigations with volatile test items, as well as systems for collection and quantification of reduced radiolabeled volatile products.
We can obtain test systems such as sediment, surface waters and soils from a variety of local and international geographical sources. Prior to study conduct, we fully characterize all test systems and confirm their viability.

Endocrine disruptor screening programme

Charles River offers custom endocrine disruptor screening programme (EDSP) consultancy and testing services, combining excellent project communication and support from our dedicated team of experts. With rapid turnaround times, we are also able to shorten timelines with our testing program.
Our experts can help at every stage, from initial data gathering through evaluation and interpretation for hazard/risk assessment. All studies are validated and performed according to GLP principles.

Analytical support

A validated analytical method is required to support many product chemistry and (eco) toxicology tests. Experienced analysts are available to establish new analytical methods or to transfer existing methodology using a wide range of up-to-date equipment.
All required physico-chemical properties for substances can be tested. The storage stability and shelf life of the formulated product can be determined under a variety of specified storage conditions. Solid, liquid, semi-solid and aerosol formulations can all be evaluated using real-time and accelerated storage stability testing. We have dedicated facilities to stress the material using monitored heat, humidity or light parameters.

ACCREDITATIONS

AAALAC, GLP, GCPv, GEP

CLIENTS

A broad range of companies producing pharmaceutical, agrochemical, chemical, biocide and animal health products. Our client base includes consortia, start-ups, virtual companies and SMEs as well as global corporations.

TESTIMONIALS

Testimonials can be provided on request.

CASE STUDY

Our clients and their programmes are protected by our strict confidentiality agreements; therefore, we are unable to discuss specific case studies.
All our study directors have extensive experience ranging from five to over 25 years, giving them the depth of expertise required to deliver to the highest standard on studies and provide a flexible, solutions-driven approach to the design of both individual studies and entire registration programmes.
With emphasis on quality and technical excellence, enforced through continuous training, internal audit programmes and proactive communication, our scientific staff will work together with your own teams to produce work of the highest standard to meet your registration requirements.

STAFF SELECTION

Director, Laboratory Sciences

- Joined Charles River in 1988
- Has responsibility for all aspects of the services provided by Charles River to chemical, agrochemical and veterinary product companies

Operational Area Manager, Chemistry

- Joined Charles River in 1988
- Experienced in xenobiotic metabolite identification, residue analysis and analytical chemistry
- Responsible for managing a team of study directors handling physicochemical, analytical and stability studies

Head, Environmental Fate and Metabolism

- Joined Charles River in 1994
- Oversees the design and conduct of studies intended to characterise the fate of chemicals in the environment and to study the nature of metabolites and metabolic pathways using a range of chromatographic and spectrophotomic techniques

Head, Regulatory Affairs

- Joined Charles River in 2010
- 20 years' experience in agrochemical, biocides and chemical regulatory affairs
- Leads a team of more than 20 regulatory affairs experts, which provides support for the registration of chemicals, biocides, agrochemicals and pharmaceutical products.

CONTACTS

Website	www.chementors.eu
E-mail	info@chementors.eu
Head office	Raisionkaari 55, FI-21200 Raisio, Finland
Tel	+358 40 7473393
Contact	Dr Jan Nylund
Directors	Jani Määttä, CEO Jan Nylund, COO
Ownership	Private
Locations	Helsinki, Tampere, Raisio, Kokkola, Hong Kong
Founded	2009

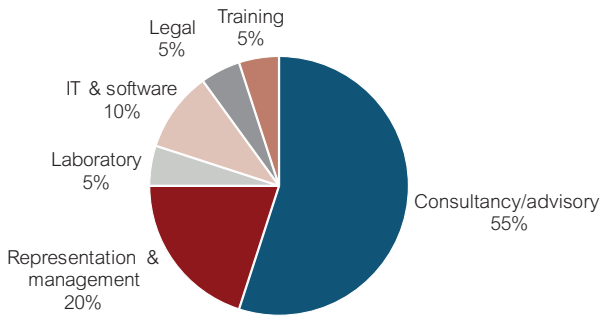
OVERVIEW

Chementors provides chemical safety services to companies affected by REACH, CLP, the biocidal products regulation and the cosmetic products regulation. We offer top notch research and expert services to support our customers' registration tasks. We help you with the whole process starting from data acquisition, testing strategies and data evaluation to preparation of the final registration documentation using ECHAs tools luclid, Chesar, R4BP and REACH-IT.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	5
No of countries represented	2
Staff, group	7
Staff, chemical service provision	7

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Finland, Hong Kong

SERVICES PROVIDED

REACH

We help you plan and carry out necessary tests for substance identification and inquiry, we assist you with assessments and statements to be submitted as well as with dossier preparation and further discussions with the authorities. We help replace discontinued substances and we provide GLP certified laboratory services. Understanding, correct interpretation and evaluation of data and research reports acquired from sources of variable quality is of outermost importance for the quality of the safety assessments.
REACH 2018 is achievable, with our help and support.

Only representative services

Non-EU manufacturers and importers have to use a European company as their representative, that is an only representative (OR), to carry out their REACH registration procedures. Choosing a reliable and competent OR is an important decision to make as the only representative enables access to the EU market for the client's products. The OR is liable under EU law that the requirements and obligations set by the regulation are met. We have the experience, knowledge and expertise to take on the responsibilities as your OR.
Chementors is a member of the Only Representative Organization (ORO), an accredited Echa stakeholder body.

China REACH and exporters to China

With our Hong Kong office as a base we make your life easier if you plan to start operations on the Chinese chemical market. We facilitate your export efforts to China and offer our network for a smoother and faster entry and market introduction. We offer through our partners an integrated package of service for New Chemical Registration to China REACH (IECSC).

CLP – SDS preparation and translation

Our extensive experience in handling and classification of chemical substances and mixtures enables us to help you with challenges connected to the CLP/GHS system. We prepare, review and translate safety data sheets (SDS), extended SDS (eSDS) and labels, covering all EU languages and many more. All designed with your brand in mind. We help with the interpretation and adaption of the exposure scenarios to be attached to the SDSs in an eSDS.
We advise you on different options on labelling and classification. We may even advise you how to modify your product if we see some feasible options!

Substance substitution – R&D-services, formulation

Increasingly stringent regulatory enforcement and changes in the classifications of substances strongly challenges R&D departments to arrive at suitably functional, environmentally sustainable solutions while maintaining and improving product performance.
With thorough experience in sciences relating to detergency and other colloid/surface phenomena, we can tackle formulation problems and challenges experienced in today's techno-chemical and cosmetics industry.

Cosmetic safety assessment and responsible person

The Cosmetic Product Safety Report (CPSR) is divided into two parts. Part A provides information on safety and important properties of the product, in addition to an evaluation of the toxicological profile of its components. Part B comprises an overall safety assessment of the product, taking into account known hazards and exposures leading to an evaluation of risks and margin of safety (MoS) in order to determine acceptable ways of use.
Usually the manufacturer or importer assumes the identity of the responsible person. The distributor within the EEA could also be required to take on the role of the responsible person, if they place a cosmetic product on the market under their own name or trademark or if they modify a product already on the market. Alternatively, the manufacturer or importer may authorise a representative to act on their behalf as a responsible person. The obligations of the responsible person are to ensure that the product is safe for its intended use and that it is used in a safe way, and to ensure that all requirements under the regulation are fulfilled. Chementors may act as your responsible person and ensure your legal presence on the EU market.

Human health and environment assessment

Determination of safe exposure levels and suggestions for risk management measures to control exposure based risks are needed when preparing chemical safety assessments, reports and waivers. Our experts help you with the calculations and evaluations as well as with supporting measurements to determine critical conditions in your processes and uses.

Biocides and consortia

The biocides regulation (BPR) require that safety assessments are performed also on formulated products, contrary to REACH which only applies to substances.
Cooperation with other producers of biocidal products is possible under certain circumstances. We assist you in negotiations with other stakeholders, co-registrants and consortia to achieve the most cost-effective solution for the authorisation challenges you may face. Simplified authorisation, product families and mutual recognition in other member states are noteworthy options.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2010	Approved service provider in REACHReady Matchmaker programme, United Kingdom
2012	Merge with FinnREACH Ltd
2013	Office in Tampere, Finland
2013	Office in Kokkola, Finland
2013	Partner in Shanghai, China
2015	Joining Smart Chemistry Park in Raiso, Finland
2015	Office in Hong Kong, China

ACCREDITATIONS

REACHReady Matchmaker programme in UK and the only representative organization ORO.

PARTNERS

Trade organisations, consultants and companies in China, Japan, US. and several EU countries.

CLIENTS

Metso Minerals Ltd, Oriola Ltd, Radico India, Hock Chemie China, Mayer Industries Estonia, KiiltoClean.

TESTIMONIALS

“As we came up with the thought to open EU markets with our cosmetic products we realised that requirements by the European regulations would be strict and complicated. Without special consultancy the mission would have been impossible. We contacted Chementors and ever since our cooperation has been efficient and profitable. Chementors is covering all regulatory issues for us including the only representative (REACH) and responsible person (cosmetics) responsibilities. Being dynamic and a customer caring company we have been really lucky to find Chementors as our partner.” – Sanjeev Bhatt, Director – Radico, India

CASE STUDY 1: Biocides

We took care of all practical issues for the registration of a biocide active substance. The work included data gap analysis – testing strategy – test planning and organising – literature review – safety and risk assessments – authority negotiations – dossier preparation. One challenge was to develop a cost efficient testing strategy and plan as the initially available data turned out to be unreliable and incorrect.

CASE STUDY 2: Toll manufacturing and Echa

Echa’s fees are based on the size of the toll manufacturer. This results in an unfair situation for small innovative companies that choose to outsource the production to toll manufacturers, especially if the toll manufacturer is a big company. Chementors sorted out the options the small company has and what the authorities stand points are.

STAFF SELECTION

Ms Maria O'Shea – MSc Environmental Science and Technology

REACH, CLP, BPR regulatory affairs and submission, five year at Echa – junior scientific officer, dossier evaluation and helpdesk, Chesar (Development Team), NONS follow up activities, GLP activities.

Dr Jan Nylund – PhD in Physical Chemistry, Pharmacy

COO, partner. REACH, BPR, cosmetics, CLP, regulatory affairs, 20 year experience of chemical industry and safety assessments, R&D and formulation work.

Mr Jani Määttä – MSc Chemical Engineering

CEO, partner; A 13-year background as CEO and partner in enterprises manufacturing and developing industrial chemicals, now settled in Hong Kong, in charge of Chementors´ global mind setting and evolution.

Mr Kenneth Bergroth – MSc Chemistry and Biochemistry

REACH, CLP, SDS-authoring, Chemical industry (R&D, production, EHSQ), Organization for the Prohibition of Chemical Weapons (OPCW) – inspector six years, ISO 9001, ISO 14001 and OSHAS 18001 auditor (IRCA).

Ms Satu Salomäki – MSc Organic Chemistry

Cosmetics, pharmacy, toxicology and risk assessment; cosmetic safety assessment, Dangerous Goods Safety Advisor (DGSA).

Ms Kati Tuominen – MSc Chemistry, Environmental sciences

CLP, SDS and label expert, DGSA, quality system expert.

Mr Antti Aalto

Sales director, partner; A ten-year background as an entrepreneur, has successfully lived the last 18 months in Hong Kong networking and adopting the Chinese business culture.

CONTACTS

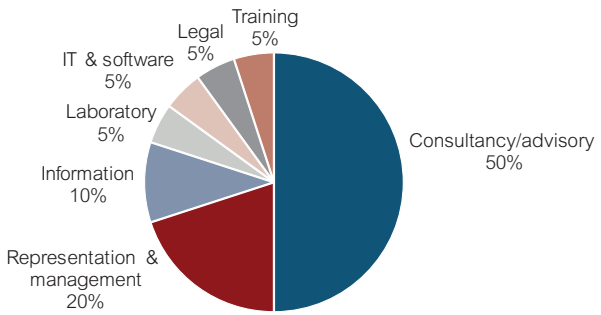
Website	www.chemsafe-consulting.com
E-mail	chemsafe@chemsafe-consulting.com
Legal offices	Chemsafe Srl, Via Ribes, 5, 10010 Colleretto Giacosa (TO), Italy
Operational offices	ChemSafe Sr, Via Lugnacco 4, 10010 Parella (TO); Italy
Tel	+39 0125 538888
Fax	+39 0125 538475
Contact	Dr José V Cantavella Cabedo, Attorney at Law
Directors	Dr Antonio Conto, European Registered Toxicologist (ERT), Managing Director
Ownership	Private company
Locations	Italy, Qatar
Founded	2001

OVERVIEW

ChemSafe's vision is to offer regulatory and technical /scientific solutions and services in the field of chemical safety with a "key point" approach and customer care attitude.

VITAL STATISTICS	2015/16
Turnover, group	€2.0m
Turnover, chemical service provision	€2.0m
No of offices	2
No of countries represented	2
Staff, group	20
Staff, chemical service provision	14

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

ChemSafe Srl, Colleretto Giacosa (TO), Italy
ChemSafe International WLL, Doha, State of Qatar

SERVICES PROVIDED

Worldwide regulatory affairs consulting

ChemSafe assists its clients with a range of regulatory affairs services Worldwide ranging from the legal side to all the technical matters in order to comply with international and national chemical control legislation.
Our technical staff has a great experience in all aspects of REACH and has prepared a great number of registration dossiers and chemical safety reports (CSR) and also had provided expert advice on specific areas of REACH, such as data evaluation and/or study monitoring.
ChemSafe has a vast experience in programme, project, Sief and consortia management.

REACH and CLP/GHS

ChemSafe provides its clients with strategic, legal and technical support in order to comply with REACH and CLP/ GHS. Our technical support includes full dossier preparation (as lead registrant or joint submissions), data gap analysis, review and analysis of physico-chemical, environmental fate. It also includes ecotoxicology and toxicological data, CSA/CSR preparation, human and environmental exposure scenarios (ES) and risk assessment, and application of alternative strategies to testing such as using a read-across approach and Qsar.
Iuclid 6 preparation and submission to Echa and pre and post dossier submission contact with the authorities.

Sief and consortia management

We can help our clients with a full/partial Sief and/or consortia management system, including preparation of all kind of legal agreements, letters of access, data sharing, maintaining contact list, archiving, billing and all the necessary daily aspects for running a successful Sief and/or consortia.

Only representative (OR) and third party representative (TPR)

In 2008 ChemSafe started to act as an only representative (OR) for non-European manufacturers and fulfilling the pre-registration and registration obligations as prescribed in Article 8 of REACH Regulation.
Non-EU companies must either rely on their importers, or retain a person in the EU to represent their interests, these are the only representatives.
Appointing your own OR gives your company business freedom and security as you will have regulatory independence from other members of your supply chain; you will also have a high level of confidentiality by separating the company name from proprietary product constituents; you will maintain supply chain privacy between buyers and sellers; provides expertise and third-party review for submissions to Echa and provides representation to both substance information and exchange forums (Siefs) and consortia.
ChemSafe is acting as OR for different types of companies coming from USA, Switzerland, South America, Middle East and Far East countries.
Furthermore we can act as a third party representative (TPR) for companies not wanting to disclose their identity to others.

Legal advice

We advise our clients on legal aspects of chemical trade around the world and related chemical control regulations, such as US TSCA inter alia.

Biocides and agrochemicals

Our team can prepare and submit dossiers for authorisation of active substances and for registration of formulated products. We can also prepare the technical equivalence data for active substances. We coordinate the regulatory strategy with the national and/or international authorities in order to deliver a successful dossier for biocidal products and agrochemicals.

Pharmaceutical services

1) Safety:
- OEL/OEB/ ASL evaluation + PDE;
- ERA (environmental risk assessment);
- *in silico* evaluation, including Qsar;
- extractables and leachables toxicological evaluation;
- quantification / qualification of impurities.

2) GMP:
- DMF preparation in CTD format (module 3, section 3.2.S) for the European registration, US and Canada.
- OQS (overall quality summary 2.3P and 2.3.S).
- preliminary evaluation of all documentation for the dossier and DMF preparation.

3) GLP activity:
- from candidate profiling to preclinical development.

Cosmetics

- general regulatory support for cosmetic products;
- competent person designation;
- data evaluation, data gap analysis, read-across methodology, *in silico* method application, testing programme design, and study monitoring/ coordination;
- PIF (product information file) or PSR (product safety report);
- administrative activity, including robust study summaries and substance information sheet (SIS) with ingredient evaluation.

Petrochemicals

We advise our clients on legal aspects of control regulations.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2001	Start-up in Italy as 'a one man' company.
2007-2008	REACH and OR services offered.
2009	Biocides and agrochemicals group creation.
2010	Technical consortia advisers for three international consortia. Staff increase to ten people.
2011	Petrochemicals derivatives, wastes, cosmetics and pharmaceuticals consortia management. Staff increased to 12 people.
2012	Qatar office opening.
2015	Operational quarters moved to Parella (TO)-Italy.
2017	ISO 9001:2015 Certification

ACCREDITATIONS

ChemSafe is a full member of ORO, the Only Representatives Organisation.
ChemSafe is a member of the Industrial Union of Turin, Italy.

PARTNERS

- ChemSafe is 100% privately owned.

CLIENTS

Our clients are manufacturers and importers involved in the market sectors of: chemicals, pharmaceuticals, agrochemicals, biocides, cosmetics, food, medical devices, nanomaterials and petrochemicals worldwide. Their size goes from multinational companies to SMEs and national authorities.

TESTIMONIALS

Any companies requesting testimonials or references will be provided with them upon individual written request.

CASE STUDY 1: REACH testing programme

Working together with a global supplier of hydrocarbons ChemSafe created a comprehensive testing/study programme for REACH registration of a wide range of products for that client.

CASE STUDY 2: REACH dossier work

More than 160 REACH dossiers done, including lead registrant and joint submission dossiers are our background; including some for UVCB substances. An important number of CSR, and hundreds of safety and extended safety data sheets (SDS and e-SDS) had also been done by our team.

CASE STUDY 3: Legal case

In 2012 ChemSafe successfully settled a legal case with the European authorities on behalf of one of our European clients.

STAFF SELECTION

Dr Antonio Conto – Managing Director

Biology degree, European Registered Toxicologist (ERT).
Founder of Chemsafe.
>26 years of experience in the toxicological and chemical fields.

Lara De Luca – Technical Coordinator Chemicals

Industrial chemist, with more than 12 years experience.
Risk assessment, exposure scenarios, CSR/CSA.

Dr José V Cantavella Cabedo – Head of Legal Affairs

Attorney at Law, JD in environmental law, with more than 20 years experience.
Environmental, chemical, oil and gas, and international law

Francesca Fasano – Head of Biocides and Agro Business Unit

Industrial chemist, with more than ten years experience.
Biocides, agrochemicals and ecotoxicology.

Elena Meriano – Head of Chemicals Business Unit

Biologist, with more than 11 years experience.
Technical dossier preparation, study monitoring, IUCLID.

Marco Rodda – Head of Pharmaceutical Business Unit

Biologist, safety evaluation of drugs, OEL, PDE, eCTD.

CHEMSERVICE

CONTACTS

Website	www.chemservice-group.com
E-mail	info@chemservice-group.com
Head offices	Chemservice GmbH, Herrnsheimer Hauptstrasse 1b, D-67550 Worms, Germany / Chemservice SA, 5, an de Laengten, L-6776 Grevenmacher, Luxembourg
Tel	+49 (0)6241 95480-0 / +352 270776-1
Fax	+49 (0)6241 95480-25 / +352 270776-75
Contacts	Maren Rectanus (Germany) Karl-Heinz Reis (Germany) Dr Dominik Kirf (Luxembourg)
Directors	Dr Dieter Drohmann, Managing Director Karl-Heinz Reis, Director Global Regulatory Affairs Thomas Schaefer, Director Data and System Services
Ownership	Privately owned group of companies
Locations	Germany, Luxembourg, Korea, France, Switzerland and CEHTRA offices
Founded	2007

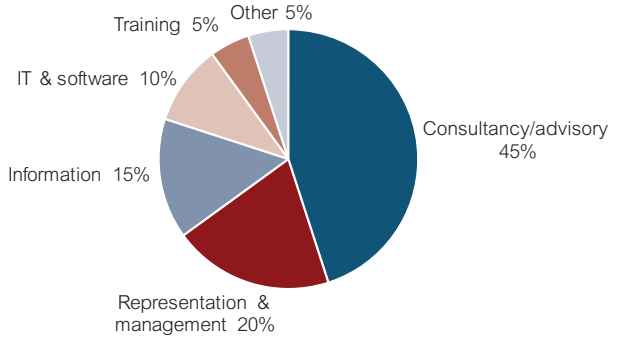
OVERVIEW

Chemservice is one of the world's leading global regulatory affairs consulting companies. We support our clients in gaining competitive advantage through the regulatory process.
The Chemservice Group has in-depth experience in regulatory affairs and international chemical control legislation, toxicology, risk assessments and environmental sciences. Our substantial network in and knowledge of industry, academia, regulatory bodies and governments are beneficial in solving regulatory issues.
Different in-house disciplines (chemists, chemical engineers, toxicologists, environmental scientists, agronomists, biologists, veterinarian, regulatory specialists etc.) enable broad issue addressing.

VITAL STATISTICS 2015/16

Turnover, group (w/o CEHTRA)	~ €3m
Turnover, chemical service provision	~ €3m
No of offices (w/o CEHTRA)	8
No of countries represented	5
Staff, group (incl. CEHTRA)	ca. 100
Staff, chemical service provision (incl. CEHTRA)	ca. 90

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Chemservice GmbH, Worms, Germany
Chemservice SA, Grevenmacher, Luxembourg
Chemservice Asia Co Ltd, Seoul, Korea
Chemservice EHNS GmbH, Worms, Germany
Consortia Management GmbH, Worms, Germany
ChemCehtra SAS, Bordeaux, France
ChemAdvocacy SA, Grevenmacher, Luxembourg
Chemineral GmbH, Luzern, Switzerland
CEHTRA Offices (UK, BE, FRA)

SERVICES PROVIDED

Global regulatory affairs consulting

Chemservice provides a broad range of services designed to assist clients in preparing for and in complying with international and national chemical control legislation. The application range for chemistry is extensive. Therefore, chemical control legislation is comprehensive in order to assure product safety, producer liability and consumer and environmental protection to regulate the marketing of chemical substances. Beside inventory notifications we conduct registrations of biocides, cosmetics, and compile dossiers for food contact clearances and food and feed additive petitions. With our regional partners and offices we support our clients to comply with the EU-REACH-like chemicals regulations in China and Korea.

REACH and GHS/CLP

We provide our clients with strategic and technical support for REACH and GHS/CLP. The technical support includes, for example, data gap analysis, registration cost evaluation, testing strategy proposals, placing/monitoring/reviewing of studies, pre-registrations and registrations, dossier preparation, compilation of chemical safety reports, exposure, hazard and risk assessments, PBT/vPvB evaluation and support on authorisation, REACH-IT and Iuclid assistance, C&L notification, safety data sheet and label creation.
Through our legal entity "ChemAdvocacy" we provide REACH authorisation services (including SEA), advocacy and product stewardship consulting.

Consortia, Sief and letter of access management

Consortia Management GmbH provides independent secretariat, trustee and accounting services to REACH consortia and Siefs in order to enable the chemical industry and its value chain to fulfil their registration obligations according to the REACH regulation. The automated online letter of access (LoA) tool provides an efficient LoA management for Sief members to acquire access rights for a specific substance for the submission of the joint REACH registration dossier. Moreover, the tool will free up resources at lead registrant or consortia level and provides professional accounting support – including trustee account management.

Only representative and third party representative

Chemservice acts for manufacturers outside of the EU as only representative and covers fully the registration and pre-registration obligations. Furthermore, we provide trustee services for indirect non-EU supply chains with final import into the EU. The importers of these non-EU manufacturers no longer have registration obligations and are being regarded as downstream users. Only one registration is needed by the only representative. Moreover, Chemservice acts as only representative for non-EU manufacturers of articles, which intentionally release substances and we act as third party representative according to REACH Article 4.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2007	Start-up in Luxembourg
2008	Opening of Chemservice office in Germany

2009	Launch of Consortia Management GmbH as full service provider for Consortia and SIEF Management
2010	Opening of Chemservice offices in Korea and Turkey
2011	Launch of Chemservice EHNS
2011	Launch of JV ChemCehtra with office in France
2012	Launch of ChemAdvocacy SA with office in Luxembourg
2014	Opening of office in Switzerland and moving into new German office
2015	Opening of 2nd Office in South Korea (Ulsan)
2016	Chemservice acquired a two-digit share of CEHTRA

ACCREDITATIONS

We are a member of ORO, the Only Representative Organisation in Brussels and comply with the quality standards of ORO.
Dr Dieter Drohmann is chairing ORO as president.

PARTNERS

Our partner companies are listed on our website.

CLIENTS

Consultant for the chemical industry and its value chain, including OEMs. Our clients range from multinational chemical companies to SMEs, formulators, traders, retailers and OEMs. We do not disclose our customers publicly, but provide reference names and testimonials upon request.

TESTIMONIALS

Persons who request testimonials or references will be provided with them upon individual request.

CASE STUDY 1: Global inventory strategy and registration

We have significant experience in global inventory registrations and conducted around 150 notifications to the Turkish inventory, 350 nominations to the inventory in Taiwan and 50 notifications to the Thai inventory. For multiple clients we have supplied global inventory strategies for new substances and conducted notifications to chemical inventories like Australia (AICS), Canada (DSL), China (IECSC), South Korea (ECL), New Zealand (NZIOC), Philippines (PICCS) and USA (TSCA).

CASE STUDY 2: REACH-Code-Model

REACH does not distinguish between direct and indirect imports into the EU. Therefore, non-EU business followed by export to EU is more complicated – in particular if several non-EU steps along the supply chain are involved and substances have been formulated into preparations with confidential composition. In a multi-level non-EU supply chain the manufacturer of a substance usually does not know through which channels, in which products and finally how much volume of his substances is being imported into the EU. It is an essential business secret (CBI) of traders or formulators what the components of their products and who their suppliers and customers are. Neither the non-EU manufacturer (represented by the OR), nor the importer can fulfil their obligations without disclosing CBI and potentially leading to loss of business.
Chemservice has developed a software based solution to track indirect EU exports. Many companies with multi-step non-EU supply chains have signed up to this system already.

CASE STUDY 3: REACH dossier work

Chemservice has experience in the creation of more than 500 Tier 1, 2 and 3 REACH dossiers, including member and lead dossiers. Moreover, a significant number of new substance registrations (non-phase-ins), inquiry dossiers, PPORDS, chemical safety reports and extended safety data sheets were successfully completed. Furthermore, we have acted on behalf of our clients with more than 2000 C&L notifications.

CASE STUDY 4: South Korean REACH

Chemservice Asia has conducted many new substance notifications to the Korean Inventory under the TCCA legislation. Experience under K-REACH: around 300 substances contracted as OR, ca. 50 small volume substance registrations, 20 substance registrations and ca. 60 exemption confirmations, experience as K-REACH consortium manager.

STAFF SELECTION

Dr Dieter Drohmann – Managing Director

- PhD in environmental sciences
- Founder of the Chemservice Group
- >20 years of experience in the chemical industry as regulatory affairs manager
- President of the Only Representative Organisation (ORO)

Karl-Heinz Reis – Director Global Regulatory Affairs

- Master in biology
- >20 years of experience in the field of risk assessments, PBT assessments and CRO study director

Dr Dominik Kirf – Senior Manager Toxicology and Risk Assessment

- PhD in toxicology
- EUROTOX certified expert for toxicology
- >10 years of experience in toxicology, regulatory affairs consulting, including risk assessments and dossier preparation

Thomas Schaefer – Director Data and System Services

- Data management, indirect non-EU supply chains, SDS and labels
- >20 years of experience in IT and data systems

Ah-Reum Seo – Technical Director Chemservice Asia (Korean)

- Chemist
- >10 years of experience in R&D and regulatory affairs
- Stakeholder in the K-REACH Advisory Group

Adding up the professional records, the Chemservice Group staff has >300 years of regulatory affairs experience.

CHEMTREC
The right information at the right time

CONTACTS

Website	www.chemtrec.com
E-mail	chemtrec@chemtrec.com
Head office	2900 Fairview Park Drive, Falls Church, VA 22042-4513, US
Tel	+1 703-741-5500
Contact	Brian Banks
Directors	John Modine, Chief Executive Joe Milazzo, Director of Operations Centre Brian Banks, Marketing Manager Kevin Bryan, Sales Manager
Ownership	American Chemistry Council
Locations	USA
Founded	1971

OVERVIEW

CHEMTREC was established in 1971 by the American Chemistry Council (ACC) to serve the chemical industry as a public service hotline for emergency responders, such as fire fighters and law enforcement, to obtain information and assistance for emergency incidents involving chemicals, hazardous materials and dangerous goods.

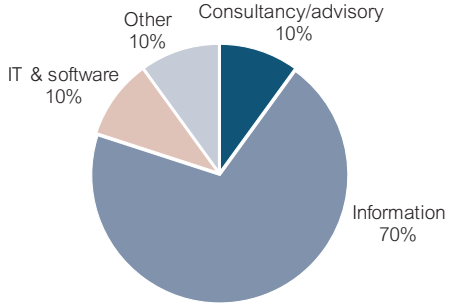
In addition to the public service component, registration with CHEMTREC authorises shippers of hazardous materials and dangerous goods the right to portray the CHEMTREC phone number(s) on their shipping documents, safety data sheets (SDS) and hazard communications labels. The portrayal of the CHEMTREC phone numbers(s) helps registrants to comply with government regulations, which require shippers of hazardous materials to provide a 24-hour emergency telephone number on shipping documents and/or SDS for use in the event of an emergency involving hazardous materials or dangerous goods. CHEMTREC registrants receive detailed notification following each incident that CHEMTREC handles.

CHEMTREC is linked to the largest network of chemical and hazardous material experts in the world, including chemical and response specialists, public emergency services, and private contractors.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	-
Staff, group	-
Staff, chemical service provision	-

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Falls Church, VA, USA

SERVICES PROVIDED

Emergency response

CHEMTREC's trained and experienced staff, provides Level 1 emergency information to help mitigate HAZMAT/Dangerous Goods incidents 24-hours per day/seven days per week. CHEMTREC relays vital data to manufacturers and shippers that an incident has occurred. CHEMTREC also acts as a hub to connect first responders with manufacturers, shippers and carriers. Clients are immediately notified that CHEMTREC has received an emergency call regarding their product or shipment.

SDS services

CHEMTREC has a library of over six million safety data sheets (SDS). Clients provide CHEMTREC with product-specific SDSs that are stored electronically and accessed in the event of an emergency involving that specific product. CHEMTREC tracks the dates of the submissions so that we help clients maintain an updated SDS library. CHEMTREC provides both SDS Access for internal distribution of SDS and SDS Distribution for external distribution of SDS. CHEMTREC can also provide SDS indexing of large volumes of SDS documents to add to your SDS library.

Medical exposure advice

CHEMTREC's medical exposure advice service is provided by trained medical professionals through our partnership with Rocky Mountain Poison and Drug Center (RMPDC). CHEMTREC's medical exposure advice service provides 24-hour coverage for both human and animal exposures. RMPDC is one of the best certified poison control centres in the world. RMPDC's poison centre is certified by the American Association of Poison Control Centers (AAPCC).

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2001	CHEMTREC provided critical information to the New York City Police Hazardous Materials Team as they evaluated the potential effect of chemicals contained in the collapse of the World Trade Towers.
2003	Worldwide Service – CHEMTREC began to offer emergency information services for worldwide.
2006	CHEMTREC hosted the first International Emergency Response Summit.
2010	CHEMTREC signed a memorandum of understanding (MOU) with emergency information organisations within South America.
2011	CHEMTREC celebrates 40 years of service.
2012	CHEMTREC signed an MOU for mutual assistance with the National Registration Center for Chemicals (NRCC) of China.
2015	CHEMTREC's SDS digital library reaches the six million SDS milestone.
2016	CHEMTREC expanded access to professional medical exposure advice services

PARTNERS

CHEMTREC has a memorandum of understanding (MOU) for mutual assistance with several emergency response organisations around the world. CHEMTREC has MOUs in place with organisations located in:

- Canada;
- Mexico;
- South America;
- China; and
- New Zealand.

CLIENTS

Due to our client confidentiality policy, CHEMTREC does not publish the names of our clients. CHEMTREC's client list does include some of the largest chemical manufacturers and distributors in the world. CHEMTREC provides Level 1 emergency information, notification and support for emergency responders, manufacturers, shippers, carriers, and the overall chemical and HAZMAT/dangerous goods industry.

CASE STUDY 1: Fire on a ship at sea, July 2012

Incident:
A container ship caught fire after an explosion below deck and the crew was forced to abandon ship. Salvage ships extinguished the fire and towed the vessel toward port. All SDSs were inaccessible and the fire brigade would not board this ship until they could review all dangerous goods SDSs. The fire brigade reached out to CHEMTREC to assist in identifying the product names of all the dangerous goods products on the ship from limited generic shipper name information that was available.
CHEMTREC's role:
From our database of over six million SDSs, CHEMTREC worked to match proper shipper names with product-specific SDS in our library. We also used our extensive database of emergency contacts to contact shippers/manufacturers and request a copy of the SDS. CHEMTREC was able to provide a complete set of SDSs to the fire brigade so that they could properly assist with this emergency.

CASE STUDY 2: Dangerous goods spill at a production plant, October 2012

Incident:
A plant worker in Japan called CHEMTREC through our interpreter to report a dangerous goods spill on their assembly line. The assembly line has been shut down temporarily until the spill can be cleaned up. The worker needed product-specific information to properly clean the spill so that the assembly plant could be brought online.
CHEMTREC's role:
CHEMTREC was able to locate the SDS and relay the emergency information to the caller through an interpreter. The caller realised that he needed additional information that was not located on the SDS. CHEMTREC contacted the manufacturer and was able to conference in the caller and interpreter to speak directly with the manufacturer to get additional information needed to help clean up the spill and restart the assembly line.

CASE STUDY 3: Chemical reaction on a military base, November 2013

Incident:
CHEMTREC received a call from a military base within the Middle East region. The caller stated that a CONEX ISO shipping container filled with special-use batteries had been submerged in water for five hours and he was unsure if the seal had been broken. The caller wanted to know what precautions should be taken by the military to open the container and evaluate the condition of the special-use batteries. The caller had the SDS on hand and requested to speak with the manufacturer of the battery for additional information.
CHEMTREC's Role:
CHEMTREC contacted the manufacturer's emergency contacts and informed them of the situation. CHEMTREC was able to conference in the caller and the manufacturer together to discuss the incident. The manufacturer was able to determine that the battery casings had likely been breached. The caller was instructed to wear a self-contained breathing apparatus (SCBA) due to the gas release that had likely occurred within the ISO container. The caller said he would call back if additional assistance was needed.

CASE STUDY 4: Propane tank explosion on the highway, March 2015

Incident:
CHEMTREC received a call from a fire brigade chief reporting a crash involving two transport trucks on the highway. After the trucks collided, one truck hauling a propane tank trailer overturned and ripped a 40cm by 10cm hole in the tank of the truck. The hole in the propane tank created a bleve explosion and burned an area approximately 0.40km in diameter. The fire brigade chief wanted advice on how to mitigate the remaining propane on scene.
CHEMTREC's Role:
CHEMTREC conferenced in the manufacturer of the material with the fire brigade chief to agree on the best method to handle the remaining material. CHEMTREC was also able to immediately notify the emergency contacts on the manufacturer's emergency distribution list.

STAFF SELECTION

John Modine – Chief Executive

John Modine comes to CHEMTREC® after more than 20 years at the American Petroleum Institute (API), where he had extensive executive-level operations management, international business development, strategic planning, and programme development experience. As vice president of Global Industry Services, John was responsible for all certification, safety, training, events and publications programmes.

Joe Milazzo – Director, Operations Centre

Joe has over 25 years of experience in the CHEMTREC Operations Centre. Joe is responsible for all of CHEMTREC emergency operations, staff training and shift staffing. Prior to joining CHEMTREC, Joe served in the US Coast Guard.

Brian Banks – Marketing Manager

Brian has responsibility for marketing and promoting CHEMTREC's existing suite of product offerings and services, managing industry relations, as well as conducting market analysis and market research to develop new products offerings and services to better serve CHEMTREC customers.

CONTACTS

Website	www.chemhse.com www.cncic.cn
E-mail	regulation@hse.cncic.cn
Head office	No. 53 Xiaoguan Str Anding menwai, Beijing, China
Tel	+86 10 64421139
Fax	+86 10 64428331
Contact	Lisa Zhong
Directors	Jiandong Chen Yubin Jie Victor Lu
Ownership	China state owned company
Locations	Beijing, China
Founded	1959

OVERVIEW

China National Chemical Information Center(CNCIC), based in Beijing and formerly named the Scientific and Technological Information Research Institute of the Ministry of Chemical Industry, has a history of almost 50 years with chemical and technical professors we have overall approximately 370 people, providing a range of services such as chemical industry consulting, professional exhibitions, standard drafting, chemical regulations consulting etc. These have all have been provided to MEP, SAWS, ChemChina and some research institutes among others.
Our product registration and compliance department is dedicated to acting as a professional technical group on compliance with the regulations in China and abroad.
Our extensive database resources on HSE (health, safety and environment), have been of great technical assistance to hundreds of chemical manufacturers and suppliers in:

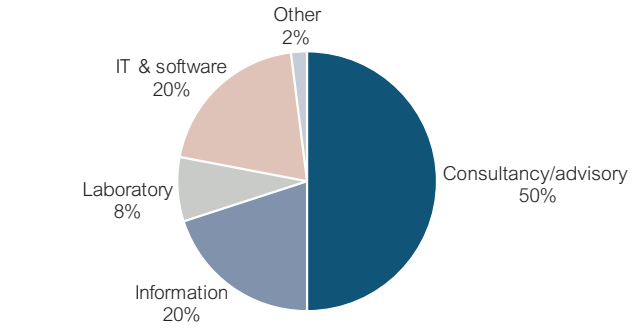
- new chemical substance notification;
- globally harmonized system of classification and labelling (GHS);
- hazardous chemical substance registration;
- pesticide registration;
- cosmetic new substance registration;
- food related products registration; and
- test arrangements etc.

We provide the perfect whole solutions to improve clients' business value, providing them with plenty of achievements, We now enjoy a high reputation both in China and the global chemical industry.

VITAL STATISTICS

	2016/17
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	370
Staff, chemical service provision	23

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Beijing office (Headquarters): NO. 53, Anwai Xiaoguan Street, Beijing 100029, China Tel: +86 10 64421139. E-mail: regulation@hse.cncic.cn

SERVICES PROVIDED

China new chemical substance notification service

"Measures for Environmental Management of New Chemical Substance" became effective on 15 October 2010. According to the measures, new chemical substances must be notified before being produced in or being imported to China. Only after the Notification Certificates of Environmental Management of New Chemical Substances are approved, can they legally produced or imported.
CNCIC is the most professional consulting firm handling China New Chemical Substance Notifications. More than a third of the notification dossiers approved by the authority are developed by CNCIC.
CNCIC provide services including:

- regulation consulting and LA-OR service;
- check main Inventories of Existing Chemical Substances;
- authoritative regulatory compliance check and notification type evaluation;
- physico-chemical properties, toxicity and eco-toxicological effect data evaluation;
- strategies of tests and optimisation of test arrangement;
- professional test summary editing/translation;
- expert assessment and waiver statement to exempt some tests;
- organisation and submission of the notification dossier;
- following-up and informing of the notification process;
- communicating with the authorities;
- maintenance after notification;
- testing Items for New Chemical Substance Notification.

According to series of testing guidelines and standards of OECD, GB etc, several tests required for notification of new chemical substances can be conducted with GLP compliance as below:

- spectrometry and chromatography;
- physico-chemical properties;
- toxicity tests;
- eco-toxicity tests.

Pesticide registration

China's pesticide registration system was set up according to the "Provisions of Pesticide Management Regulations" and "Measures for pesticide regulations implementation". A pesticide registration certificate is indispensable certificate for entry into China pesticide market.
Pesticide applicant must submit relevant documentation to the Ministry of Agriculture in accordance with "Pesticide Registration Data Requirement" including:

- dossier preparation;
- physico-chemical tests;
- toxicity tests;
- residue tests;
- eco-toxicity tests;
- and efficacy etc;
- communication with ICAMA;

Pesticide registration certificates can only be issued if the requirements are met.
CNCIC is the only consulting firm that can handle both China New Chemical Substance Notification and China Pesticides Registration.

Globally harmonized system of classification and labelling of chemicals (GHS) related services in China

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS, or "Purple Book") is a regulatory document published by United Nations to guide countries to control chemical hazards and protect human health and the environment. With a global harmonised standard in chemical hazard classification and labelling, it can enhance the protection of human health and environment, reduce the duplication of chemical test and assessment, and facilitate international chemical trade. CNCIC provides GHS related services in China, including:

- identification and classification of chemical hazards, and risk assessment;
- preparation of GHS-SDS and precautionary labels;
- search and query services for data necessary for classification;
- test arrangements for identification and classification of chemical physical hazards;
- 24h emergency hotline service;
- registration of hazardous chemicals.

Food related product compliance and notification service

CNCIC provides notification services according to the food related regulations, including:

- regulation consulting;
- regulatory compliance evaluation;
- prepare the declaration dossier for clients;
- data review and reports translation;
- test arrangement and communication;
- attend the technical review meeting on behalf of clients;
- prepare the supplementary data after the accreditation council;
- communication with authority during the notification and assist clients to solve the potential problems.

Cosmetic new materials notification

China Cosmetics Administrative Licensing is the administrative approval for the use of new cosmetic ingredients, the production of domestic special functional cosmetics product, and the first import of cosmetics product. All imported cosmetics, including special and non-special, must not be sold until approved by the State Food and Drug Administration prior to sale.
CNCIC provides notification services to the authority, including:

- new cosmetic ingredient administrative licensing notification;
- domestic special functional cosmetics product administrative licensing notification;
- domestic non-special functional cosmetics product record certificate application;
- import of non-special functional cosmetics record certificate application; and
- import of special functional cosmetics administrative licensing notification.

Healthy food/medical devices relevant chemicals regulation consulting

Fertiliser registration

Global inventory of chemicals query

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1959	Science and Technology Information Research Institute of China Ministry of Chemical Industry established in Beijing, China. In the planned economy era of China, it was part of Chinese government.
1984	Reformed to Economical Information Center of the Ministry of Chemical Industry.
1992	Reformed to China National Chemical Information Center, a China state owned company.
1995	Product Registration and Compliance Department, founded as a branch of China National Chemical Information Center.

ACCREDITATIONS

CNCIC is the biggest and most famous chemical research institute, consulting firm, and information/regulation service provider in China with more than 50 years of history. It has played an active role in building China chemical HSE, and national environmental standards/regulations. For years, CNCIC has provided instant, efficient, and professional services in Chinese standards/regulations for more than 100 domestic and overseas manufacturers and traders involved in chemicals, pesticides, food packaging material, etc.

TESTIMONIALS

"CNCIC provides instant and professional service to help us successfully notified our new chemical substance product so that we can export our product to China smoothly," says a chemical producer.
Another client says: "It takes less time and gets more professional services for us to commission CNCIC for China chemical regulation issue. They are worth trusting!"

STAFF SELECTION

Jolie Liang

Jolie Liang is the GHS manager of Product Registration and Compliance Department of CNCIC, focusing on Chinese GHS law and regulations, with an emphasis on dangerous chemical. She advises companies on regulatory compliance issues, especially about GHS SDS and labelling. Moreover, she also specialises in the risk assessment of the new chemicals.

Amy Yu

Amy Yu is pesticides registration manager of Product Registration and Compliance Department of CNCIC. Amy graduated from Beijing University of Chemical Technology in 2005. With ten years of experience in China and overseas pesticides registration, she leads a specialised and professional team for agricultural chemicals compliance.

Richard Tong

Richard Tong focuses on Chinese chemical regulations with an emphasis on new chemicals, helping clients solve problems in China New Chemical Substance Notification. Richard is also a senior engineer with over ten years' experience in chemical consultant. Richard has plentiful experience in new chemical notification; he has successfully achieved more than 700 registration certificates for simplified notification and more than 100 copies registration certificates of general notification. He earned his MS degree from Beijing University of Chemical Technology in 2005.

Minyan Liang

Minyan Liang is a senior engineer with more than ten years of experience in Chinese chemical regulation. She is the director of Product Registration and Compliance Department of CNCIC, focusing on Chinese chemical regulations, Standards, with an emphasis on new chemical substance notification, toxicology and ecotoxicology. She was in charge of many new substance notification cases and has rich experiences on regulations, tests, toxicology and ecotoxicology.

Lisa Zhong

Lisa Zhong, DCST, is an engineer with more than seven years of experience in Chinese chemical regulatory affairs. She is focusing on new chemical substance notification, test management on test data eg. physico-chemical data, toxicology and ecotoxicology studies. She also participates in food contact material notification and cosmetic notification in China. She has rich experiences on regulations, tests, toxicology and ecotoxicology.

CONTACTS

Website	www.emmcchir.org
E-mail	emmcchir@ualg.pt
Head office	University of Algarve, Gambelas Campus, 8005-139 Faro, Portugal
Tel	+35 1 289 800 003
Fax	+35 1 289 800 025
Contact	Isabel Cavaco (Programme Coordinator)
Directors	Emilio Tagliavini (University of Bologna, Italy) Teresa Fernandes (Heriot-Watt University, UK) Daniel Sainz (University of Barcelona, Spain) Ana Rosa Garcia (University of Algarve, Portugal)
Ownership	Public institutions
Locations	Portugal, Spain, Italy, UK
Founded	2012

OVERVIEW

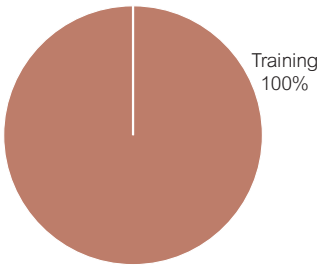
The Erasmus Mundus master course in chemical innovation and regulation, EMMC-ChIR, is a joint MSc degree offered by the Consortium of the University of Algarve, University of Barcelona, University of Bologna and Heriot-Watt University. Students study in at least two different countries, and gain from the enlarged academic offer, experience and services of four universities.

The degree has duration of two years: one year of 30 optional stand-alone, one-week modules, and one year of research. Modules are offered in the fields of design of new safe chemical substances, industrial processes, marketing and public perception of the chemical risk, assessment of chemical, toxicological and environmental risks and international chemical regulations.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-.
No of offices	4
No of countries represented	4
Staff, group	13,976
Staff, chemical service provision	51

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

University of Algarve, Faculty of Science and Technology, Campus de Gambelas, 8005-139 Faro, Portugal;
University of Barcelona, Gran Via de les Corts Catalanes, 585 08007, Barcelona Spain;
Alma Mater Studiorum – University of Bologna, Via F. Selmi, 2, 41206, Bologna, Italy;
Heriot Watt University, Riccarton, Edinburgh EH 4AS, United Kingdom.

SERVICES PROVIDED

Higher education and training

The EMMC-ChIR is a European Joint MSc Degree offering training in the fields required for chemical safety management:

- design of safe chemical substances;
- sustainable industrial implementation of chemical processes;
- management and marketing of new chemical substances;
- assessment of toxicology risks;
- assessment of environmental risks;
- assessment of physical and chemical risks;
- safety of nanomaterials; and
- REACH and international regulations on chemical safety.

Internships

The EMMC-ChIR is open to collaboration with industry stakeholders. Collaboration may involve internship placements of students within the fields described above, or research projects on common interest topics.

Symposium

The EMMC-ChIR organises annually an international symposium on chemical innovation and regulation, aimed at bringing together the industry, research and higher education students.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2012	EMMC-ChIR Consortium created
2012	Erasmus Mundus Master Course award by the European Commission, under the Erasmus Mundus Action 1 Programme
2013	EMMC-ChIR 1st edition. Classes at the University of Algarve, Portugal
2014	EMMC-ChIR 2nd edition. Classes at the University of Barcelona, Spain
2015	EMMC-ChIR 3rd edition. Classes at the University of Bologna, Italy
2016	EMMC-ChIR 4th edition. Classes at the University of Algarve, Portugal
2017	EMMC-ChIR 5th edition. Classes at the University of Barcelona, Spain

ACCREDITATIONS

Course accredited as a 2nd Cycle Higher Education Degree by the competent bodies in Portugal, Spain, Italy and the UK.

PARTNERS

- University of Sao Paulo (Brazil)
- Central South University (China)
- Hokkaido University (Japan)
- University of Pune (India)
- Norsk Institutt for Luftorskning (Norway)
- Centro de Química Estrutural (Portugal)
- Echa – European Chemicals Agency (Finland) (included in the agency's graduate scheme)

CLIENTS

- The EMMC-ChIR accepts candidates holding a higher education diploma issued by a competent higher education authority attesting the completion of a degree equivalent to a 1st cycle (BSc, 180 ECTS), in a field where chemistry plays an important role. This may be a degree in chemistry, chemical engineering, biology, pharmaceutical sciences, biochemistry, environmental engineering, chemical engineering, food engineering, clinical analysis, or equivalent.
- All candidates are evaluated for acceptance to the course.

TESTIMONIALS

From EMMC-ChIR alumni anonymous survey:
"This master course provided us plenty of modules which cover many areas. We are free to choose any course we like, according to our interest."
"Multidisciplinary"
"Some professors are terrific in academy and also charming in personality and teaching style! The host institution is an open campus for international students, and the programme director is very passionate and gave us lots of help!"
"It is a life changing programme in every aspect"
"It helped a lot my CV"
"Great programme-great people-life changing experience"
"The EMMC-ChIR has given me the courage to transition into the regulatory field from academia. Though I have yet to be formally accepted into my desired position, I am quite excited to try a relatively new field. More than academics (and in my experience the professors are outstanding), the cultural exchange (including new languages) in my mobility programme has allowed me to grow as a person, and perhaps that's what pushed me to test the waters of new career track. So, thank you, EMMC-ChIR, for giving me that boost to move forward!"

STAFF SELECTION

Isabel Cavaco – Programme Coordinator, University of Algarve

Degree in Chemical Engineering by Instituto Superior Tecnico (IST), PT (1992); PhD in Chemical Engineering by IST (1998).
From 1998. Lecturer of Analytical Chemistry in UAlg;
From 2004: collaborated and lectured in national masters (UAlg) and in the EMMC in Water and Coastal Management and the EMMC in Quality in Analytical Laboratories in PT, PL, ES, NO, China and Colombia.
2008-2013 Programme Coordinator of the Erasmus Mundus Master Course EMQAL. Since 2012 – Programme Coordinator of the EMMC-ChIR. Supervised and co-supervised 21 master and one doctorate students. Published 25 papers in international peer-reviewed journals in bioinorganic chemistry.

Daniel Sainz Garcia – Programme Director, University of Barcelona

Degree in Chemistry by the Universitat de Barcelona (UB) (1981); PhD in Chemistry by UB (1989).
1989-1990 Spanish MEC fellowship at Institut für Technische Chemie und Petrolchemie in Aachen (Germany)
1986-1995: Associated Professor at UB
From 1995: Professor of Inorganic Chemistry at UB
2002-2008: Delegate of the Rector for Safety, Health and Environment at UB
2005-2010: Member of the Commission of Environmental Quality, Sustainable Development and Health and Safety from Conference of Rectors of Spanish Universities
2009-2012: Member of the Spanish National Commission on Prevention of Occupational Risks at the university
Author of 20+ peer-reviewed papers in Homogeneous Catalysis and 4 books of quality and safety in Chemistry

Emilio Tagliavini – Programme Director, University of Bologna

Degree in Chemistry from the University of Bologna 1979.
From 1983 Lecturer of Organic Chemistri at UniBo.
From 1992 Associated Professor in Organic Chemistry at University of Napoli.
From 1993 Associated Professor of Organic Chemistry at UniBo.
From 2005 Full Professor of Organic Chemistry at UniBo.
From 2004 to 2010 head of the Degree Course in Environmental Sciences and of the Master Degree in Chemistry of UniBo. Supervisor of Master students in Chemistry and in Environmental Sciences. Supervisor of PhD students in Chemistry and in Environmental Sciences. Author of about 80 peer-reviewed papers

Teresa Fernandes – Programme Director, University of Heriot Watt

Worked in the assessment of effects of pollutants on natural systems for last 20 yrs. 2006-2009: external scient. expert of the EC Scient. Commit. on Emerging and Newly Identified Health Risks. To date: external scient. expert on Risk Assessment of the Scient. Commit. of the EC; adviser to the ISO/TC 229 Task Group on Nanotechnology and Sustainability, and to the Irish EPA in the area of Nano ecotoxicology. Member of the Network of excellence NanoimpactNet and of the recently established "Nanosafety Cluster", where she is a co-chair of the Working Group 'Hazard'. Member of the Nanotechnology Advisory Council of the Society of Environmental Toxicology and Chemistry. Invited speaker at a wide range of international Conferences and meetings.

CONTACTS

Website	www.cirs-reach.com
E-mail	service@cirs-reach.com
Head office	11/F, Bldg 1, Dongguan Hi-Tech Park, 288 Qiuyi Rd, Binjiang District, Hangzhou, China
Tel	+86 8720 6574
Fax	+86 8720 6533
Contact	David Wan
Directors	Lucy Li, CEO Walt Lin, Vice President of CIRS Group Louise Halpin, Managing Director of Ireland Office David Wan, Head of Strategy Operation Michael Zhang, Chief Technology Officer
Ownership	Private company
Locations	China (Hangzhou, Beijing and Nanjing), Ireland (Ardee)
Founded	2007

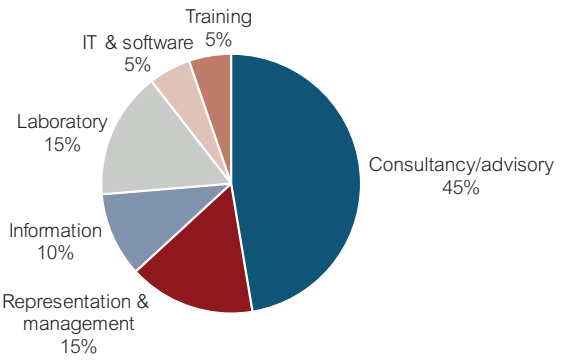
OVERVIEW

CIRS is an independent product safety and chemical management consulting service provider. We provide valued product regulatory compliance service, tailored solution and original information to help industries gain competitive advantages, including chemical, cosmetics, food, disinfectant, detergent, consumer goods and medical device.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	6
No of countries represented	2
Staff, group	200
Staff, chemical service provision	Approx 50%

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

CIRS HQ – 11F Building 1, Dongguan Hi-Tech Park, 288 Qiuyi Road, Binjiang District, Hangzhou 310052, China
CIRS Europe – Unit 1 Ardee Business Park, Hale Street, Ardee, Co. Louth, Ireland
CIRS Beijing – Room 1109-1111, No.7 West Block, Dacheng Plaza, 28 Xuanwumen, Xidajie, Xicheng District, Beijing, China
CIRS Testing Centre – 1/F, No,4 Building, Huaye Hi-Tech Industrial Park, No.1180, Bin'an Road, Binjiang District, Hangzhou, China

SERVICES PROVIDED

Global GHS compliance service

North American SDS and labelling, EU CLP SDS and labelling, China SDS and labelling, Asia Pacific SDS and labelling; China chemical consumer product labelling, China 24hrs emergency telephone number service.

Global chemical notification

EU REACH only representative, EU REACH registration, China New Chemical Substance Notification, China Hazardous Chemical Registration, K-REACH and Kosha Registration, Taiwan TCSCA and Osha registration, chemical notification in other Regions: Japan, Philippines, US and Australia etc.

Food and food-related product compliance in China

Ingredient review and analysis of pre-packaged food, label translation, reviewing and preparation for pre-packaged food, infant formula food registration, food for special medical purpose (fsmp) registration, new food contact additive/resin notification, new food additive registration, new food raw material registration, health food registration.

Cosmetics and ingredients registration in China

CFDA registration, new cosmetic ingredient registration, toxicology safety assessment, formula and label review, the customs clearance assistance, regulatory compliance testing.

Medical devices registration in China

Medical devices registration (recording), clinical trial, quality management system (qms) consulting, compliance analysis and project assessment

Pesticide and disinfectant registration in China

Notification for disinfection products, pesticide registration, regulatory consulting service for disinfection products and pesticide products, permit assistance for import and export pesticide product or non-pesticide used products.

Testing service

China eco-toxicology, SVHC list testing, china rohs, *in vitro* testing, consumer goods safety testing, hazardous chemical testing, food contact material testing (EU, US and China)

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2007	Foundation, Hangzhou, China
2008	Office in Dublin, Ireland
2009	Member of IDA of Ireland
2010	China first Chemical Safety Report completed by CIRS
2011	First Summit Meeting on Chemical Regulation in AP
2011	Partnership with JEMAI and become JAMP member
2011	Nanjing Office established
2013	CIRS Testing Centre (C&K Testing) established
2015	First Summit Meeting on Cosmetics Regulation in AP
2015	Beijing Office established
2016	Milestone of the 100th typical notification of China REACH
2016	Strategic cooperation partnership with 3E

ACCREDITATIONS

Certified SDS service provider, CNAS Laboratory, JAMP membership certificate, China CIQ qualification certificate, China metrology accreditation, CPSC lab accreditation, IDA Ireland support

PARTNERS

JEMAI, Eurofins, Doruksistem, KTR, Flashpoint, ExperTox, Arcadis, Cafe24, SRICI.

CLIENTS

CIRS has worked with more than 4,000 clients and partners across many industries, including chemical, cosmetic, biocide, agrochemical, food, medical device and consumer goods. 70% Chinese chemical companies are using CIRS's services, including global GHS, China REACH, EU REACH etc. Over 500 international corporates are using our services to fulfil their regulatory obligations in China.

CASE STUDY 1: Comprehensive services in supply chain

Provided comprehensive hazardous chemical regulatory compliance services for three Germany respectable automobile manufacturers to fulfil their regulatory obligations in supply chain in China, including public policy strategies, regulatory updates, hazardous chemical operation licenses, hazardous chemical registration, storehouse inspection, logistics audit, hazardous waste treatment and China GHS.

CASE STUDY 2: China new substance notification strategy

Provided China new chemical substance notification for a well-known public specialty chemical company. The animal testing studies were required for one of their substances according to data requirements. However, this substance is used as cosmetic ingredient and new vertebrate animal experiments could not be accepted by business strategies. It is important to note that CIRS found its analogues, which had full studies, and serial notification was finally approved by MEP due to CIRS's scientific demonstration and persistent effort.

CASE STUDY 3: Global GHS

Provided SDS authoring and label designing service to several international chemical suppliers from various industries like petrochemical, automobile, drugs and reagents and so on. CIRS provided classification comparisons, multi-language SDS and labelling service which covers global market, including EU, North America, Asia Pacific etc. CIRS has designed safety label for kit-packaged reagent products, ensuring the regulatory-compliance requirements along with the paste needs.

CASE STUDY 4: Read-across and Qsar

Provided REACH full registration (lead registrant project) for a well-known bio-pharmaceutical manufacturer. As toxicological and ecotoxicological data are unavailable, data matrix was built and applied to generate those data by read-across and Qsar. Approximately 200,000 EUR was reduced as well as the dossier preparation period was shortened accordingly.

STAFF SELECTION

Queenier Yang – Assistant Manager/Senior Regulatory Consultant

Queenier Yang is responsible for overseas chemical regulations, especially for EU REACH, US TSCA, Canada DSL/NDSL, Australia NICNAS, KREACH, etc. With practical experience on data gap analysis, her team completed more than 100 registration dossiers, including 20+ LR dossiers. By using Qsar and read-across expertly instead of testing, she also succeeds in complying with TSCA、DSL/NDSL and K-REACH for chemical industry.

Grace Ma – Deputy Manager of R&D Department

Grace is a Global Chemical Regulation Senior Technical Consultant with 8 years' experience. She is working at China chemical regulation compliance, China New Chemical Substance Notification (MEP Order No.7), Taiwan Chemical Regulations (TCSCA and Osha), and non-testing methods (Qsar, read across, etc). She has published several pieces of peer-reviewed SCI paper on Qsar and toxicology. The Qsar models built by her applied for two items of computer software copyright and two patents. Dozens of Qsar reports authored by her have been accepted by the technical review committee of China New Chemical Substance Notification, EU REACH and Taiwan chemical regulations.

Bruce Wang – Head of China New Substance Notification

Over five years' experience working on China new chemical substance notification and more than 100 typical notifications of new substances have been completed by his dedicated team as well as more than 1200 simplified notification. In addition, he has a store of experience in chemical risk assessment and China GHS.

Cloris Pan – GHS Team Leader/Senior Regulatory Consultant

Ms Cloris Pan has several years working experience and plenty of in-depth research on global GHS implementation along with hazardous chemical managements in Asia Pacific. In 2016, more than 500 service projects have been provided by her team as well as more than 20 tailored training for industries and China governments.

April Guo – Cosmetics Regulatory Affairs Manager

April Guo has involved in Chinese cosmetics regulations for more than five years. She currently works for Chemical Inspection and Regulatory Service (CIRS) and leads a cosmetic registration and cosmetic ingredient assessment team in China.

Cathy Yu – Head of Food Safety and Regulatory Affairs

Ms Yu has experience in providing food regulatory compliance services for overseas companies from over 20 countries. She manages CIRS' Food department, which focuses on food and food contact material regulatory compliance, health food registration, nutrition supplement filing as well as infant formula registration.

Coordinating Informational Service Center
of CIS Member States
on approximation of regulatory practices

CONTACTS

Website	www.ciscenter.ru
E-mail	info@ciscenter.org
Head office	Lyusinovskaya ul, 36/1
Tel	+7 495 745 38 00
Fax	+7 495 745 38 00
Contact	Natalia Druzhinina
Director	Dmitry Skobelev
Ownership	Non-profit organisation
Locations	Russia
Founded	2006

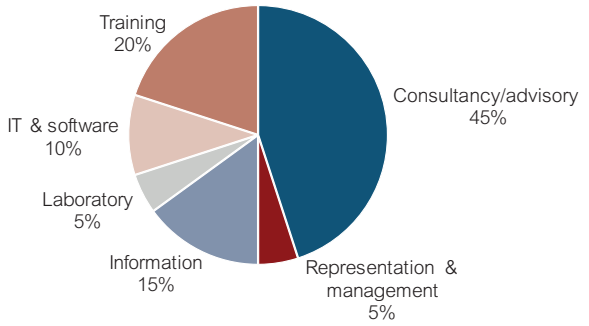
OVERVIEW

CIS Center as a non-profit organisation consolidates government and commercial structures with the well-experienced experts in the field of regulation and safe handling of chemicals. The mission of CIS Center is to provide professional consultancy assistance for government and enterprises regarding chemicals safety across the supply chain and throughout the whole product lifecycle in order to reduce trade barriers. We can help your company find individual solutions in such areas as the identification of chemicals, creation and registration of Russian SDS, classification and labelling according to Russian national standards, risk assessment and risk management, best available techniques (BAT) implementation, ecological certification and ecolabelling, Russian national regulatory compliance training and other.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	2
No of countries represented	1
Staff, group	84
Staff, chemical service provision	32

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Russia

SERVICES PROVIDED

Identification

CIS Center provides services for substance identification in compliance with REACH, namely:

- substance's identifiers search and selection;
- search for information on the substance composition and formula;
- Russian laboratories physical and analytical test operations in accordance with REACH Regulation; and
- mini dossier creation.

Russian SDS (Russian Safety Passport, RSP)

All companies importing chemicals into the Russian Federation have to be in compliance with national requirements concerning safe handling, transportation and storage. This includes the creation of a Russian SDS according to GOST 30333 in the Russian language with its obligatory expertise and appropriate registration that is the one of the main CIS Center activities. We thereby provide our customers with the best level of service on the creation and registration of Russian SDS.

Classification and labelling according to Russian national standards

Hazard classification and labelling according to Russian legislation has a number of important features, especially with regards to transport information. Our experts can help you to classify your product according to the following national standards:

- classification of chemicals and mixture (the series of standards);
- labelling of chemicals. General requirements;
- dangerous goods. Classification and marking; and
- marking of cargoes.

CIS Center will help you choose the right classification code and handling marks and prepare the proper label.

SDS creation

CIS Center provides services on classification, labelling and Safety Data Sheet creation of substances and mixtures, according to legislation of EU, US, South Korea, China, Brazil, Australia, Singapore and elsewhere.

Risk assessment and risk management

CIS Center activities lie in the field of exposure assessment, risk estimation and evaluation of chemicals in order to minimise negative impact of chemicals on human health and the environment in accordance with the best available risk management practices. Additionally CIS Center provides training courses on chemical risk assessment and management for the chemical sector of Russian industry, Customs Union officials and regulatory experts.

Consulting in the field of Russian regulation on chemicals

The CIS Center team has extensive background knowledge and experience of national legislation and can provide you with up-to-date information on chemical regulations within the Russian Federation covering the hazard communication, reporting and testing of new chemicals, chemical inventories and the evaluation of existing chemicals.

Ecological certification and ecolabelling

CIS Center provides assistance on voluntary ecological certification and ecolabelling to companies of Russian chemical sector, exporting chemicals abroad, as well as intending to participate in public procurements of importing countries, which tenders require to provide:

- life cycle assessment of the products and processes to estimate the real impact on human and environment, and
- supporting documentation (including ecological certificates and declarations).

Best available techniques (BAT) implementation

One of the dynamically developing activities of CIS Center is the methodological and scientific assistance to the implementation of new regulation based on the best available techniques in the Russian Federation. CIS Center participates in the OECD project on BAT

representing position of the Russian Federation. Also we published collections of articles on BAT providing analysis in this sphere and developed the series of the national standards in this field.

Standardisation

CIS Center coordinates activities of several technical committees (TC) including TC 339 "Safety of raw materials and substances" and TC 60 "Chemistry" in the Russian Federation. Our experts are directly involved in the development of the national and intergovernmental (in the territory of CIS members countries) standards regarding chemical regulation and safe handling, including the GHS implementation.

REACH, GLP, GPS and Russian national regulatory compliance training

CIS Center organises training and conferences in the field of chemical control and safety regulations. We run regular training sessions and seminars on the following topics:

- classification, labelling and SDS development under the Russian national standards;
- preparation of the test facilities to comply with the GLP principles;
- chemical risk assessment and management and other training.

Other

CIS Center was authorised by ASTM International to offer the ASTM proficiency test programme (PTP) in Russia and CIS countries. CIS Center in conjunction with ASTM continues and expands the PTP for laboratories, through interlaboratory comparative tests on the measurement of the composition, and properties of petroleum products (gasoline, diesel fuel, motor oil). In the near future CIS Center is planning to provide training on the proficiency test programme.

- CIS Center is a partner of ChemADVISOR, Inc. and an official distributor of LOLI database and global chemical regulatory reports in Russian-speaking territory. Our team have localised the LOLI Database and some other IT products for the Russian market.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2006	CIS Center founded in Moscow, Russia with the full name Coordinating informational Service Center for enterprises. Assistance in the field of chemical safety.
2006	Development of intergovernmental standards on GHS for the CIS member states.
2008	CIS Center registered as a non-profit organisation.
2009	• Organisation of the second annual conference of CIS member states "Safety regulation of chemicals. UN Recommendations and European regulations REACH and CLP" (Minsk, Belarus). • Development of national standard for GLP.
2010	Organisation of the third annual conference of CIS member states "Safety regulation of chemicals. UN Recommendations and European regulations REACH and CLP" (Baku, Azerbaijan).
2011	Organisation of the fourth annual conference of CIS member states on chemicals regulation (Astana, Kazakhstan).
2012	• Organisation of the fifth annual conference of CIS member states on chemicals regulation (Kazan, the Republic of Tatarstan, Russia). • Development of international standards on GHS and GLP-OECD for CIS countries.
2013	• CIS Center authorised by ASTM International. • Organisation of the sixth annual conference of CIS member states on chemicals regulation (Minsk, Belarus). • CIS Center became an official partner and distributor of ChemADVISOR products in Russian-speaking territory.
2014	• Organisation of the seventh annual conference of CIS countries on chemicals regulation (Moscow, Russia).
2015	• CIS Center and CRAD Cevre Risk Analiz Den. Ve Egitim Hiz. A.S. became partners. • Organisation of the eighth annual conference on chemicals regulation in the CIS member states (Istanbul, Turkey). • Renaming "Coordinating Informational Service Center for enterprises. Assistance in the field of chemical safety" into "Coordinating Informational Center of CIS Member States on approximation of regulatory practices" (the short name remains the same – CIS Center). • Participation of the CIS Center experts in the joint OECD-UN GHS Committee project on the assessment the potential development of a Global list of chemicals, classified according to the GHS.
2016	• Organisation of the round table on the topic "Technological environmental legislation and BAT economic efficiency". • Participation of the CIS Center experts in the joint OECD-UN GHS Committee project on the assessment the potential development of a Global list of chemicals, classified according to the GHS.

PARTNERS

ASTM International, ChemAdvisor, CRAD Cevre Risk Analiz Den. Ve Egitim Hiz AS

CLIENTS

CIS Center assists a broad range of companies of the chemical and petrochemical industry. We work with both large international companies and SMEs.

CASE STUDY: Russian SDS (Russian Safety Passport, RSP)

Russian Technical regulation "On Safety of Chemical Products" was adopted on October 7, 2016 through government Decree No.1019 a five years transitional period (ending on July 1, 2021). During this transitional period the Russian SDS development is not obligatory. However, the reality is that customs can have their specific requirements and usually demand to show this document at the custom border. In our practice we are often faced with a situation where companies urgently ask us to help with Russian SDS development. They want to get them as soon as possible; otherwise they will lose a lot of money due to the delay at customs. Such companies usually know about Russian SDS, but think that if they translate an existing SDS (eg EU-SDS) into Russian it will be enough. Unfortunately, they are often unaware that although Russian safety chemical legislation harmonised with GHS, it has a number of distinct features (specific format with title page, period of validity, dual classification, obligatory links to the sources of provided information and etc.). This means that direct and even proper translation of the SDS into Russian is not the right solution. To become legal the Russian SDS shall go through the procedure of expertise and registration. The successful registration is confirmed at the title page with a unique registration number and valid period. CIS Center believes that it might be practical to develop Russian SDS in advance which enables to save time and money by avoiding delays at customs.

STAFF SELECTION

CIS Center team

CIS Center team members are highly competent and have great experience in the field of chemicals regulation throughout the whole product lifecycle, including but not limited to chemicals identification, hazard classification, risk assessment, Russian SDS and labelling development. Our experts within the delegation of the Russian Federation participate in the meetings of the UN Sub-Committee of Experts on the GHS, Chemical Dialogue APEC, OECD Chemical Committee as well as SAICM activity. Our specialists are directly involved in the development of the Russian Federation standards and always have up-to-date information on national and international chemical control legislation.

CiToxLAB
Safety and Health Research Laboratories

CONTACTS

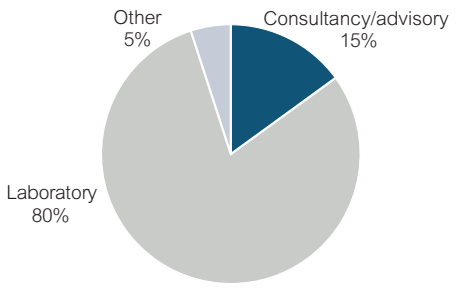
Website	www.citoxlab.com
E-mail	contact.france@citoxlab.com contact.hungary@citoxlab.com
Head office	CiToxLAB, B.P. 563, Evreux, France
Tel	France +33 (0)2 32 29 26 26 Hungary + 36 88 545-300
Fax	France +33 (0)2 32 67 87 05 Hungary +36 88 545-301
Contact	Director of Business Development and Project Management clientservices@hu.citoxlab.com
Directors	Olivier Foulon, CiToxLAB in France Alyson Leyshon, CiToxLAB in Hungary Andrew Makin, CiToxLAB in Denmark Andrew Graham, CiToxLAB in North America Guy Leclerc, AccelLAB a CiToxLAB Group Company
Ownership	Private company
Locations	France, Denmark, Hungary and North America
Founded	1969

OVERVIEW

CiToxLAB offers a comprehensive range of pre-clinical services for pharmaceutical, biotechnology, chemicals, cosmetics, medical devices and food companies worldwide. Our scientists and regulatory experts provide customised advice to help your development projects progress in the most effective way. After the creation of the Group in 2011, CiToxLAB has now more than 1000 employees working at six sites in France, North America, Denmark and Hungary.
Proximity, the latest technologies and easy access to scientists, make CiToxLAB your one-stop CRO for pre-clinical research. We offer maximum flexibility and expertise, major factors that guarantee the quality of your non-clinical programmes.

VITAL STATISTICS	2015/16
Turnover, group	> €90m
Turnover, chemical service provision	n/a
No of offices	6
No of countries represented	All
Staff, group	1000
Staff, chemical service provision	850

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

CiToxLAB has facilities located in France, Denmark, Hungary and North America.

SERVICES PROVIDED

Chemical, biocide and agrochemical testing for registration

To meet the wide range of regulations in force around the world for chemical, biocide and agrochemical product registrations, many of the largest international companies entrust CiToxLAB with their physico-chemistry, ecotoxicology and mammalian regulatory testing.
Experts with in-depth knowledge of authority requirements can advise you about the most appropriate testing for your active ingredients and products, to meet your international registration or classification and labelling needs.
For REACH and other chemical notifications, we provide complete regulatory packages and data-gap studies. We also propose a one-stop service for studies from Qsar and characterisation to ecotoxicology and long term rodent toxicology studies. We are experienced in dealing with a wide range of chemistry, including metals and UVCBs, and perform studies by all administration routes.

Cosmetics

CiToxLAB has been working with industry in the development of cosmetics, skin care products and perfumes (ingredients and finished products) for more than 45 years. Since the ban on animal testing for cosmetics came into effect, we have been at the forefront in implementing new *in vitro* alternative assays. Today, we offer one of the most extensive ranges of *in vitro* tests in Europe for safety assessment of raw ingredients and finished products: regulatory toxicology tests *in vitro* for topical (skin/eye) corrosion and irritation (BCOP – OECD 437, EpiOcular™ Eye Irritation test -OECD 492), skin sensitisation (DPRA – OECD 442C, KeratinoSens™- OECD 442D, h-CLAT – Draft OECD), phototoxicity (photo-3T3 NRU – OECD 432; PhotoEpiskin™ and transcutaneous absorption/penetration, as well as all genotoxicity and cytotoxicity tests. Studies are conducted in a GLP environment.
Additional services include state-of-the-art genomics techniques (NGS, Affymetrics genechips), flow cytometry, cellular and image analysis, and bioanalysis techniques.
CiToxLAB is a member of EU-Netval (European Union Network of Laboratories for the Validation of Alternative Methods) and involved in EURL Ecvam validation studies that serve to assess the reliability and relevance of alternative methods with a potential to replace, reduce, or refine the use of animals for scientific purposes.

General toxicology and expert services

CiToxLAB is your one-stop CRO for general toxicology studies, whether you are in the pharmaceutical, biotechnology, chemical, medical device, food additive, veterinary or crop protection industry.
From method development and the first investigational new drug screening tests, through pharmacokinetics, genomics and safety assessments, to full toxicology packages including reproduction, embryo-fetal / juvenile development and carcinogenicity, our experts can accompany you with customised advice and offer you a whole range of GLP-compliant studies.

Inhalation toxicology

CiToxLAB, Hungary has performed more than 300 studies via the inhalation route over the past five years ranging in duration from acute to six months.

- OECD TG 403 – acute LC50 inhalation;
- OECD TG 436 – acute toxic class inhalation;
- OECD TG 412 – sub-acute inhalation;
- OECD TG 413 – sub-chronic inhalation; and
- EUR 20268 EN – quantifying inhalable fraction.

Partner with our team of senior inhalation toxicologists and aerosol specialists. We provide support and guidance at all stages of programme development. Technical facilities and expertise include:

- Exposure/administration suites;

- Inhalation delivery in rodents and non-rodents;
- TSE directed flow (flow-past) systems:
  - Nose-only or oro-nasal exposure;
  - Prevents re-breathing;
  - Restraint designed to minimise thermal stress;
  - Maintains homogeneous breathable atmosphere at all levels of the inhalation tower;
  - State-of-the-art technologies to generate powder, liquid or vapour atmospheres;
  - Early stage toxicology evaluation with intra-tracheal aerosol delivery;
- Experienced with fibres.

Ecotoxicology and biodegradation

CiToxLAB offers a wide range of laboratory based ecotoxicology and biodegradation studies to meet current ecological and nature preservation concerns and the needs of industries, including chemical, plant protection and biocide sectors. We have specialised expertise in complex substances such as metals, UVCBs and polymers.
The design of each study, including media preparation and analytical services, is tailored to ensure your compound registration programme meets regulatory requirements for aquatic and terrestrial environmental risk assessment.

- Ready biodegradability test (OECD 310)
- Activated sludge, respiration inhibition test (OECD 209)
- Aerobic and anaerobic transformation in soil (OECD 307)
- Soil micro organisms: nitrogen transformation test (OECD 216)
- Aerobic and anaerobic transformation in aquatic sediment systems (OECD 308)
- Terrestrial plant growth test (OECD 208)
- Aquatic toxicology (acute, long term, reprotoxicty)
- Terrestrial (short and extended/reprotoxicity studies)
- Avian (acute and reprotoxicity studies)

Under the EU REACH regulations and for CLP, an integrated assessment of persistence, bioaccumulation and toxicity (PBT) is required, based on the evaluation of expected chemical behaviour and toxicity in the environment.

- CiToxLAB offers testing services that address the required PBT assessment of chemicals, agrochemicals and biocides.

Medical device testing

AccelLAB is a CiToxLAB Group contract research organisation (CRO) dedicated to the medical devices and biotechnology industry which specialises in the fields of the cardiology and the orthopedics. AccelLAB offers a completely integrated research centre allowing to lead efficiency and safety studies of renowned quality, AAALAC accredited and successfully audited by the FDA. AccelLAB has a staff of around 100 people and the facilities (about 40,000sq feet total) are equipped with the state of the art technologies in the fields of surgery and medical imaging like scanning and MRI.

- Study design and protocol preparation
- *In vivo* experimentation in pigs, sheep, dogs and rabbits
- Recognised expertise in experimental surgery and vascular intervention
- Complete clinical pathology
- Complete histopathology
- Robust regulatory environment
- State-of-the-art imaging, including: digitised angiography, portable digitised X-ray, OCT, utrasound (IVUS, TTE, TEE, ICE and 3D), CT-scan, MRI, Faxitron, micro-CT

AccelLAB areas of expertise:

- Restenosis (stents, absorbable scaffolds and drug coated balloons, coronary and periphery);
- Structural heart disease (TAVR, apical closure device, LAA closure device, surgical valves);
- Cardiac rhythm management (pacemakers, defibrillators);
- Heart failure (reperfusion devices, cell therapy, gene therapy and pharmaceutical approaches);
- Bone defects and fracture repair (orthopaedic implants and biologics);
- Osteoarthritis and articular cartilage repair;
- Posterolateral (PLF) and intervertebral fusion;
- Otorhinolaryngology-ENT (bioresorbable stents) ;
- Dermatology (wound healing, dermal fillers);
- Ophthalmology (oculoplasty).

Developmental and reproductive toxicology

CiToxLAB offers you developmental and reproductive toxicology studies accepted by worldwide regulatory authorities for the safety testing of pharmaceuticals, biologics, gene-therapy products, food additives, chemicals, agrochemicals, veterinary medicines and consumer products. Studies cover the whole scope of developmental and reproductive toxicology, testing for potential effects on fertility, through embryofetal, post-natal and juvenile stages, up to second generation reproduction. Specialised evaluations can be combined in your DART studies, such as neurobehavioral testing, sperm analysis, developmental immunotoxicology, neuro-histomorphometry, skeletal development and genomics.
Routine testing includes OECD 421, 422, 414 (rat and rabbit) and OECD 443 Extended one generation studies with neurotoxicity and immunotoxicity.

ACCREDITATIONS

GLP certified, AAALAC accredited, ISO 9001, ISO 14001, ISO 50001

CLIENTS

CiToxLAB works with the major players in each industrial sector.

STAFF SELECTION

David Esdaile – Director of Science and Regulatory Affairs

David Esdaile is the Director of Science and Regulatory Affairs at CiToxLAB in Hungary and has 32 years experience in pre-clinical research. David has experience in all areas of toxicology testing including project development, acute, sub acute and chronic studies in mammalian species, carcinogenicity, inhalation, reproduction toxicity, genotoxicity, dermal toxicity, skin sensitisation, skin penetration, structure-activity assessments, ecotoxicity and physical chemistry.

François Spezia – Head of the Developmental and Reproductive Toxicology

François Spezia is the Head of the Developmental and Reproductive Toxicology Department at CiToxLAB in France. François has more than 25 years of experience in this specialty area.
François Spézia, who is a European registered toxicologist, has developed and validated several *in vitro* and *in vivo* models for evaluating adverse effects on reproductive functions (eg embryotoxicity, fertility). He also participated in the production of an international glossary on the terminology of development anomalies in laboratory animals. Dr Spezia offers expert consulting in all topics related to chemical-induced reproductive and developmental toxicity testing.

Guy Leclerc – CEO of AccelLAB, a CiToxLAB Group Company

AccelLAB was founded in 2004 by Dr Guy Leclerc, an Interventional Cardiologist who headed the department of Cardiology and Cardiac Surgery of the Centre Hospitalier de l'Université de Montreal (CHUM). As an interventional cardiologist practitioner, Guy Leclerc has been a pioneer in applying what we call today translational research in the field of medical devices, helping client companies in the development of new cardiac stents, valves, pacemakers, etc. The services were more recently enlarged to other areas such as orthopedic, ENT (ear, nose and throat) and dermatology specialties.

CRAD
Çevre Risk Analiz Denetim

CONTACTS

Website	www.crad.com.tr
E-mail	info@crad.com.tr
Head office	CRAD A.Ş. Atakent Mh.Turkler Cd.Gokturk Sk.No:8 Umraniye, Istanbul, Turkey
Tel/ Fax	+90 216 335 4600/ +90 216 335 4606
Contact	Melih Babayigit
Directors	Melih Babayigit, Managing Director
Ownership	Private company
Locations	Turkey
Founded	2008

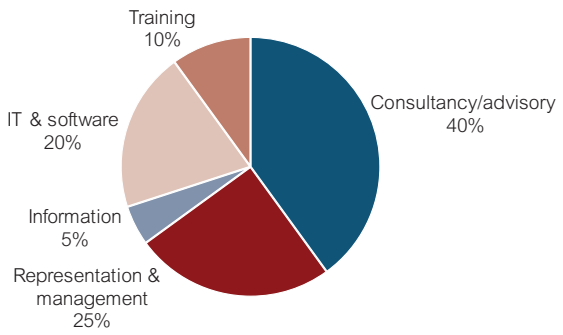
OVERVIEW

CRAD is the leading consultant company in Turkey, providing chemical regulatory compliance consultancy for the global chemical industry. With a well equipped team of consultants and with their knowledge of local regulations as well as of global and EU chemical products regulations, CRAD is capable of providing services within a wide context. Our multidisciplinary service portfolio allows our clients to have a better understanding of the compliance process, with similarities and differences between regulations in Turkey and EU. Serving more than 300 global chemical manufacturers worldwide for their compliance to Turkish Chemical Control Regulations such as CICR, Turkish CLP, Turkish compliant SDS authoring, we are ready to serve for their compliance with the KKDIK which will be the Turkish implementation of the EU REACH regulation. CRAD, acting as OR and registrant for product and substance registration schemes supports your compliance for the products placed on the Turkish market without any concerns on CBI for the exporters that they may need to share with their local distributor. Thanks to our strategic partners around the globe CRAD is also capable of providing its clients global information with a local twist. With our awareness about our responsibility to both the human and environment aspects, we not only serve our clients, but also keep an eye on our responsibilities towards the welfare of humankind and environment, particularly within the scope of our services. Aiming to be a one-stop compliance solution centre, we always aim to enlarge our portfolio of services. As of 2016 CRAD serves with a team of 14 consultant who are experienced in their field of service. A team of hazard communication experts serves our clients in SDS and label compliance for products placed on the market in Turkey and the EU.

VITAL STATISTICS 2015/16

Turnover, group	>€1m
Turnover, chemical service provision	>€1m
No of offices	1
No of countries represented	18
Staff, group	18
Staff, chemical service provision	14

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

General consulting services

We provide OR Services including registration and notification service for the Turkish REACH which is called KKDIK. Our team's expertise on Turkish, EU and global chemical regulations lets our clients have a focused insight into Turkish chemical regulations and helps them solve their problems with work and cost efficient compliance solutions for placing their products on the Turkish market. Also our regulatory follow up service lets companies be aware of future regulations and enables them to plan their strategy at the earliest moment possible. We also provide REACH compliance services for non-EU companies especially in Turkey and close regions such as MENA, with our capacity enriched by our strategic partners' expertise.

Notification, registration and only representative services

We represent companies fully on notifications and product registrations in Turkey. Our service lets global chemical industry to comply with Turkish chemical regulations in a concern free environment about their CBI concerns. They do have the comfort and confidence of keeping their CBI and strategic data undisclosed to their commercial agents. Another advantage of our representation service is that it allows the freedom of changing the commercial supply chain, without being restricted by registration ownership of the former commercial agent.

KKDIK (Turkish REACH) compliance services

Turkey will implement EU REACH-like regulation called KKDIK. The regulation is expected to be published in 2017. According the latest draft that was released by the competent authority for consultation the critical dates of the regulation are as follows:

- pre-registrations for any substance manufactured or imported 1mta or above have to be submitted starting from the sixth month of publication till 31.12.2019;
- registrations for the pre-registered substances have to be submitted between the dates 1.1.2020 and 31.12.2022;
- after 31.12.2022 substance manufactured or imported above 1mta can only be placed on the market after registration;
- SDSs have to comply with KKDIK after 31.12.2022. Until that date the SDS can comply with KKDIK or the existing SDS regulation 29024; and
- restrictions (annex XVII) will apply per the details given in the regulation respectively varying from 6 months after the publication, 31/12/2018, 31/12/2019, 31/12/2021.

CRAD is ready to support you in KKDIK compliance with our team who have an extensive EU REACH regulation experience and expertise. We do act as an OR for KKDIK pre-registrations and registrations, support your Sief communications and provide translation services for robust study reports and chemical safety assessment reports which will be required in Turkish for KKDIK registrations. Also we do provide training to your team for understanding their obligations under KKDIK.

Chemical safety assessor services to comply with Turkish KKDIK (T-REACH) Regulation

Registration under the scope of KKDIK will require certified chemical safety assessors (cCSA). The cCSA will be preparing the registration dossiers for the KKDIK. CRAD is ready to serve with its team of cCSA for the preparation of registration dossiers and preparing e-SDS to comply with the Turkish REACH KKDIK. We are as well ready with our trainings for the certified CSAs.

Biocidal/ detergent / veterinary product registration services

With extensive communication capabilities with relevant Turkish authorities, we serve our clients with the best level of information and most efficient approach related to several product registration schemes such as biocidal products, plant protection products, cosmetic, household products etc. With our capacity and experience on dossier compilation and registration we provide a result-oriented service for our clients. Also representing companies in means of registration keeps manufacturers away from the CBI concerns.

Label compliance and (M)SDS authoring services

Turkish SDS provisions require SDSs to be authored by a locally certified personnel to author the SDS in compliance with the regulation and represent his certification when required by the authority. A compliant SDS and label are also one of the main components of a product registration dossier. CRAD's team of experts in the field of classification and hazard communication provides you the SDS and label compliance and defends your cause to the authority when a case of dispute arises With our follow up service we also provide updated SDSs when the related regulations requires an obligatory revision.

Classification, SDS and chemical inventory software tools

Thanks to our strategic partner Safeware Quasar's expertise on regulatory compliance IT solutions and our in-house IT capabilities we provide "plug and play" and bespoke IT solutions for the chemical industry.

Regulatory compliance training and bespoke training

Whenever your team needs a focused insight into the Turkish regulations on chemicals, we are ready to provide a webinar for your regulatory team or an in-house training course for your team members located in Turkey with our key staff who are recognised as key speakers at international regulatory events.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2007	CRAD established
2008	CRAD staff certified as SDS author by TSE
2008	Market leader in REACH compliance services in Turkey
2009	In-house training class for 20 became available
2009	CRAD has been accredited to official REACH group of MoEF
2009	CRAD launched services for Turkish regulatory compliance
2010	CRAD joined the GCC Network
2012	CRAD enlarged its offices to 420 sqm at its HQ.
2013	CRAD launched services to comply with Turkish SEA (CLP)
2014	CRAD started providing certified SDS author trainings
2015	Team of consultants at CRAD increased to 14 to serve our clients better and faster.
2015	Turkish SDS authored by CRAD exceeded 15,000 More than 3,000 substances notified to the Turkish C&L Inventory representing over 200 global chemical companies.

ACCREDITATIONS

Certified for SDS training
Certified SDS author (all team)
Turquality and TSE certified consultant company
Member of REACH discussion group at Turkish CA

PARTNERS

Cambridge Environmental Assessments / ADAS RSK UK
Safeware Quasar Ltd UK
Repre Ltd Japan
Member of the GCC-Network/ Member of CHCS
Full list of our strategic partners can be found on our website.

CLIENTS

Due to our confidentiality agreements and the nature our business, we do not release the identity of our customers. We do serve from SMEs to globally well know, NYSE listed, chemical enterprises.

TESTIMONIALS

References can be provided upon request as far as our agreements with our clients' permits.

CASE STUDY 1: Registering products with an appointed representative

A biocidal product producer based in the EU was having problems registering and marketing their biocidal products in Turkey, due to their former sales agent's using their formula and trade name for registering the product. As the regulation doesn't allow a second product to be registered with the same trade name, that former registration was preventing our client registering and marketing their product in Turkey. We applied to the competent authority about the case and proposed that they ask for an appointment letter to be confirmed by Turkish consulates at the registered locations of the manufacturer, to prevent such dispute cases. The competent authority accepted our proposal for general implementation principle. and we successfully registered our client's products as a representative independent from the supply chain. Unauthorised registrations of the former registrant were rejected.

STAFF SELECTION

Melih Babayigit – General Director – SDS Lecturer and Author and Classification Expert

Babayigit has 20 years of experience in the chemical industry and for the last ten years he has been particularly focused on global and emerging regulations on chemicals. He has been one of the leading key experts in Turkey in the field of hazard communication and product compliance. He is an appointed consultant to the competent authorities for PPP and biocidal product registrations schemes. He is regularly published in industry magazines including Chemical Watch and is a highly sought after speaker at regulatory events. He is a member of CHCS and a certified SDS trainer and author.

Bulent Özdemir – BSc-Biolog-MSc OHS SDS Author and Classification Expert

Bulent Özdemir holds the academic degree of MSc in biology. He has 20 years' experience in the chemical industry. After joining the CRAD in 2007 he has focused on risk assessment and hazard communication about chemicals. Mr Özdemir serves as an expert in the classification of chemicals, and the generation of safety data sheets with multidisciplinary approach. He is a certified SDS trainer and author and Certified H&S expert.

Other members of the CRAD team

In order to provide multidisciplinary services to our clients we formed a team of competent experts with academic and industrial experience and experience in several fields such as; Mr Mehmet Yolcu (BSc chemistry, certified H&S expert), Ms Sevgi Tan (BSc chemistry), Ms Havva Bilgili (BSc chemistry), Ms Büşra Tarakçı (BSc chemistry), Ms Elif Koç (BSc chemistry), Mr Harun Sevim (BSc environmental engineering), Mr Nazım Erdoğan (BSc environmental engineering), and all are certified SDS authors with a range of experience from three to eleven years.

cyprotex
AN EVOTEC COMPANY

CONTACTS

Website	www.cyprotex.com
E-mail	enquiries@cyprotex.com
Head office	Cyprotex, Alderley Park, UK
Tel	+44 (0) 1625 505100
Fax	+44 (0) 1625 505199
Contact	Brent Gilbert (b.gilbert@cyprotex.com)
Directors	Dr Werner Lanthaler (CEO Evotec) Dr Cord Dohrmann (CSO Evotec) Dr Mario Polywka (COO Evotec) Enno Spillner (CFO Evotec)
Ownership	Evotec AG
Locations	UK, US
Founded	1999

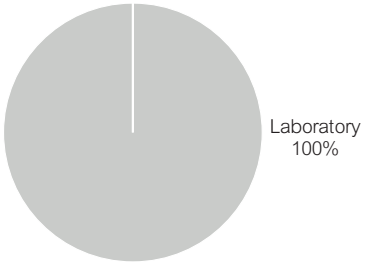
OVERVIEW

Established in 1999, Cyprotex specialises in ADME-Tox and has laboratories in the UK and the US. We have expertise in a variety of *in vitro* dermal, ocular, endocrine and genotoxicity assays in addition to a range of standard ADME and *in vitro* systemic toxicity assays. Our services are used by the cosmetics and personal care industries, agrochemical, industrial and household chemical manufacturers, and pharmaceutical and medical device companies. Many of our assays are used in support of labelling (CLP / GHS) and product registrations (REACH, TSCA, cosmetics regulations, pesticide regulations), as well as pharmaceutical development and approval (IND / NDA). Our facility located in Kalamazoo, MI, US offers many OECD compliant services under GLP and non-GLP conditions. Endocrine disruption assays can be performed in accordance with US EPA OCSPP requirements, or are also available as screening assays. Our sites in Watertown, MA, US and at Alderley Park, UK can also support *in vitro* ADME and *in vitro* systemic toxicity studies.

VITAL STATISTICS

	2015/16
Turnover, group	~ £16 m (2015)
Turnover, chemical service provision	~ £1.4 m (2015)
No of offices	3
No of countries represented	Global
Staff, group	~150
Staff, chemical service provision	~30

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

UK (Alderley Park)
USA (Watertown, MA & Kalamazoo, MI)

SERVICES PROVIDED

In vitro skin sensitisation package

Cyprotex offers an *in vitro* skin sensitisation package which covers the three key events of the adverse outcome pathway (AOP). The assays, which are also available individually, are:

- the Direct Peptide Reactivity Assay (DPRA, OECD 442C) for key event 1
- KeratinoSens™ (OECD 442D) for key event 2; and
- the human Cell Line Activation Test (h-CLAT, OECD 442E) for key event 3

Cyprotex also developed SenCeeTox® which is suitable for testing insoluble compounds or formulated products, as it utilises a 3D skin model for testing.

In vitro skin models

Cyprotex offers *in vitro* test methods for assessing skin irritation (OECD 439) and skin corrosion (OECD 431) using reconstructed 3D skin models, and skin absorption (OECD 428) using *ex vivo* human skin. We also offer the 3T3 NRU test for assessing phototoxicity (OECD 432) and dermal phototoxicity testing using a 3D reconstructed skin model (ZEBET). Cyprotex have a number of different systems for evaluating skin metabolism.

In vitro eye models

Cyprotex offers the reconstructed 3D EpiOcular™ model for assessing eye irritation (OECD 492) and the Short Time Exposure (STE) test for serious eye damage or ocular corrosion using the SIRC cell line (OECD 491).

In vitro genotoxicity

Cyprotex offers a range of regulatory and screening assays to assess genotoxicity including the Ames test (OECD 471), the *in vitro* chromosomal aberration test (OECD 473), and the *in vitro* micronucleus test (OECD 487).

Endocrine disruption

Assessment of potential endocrine disrupting chemicals (EDCs) can be performed to US EPA OCSPP and GLP specifications, or under efficient non-GLP screening conditions. The available tests include oestrogen receptor binding, androgen receptor binding, oestrogen receptor transcriptional activation, steroidogenesis, aromatase, androgen receptor transactivation and androgen receptor modulation.

In vitro toxicology

Cyprotex offers a wide range of mechanistic and organ-specific *in vitro* toxicology services. We have methods for assessing respiratory irritation, vaginal irritation, oral irritation, hepatotoxicity, cardiotoxicity and neurotoxicity.

In vitro ADME

Our ADME services include a broad variety of assays to evaluate metabolism, permeability (including transporter interactions), distribution (protein binding), and bioanalysis using LC-MS/MS and gas chromatography.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2010	Acquired Apredica, LLC
2011	Awarded EPA ToxCast™ Contract
2014	Acquired business and assets of CeeTox
2015	BioNow company of the year
2016	Society of Toxicology best publication award (Medical Device Category) Acquired by Evotec AG

ACCREDITATIONS

Studies can be performed under GLP
OECD-compliant methods available

PARTNERS

We work with a number of different partners to expand the range of services which are available to our clients.

CLIENTS

Cyprotex works with a range of different sized clients from SME's through to large multinational corporations. We serve a number of different industries, including the chemical, pharmaceutical and biotech, pesticide and cosmetics and personal care industries.

TESTIMONIALS

Available on request

CASE STUDY 1: Supporting the US EPA's ToxCast project

In 2011, Cyprotex was awarded a contract by the US EPA to support the ToxCast™ (Toxicity Forecaster) project. ToxCast™ is an initiative administered and maintained by US EPA which utilises high-throughput screening methods and computational toxicology approaches to rank and prioritise chemicals. Accumulated ToxCast™ data is part of the Toxicity Testing in the 21st Century (Tox21) initiative which is comprised of publicly accessible information on over 10,000 chemicals. Cyprotex supports the ToxCast™ programme by the provision of services such as steroidogenesis, metabolic clearance, permeability, and protein binding. Cyprotex was also heavily engaged in the US EPA's Endocrine Disruption Screening Program, having validated 5 of the *in vitro* assays used as an initial step to identify compounds that may interfere with various targets related to endocrine function. These services, performed in accordance with EPA test guidelines as well as in a screening format, continue to be contracted by Cyprotex customers for screening and regulatory purposes.

CASE STUDY 2: Development of an *in vitro* 3D skin sensitisation model for testing formulated products

Cyprotex has developed an *in vitro* assay (SenCeeTox®) that is able to identify test materials that may initiate the type IV hypersensitisation reaction. Most *in vitro* assays are limited to specific solvents, which can be a challenging hurdle when a highly insoluble test material is presented. The advantage of SenCeeTox® is that it utilises a 3D reconstructed skin model which is compatible with a wide range of solvents. In addition to work completed with finished cosmetics, formulations and mixtures, Cyprotex, in conjunction with a world-class developer of medical devices, was able to show that the SenCeeTox® assay could identify potential skin sensitisers that may be present in the extracts from these medical device products. Therefore, the assay may be a suitable substitute for the Local Lymph Node Assay or Guinea Pig Maximisation and Buehler Tests.

CASE STUDY 3: Development of a new screening method for endocrine disruption

In response to the growing need for the identification of compounds able to alter the function of the endocrine system, Cyprotex has developed a methodology to identify substances that inhibit or accelerate key steps in the steroidogenic pathway. A well-validated cell line used to identify substances that ultimately perturb synthesis of the sex steroids testosterone and 17β-estradiol was chosen for these studies, Cyprotex, in conjunction with a partner laboratory, have developed a methodology that can be used to analyse alterations in the synthesis of key intermediate steroids, such as cortisol and DHEA, in addition to testosterone and 17β-estradiol. As well as identifying potential hazards associated with exposure to endocrine-active compounds, this service has been contracted by biotechnology and pharmaceutical companies that are attempting to identify substances that alter this pathway in order to treat endocrine-related diseases.

STAFF SELECTION

Director of Operations

Each Cyprotex site has a Director of Operations who is responsible for the management of all aspects of the operations at the individual facility.

Study Directors

Highly experienced PhD level scientists who manage the GLP and non-GLP studies in the laboratory.

Quality Assurance Auditor

Independent monitor of GLP studies performed at Cyprotex.

Head of ADME

Leads the ADME function at Cyprotex and is responsible for the planning, implementation and delivery of the full range of standard and customised ADME services to our clients in addition to internal R&D projects.

Head of Toxicology

Leads the toxicology function at Cyprotex and is responsible for the planning, implementation and delivery of standard and customised *in vitro* toxicology services to our clients in addition to internal R&D projects.

DEKRA

CONTACTS

Website	www.chilworth.co.uk www.dekra-insight.com
E-mail	info-uk@chilworthglobal.com
Head office	Phi House, Southampton Science Park, Southampton, SO16 7NS, UK
Tel/ Fax	+44 (0) 23 8076 0722/ +44 (0) 23 8076 7866
Contact	Dr David Firth, Mr Daniel Baker, Mr Jochen Dettke
Directors	DEKRA SE
Ownership	Wholly owned subsidiary of DEKRA SE
Locations	Worldwide
Founded	1925 (DEKRA)

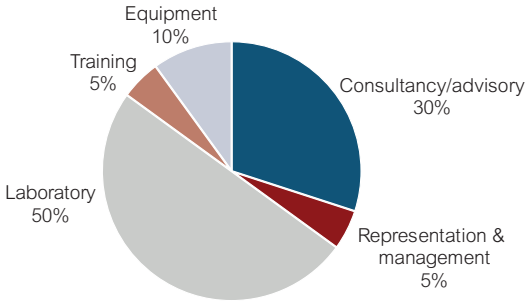
OVERVIEW

In process safety, data is everything. Our comprehensive testing services – from dust explosion and chemical reaction hazards to electrostatic properties and thermal stability – help your teams create safe operating parameters with precision and certainty.
We provide comprehensive engineering and advisory services, from explosion risk analysis to safety measure selection and design. Our professionals are proven thought leaders, thoroughly experienced in what to look for and how to find it. Combined with our world-class laboratory testing services and a global base of experts fluent in local codes, standards, and cultures, we help you gain the knowledge and information needed to protect your operations from risk.

VITAL STATISTICS 2015/16

Turnover, group	€2.5bn
Turnover, chemical service provision	€700m
No of offices	30+
No of countries represented	80+
Staff, group	35,000+
Staff, chemical service provision	500+

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

DEKRA SE, Handwerkstr 15, D-70565 Stuttgart, Germany

SERVICES PROVIDED

Process safety management – consulting

Process safety management is the bedrock of excellence in process safety performance. Our global teams of PSM specialists provide the experience, knowledge and insight to support you with all the elements of your PSM programmes, whether they are concerned with process hazard assessment, risk analysis, mechanical integrity, commitment to process safety, learning from experience or management of change. Whatever the maturity level of your PSM programmes, we can help you:

- design and create relevant PSM programmes;
- support your company in implementation monitoring and sustainability;
- correct and improve deficient programmes; and
- audit PSM programmes, comparing with best practices worldwide.

Process safety engineering – specialist consulting

Implementing process safety programmes requires specialised skills and competencies. Process safety excellence requires technical and management proficiency – sometimes in-house and sometimes called in to respond to a specific requirement or unique situation.
Whatever your specialist technical needs, we have the skills and breadth of experience to support your business. Whether you are carrying out a process safety review, implementing safety audits or ensuring compliance with standards or regulations, we have the up-to-date resources and skills to complete the task. If you require help with problem solving or incident investigation, you can rely on impartial advice and support from our experienced team whenever you need it.

Process safety information – laboratory testing

Good process safety practice demands a thorough understanding of the hazardous physical and chemical properties of materials you process. However, we recognise that data alone is rarely useful – it is the interpretation of the data and its implication for your plant that really makes a difference.
We can manage your entire materials testing requirements, offering a turnkey service that not only collects data through rigorous experimentation and testing but also interprets and reports the results. Our global network of testing facilities gives your business full access to cutting-edge techniques and dedicated laboratory testing teams. We offer more than 300 standard testing procedures, as well as the research capability to conduct unusual or complex customised testing.
The result is an expert and trusted service that not only delivers quality controlled results, but removes the pressure on resources, continuity and compliance associated with in-house testing.

Material testing

Our laboratories in the UK can handle powdered materials, gases or vapours, even if they are toxic or highly active and can offer a fast turnaround service if required. We strive to ensure only essential testing is undertaken, that our reports are comprehensive and meaningful, and that specialists are on hand to provide expert advice on the interpretation of results. We pride ourselves on providing a broad range of fire and safety services; including fire risk assessments.

Laboratory testing

Our CPE teams provide laboratory testing data with expert consultancy, for the identification and assessment of exothermic reaction hazards, thermal stability screening, reaction and adiabatic calorimetry, runaway simulation, engineering solutions and emergency vent design (DIERS). Laboratory testing services also available include:

- explosivity, CRH and exothermic chemical reactions, fire and thermal instability and consulting and testing for energetic material assessment, propellants, pyrotechnics and explosives.

Regulatory testing

Our services include the complete range of physico-chemical tests required for European regulatory purposes. Through our colleagues at DEKRA, we can also provide expert testing for:

- physico-chemical analysis;
- RoHS testing;
- REACH SVHC candidate list substance testing;
- materials testing;
- product testing, eg toys, food contact materials, etc.

Both REACH and CLP require information to be put into an MSDS data sheet. Our range of laboratory services from our GLP compliant testing laboratory enable compliance and regulation for:

- aerosols, explosives and oxidisers;
- pharmaceuticals and agrochemicals;
- biocides and plant protection products;
- explosives and oxidisers; and
- transportation of dangerous goods following the UN Manual of Tests and Criteria (CLP, ADR, IMDG, Iata etc).

Process safety training

Sharing knowledge is what we do; it is our guiding principle. By sharing our expertise, we develop long-term customer relationships that give the in-depth understanding required to achieve excellence in process safety engineering and its management. We offer a range of structured courses, taught by our team of leading experts, which train, educate and develop skills for a range of audiences, including:

- individual and team training;
- company-wide training to a consistent standard; and
- global group training to a consistent corporate standard.

The Process Safety Academy offers the most specific and relevant training of its type in the world, delivered globally in multiple languages across a comprehensive range of platforms and media. Ways to learn include:

- in-company courses tailored for your industry or company – and to different levels;
- open public courses – delivered to a global standard;
- internet-based learning programmes; and
- broadcast and interactive webinars.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1986	Foundation of Chilworth Technology Ltd.
1991	Chilworth Technology Inc established in US.
1995	Received Good Laboratory Practice accreditation.
2001	IChemE safety and environmental awards winner.
2003	Chilworth goes global; capabilities established in France, Italy and India.
2008	Chilworth acquires Spanish facility.
2009	Acquired JCI, the UK's electrostatic measurement experts.
2011	Wholly acquired by DEKRA, Europe's leading safety provider.
2013	New office and laboratory open in Shanghai and a new office for the Netherlands and Benelux.
2015	Merged with sister companies to create the service unit DEKRA Insight

ACCREDITATIONS

Good Laboratory Practice (UK); ISO9001 (UK); OHSAS18001 (UK); ISO 17025 (US)

CLIENTS

We work with a number of multi-site, blue-chip clients in a variety of processing industries including the petrochemical, chemical, pharmaceutical, food, drink, paper and packaging, plastics and rubber, agrochemical, automotive, aerospace and power generation sectors.

TESTIMONIALS

Testimonials can be provided on request.

CASE STUDY 1:

Our Chemical Process Evaluation laboratory worked intensively with development chemists at a global producer of pharmaceuticals to characterise a range of materials' stability limits and examine the thermodynamics and kinetics of the formation reaction and subsequent steps of the process. Using a range of techniques, we were able to identify onset conditions for the decomposition and ensure that safe process temperatures were established and respected across the process whilst quantifying runaway reaction scenarios and determining emergency relief system requirements for the identified scenarios using DIERS methods for two-phase relief – ensuring a safe system of work was validated and documented.

CASE STUDY 2:

Supporting a global manufacturer and marketer of differentiated chemicals, we tailored an extensive portfolio of tests of a diverse selection of materials under both REACH and CLP criteria were established and respected across the process whilst quantifying runaway reaction scenarios and determining emergency relief system requirements for the identified scenarios using DIERS methods for two-phase relief – ensuring a safe system of work was validated and documented.

CASE STUDY 3:

Cooperating with a number of service providers from Europe to the Far East, we have carried out a range of physico-chemical properties testing for REACH registration of products across a broad range of applications, while acting as study managers for a range of toxicology and ecotoxicology test programmes.

CASE STUDY 4:

DEKRA operates the hazardous substance use clearance for a big producing company in the automotive sector for more than ten years now.

All new substance requests of R&D, as well as of production, are processed by DEKRA experts. They check the product's classification and the occupational conditions during use. Approval will only be granted if all hazards are under control. Here, quick reactions are just as important as responsible expert decisions. Through this business process outsourcing, the client benefits from high availability, flexibility and scalability of our expert resources.

STAFF SELECTION

Dr Stephen Rowe – Regional Director – Process Safety EMEA

With more than 20 years' experience in process safety, Steve has particular expertise in chemical reaction hazards testing, exothermic reaction hazards consulting and dust, gas and vapour flammability testing and consulting programmes.

Dr David Firth – Global Sales Director – Process Safety

Covering all areas of process safety, David has many years of experience working with customers in a variety of industries including chemicals, pharmaceuticals, agrochemicals, paint, polymers, adhesives, electronics, fuel additives, synthetic fibres and many others.

Mr Daniel Baker – Laboratories Manager – Process Safety EMEA

Responsible for the management of our laboratories, Daniel has more than a decade of experience in testing and project management and brings a wealth of knowledge on regulatory test requirements. As a qualified DGSA, he provides guidance on the implication of results on classification of products.

Mr Jochen Dettke – Head of REACH Registration Team in Germany

A product manager at DEKRA Assurance Services GmbH – based in Stuttgart, Jochen heads up the REACH registration team in Germany, providing consultancy and testing advice from portfolio optimisation, through data acquisition and into dossier preparation. He also supports with occupational safety and hazardous substance management.

CONTACTS

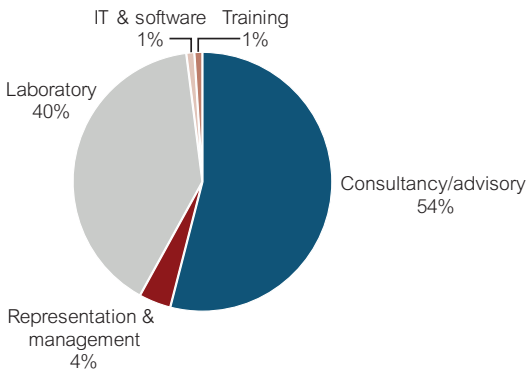
Website	www.dhigroup.com www.tox.dhigroup.com
E-mail	jet@dhigroup.com
Head office	Agern Allé 5, DK-2970 Hørsholm, Denmark
Tel	+ 45 4516 9200
Fax	+ 45 4516 9292
Contact	Jens Tørsløv, Head of Projects
Directors	Antoine Labrosse, Chief Executive Officer Arne Rasmussen, Chief Financial Officer
Ownership	Private, Not-for-profit organisation
Locations	30 worldwide offices and operations
Founded	1964

OVERVIEW

DHI is a global and independent consulting and research organisation within the fields of water, environment, health and toxicology. To ensure product safety and mitigate environmental risk, we assess the impact of products and processes on humans and the environment. Our extensive knowledge in this field provides support to authorities and industries around the world. Our expertise in risk assessment, chemicals regulation, toxicology and ecotoxicology help the industry make critical decisions about chemical substances, assist it in complying with regulations on health, safety, and prepare applicable documentation for registrations etc. Our integrated approach combines chemical consulting and profound insight in regulatory requirements with leading edge IT solutions and a top professional laboratory.

VITAL STATISTICS	2016/17
Turnover, group	€119 m
Turnover, chemical service provision	€10 m
No of offices	30
No of countries represented	43
Staff, group	1,112
Staff, chemical service provision	56

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Australia, Austria, Brazil, Brunei, Bulgaria, Canada, China, Czech Republic, Denmark, France, Germany, Hungary, India, Indonesia, Italy, Malaysia, New Zealand, Norway, Peru, Poland, Romania, Singapore, Slovak Republic, South Africa, Spain, Sweden, Turkey, UK, US, Vietnam.

SERVICES PROVIDED

REACH and regulatory compliance services globally

DHI provide expert services within registration of chemicals in the EU and at a global scale. We offer our customers a one stop solution for regulatory services worldwide:

- guidance and strategic counselling on chemicals legislation and registration tasks;
- preparation of registration dossiers, safety assessments and testing strategies integrating use of non-test methods as Qsar and read-across; and
- strategic decisions on substances of very high concern, application for authorisation, analysis of alternatives and SEA.

DHI offers to facilitate Siefs and consortia, third party representation and only representative (OR) services.

Product stewardship, regulatory services and software tools

DHI facilitates company specific GHS strategies for global companies as well as classification and labelling of chemical substances and mixtures. Preparation of safety data sheets, exposure scenarios and tools for chemical management, SDSs and exposure scenarios. Training courses and webinars offered in CLP, SDS, exposure assessments and related areas. Provider of chemicals management systems and content for SDS software including worldwide lists on classification, substance names, exposure limits, CAS numbers, phrase modules with 4,500+ phrases in more than 40 languages.

Environmental laboratory

The DHI GLP certified environmental laboratory offers:

- OECD ecotoxicological studies in water, sediment and soil;
- standard and tailored tests on biodegradability, ecotoxicity, endocrine disrupting effects and bioaccumulation of chemicals;
- whole effluent testing of offshore and other discharges; and
- testing under the scheme for pharmaceuticals according to the European Medicine Agency (EMA).

Biocides and pesticides

DHI offers regulatory and documentation assistance for both industry and authorities:

- preparation of dossiers on biocidal active substances, biocidal products and biocidal product families;
- preparation of dossiers on active substances and plant protection products;
- exposure assessment and risk assessment for human health, animals and the environment;
- data search, information retrieval, data gap analyses;
- toxicological evaluations;
- ecotoxicological tests; and
- phrasing of claims, notifications and expert reports.

Medical devices, pharmaceuticals and cosmetics

Within medical devices, cosmetics, medicinal products, veterinary and herbal medicine, DHI supports industry and authorities with human and environmental risk and safety assessments and documentation. Services include data screening, literature searches, evaluation of biocompatibility, comparative evaluation of materials/toxicity, Qsar for prediction of toxicological effects of chemical substances, preparation of cosmetic dossiers, safety assessments (CPSR with database) and selection of tests in accordance with ISO 10993 and regulatory services (EMEA, FDA, ISO 10993, ICH).

Food and feed safety, drinking water

Regulatory advice, and safety or risk assessments of novel foods, food contact materials, dietary supplements, food and feed additives, contaminants, naturally occurring toxins, technical processing aids, whole foods and drinking water.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1964	Danish Hydraulic Institute (DHI) founded
1973	Approved as Authorised Technological Service Institute by the Danish Minister for Higher Education and Science
1982	VKI laboratory accredited by DANAK, the Danish Accreditation Fund
1989	VKI laboratory authorised to carry out test in compliance with the OECD principles of GLP
2000	Designated as a resource centre for the Global Water Partnership
2001	Merge with VKI Institute for the Water Environment
2004	Designated the United Nations Environmental Programme (UNEP) Collaborating Centre for Water and Health
2005	Merge with Danish Toxicology Centre (DTC) and establishment of the Environment and Toxicology unit.
2016	Offices in 30 countries around the world

ACCREDITATIONS

DHI works in accordance with the quality management system standard:

- ISO 9001 as certified by Bureau Veritas.

Ecotoxicology tests:

- in accordance with ISO 17025; accredited by DANAK – the Danish Accreditation Fund;
- in compliance with the OECD and Principles of Good Laboratory Practice (GLP).

PARTNERS

Consultancy: KIST-Europe (Korea).
Software supplies: ECOonline; Knauf; Radiometer; InterSolia AB.
DHI Environment and Toxicology is engaged in a R&D partnership aiming at innovative solutions in the chemicals area.

CLIENTS

DHI Environment and Toxicology provide regulatory compliance services to a range of industries and industrial organisations within chemicals and metal industry, pharmaceutical and medico. We have a strong foothold in Korea together with our Korean Partner, KIST.

TESTIMONIALS

Specific references can be provided to potential clients upon request.

CASE STUDY 1: European biocidal products Regulation (BPR) approval of ECA Consortium for active substance

Within a short timespan, DHI assisted 15 companies with formation of the ECA Consortium – a non-profit association dedicated to promote the use of ECA (Electro Chemical Activation) technology. DHI assisted in the communication between the European regulatory bodies (EU Commission and Echa – the European Chemicals Agency), the ECA Consortium and member state authorities. DHI also prepared data gap analysis, quantified a detailed cost analysis study and completed an active substance dossier containing more than 250 endpoints including a thorough exposure and risk assessment. The dossier was submitted before deadline and subsequently approved by Echa resulting in all members and associated members of the ECA Consortium successfully listed as approved biocidal active substance and product suppliers under Article 95 list of BPR which sets the legal basis for placing active substances or products on the market in the EU.

CASE STUDY 2: Registration in South Korea (K-REACH)

DHI has joined a partnership with the Korean Institute of Science and Technology (KIST) and offers access to Korean speaking specialists in K-REACH. Our services include OR representation by a Korean partner based in Seoul. Via the partnership DHI offers compliance with K-REACH including the yearly updates of notification of chemical substances and preparation of registration dossier.

STAFF SELECTION

Jens Tørsløv, PhD – Head of Projects

Extensive experience as project manager with references within REACH registration and CSR, analysis of alternatives, industry strategy on SVHC and application for authorisation. Jens Tørsløv joined the management team of Department of Environment and Toxicology DHI in 2007 and plays a key role in coordination and marketing of the REACH services. He has more than 25 years' experience providing services to industry and authorities on environmental and human risk assessment of chemicals, industrial pollution control, capacity building. A position by the Commission (ECB, Ispra) during the years of preparation of REACH gave a solid background within the REACH legislation and its practical implementation.

Helle Westphal, MSc, Pharmacy – Head of Department

Expert knowledge of European chemicals REACH legislation and broad knowledge on other parts of the European regulation related to chemicals, cosmetics etc. Helle Westphal has 25 years of experience in strategic and practical consultancy in health and environmental issues, including development and implementation of chemicals management systems and cleaner technologies in a number of companies. Toxicological risk assessments and a good general knowledge of the European environmental regulation. 20 years of management experience.

Michael Fink, MSc, Biology – Senior Expert

Biocidal regulatory expert specialised in how industry can maneuver according to the requirements of the BPR and the associated regulations. He has evaluated toxicological risk assessments, human exposure scenarios and efficacy of dossiers on biocides on behalf of both the authorities and industry. He is highly experienced in providing strategic advice for industry in planning cost efficient authorisations of biocidal products and biocidal product families. Experience in managing consortia and highly skilled in negotiating with Echa and member state authorities.

Poul Bo Larsen, MSc, Pharmacy – Chief Toxicologist

Has more than 25 years' experience in regulatory toxicology and human health risk assessment of chemicals/chemical pollutants. Has been employed at the Danish Technological Institute, the Institute of Toxicology at the National Food Agency and for more than 14 years at the Danish EPA. Participated as a national expert on human health risk assessment of chemicals in various working groups at national level in OECD and the EU including the Risk Assessment Committee at Echa. Has worked with regulation and assessment of hydrocarbons and with the EU risk assessment document and regulation and assessment of manufactured nanomaterials within EU and OECD.

Anja Kamper, MSc, Biology – Lead Biologist, Ecotoxicology and testing

Has extensive experience within ecotoxicological and biodegradability testing of chemicals in aquatic and terrestrial systems, managing and performance of laboratory studies according to OECD Principles of Good Laboratory Practice (GLP), quality assurance and quality control of laboratory activities. Furthermore, she has experience in environmental risk assessment and classification of chemicals and products.

doruksistem
Kimyasal Yönetim Sistemleri
Chemical Management Systems

CONTACTS

Website	www.doruksistem.com.tr and www.treach.com.tr and www.msds.com.tr
E-mail	info@doruksistem.com.tr
Head office	Itri Dede Sokak No:17 DorukSistem Building Kızıltoprak Kadikoy, 34725 Istanbul, Turkey
Tel/ Fax	+90 (0) 216 337 8383/ +90 (0) 216 337 9027
Contact	Selcuk BILGIN (selcuk.bilgin@doruksistem.com.tr)
Directors	Selcuk BILGIN – CEO / Founder Isil ERTUNCAY – General Coordinator Baris NAIM – Regulatory Compliance (RC) Department and (TR & EU) REACH Department Manager Mehtap VURAL – Process Safety (PS) Department Manager
Ownership	Incorporated company
Locations	Turkey
Founded	2005

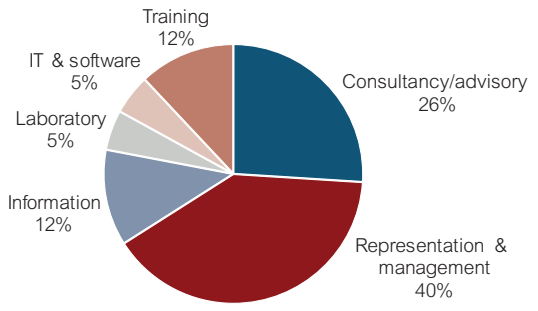
OVERVIEW

DORUKSISTEM Engineering Technology and Consultancy Co Inc was established in 2005 to guide and lead the chemical industry, industrial chemicals, cosmetics manufacturers, pesticide agrochemicals and biocidal products registrants, grower/commodity groups, trade associations, exporters, importers and chemical process industry to compliance with Turkish, EU and global regulations and in dealing with issues that affect their ability to do business effectively.
DORUKSISTEM consultants have been involved in the preparation of vulnerability analyses, including the evaluation of regulatory, quality control, and business systems, and the development of standard operating procedures, global regulatory models, and compliance manuals and programmes.
With a strong presence in Turkey, DORUKSISTEM has provided cost-effective regulatory support and testing services to many valued companies while doing businesses in both the EU and Turkey.
DORUKSISTEM is the most experienced leader consultant company in Turkey and your partner on the way of TREACH (KKDIK).

VITAL STATISTICS 2015/16

Turnover, group	> €3m
Turnover, chemical service provision	-
No of offices	2
No of countries represented	12
Staff, group	35
Staff, chemical service provision	25

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

DORUK SİSTEM AS, KIZILTOPRAK KADIKOY ISTANBUL, TURKEY
DORUK SİSTEM AS, MARTEK/TUBITAK GEBZE, KOCAELI, TURKEY
We support our clients in all countries globally.

SERVICES PROVIDED

REACH (TREACH / KKDIK) services

DORUKSISTEM's consultants have significant experience in the provision of a wide range of REACH and TREACH support to our clients. These services include initial work such as regulatory strategy and advice, data evaluation and the use of intelligent testing strategies, followed by study placement and monitoring. We prepare and submit registration dossiers and chemical safety reports including exposure assessments and if necessary risk characterisation. We also provide post-submission support during evaluation and authorisation phases, including completion of authorisations applications.
DORUKSISTEM has significant experience in Turkish chemical regulations and project management and Sief and consortia management and we can also act as your only representative (OR) registrant or third party representative in Turkey.
Visit our web page www.TREACH.com.tr

CLP (SEA) and SDS (GBF) services in Europe and Turkey

- Identification of obligations under the CLP Regulation
- Implementation of strategy for CLP compliance
- Classification and reclassification of substances and mixtures in accordance with the CLP Regulation
- Safety data sheets-SDS (GBF) authoring and review
- CLP notifications dossiers / CLP-group notifications dossiers

Biocides and agrochemicals services in Turkey

- Identification of obligations under the Turkish BPR
- Implementation of strategy for Turkish BPR and agrochemicals product regulations compliance
- Preparation of dossiers (approval of active substances and authorisation of biocidal products) and submission
- Turkey representative
- Data gap analysis
- Studies / tests / reports (physico-chemical properties, efficacy,
- Environmental fate, ecotoxicology and toxicology)
- Risk assessments
- Liaison with authorities and post-submission support
- Classification and labelling of biocides according to the SEA/ CLP
- Creation and review of TREACH compliant safety data sheets

Process safety

Risk analysis and management

Industrial risks:
- preliminary hazard analysis;
- hazard assessment;
- safety reports and EPD (Seveso, explosives regulation);
- quantitative risk assessment;
- risk based land-use planning;
- accident investigation.

Process hazard analysis (PHA):
- HAZOP (hazard and operability analysis)
- LOPA (layer of protection analysis)
- "What if"
- FMEA (failure mode and effects analysis)
- HAZID (hazard identification analysis)
- process safety in accordance with applicable standards

SIL analysis (safety integrity level)
Reliability, availability and maintainability studies
- reliability centered maintenance (RCM)
- risk based inspections (RBI)

Safety and emergency planning and management

Process safety management
Comprehensive safety audits
Safety management systems (sms)

Regulatory safety inspections

Seveso and Atex regulations implementation

DORUKSISTEM can assist you with assessing, designing and permitting of storage facilities for hazardous chemicals, modelling of external safety (Seveso) and assessing aspects such as explosion safety (Atex).

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2005	DORUKSISTEM founded in Istanbul, Turkey.
2006	DORUKSISTEM launched leading edge solutions for authoring and managing production quality and R&D management systems for the chemical process industry.
2007	DORUKSISTEM completed more than 50 TSE/TSEK certification for the Turkish chemical industry.
2008	MSDSMARKET is established and published on www.msdsarket.com.tr
2010	DORUKSISTEM Head Office opened. More than 4,500 CICL (Chemical Inventory Control Legislation) notifications completed for several global companies.
2011	DORUKSISTEM awarded ISO 9001 by Bureau Veritas.
2012	Process safety department established.
2013	Process safety business collaboration with INERCO started.
2014	More than 35,000 SDSs completed according to Turkish SDS legislation (DSD/DPD/CLP) in total.
2015	DORUKSISTEM R&D Technology branch opened at Tubitak Research Complex ın free zone Martek Kocaeli Area.
2016	DORUKSISTEM approved as an associated member of ORO, the Only Representatives Organisation

ACCREDITATIONS

DORUKSISTEM is an associated member of ORO, the Only Representatives Organisation
DORUKSISTEM is a member of ICI, Istanbul Chamber of Industry
DORUKSISTEM is member of ICC, Istanbul Chamber of Commerce
DORUKSISTEM is a member of SRA, the Society for Risk Analysis
DORUKSISTEM works in accordance with the quality management system standard: ISO 9001 as certified by Bureau Veritas
DorukSistem is a member of American Chemical Society

PARTNERS

INERCO, Spain, TWI – The Welding Institute, Cambridge, UK, IHS, USA, REACH ITEGRA, Spain, REACH ChemAdvice GmbH, Germany, EXPONENT, UK, CHEMADVISOR, USA, NEXREG, Canada, CIRS, China, SCAS, Japan, NAM & NAM, Korea, CIS, Russia, SIAM Chemeter, Spain, CGE RISK, Holland, MAXGRIP Holland

CLIENTS

DORUKSISTEM clients are involved in many businesses, including industrial, basic, specialty, agricultural, and biocidal chemicals, biotechnology, nanotechnology, cosmetics, fibres; iron and steel, tyres, paints and coatings; plastic products; and chemical manufacturing, warehouse and logistics companies, as well as from manufacturing industry, formulation, distribution and consumer product sectors. Our clients include: Honeywell, Cargill, Ashland, Air Products, Ihs, Lyondellbasell, Cancarb, Cerfrit, Buckman, Albesiano, Vonnroll, Cortec, Cray Valley, Croda, Cytec, Sealed Air, Dow Agro Sciences, Dunlop Adhesives, IMCD, Gazprom, Hemel, Ineos, Kafrit Group, Kg Chemicals, Kodak, Laviosa, Metro Groups, Novartis, Phiilsa, Aygaz, Kardemir, Toros Fertiliser, Tata, Rütgers, Struktol, Sensient, Showa Denko, Siemens, Tetra Chemicals, Thermphos, Tournaire, Ube Industries, Uralchem, Mane, Yamalube, Morgan Plc, Knauff, Shell, Zeon and more.

TESTIMONIALS

Specific references can be provided to potential clients upon request.

CASE STUDY 1: Ashland Inc notification of the substances under Turkish CLP (SEA)

Ashland Inc had an issue with notification of their substances (>450) under Turkish CLP (SEA). The deadline for the notification of the substances was 1 June 2015. As their OR, the regulatory compliance process of Ashland had to be accomplished perfectly by us. For that purpose, all exported products to Turkey by the company were studied, and cross-checked against the classification of the substances with the data of Turkey's Ministry of Environment and Urbanism. And finally, all dangerous substances were successfully notified to the ministry's system. This allows Ashland to continue to sell its products on the Turkish market via its Turkish distributors.

CASE STUDY 2: Honeywell SDS compliance project

Honeywell International, Inc is one of the biggest chemical suppliers in Turkey as well as in the whole world. The 13 December 2014 regulation was published in the Official Gazette. This methodises Turkish SDSs. All Honeywell products exported to Turkey must have Turkish SDSs in compliance with the regulations. Compliance is needed because, literal translations of the SDSs are not sufficient to legitimise them. Unlike other countries, Turkey's system demands that the declaration of the SDSs competent author's name and his/her certificate number be included. Unless having taken training ending with an examination and succeeding it, it is not possible to prepare SDSs according to Turkey's SDS Regulation. So, to the present day more than 250 SDSs have been generated for Honeywell and 3,000 more are in process within the scope of their SA project. They are all revised when necessary, regenerated after the regulation changes and kept up to date. All previously prepared labels of those products are revised too according to SEA (Turkish CLP).

CASE STUDY 3: CICL overview in Turkey

The regulation of CICL (Chemical Inventory Control Legislation) was published on 26 December 2008. Since then more than 4,500 notifications have been completed for several global companies. Notifications are done to the online system of MoEU as CICL notifications. Companies assign us to be their OR to complete their CICL notifications, together with the other regulatory compliance processes. CICL (KEK) demands substances are declared by calculating the average tonnage for the last three years of their exports to Turkey. This process is repeated every three years.

STAFF SELECTION

Doruksistem RC – Regulatory Compliance team

DORUKSISTEM RC team members are highly competent and have great experience in the field of chemicals regulation throughout the whole product lifecycle, including but not limited to chemicals identification, hazard classification, risk assessment, RSP, SDS and labelling creation. Our specialists always have up-to-date information on national and international chemical control and related legislations.

Doruksistem PS – Process Safety team

DORUKSISTEM PS have experienced team of professionals and specialists in all areas of Industrial safety and risk prevention to meet the challenges of the industrial safety and risk management, as well as providing technical assistance to ensure safety levels are consistent with its business, the environment and compliance to regulatory requirements.

Doruksistem Rdt – R&D Technology team

DORUKSISTEM RDT team is a highly competent and concentrated team in the field of quantitative structure–activity relationship models (Qsar models), regression or classification models used in the chemical and biological sciences and engineering.

knoell worldwide registration

CONTACTS

Website	www.knoell.com
E-mail	info@knoell.com
Head office	Dynamostraße 19, 68165 Mannheim, Germany
Tel	+49 (0)621-718858-0
Fax	+49 (0)621-718858-100
Contact	Dr Michael Cleuvers
Directors	Dr Hans-Emil Knoell Dr Runar Eberhardt Torsten Hauck Dr Marika Suhm-Tintelnot Dr Michael Cleuvers
Ownership	Private company, majority-owned
Locations	Germany, UK, Switzerland, the Netherlands, Spain, Portugal, France, China, Thailand, US, Japan, Korea
Founded	1996

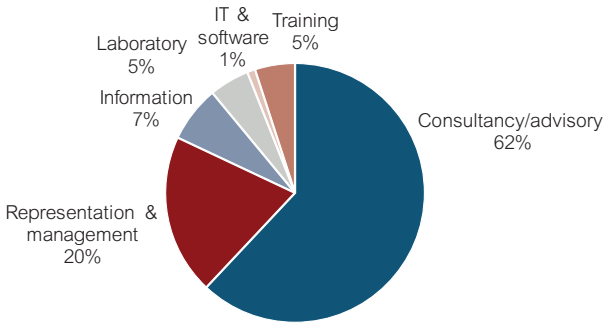
OVERVIEW

We are a full service provider in global regulatory affairs for industrial/ specialty chemicals, agrochemicals, biocides, pharmaceuticals, veterinary medicine and medical devices. Additionally we offer a wide range of services in the field of product safety (eg preparation of (extended) safety data sheets, classification and labelling of substances and mixtures). We will work with you to ensure that your products are in compliance with the latest developments, not only in Europe (EU and non-EU), but also in the US, Canada, South America and the entire Asia-Pacific region (China, Taiwan, Japan, Korea, Australia, and the entire Asean region). With a global network of subsidiaries and co-operation partners, we match our services to support your business needs.

VITAL STATISTICS

	2016/17
Turnover, group	> €60m
Turnover, chemical service provision	> €20m
Number of offices	17
Number of countries represented	12
Staff, group	approx. 600
Staff, chemical service provision	>180

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Dr Knoell Consult GmbH, Mannheim, Germany
Dr Knoell Consult GmbH, Berlin, Germany
Dr Knoell Consult GmbH, Leverkusen, Germany
Knoell NL BV, Wageningen, the Netherlands
Dr Knoell Consult Ltd, Cardiff, UK
Knoell Iberia SL, Madrid, Spain / Knoell Iberia SL, Lisbon, Portugal
Dr Knoell Consult Shanghai Ltd, Putuo, Shanghai, China
Dr Knoell Consult Schweiz GmbH, Basel, Switzerland
Dr Knoell Consult Thai Co Ltd., Chiang Mai, Thailand
Cyton Biosciences Ltd, Bristol, UK
Critical Path Services, LLC, Garnet Valley, PA, US
Critical Path Services, LLC, Research Triangle Park, NC, US
Critical Path Services, LLC, Carrolton, TX, US
Knoell France SAS, Lyon, France
Knoell KK, Tokyo, Japan
Knoell Korea Ltd, Seoul, Republic of Korea

SERVICES PROVIDED

Global registration of industrial and specialty chemicals

Dossier preparation and submission: Iuclid 6 files for REACH, TSCA registration including PMN support, registration dossiers for Canada, Korea, China, Taiwan, Japan and the Asean countries. Toxicological and ecotoxicological hazard and risk assessment, exposure modelling, post-submission support, communication with authorities, OR- and TPR-services, and full consortia management. Data review and analysis: strategic advice regarding testing and registration strategies, *in silico* methods (Qsar), read-across and waiving strategies), literature searches, data evaluation, data gap analysis, and study monitoring.
Product stewardship: classification and labelling under GHS, CLP, and Osha HazCom; development and management of safety data sheets (SDSs) and extended safety data sheets (eSDSs); supply chain management and communication; management and support of formulators and article manufacturers concerning regulatory compliance in their global markets.

Global registration of agrochemicals and biocides

Strategic advice and consulting, literature research, data evaluation, data gap analysis, completeness checks, study management and monitoring. Dossier preparation, biological efficacy, residues and metabolism, import tolerance dossiers, dietary safety, toxicology, human exposure, exposure modelling, PEC-reports, environmental risk assessment, ecotoxicology, study-monitoring and management of bee studies, endocrine disruptors and CADDY-dossiers.

Medical devices, pharmaceuticals, cosmetics

Classification of medical devices, support in CE-marking (class I, IIa, IIb, III including consultation), FDA clearance/authorisation (510(k), PMA), CMDR registration (CMDCAS), Taiwanese registration (TCP II, ISO 13485), Australian registration (TGA), biological safety assessment, review technical file, biocompatibility testing strategy and supervision of test (including justified waiving), material characterisation including toxicological evaluation, clinical evaluation, pre- and post market vigilance/safety, implementation and review of QM system (ISO 13485/MDD/IVDD/IAMD and/or QSR), review and preparation risk management file, auditing (internal, pre-regulatory, supplier), training.
Non-clinical/ pre-clinical services for human pharmaceuticals (study management, toxicology, pharmacology, metabolism, pharmacokinetics, bioanalysis, biosafety testing), medical writing (eg expert opinions, study reports), registration of cosmetics (INCI-listing, labelling etc), food and food additives, food contact materials, registration of substances in contact with drinking water.

Animal health products (pharmaceuticals, immunologicals, feed additives)

Our animal health consultancy service provides specialist multi-disciplinary technical expertise in quality, safety and efficacy, as well as regulatory affairs for a wide range of product types, for example pharmaceuticals (active substances and finished products), immunologicals, feed and feed additives, borderline products and general care products. We can assist clients at any stage of their project – from product development and clinical testing, through the authorisation procedure and to maintenance of product licences. Within the EU, we

can also provide pharmacovigilance, quality assurance, and key person cover services for clients. Our team comprises veterinarians, chemists, toxicologists and regulatory experts.

Analytical laboratory services

Crop protection and agrochemicals: magnitude of residue, terrestrial field soil dissipation, and environmental fate studies including hydrolysis, adsorption/desorption, and soil and aquatic metabolism/transformation. Method validations and method development.
Biotechnology: LC–MS/MS, ELISA, and other methods.
Industrial chemicals: trace level analysis in ground, drinking, and waste waters; polymers and product contaminants; Pharmaceuticals and medical devices: single and multi-dose GLP studies; GLP bioanalytical PK/TK in plasma, serum, and tissues with experience in humans and animals.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1996	Foundation, Mannheim, Germany.
2002	Office in Leverkusen, Germany.
2007	Foundation of Dr Knoell Consult Switzerland GmbH, Basel.
2009	Establishment of Knoell Academy for training and in-house seminars covering all our fields of expertise.
2009	Foundation of Dr Knoell Consult Ltd, in Cardiff, UK.
2009	knoell contributed to more than 100 dossiers for plant protection products.
2010	knoell prepared biocide dossiers for 25 active substances (56 products in 15 product types).
2010	Opening of a new office in Wageningen (NL).
2010	Acquisition of Cyton Biosciences Ltd, Bristol, UK.
2010	Extension of regulatory affair services to Japan and Asia/ Pacific region.
2010	Foundation of Dr Knoell Consult Shanghai Ltd, in China.
2010	Successful preparation of more than 400 REACH dossiers and more than 100 chemical safety reports.
2010	knoell has been appointed as institution for the training of experts in toxicology.
2012	Foundation of Dr Knoell Consult Thai Co. Ltd, in Thailand.
2012	Opening of a new Office in Berlin, Germany.
2013	Foundation of Knoell Iberia SL, in Madrid, Spain.
2013	Acquisition of Critical Path Services, LLC, based in Pennsylvania, US.
2013	Acquisition of Shotwell & Carr, LLC, Carrolton, Texas, US.
2014	Opening of a new office in Lisbon, Portugal.
2014	Foundation of Knoell France, SAS, Lyon, France.
2014	Opening of environmental fate laboratory, in addition to already existing analytical and bioanalytical laboratory, at Critical Path Services, Pennsylvania, US.
2015	Acquisition of Sitmae Reach Services (now renamed to Knoell NL B.V.).
2016	Foundation of Knoell K.K., in Tokyo, Japan.
2016	Foundation of Knoell Korea Ltd., Seoul, Republic of Korea.

ACCREDITATIONS

Qualified Cefic – partner.

PARTNERS

SCAS Japan, SCAS Europe, Ibacon, Currenta, Tier3 solutions, Biotek, Cekindo, BST Business Science & Technology, RPhG Russian Pharmalicensing Group, AnaPath GmbH, DG Specialtiy Inc.

CLIENTS

We deliver flexible services to globally acting chemical companies as well as to small- and medium-sized enterprises. We work on- and off-site to support our customers' specific local needs.

TESTIMONIALS

The Spanish Ministry of Environment described our dossier for a wood preservative as, "the best organised and well-done dossier in comparison with the rest of dossiers received from other companies."
Additional testimonials can be provided on request.

CASE STUDY 1: Global notification of chemicals

knoell managed to perform notifications for several substances simultaneously in China, Korea and Japan. By preparing a robust testing and notification strategy, we have been able to find synergies and to limit the testing costs. To achieve this, we established a project team including experts in regulatory affairs, chemists, toxicologists, ecotoxicologists, and Qsar-specialists.

CASE STUDY 2: Agrochemicals

knoell successfully managed the submission of an AIR 2 dossier (Annex-I renewal procedure) on behalf of a task force of almost 30 member companies spread worldwide. knoell wrote and compiled all study summaries, risk assessments, and dossier chapters. knoell also developed and maintained a strong relationship with the authorities to whom the dossier was submitted. The project was well-recognised by the client and the authorities. The team consisted of over 50 individuals who dedicated themselves to this project for two years. Follow-on work is on-going and entails the development of national product dossiers for the respective active ingredient.

CASE STUDY 3: Biocides

knoell has not only supported the approval of many active substances at an EU level but has also successfully supported the introduction and authorisation of numerous biocidal products in multiple markets within the EU according to the respective regulatory requirements. Currently we are working on several biocidal product family dossiers with a multitude of PT's and products/metaSPCs. For products that fall into the scope of both BPR and other legislations such as that covering veterinary pharmaceuticals and cosmetic products, synergies were quickly realised on such borderline cases due to our expertise. In Asia and Latin America, we had to face the lack of a uniform legislation regulating biocidal products. Therefore we first had to define the applicable specific legislation to which the biocidal product was subject, and then we prepared the local product registration. Based on our experience in both EU and non-EU countries, label claims are key to the registration/ authorisation process and can make a huge difference in how a product is considered by an authority.

STAFF SELECTION

Toxicology > 45 toxicologists
Regulatory affairs agrochemicals/biocides 30 specialists
Ecotoxicology > 40 ecotoxicologists
Dietary safety >20 specialists
Product safety specialists (C&L, MSDS preparation) > 60 specialists
Global regulatory affairs for chemicals > 30 specialists
Consortium management, OR, TPR > 25 consortium managers
Residues and metabolism > 20 specialists
Environmental fate and risk assessment > 60 specialists
Efficacy, biological dossiers > 30 specialists
Human pharmaceutical experts >20
Medical Device evaluation, testing and certification >10
Animal health experts >20

EAG LABORATORIES | WE KNOW HOW™

CONTACTS

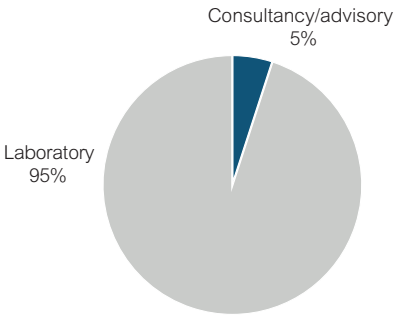
Website	www.eag.com
E-mail	info@eag.com
Head office	4747 Executive Drive, San Diego, CA, US
Tel/ Fax	+1-800-366-3867
Contact	Kristein King
Directors	Siddhartha Kadia, PhD, Chief Executive Officer
Ownership	Private company
Locations	China, France, Germany, Japan, Singapore, Taiwan, US
Founded	1978 (as Charles Evans & Associates)

OVERVIEW

EAG Laboratories is a global scientific services company that provides testing, analytical and characterisation services to technology and life science-related industries. We've brought together the most respected brands in environmental science to offer chemical companies a better choice for contract research services. With over 140 years of combined experience, EAG companies (formerly known as Wildlife International, PTRL West, PTRL Europe and ABC Laboratories) deliver the full range of aquatic, avian and terrestrial toxicology and other environmental testing services required by global agricultural, pharmaceutical, consumer product and chemical industries.

VITAL STATISTICS	2015/16
Turnover, group	US$250m
Turnover, chemical service provision	~$100m
No of offices	23
No of countries represented	7
Staff, group	1,200
Staff, chemical service provision	~500

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

China, France, Germany, Japan, Singapore, Taiwan, United States

SERVICES PROVIDED

Environmental fate and biodegradability testing

Unparalleled experience in the identification and quantification the fate of test substances in soil, water and other complex environmental matrices, complemented by in-house radiolabeling and structural elucidation expertise biodegradation screening and testing (OECD 301, 310, 314, 303 etc). Environmental fate testing (OECD 307, 308, 309, 106). All these studies can be performed including metabolite identification. Specific expertise in the context of REACH is in the field of biodegradability screening and simulation testing.

Endocrine disruptor screening and testing

Further specific expertise lies in the field of endocrine disruption screening and testing, We have in-house histopathology services to evaluate the potential of chemicals to affect endocrine-sensitive tissues in fish, amphibians and frogs.

Sediment toxicity and terrestrial plant testing

Testing and study design expertise in terrestrial and aquatic plant testing and evaluation of products to sediment dwelling organisms. Greenhouse facilities provide ample space for testing multiple species and advanced study designs. Sediment testing includes freshwater and marine acute and chronic tests.

Ecotoxicology testing

We offer the full suite of acute and chronic aquatic and terrestrial toxicology services required to assess the acute and chronic effects of chemicals on amphibians, earthworms, honeybee and select non-target insects, as well as freshwater and saltwater invertebrates and fish in an AAALAC-accredited, GLP-compliant environment, and are capable of supporting a large number of concurrent studies.

Avian toxicology

One of the largest and most respected avian toxicology laboratories in the world, we offer unparalleled skill in performing avian acute and reproduction studies, as well as the ability to develop and conduct specialty studies designed to meet client-specific needs.

Residue analysis

Unparalleled method development know-how in the challenging discipline of residue chemistry, along the full complement of ground and surface water monitoring, dislodgeable foliar residues, magnitude of residue analyses, as well as worker and domestic exposure studies

Radiolabelling and custom synthesis

Expert ^{14}C and ^{3}H radiolabelling of active ingredients for metabolism, environmental fate and effects testing; custom synthesis of active ingredients and metabolites and impurities – with dedicated in-house analytical for GLP-certification of materials

Dermal absorption/percutaneous absorption testing

Testing outlined in OECD 427 (*in vivo* studies in rodent models) and OECD 428 (*in vitro* studies using human and animal skin), which are often performed in parallel to predict dermal absorption in humans (sometimes called 'the triple pack' or 'parallelogram' approach).

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1978	Established as Charles Evans & Associates
1987-2010	Expanded operations in US, Europe and Asia
April 2012	Acquired PTRL West and PTRL Europe
Dec. 2012	Acquired Wildlife International, Ltd.
July 2015	Acquired ABC Laboratories

ACCREDITATIONS

Good laboratory practice (GLP) – multiple inspections by EPA with no findings

CLIENTS

- Agricultural chemicals
- Basic, industrial and specialty chemicals
- Pharmaceutical and biopharmaceuticals
- Biocides
- Consumer products
- Animal health
- Food and feed
- Medical devices
- Aerospace/Defence
- Technology
- Law/litigation (Intellectual property and product liability)

CASE STUDY: Glyphosate: fish short term reproduction assay (FSTRA) with the fathead minnow (Pimephales promelas) – a paper presented at SETAC US 2012, S. Schneider et al, Wildlife International

The objective of this assay was to determine if glyphosate might impact the hypothalamus-pituitary-gonadal (HPG) endocrine axis resulting in the disruption of reproduction in fish. Breeding groups of fathead minnows (Pimephales promelas) were exposed to glyphosate under flow-through conditions at mean measured concentrations of 0.046, 0.23, 1.2, 6.2 and 33mg ae/L for 21 days. Endpoints that were evaluated for endocrine disruption of the reproductive system included fecundity, fertility, secondary sex characteristics (including tubercle and fatpad scores), gonadosomatic index (GSI), histopathology of gonads, as well as plasma vitellogenin. Other endpoints included survival, general observations of health, weight, and length. There were no apparent effects on survival, growth, reproduction, secondary sex characteristics, GSI, VTG or gonad histopathology in male or female fish exposed to glyphosate for 21 days. Based on the endpoints evaluated, glyphosate does not appear to impact the function of the hypothalamuspituitary-gonadal (HPG) endocrine axis in fathead minnows.

STAFF SELECTION

Henry Krueger, PhD – Vice President, Toxicology

Director of aquatic toxicology with our Easton, Maryland site (formerly Wildlife International) since 1995, Dr Krueger is esponsible for all aspects of the aquatic toxicology programme including fish and amphibian endocrine disruptor studies. Expert aquatic toxicologist, with specific expertise in bioaccumulation testing sediment toxicology testing and endocrine test design, conduct and interpretation.

Timothy Springer, PhD – Director of Special Projects

Dr Tim Springer manages special projects and technical support. He was responsible for the development of the abbreviated *in vivo* fish bioconcentration test. Dr Springer has played a critical role in the revision of the OECD guideline 305, and in development methods to estimate BCF values using data from BMF studies.

Edward Schaefer – Director of Fate and Biodegradation

Mr Schaefer has more than 20 years of experience in the area of degradation and environmental fate testing. Responsible for study design and oversight of testing programmes. Key contributor to development of EPA/OECD test guidelines – specifically OECD guideline 314.

David Dohn, PhD – General Manager

With more than 35 years' experience in the environmental testing arena, Dr Dohn is an expert in plant, animal, and soil metabolism studies for pesticide registration, biochemical toxicology, designing regulatory packages for pesticide registration in North America and Europe.

Jon Rhodes – Senior Scientific Advisor

Mr Rhodes brings more than 25 years of perspective on successful scientific and regulatory approaches to new product development and existing product support activities, with particular expertise in the regulatory requirements for assessing the impact on non-target organisms.

James Schmidt – Senior Scientific Advisor

Mr Schmidt offers three decades of experience in xenobiotic metabolism and bio-analytical chemistry, and has special interests in agrochemical environmental fate and metabolism, metabolic stability, metabolite profiling and identification, chiral separations, and pharmacologically active metabolites.

EBRC Consulting GmbH

CONTACTS

Website	www.ebrc.de
E-mail	info@ebrc.de
Head office	Raffaelstraße 4, 30177 Hannover, Germany
Tel	+49 511 898389 0
Fax	+49 511 898389 10
Contact	Torsten Grewe
Directors	Dr Rüdiger V Battersby
Ownership	Privately owned
Locations	Germany
Founded	1993

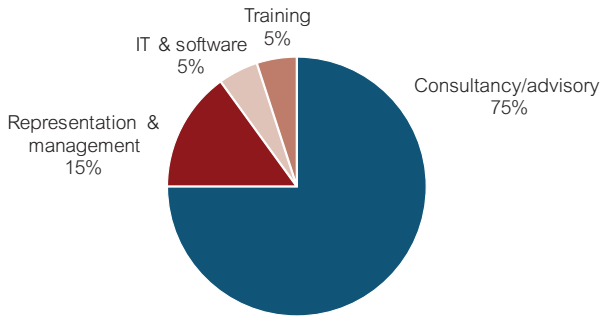
OVERVIEW

EBRC is a privately-owned consulting organisation based in Hannover, Germany, providing consulting services with a focus on chemical, biocidal and agrochemical industries. Specialised scientific experience is available in all key disciplines relevant for product safety with respect to human health and environment. Task force management and coordination of industry consortia is another important aspect of our work.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	58
Staff, chemical service provision	33

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

EBRC Consulting GmbH
Raffaelstraße 4
30177 Hannover
Germany

SERVICES PROVIDED

Industrial chemicals – REACH

EBRC offers comprehensive scientific, regulatory and administrative support on industrial chemicals, including:

- data gathering, literature searches, and evaluation;
- data gap analysis, closing of data gaps, and study monitoring;
- chemical safety assessment (CSA) and report (CSR);
- PBT and vPvB assessment;
- technical dossier (Iuclid 5 and 6);
- identification of known uses;
- development of exposure scenarios for HH and ENV;
- risk characterisation;
- classification and labelling;
- safety data sheets;
- consortium and Sief management; and
- preparation of CLH dossiers

Agrochemicals

Active substance approval and national product registration.
EU notification of active substances governed under regulation (EC) No 1107/2009:

- support of existing substances in the context of the renewal programme of the EU (AIR);
- support of new active substances;
- completeness checks, validation of existing studies, literature surveys; and
- full dossier preparation including risk assessments, literature search report, submission and defence of dossiers in the review and evaluation process.

Product registration dossiers for national authorisations in EU member states including zonal dossiers:

- all dossiers (dRRs) for registration and re-registration of plant protection products, label extensions and formulation changes;
- services include compilation of all required documents, conduct of exposure and risk assessments, biological dossiers, advice in closing data gaps, the supervision of experimental studies, as well as submission of the application to competent authorities and attendant contacts / services during the registration process;
- previous experience (among others) includes herbicides, fungicides, insecticides, rodenticides, nematicides and growth regulators.

Biocides

EBRC provides experienced support for all key phases of the evaluation and registration process of biocides.
Dossier preparation and defence in the regulatory process both for active substances and biocidal products are our primary services.

- active substances (Inclusion into the BPR list of approved substances (Reg. (EU) No 528/2012))
- biocidal products (registration/authorisation in EU member states)
- task force/consortia management;
- evaluation of substances – as specified for industrial chemicals and agrochemicals above.

Special services

EBRC has in-house experienced scientific support for a wide range of statistical services:

- statistical (re-)evaluation of data;
- implementation of EU-models and/or scenarios (eg as given in OECD emission scenario documents);
- ready-to-use spreadsheet solutions for various applications (eg substance specification);
- probabilistic exposure assessments;
- derivation of species sensitivity distributions; and
- Bayesian approaches for (occupational) exposure assessments.

Based on long-term involvement in major EU risk assessment projects,

EBRC is very familiar with handling extensive databases, including:

- importing and (re-)structuring of data;
- online generation status update reports; and
- provision of web-interfaces for data-entry and analysis.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1993	Foundation of EBRC (initial staffing: six people)
2016	Continual growth, leading to a current staff count of 58

CLIENTS

A wide range of companies producing agrochemicals, biocides and industrial chemicals and/or formulated products.

CASE STUDY 1: MEASE

On behalf of EUROMETAUX, EBRC developed a tool for the estimation and assessment of occupational exposure (MEASE) which combines approaches from the EASE expert system, from the TRA tool and from the health risk assessment guidance for metals (HERAG). It represents a widely-used first tier screening tool for occupational inhalation and dermal exposure to metals and inorganic substances.

CASE STUDY 2: HERAG (Health Risk Assessment Guidance)

With its extensive background in metals risk assessments, EBRC was contracted from 2005-2007 by the European Metals Industry to compile a guidance document for the human health risk assessment of metals and inorganic metal compounds. The HERAG documents provide guidance to the worldwide regulatory and scientific community on several aspects of risk assessment methodology for metals where classic tools developed for organics are not applicable.

CASE STUDY 3: RiCoG

The rigorous containment guide (RiCoG provides guidance to registrants of isolated intermediates on how rigorous containment (RiCo) of their intermediates can be assessed and documented according to the stipulations of regulation (EC) 1907/2006 (REACH). In an integrated assessment of SCC for an entire process (adopted from an approach published by Hirst et al. (2002)), RiCoG can be used to prioritise individual process steps requiring higher tier assessments, and provides an easy and structured way to assess and to document RiCo for the remaining process steps. Experts from various metals' industries have contributed with their practical experience to the development of RiCoG.

CASE STUDY 4: Development of standard handling frequencies of rodenticide baits

Due to the non-existence of robust figures describing the handling frequency of baits by professional pest control operators, EBRC was entrusted by the rodenticides industry to derive a suitable proposal. Data were collected from various (quite heterogeneous) sources (industry and pest control business) and analysed statistically. Based on this analysis, the European Commission and EU member states agreed on default bait handling figures which are the current standard for operator exposure assessment and have been a key prerequisite for including anticoagulant rodenticide active substances in Annex I of Directive 98/8/EC.

STAFF SELECTION

Rüdiger Battersby – Director

Dr Rüdiger Battersby is the founder and director of EBRC. After his PhD in biochemistry, he took up a position as manager of a contract research organisation in Hannover (IBR), from where he switched to EBRC. Apart from his responsibilities as managing director and principal coordinating toxicologist, he acts as supervisor for all of EBRC's agrochemical, biocidal and industrial chemical risk assessments. His professional expertise encompasses involvement in the German government's review programme (BUA) on existing chemicals, representation of industry consortia in RA conducted under the ESR programme (793/93) and at EU-TCNES level, as well as the conduct of several dozen occupational exposure surveys in various sectors of the chemical industry. Among other professional activities, he is an appointed member of the German Expert Gremium for Chemicals Safety of the German Chemical Society.

Arne Burzlaff – Senior Registration Manager Industrial Chemicals

Dr Arne Burzlaff graduated as a chemist (2000) and obtained a PhD in technical chemistry/biotechnology (2005). He worked for the German Federal Institute for occupational safety and health, Division for Chemicals and Biocides Regulation (2005-2007), on dossier evaluation for biocides, collaboration in EU working groups and scoping issues on borderline cases among legal frameworks. Since 2007 he has been working at EBRC as senior scientist/toxicologist. In this position he has been compiling REACH registration dossiers, with a focus on human health hazard assessment and risk characterisation, and initiation and monitoring of experimental studies on industrial chemicals.

Andreas Büsing – Senior Registration Manager Agrochemicals

Andreas Büsing graduated as a biochemist at the University of Hannover (1984). After years of experience in biochemical analytics with specific emphasis on the development and validation of immunoassays, he has been working at EBRC as registration manager for agrochemicals since 1999. His main responsibilities at EBRC include the co-ordination and supervision of dossiers for product registration and active substance approval under Regulation (EC) No 1107/2009, with focus on ecotoxicological risk assessments, data gap analysis and monitoring of experimental studies on active substances and plant protection products.

Silke Burger – Senior Registration Manager Biocides

Dr Silke Burger graduated as a biologist (2000) and obtained a PhD in molecular biology/toxicology (2004). Since 2006 she has been working at EBRC as registration manager for biocides.
In this position she has been compiling dossiers in support of active substances approval according to Directive 98/8/EC and BPR (Reg. (EU) No 528/2012) and registration of biocidal products with a focus on human and environmental exposure assessments and risk characterisations, and further initiation and monitoring of experimental studies on active substances and biocidal products.

Daniel Vetter – Senior Consultant Special Services

Daniel Vetter graduated as Dipl-Ing agr at University of Hannover (2003). His main responsibilities at EBRC include the development and implementation of novel statistical techniques in human health risk assessments. He developed MEASE, an assessment tool for occupational exposure providing first tier estimates of inhalation and dermal exposure to metals. As part of his current work, he incorporates probabilistic techniques into the HEC (human equivalent concentrations) approach.

CONTACTS

Website	www.ecoonline.com
E-mail	geir.falko@ecoonline.com
Head office	Trudvangveien 77, N-3117 Toensberg, Norway
Tel/ Fax	+47 33 01 68 00/ +47 33 01 68 01
Contact	Mr Geir Falkø, VP Sales and Marketing
Directors	Mr Øyvind Thorsen, CEO Mr Morten Floberg Evensen, CFO Mr Luis G Paulsen, VP Development
Ownership	Privately held, employees
Locations	Norway, Sweden, Finland, Denmark, Switzerland
Founded	2000

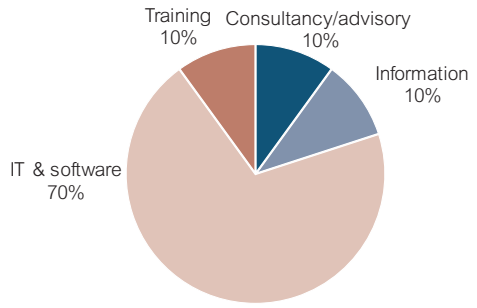
OVERVIEW

Leave paper and complexity behind. EcoOnline is offered as you would expect from a modern online service.
Connect directly online with your customers and suppliers in order to exchange, communicate and manage chemical information and SDS.
Try one of the most widely used services for SDS authoring, distribution, communication and chemical inventory management in Northern Europe.
EcoOnline has pioneered the industry since 2000, with more than 5,000 enterprises working in services online.
With solutions for handheld devices, QR codes, XML exchange and more, we are about to introduce even more features to ensure that our clients benefit from simplified work processes, flexibility and mobility, and a great user experience.
All parts of the platform are offered via the cloud. Connecting suppliers and downstream users online reduces time and costs involved in nearly all aspects of handling SDSs and managing chemical inventories. A device with a web browser and internet connection is the only requirement.
EcoOnline's services are available in 25 languages, and they are designed to meet your requirements for the REACH area. Working closely with our customers, leading consultants and members of industry, our aim is to become the most preferred platform for SDS communication and management in Europe.
We support open standards, and participate pro bono in development projects for XML and BIM (construction industry and building materials).
Try us before you make your decision! A team of 90 employees, and a network of highly qualified consulting partners are ready to give a demonstration and offer a test of the applications and benefits.
Welcome!

VITAL STATISTICS 2015/16

Turnover, group	€10 m
Turnover, chemical service provision	-
No of offices	6
No of countries represented	8
Staff, group	90
Staff, chemical service provision	-

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Norway
Sweden
Finland
Denmark
Switzerland

SERVICES PROVIDED

Cloud/online:

- SDS/eSDS authoring;
- SDS/eSDS distribution;
- SDS/eSDS database;
- chemical inventory management;
- workplace risk assessment;
- employee exposure tracking and storing;
- up and downstream reporting;
- supply chain communication;
- metadata and XML data exchange; and
- mobile applications.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2000	Founded by Mr Kjell Hamnes, long time industry professional with a vision to create the first and most widely used online platform for SDS communication and chemical inventory management. HQ in Tønsberg, Norway.
2001	Launched the first integrated online service.
2007	Opened office in Gothenburg, Sweden.
2011	Opened office in Helsinki, Finland.
2011	Launched leading edge solutions for authoring and managing exposure scenarios. Technical documentation and articles covered. Established representation in Germany.
2012	Ready with first mobile applications and XML comm modules. Established representation in Denmark, Iceland and Poland.
2013	Service for SMEs in the building and construction sector. QR code application for mobile
2014	More mobile applications, and new features
2016	Acquired ChemiControl and opened office in Denmark

PARTNERS

EcoOnline works closely with leading local, regional and international consulting partners in many different areas, including SDS authoring, substance inventory management, CLP, risk assessment, dossier preparations, authority notification and occupational health.
Work with us!

CLIENTS

Small and large, public and private, multinationals and locals, our clients represent most segments and industries.
More than 5,000 enterprises connect to the services.

TESTIMONIALS

We'll be happy to provide you with referrals that are relevant to you! Please contact us.

CASE STUDY 1: Automotive industry

- auto dealers and their suppliers connect directly.
- auto dealers and repair workshops get their SDS directly in their inventories, and reduce time spent on managing inventory and performing relevant tasks.
- suppliers reduce time and costs in distributing SDS.

CASE STUDY 2: Diagnostics manufacturer and their suppliers of laboratory products

- the diagnostics manufacturer is part of a large international corporation, with production sites and laboratories in many locations
- its suppliers upload the relevant SDSs directly to the diagnostics company's inventory.
- the diagnostics company can then use all the data from the SDS without having to re-enter them.
- all designated staff can work and share information in the same system, from any location.
- this improves communication, simplifies work processes, increases speed, and reduces time spent on relevant tasks.
- no installations are required, no local IT maintenance costs involved.

CASE STUDY 3: Universities, hospitals, municipalities, public institutions

- a majority of universities, municipalities, schools and hospitals in Norway are connected to the service.
- SDSs are uploaded directly to their inventories.
- all data in the SDS are immediately available for use, and automatically updated.
- the suppliers benefit from easy authoring and distribution of SDSs, and the service to customers is greatly improved.
- communication upstream to the supplier is simplified in the platform
- no local installations are involved, the entire service is available to all users over the internet.
- this saves time and money in the process of authoring, distributing and managing the SDSs and documentation..

CASE STUDY 4: Building and construction sector

- automated service enabling direct communication between materials supplier, construction company and building project.
- SDSs are automatically transferred to the inventory for the project
- saves time and workload for all parties.
- ensures all correct documentation is in place, including technical information and workplace safety.
- BIM to become integral part of overall delivery

STAFF SELECTION

Mr Kjell Hamnes – Founder and Product Evangelist

Mr Hamnes founded EcoOnline. He has pioneered the development of online tools for SDS authoring and management, and is a widely used resource by industry and authorities on the issues of legislation and compliance.

Ms Martina Jonsson – Product Management Sweden

Martina is CEO Sweden, and international product manager. She is a key figure in Sweden on the issue of REACH and SDS management.

Ms Line Weis Madsen – Product Management Denmark

Line is DEO Denmark. She advises Danish nationals and multinationals on chemical management.

Mr Pål Mørken – Product Management Norway

Pål serves as VP of services and training. He has a long and extensive career within chemical health and safety, and is trained OHS professional at Harvard.

Mr Ari-Pekka Kangasmäki – Product Management Finland

Ari is the leading authority on SDS authoring and inventory management, advising Finnish multinationals for over 20 years.

Mr Øyvind Thorsen – CEO

CONTACTS

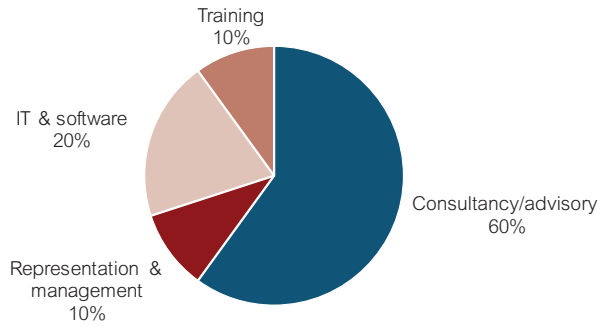
Website	www.erm.com
E-mail	rudolf.wilden@erm.com
Head office	Frankfurt: Siemensstraße 9, 63263 Neu-Isenburg, Germany
Tel	+49 6102 206-247/ +49 6102 206 202
Contact	Dr Rudolf Wilden, EMEA Product Stewardship Lead
Directors	430 Partners globally, including John Simonson (UK), Sarah Medearis (US), Samir Menon (US), Jen Whitney (US), Jo Lloyd (UK), Simon Aumonier (UK), Richard Elsmore (UK), Rudolf Wilden (Germany), Robert Janssen (Germany), James Leu (Taiwan)
Ownership	Private limited company
Locations	140
Founded	1971

OVERVIEW

Environmental Resources Management (ERM) is one of the world's leading providers of EHS and sustainability management, technical consulting and IT implementation services, with considerable experience in providing global product stewardship services. Global product stewardship (GPS) is positioned within ERM as a strategic growth initiative. ERM offers integrated product service across all divisions within the company. ERM has more than 150 professionals with extensive specific GPS experience located at various offices worldwide. These consultants are able to utilise the full resources of ERM globally to provide full back-up for all GPS-related services.

VITAL STATISTICS	2015/16
Turnover, group	$648m
Turnover, chemical service provision	$28m
No of offices	160
No of countries represented	40
Staff, group	> 5,000
Staff, chemical service provision	>150

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

We support our clients in all countries globally.

SERVICES PROVIDED

Product stewardship programmes

- programme development
- information management / IT enterprise sustainability systems
- auditing
- post-merger integration
- product due diligence

Global registration and authorisation of chemicals

- training/ impact assessments
- preparation of lead and member registration dossiers
- chemical safety assessments
- CLP notifications
- socio-economic analyses (SEA)
- analyses of alternatives (AoA)
- preparation of applications for authorisation
- Sief management

Global registration of biocidal actives and products

- regulatory support for both active substances and biocidal products
- experience of compilation and submitting active dossiers for a wide range of product types
- routine submission of national registrations

Global registration of agrochemicals

- extensive experience in the preparation, submission and regulatory support of dossiers and national draft registration reports
- excellent track record of successful approvals and national authorisations

Toxicology, ecotoxicology and risk assessment

Study placement/ protocol review and development, development of (robust) study summaries, review of data for classification purposes, EHS risk assessments.

Safety data sheet (SDS) authoring

Data collection /management, data entry/ review, classification support for chemical products and dangerous goods, safety data sheet and label authoring, SDS and label review and improvement

Global downstream product legislation, eg food contact

- food contact notifications
- compliance with country-specific legislation
- national registrations
- local/ regional registrations
- labelling and claims support

Lifecycle assessment and sustainability

- carbon footprinting and emission inventories
- lifecycle management (LCM) also to ISO14040
- design for environment (DfE)
- environmental product declarations (EPDs)
- lifecycle analysis (LCA)

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2016

- Acquisition of JSC
- Successful implementation of global chemical registration programmes including EU, US, Canada, China, South Korea, Japan, Philippines, AUS+NZ
- Completion of 10th REACH authorisation application

2015

- Acquisition of ReachCentrum leveraged expertise cross-regionally into Korea Reach programme support
- Successful development and implementation of targeted lifecycle sustainability programme at Sky TV

ACCREDITATIONS

ISO 9001 and ISO 14001

PARTNERS

Partner of Cefic, ACC, SAP, Lisam, Enablon, Sphera

CLIENTS

In the past five years we have worked for more than 70% of the Global Fortune 100 and more than 50% of the Global Fortune 500 companies.

TESTIMONIALS

"We have been working with the ERM team on REACH for a number of years now, and there are very good reasons to continue and expand this collaboration. Both on practical, communicative and technical-scientific levels ERM has provided us with active, solid and high-quality support for MSD's REACH programme. We are pleased to observe that our collaboration has turned into a true partnership." – Frits Wielaard, REACH programme manager, Merck Sharp & Dohme.

"ERM have provided support and advice for us throughout the pre-registration and registration phase of REACH and have always been totally professional, flexible and quick to respond to our needs. They provide an excellent service and we look forward to continuing our partnership with them in the years to come." – Steve Williams, Regulatory Manager Europe, Knauf Insulation.

"ERM has been Momentive's partner in the implementation of REACH since the beginning and has always provided the expert support we needed through the different stages of the project." – Ralf Maecker, Momentive Performance Materials.

CASE STUDY: Development and implementation of global chemical stewardship programme for Fortune 100 chemical distributor

ERM worked with the client to develop and roll out a comprehensive global chemical compliance programme which:

- addressed critical, immediate, non-compliance issues based on business risks and priorities;
- supported, as needed, the registration, notification and declaration of chemicals, polymers and biocides;
- benchmarked the clients programmes against its peers; and
- trained employees in applicable requirements and systems

A collective effort which has resulted in the development and implementation of chemical compliance programmes and systems which provide a framework for sustainable, consistent and dependable ongoing global operations.

STAFF SELECTION

John Phillips – Technical Director and Senior Chemist

Extensive experience in the development of global stewardship programmes, practices and systems that meet regulatory requirements and industry standards, facilitate global business growth and improve corporate reputation.

Dr Steven Peterson – Senior Ecotoxicologist

PhD in biological sciences with 20 years of experience in risk assessment, ecological research, environmental science with consulting firms, academic institutions and government.

Dr Alfred Wiedow – Senior Toxicologist, DABT

More than 35 years of regulatory toxicology experience from working in the chemical industry, a governmental agency and academic research institutions. He is a recognised scientist in the fields of human and ecological toxicology and risk assessments and has initiated over hundreds of toxicity studies covering many cradle to grave scenarios.

Dr Tim Barber – Principal Scientist

Dr Barber has more than 25 years of experience supporting the chemical industry with expertise in environmental geochemistry, fate and transport modelling, eco-toxicology, and risk assessment. He has evaluated environmental issues associated with down-the-drain disposal, biodegradation and sorption in wastewater treatment plants, and environmental risks associated with land-applied biosolids and discharge to surface water.

Dr Mark Lafranconi – Senior Toxicologist, DABT

DABT certified toxicologist with nearly 30 years in the industrial sector designing, implementing, interpreting, and reporting hazard and risk assessment studies for evaluating human health effects and risk management of chemicals used in consumer products.

Kathleen Sellers, PE – Technical Director

Assists clients in building and auditing global product sustainability programmes and fulfilling specific regulatory requirements for chemical registration and reporting, hazard communication, and other product compliance requirements. Recently published her fourth book, *Product Stewardship, Life Cycle Analysis and the Environment* (CRC Press 2015).

Christina Clement – Principal Scientist

More than 20 years of experience in regulatory compliance and toxicology, hazard communication, and environmental health and safety (EH&S). She offers proven experience in consulting on global regulatory compliance in the areas of Osha, GHS, CLP, TSCA, Fifra pesticide registration, and import/export of industrial chemicals and consumer products. A Six Sigma Black Belt familiar with numerous operating systems, such as SAP and Oracle.

Dr Elsie Millano – Technical Director

BSc in chemical eng and PhD in civil eng environmental area. Over 25 years of environmental consulting experience in human health risk assessments, including exposure assessments, fate and transport evaluations, and risk calculations.

Dr Cécile Rousseau – GPS Lead France+BeNe

MSc physical chemistry and analytical methods, PhD Environmental chemistry and modelling, with more than 12 years' experience in the chemical sector, competent authorities and product stewardship services for REACH-CLP and biocides.

Dr Dave Best, Technical Director

PhD in microbial biochemistry with more than 20 years in the chemical industry as an environment, health and safety manager. Senior expert in analysis of alternatives, socio-economic analyses, classification and labelling and REACH dossier compilation.

Dr Eunjae Shin – GPS Lead South Korea

PhD in chemical engineering with over 12 years of experience in chemical registration (TCCA, K-REACH, Osha), chemical regulatory review, and chemical management advisory services.

Hironori Takamura – GPS Lead Japan

Engineer with more than 15 years' experience in chemical regulatory consultancy as well as development and implementation of large-scale chemical information management systems.

Yajuan Pi – GPS Lead China

Ms Pi leads the China Product Sustainability team. She supported numerous clients with new substance notification, regulatory reviews and chemical compliance assessments since implementation of Decree 591.

Dr Eckhard Schäfer – Principal Consultant

Senior chemist with 30 years' experience in exposure assessments, chemical safety assessment, industrial hygiene and auditing.

Jennifer Hasel – Principal Consultant

Senior regulatory expert in the field of classification and labelling, SDS authoring, dangerous goods transport, occupational H&S & audit.

Martin Heß, Principal Consultant

Engineer with over 15 years' consulting experience in analysing and improving HSE and product stewardship business processes. He supports companies with implementation of management systems, audit programmes, training/ workshop programmes.

CONTACTS

Website	www.eurofins.com
E-mail	info-munich@eurofins.com
Head office	Brussels, Belgium
Tel	+49-89-899 650-0
Fax	+49-89-899 650-11
Contact	Dr Iris Pfisterer
Directors	Gilles Martin, Chief Executive Officer
Locations	250 locations worldwide, main offices for REACH services in Germany
Founded	1987

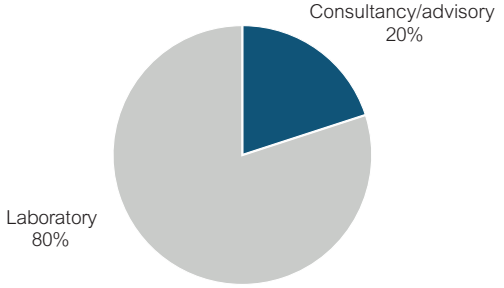
OVERVIEW

With more than €1.95bn annual revenues in 2015 and 25,000 employees in around 250 sites across 39 countries, Eurofins is the global eader in the pharmaceutical, food and environmental testing market and offers also an unparalleled range of testing and support services for the chemical, agrochemical, biocide and cosmetic product sectors.
As one of the most innovative and quality-oriented international players in its own industry, Eurofins is ideally positioned to support its clients´ increasingly stringent quality and safety standards and the demands of regulatory authorities around the world.
As a global service provider to the chemical industry, Eurofins offers a comprehensive range of testing and consultancy services. Our state-of-the-art and progressive laboratories are operated by highly skilled scientists and regulatory specialists who have many years of relevant experience and qualifications, and who can be flexible in relation to client needs. This enables us to support you with all steps of the regulatory processes for REACH, BPR, agrochemicals and cosmetics.
In vivo toxicology services are offered in cooperation with BSL Bioservice Scientific Laboratories Munich GmbH.

VITAL STATISTICS 2015/16

Turnover, group	>€1.95 bn
Turnover, chemical service provision	-
No of offices	>250
No of countries represented	39
Staff, group	>25.000
Staff, chemical service provision	-

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Eurofins is located globally in 39 countries. Our main testing facilities for chemical / REACH services are located in Germany.

SERVICES PROVIDED

For the chemical, agrochemical, biocides, cosmetics and food industry Eurofins offers a broad scope of biological safety studies, which meets the international regulatory requirements and includes the following services.

Toxicology for chemicals, PPPs, biocides and food additives

We cover all common toxicology services relevant for chemicals, plant protection products (PPP's) and biocides. This includes the classical *in vivo* studies from acute to repeated dose and teratogenicity studies. In addition, Eurofins puts a high emphasis on alternative *in vitro* testing strategies with regard to the 3R strategy for refinement, replacement and reduction of animal studies. We have established a big range of *in vitro* assays for all endpoints where this is possible yet.
Our services include:

- irritation/corrosion (*in vitro* / *in vivo*);
- sensitisation (*in vitro* / *in vivo*);
- dermal absorption (*in vitro* / *in vivo*);
- genetic toxicity (*in vitro* / *in vivo*);
- acute toxicity;
- repeated dose toxicity;
- reproductive and developmental toxicity (DART);
- toxicokinetics;
- carcinogenicity;
- neurotoxicity;
- endocrine disruptor testing; and
- mode of action studies.

Ecotoxicology and physico-chemical properties

Physico-chemical and ecotoxicology services including aquatic and terrestric studies as well as studies on biodegradation and environmental fate and behaviour are also part of our portfolio.

REACH services

With regard to REACH we can offer the full portfolio of studies, required for the different tonnage levels according to Annex VII-X of the REACH directive. Due to the large variety of chemicals tested for the REACH deadlines in 2010 and 2013 we are well prepared to effectively support you also for the 2018 deadline or NONS registrations.
Furthermore, as ECHA will continue with the evaluation of the registered substances and testing proposals, we are happy to perform those higher tier studies for you and support you in updating your dossier. Studies like 90-day toxicity (OECD 408) and reproductive and developmental toxicity (OECD 414) are performed at our facilities on a routine basis and we also offer the EOGRTS (OECD 443).

Endocrine disruptor testing

In response to the EPA announcement of the Endocrine Disruptor Screening Programme for pesticides, chemicals and environmental contaminants, we have established endocrine disruptor testing services and can offer the full Tier 1 testing battery.

In vitro safety testing for chemicals and cosmetics

- mutagenicity, clastogenicity, carcinogenicity
- skin and eye irritation/ corrosion – several models
- dermal absorption
- photo-induced toxicity
- reproductive toxicity (embryonic stem cell test)
- sensitisation – DPRA, hCLAT, Keratinosens (participation in a ring trial for another skin model)

Furthermore, for cosmetics Eurofins provides a complete service portfolio including *in vitro* toxicology, clinical safety studies, clinical efficacy studies and consumer research and sensory evaluation.

Regulatory services, testing strategies and individual study designs

With around 30 years of experience with regulatory studies, our team of scientists will provide you with expert advice not only for standard studies, but also for individual study designs and testing strategies, taking into account substance properties as well as interdependency of many studies required for example for REACH, cosmetics and agrochemicals In addition we are backed up by an experienced regulatory division within Eurofins that can support you regarding regulatory issues of chemicals, agrochemicals and biocides starting from data gap analysis until dossier and CSR preparation as well as post submission support.

SVHC and restricted substances under REACH

SVHC testing on products: laboratory testing provides information on SVHC substance identification and concentration to help companies meet their REACH SVHC obligations. By means of different analytical methods (GC/MS, ICP-MS,…), Eurofins can provide a comprehensive screening test of your whole product to ascertain if any substance in the candidate list is present in any of the components of the product.
BOM assessment: we can help to manage and monitor your supply chain by helping to collect BOM (bill of materials) from your suppliers. This information is essential in the process of controlling the occurrence of any SVHC through your supply chain. Based on BOM, and subsequent BOS (bill of substances) generation, our experts can help to assess your product and evaluate the likelihood of containing any SVHC in any of the components of the product, hence helping to save testing costs and focusing the analytical efforts on those specific components that would have been evaluated as risk materials
Restricted substances testing: Eurofins offers also a wide range of analytical tests to cover specific restricted substances under REACH Annex XVII. The substances listed under this Annex are specifically restricted in certain products and materials and for certain uses. That means, not all these restrictions may apply to your specific product.
Our experts will help to assess your product and propose a test plan to cover those tests that may apply to your article based on its use and its composition. Some of the tests included in our offer, within others: phthalates, PAHs, cadmium, lead, benzene, flame retardants, azo colourants etc.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1987	Foundation of Eurofins Scientific
	Continuous growth and aquisitions
1997	IPO on the French Stock Exchange
2008/09	Establishment of Eurofins REACH Services
2012	Change from Société Anonyme to Societas Europaea
currently	Global leader in the pharmaceutical, food and environmental testing market

ACCREDITATIONS

Good Laboratory Practice (GLP)
DIN EN ISO IEC 17025
Good Manufacturing Practice (GMP)
FDA approved
AAALAC Accreditation
Radioactive handling permission

CLIENTS

Chemical industry
Agrochemical industry
Biocides industry
Cosmetic industry
Food industry
Pharmaceutical/ biotech industry
Medical device industry

STAFF SELECTION

Dr Angela Lutterbach, Head of Testing Facility Eurofins Munich

Dr Angela Lutterbach has more than 25 years of experience working in the contract research industry. She started working at Eurofins Munich (formerly BSL BIOSERVICE) in 1995 as study director for safety toxicology and safety pharmacology and holds the position Head of Testing Facility at Eurofins Munich since 2001. Dr Lutterbach has a PhD in veterinary medicine and is a member in various expert groups.

Dr Marc Kunze, Scientific Director *in vivo* Toxicology

Dr Kunze studied pharmacy and toxicology and holds a PhD in medicinal chemistry and a master in toxicology. After several years at the university giving lectures on pharmacology and toxicology, he moved to the pharmaceutical industry. He specialises in non-clinical and clinical toxicology within drug development and risk assessment of chemicals. As Scientific Director *in vivo*, Dr Kunze acts as an internal and external consultant for all areas of toxicology. In addition he is responsible for preparation of study designs and project management of regulatory toxicological studies.

Dr Andreas Wais, Managing Director Eurofins Regulatory

After his Diploma in Chemistry and a PhD in agronomy, Dr Wais became scientific secretary of the senate commission on chemicals in agriculture of the German Research Council (DFG) in Bonn as a postdoc. From there he joined RCC in the mid 90's, heading the residue and field trials department. Having a huge number of client contacts, he was promoted to Project Leader of the in 2002 newly formed Business Unit Agro.
Key responsibilities: Studies and regulatory affairs. Dr Wais was then promoted to Global Director Business Unit AgroChemicals and Biocides. From June 2011 he changed his responsibility to the position of General Manager of Global Registration and Strategic Consulting.
In March 2012 Dr Wais left Harlan with most of the Agro regulatory team and became Managing Director of Eurofins Regulatory AG in Switzerland, offering agro/chemical and biocidal regulatory services. He has more than 25 scientific publications, more than 40 scientific lectures worldwide and presented more than ten scientific posters. He had scientific sojourn in Brazil at University of Sao Paulo (ESALQ and CENA in Piracicaba).

Dr Iris Pfisterer, REACH Manager

As REACH Manager at Eurofins, Dr Iris Pfisterer is dedicated to support our clients with all enquiries and questions about REACH and project manages large projects. This may include projects from data gap analysis via laboratory testing to the final dossier preparation. Dr Pfisterer holds a master's degree and PhD in biology and has supported our clients at Eurofins since 2009.

Francesco Gatti, Cosmetic Services

Francesco Gatti works for CROs since 2007, immediately after his degree in Biotechnology. During his carrier he held positions in technical sales and laboratory management. His area of expertise includes cosmetics, biocides, chemicals and pharmaceuticals.
Besides REACH, agrochemicals and biocides projects his work within Eurofins is focused on supporting cosmetic clients where Eurofins provides an extensive portfolio, from safety to sensory analysis.

Other staff

Our highly educated and experienced staff comprises a large proportion of scientists as well as regulatory experts with a wide variety of expertise. They will provide you with excellent services and are dedicated to meeting your individual needs with a high level of flexibility.

Exponent® International Limited

CONTACTS

Website	www.exponent.com
E-mail	jreddy@uk.exponent.com
Head office	The Lenz, Hornbeam Business Park, Harrogate, North Yorkshire, HG2 8RE, UK
Tel/ Fax	+44 (0)1332 868000/ +44 (0)1332 868099
Contact	Julian Reddy
Ownership	Wholly owned subsidiary of Exponent Inc.
Locations	Harrogate, Derby, London and Edinburgh, UK; Basel, Switzerland
Founded	2002

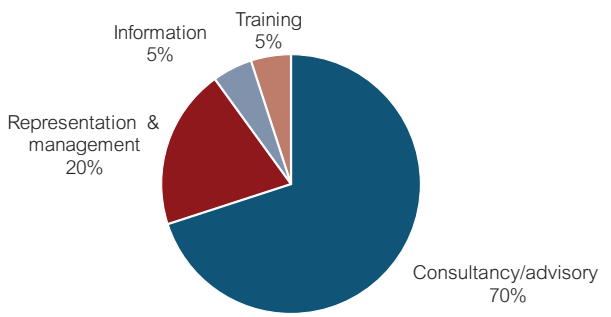
OVERVIEW

Exponent is one of the world's largest regulatory, engineering and scientific consultancies providing innovative solutions to complex technical problems. Exponent International Limited is a wholly owned subsidiary of Exponent Inc and is the European arm of the Chemical Regulation and Food Safety practice, with offices in Harrogate and Derby in the UK and Basel in Switzerland. Exponent combines unparalleled technical expertise with the ability to focus this knowledge to meet our clients' needs within short timeframes. Our ability to create multidisciplinary teams of scientists, regulatory consultants and project managers means that we can help our clients meet all aspects of their chemical regulatory obligations in a cost efficient and timely manner. We have the expertise and in-house resources to perform rapid-response evaluations to provide our clients with the critical information that they need to make day-to-day strategic business decisions.

VITAL STATISTICS

	2015/16
Turnover, group	Est US$15m
Turnover, chemical service provision	Est US$5m
No. of offices	3
No. of countries represented	35
Staff, group	70
Staff, chemical service provision	30

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Global head office (Exponent Inc): 149 Commonwealth Drive, Menlo Park, CA 94025, US
Other UK offices: 1 Pride Point Drive, Pride Park, Derby, DE24 8BX, UK; 31 Southampton Row, London WC1B 5HJ, UK and Bush House, First Floor, Office F8, Milton Bridge, Midlothian, EH26 0BB, UK
witzerland office: Nauenstrasse 67, Basel, 4052, Switzerland
Plus numerous other offices in the US, Germany and China

SERVICES PROVIDED

REACH services

Exponent's consultants have significant experience in the provision of a wide range of REACH support to our clients and have prepared approx. 150 lead registrations for the first two deadlines and are now working on over 100 more for the final deadline. These services include initial work such as regulatory strategy and advice, data evaluation, Qsar and the use of intelligent testing strategies, followed by study placement and monitoring. We prepare and submit registration dossiers in Iuclid and chemical safety reports including exposure assessments, using Chesar, higher tier modelling and if necessary risk characterisation. We also provide post-submission support during evaluation and authorisation, including completion of authorisation applications. Exponent has significant experience in programme and project management and Sief and consortia management and we can also act as your only representative registrant or third party representative.

Global chemical notifications

Our consultants have considerable experience in compiling and submitting chemical notifications worldwide; our team of specialists prepare and submit chemical notifications to all countries that operate a relevant scheme. We can prepare and submit dossiers for Australian, Canadian, New Zealand and Swiss registrations and can act as sole representative notifier utilising our Swiss office. We have a network of well-established local agents to help with the preparation and submission of regulatory documentation in China, Japan, Korea, the Philippines, Taiwan and Turkey and can call upon the experience of our US colleagues for TSCA notifications.

Biocide services

Exponent's biocide group has a wealth of regulatory expertise gained from working as government regulators, in industry, contract research organisations and as independent regulatory consultants. We have a proven track record of assisting clients achieve active substance approvals and product authorisations under the biocidal products Regulation (EU) No 528/2012 (BPR) and biocidal products Directive (98/8/EC). We are experienced in the interpretation of data, scientifically defensible data waiving and complex exposure modelling / risk assessments. We assess and construct product/family dossiers under the BPR, using Iuclid and R4BP. We also assist clients to achieve authorisations under global national regulations in many non-EU countries. We provide bespoke training packages and consultation on regulatory strategy, product stewardship, portfolio management and task force/consortia management/representation.

Cosmetic and consumer product services

Our cosmetics regulatory and safety team has provided assistance to cosmetic product brand owners and to retailers who are established in the EU, US and China selling to a global market. Services provided include 'hot line' regulatory consultancy, provision of cosmetic product safety reports, ingredient safety reports, product formula and labelling reviews, product information auditing, help with ingredient selection and advice for new product development. While we can offer consultancy as needed, we also offer a 'full service' where we take on full responsibility for a product being sold in the EU and act as the responsible person, for this service the Exponent company name and address is printed on the product label. Having offices both in the UK and on mainland Europe allows us to offer a choice of address for our clients.

Other regulatory regimes

Exponent's consultants have significant experience in assisting clients with EU agrochemical and food regulatory requirements including food contact notifications. For agrochemicals we can assist with regulatory strategy, data gap analysis, study monitoring, risk assessments and completion of active substance and product registration dossiers. This includes in-depth support such as managing compounds to Annex I inclusion. For clients in the food industry we can develop strategies for technical and regulatory challenges, develop food safety systems and help meet regulatory requirements, including submission of application dossier for authorisation of for food additives, food contact materials, novel foods and health claims

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1967	Parent company Exponent Inc formed.
2001	Novigen Sciences formed.
2002	Novigen acquired by Exponent. Exponent International Limited established in the UK.
2006	Exponent REACH team formed.
2008	Derby, UK office opened.
2010	Basel, Switzerland office opened.

ACCREDITATIONS

ISO 9001 certified

PARTNERS

We have no formal partners, but use an informal network of legal firms, CROs and in-country agents to provide the best service to our clients for REACH and global chemical notifications.

CLIENTS

Exponent Inc has worked with more than 5,000 clients and Exponent International has undertaken work for over 500 clients globally. Exponent has provided regulatory support to a range of companies across many industries; companies ranging from SMEs working in one industry to global companies conducting business in all areas of the chemical industry.

TESTIMONIALS

"Exponent International has consistently provided high-quality REACH and biocides services and support to our company for over five years. They produce work of the highest quality at competitive prices and are always prepared to go that bit further to ensure that they can deliver what we need within challenging deadlines. Their excellent technical knowledge and abilities mean that they are always the company we go to when we need help in these areas." – Regulatory Affairs Manager, global cleaning and maintenance products manufacturer

"I am so impressed with how this went – how incredibly dedicated and persistent you all are. Your work is invaluable – you exceeded my expectations and I feel confident that this work will make a big impact on the product that will ensure its success. I look forward to working with you in the future!!!" – Producer Design Team.

"Exponent provided support and expert knowledge in the lead up to an important new product launch. We see them as an ideal partner and support, working alongside our in-house technical team." Senior Technologist

"Congratulations to you and your crew at Exponent working on this project and many thanks for all the efforts and support over the past few years." – Global Regulatory, New Technologies Lead.

CASE STUDY 1: Provision of technical support to an organometallic consortium

Since 2009, Exponent has provided technical support to a consortium of organometallic substance manufacturers. Exponent performed the technical work required for all their substance registered in 2010, 2013 and we continue to provide support as we now head to 2018. The tasks that have been undertaken in support of this project are identification of data gaps, use of intelligent testing strategies to address gaps and, where necessary, placing and monitoring of studies. In addition Exponent is responsible for the preparation and update of the registration dossiers in Iuclid 6 and for the production of CSRs, proposing use descriptor codes for exposure assessments and in generating exposure scenarios. Due to the properties of the substances, creative yet pragmatic solutions have been necessary to demonstrate safe use and to deal with questions from Echa. In addition we have provided a considerable amount of support for post registration activities and have been involved with compliance checks as part of a dossier evaluation and also substance evaluations.

CASE STUDY 2: Global regulatory support

Exponent provides ongoing regulatory support for a major client ensuring they meet all their regulatory obligations globally. In particular we provide strategic advice for all jurisdictions that have a notification scheme in place and also those where regulations are emerging so the client are aware of any actions they will need to undertake to stay in compliance. Where possible we work to ensure that legislative requirements from a number of countries can be effectively overlapped and that data requirements are minimised. Exponent prepares and submits the technical dossiers and risk assessments that are required and this includes higher tier notifications in countries such as China and Korea. We handle all post submission obligations including annual reporting and first importing documentation.

CASE STUDY 3:

Exponent has provided assistance from data package development right through to active substance approval and product authorisation. This involved providing initial strategic advice, data gap analysis, data interpretation, study placement and monitoring, devising robust waiving strategies and bridging argumentation, exposure modelling, human health and environmental risk assessments, preparation and submission of the dossier and attending working group and competent authority meetings during the evaluation process. Discussions were held with the evaluating competent authority to confirm acceptance of the proposed product families, prior to Exponent's specialists compiling the dossiers in Iuclid. Our team also performed technical equivalence assessments. This is just one example where Exponent's expertise has contributed towards a positive outcome for our clients. Overall, our highly trained scientists have written over 30 active substance dossiers and numerous representative product dossiers across 17 product types, within the ongoing EU biocides review and for new biocidal active substances.

STAFF SELECTION

Dr Caroline Harris – Centre Director (UK)

Dr Harris is the head of Exponent International and director of Exponent's Chemical Regulation and Food Safety Centre. She has a strong international reputation and acts as a technical consultant to a number of international bodies, including the FAO and the WHO, and has been a member of the UK's Advisory Committee on Pesticides since 2009.

Mr Julian Reddy – Head of Industrial Chemical Notification Services

Mr Reddy is a very experienced regulatory project manager and has supervised complex regulatory programmes undertaken on industrial chemicals for 20 years. In addition, to EU REACH he has particular experience of Asian chemical notification schemes. Mr Reddy manages Exponent's Derby office, which specialises in industrial chemical notifications.

Dr Karen Howard – Head of Biocides (Europe)

Dr Karen Howard is a senior environmental chemist with over 20 years' experience working in chemical regulation. She has cutting edge knowledge of EU biocide regulation and is extensively involved in provision of strategic advice, biocide dossier preparation and post-submission support for individual clients and task forces. Dr Howard leads the Exponent EU Biocides Business.

Mr Iain Brunning – Head Of Cosmetic Safety and Regulatory Affairs (Europe)

Mr Brunning has experience working within manufacturing, brand development, and the retail environment and has led the development of business initiatives including cosmetic safety, regulatory compliance, sustainability, and stewardship affecting consumer products for over 20 years. Mr Brunning leads the Exponent EU Cosmetic Business.

Dr Rhodri Evans – Head of Food Safety & Regulatory Affairs (Europe)

Dr Evans joined Exponent International after 15 years working with the national food regulatory authorities in the UK and Ireland. Dr Evans has a detailed understanding of European and international regulation and authorisation of chemicals in the food chain, including food additives, flavourings, enzymes and contaminants, as well as food contact materials.

fieldfisher

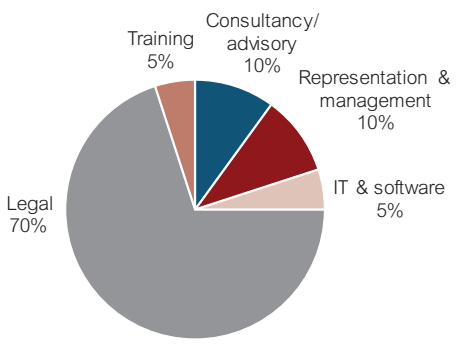
CONTACTS	
Website	www.fieldfisher.com
E-mail	claudio.mereu@fieldfisher.com
Head office	Riverbank House, 2 Swan Lane, London, EC4R 3TT, UK
Tel	+44 (0)20 78614000
Fax	+44 (0)20 7488 0084
Contact	claudio.mereu@fieldfisher.com
Directors	Claudio Mereu, Partner, Brussels Koen Van Maldegem, Partner, Brussels
Ownership	Limited Liability Partnership
Locations	Birmingham, Brussels, Düsseldorf, Hamburg, London, Manchester, Milan, Munich, Paris, Rome, Turin, Venice, Shanghai, Silicon Valley.
Founded	1835

Overview

Fieldfisher is a full service European law firm comprising over 490 lawyers, 205 of whom are Partners. Fieldfisher advises international clients on domestic and EU law on large and complex multi-jurisdictional matters. With five partners and ten professionals in Brussels, Fieldfisher's EU Regulatory Group is the largest fully dedicated EU regulatory team and is the only team combining advisory, consortia management and litigation work on REACH, pesticides and biocides (at the EU and national levels) thereby constituting the go-to firm for product defence.
The Brussels office advises and represents clients on matters arising under several areas of EU products legislation, including general product safety and eco-design requirements, and more broadly EU market access legislation.
Our main areas of expertise relate to chemicals, pesticides, biocides, cosmetics, food and food packaging, pharmaceuticals, medical devices, IT and other electronic products, autos and auto parts, toys and sports equipment, textiles and apparel, and other consumer and industrial products.
We also address related data protection and data privacy, competition and other business law issues that arise when drafting and negotiating commercial agreements or setting up and running consortia under REACH, BPR and pesticides laws.

Vital statistics	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	14
No of countries represented	7
Staff, group	917
Staff, chemical service provision	15

Service area breakdown



GLOBAL OFFICES

Birmingham, Brussels, Düsseldorf, Hamburg, London, Manchester, Milan, Munich, Paris, Rome, Turin, Venice, Shanghai, Silicon Valley.

SERVICES PROVIDED

Chemicals

With more than 20 years' experience in EU chemical law – compliance, consortia management and litigation, we provide a broad spectrum of chemicals-related advice, and have substantial experience in dealing with the most significant REACH implementation and compliance issues relevant for individual companies or groups of companies. We advise both private clients and consortia (we handle currently more than 25 REACH consortia). We have particular expertise in assisting companies in challenging Echa and Commission's decisions before the Board of Appeal and the European Court. For example the team has been acting against Echa in relation to a Sonc decision, which it successfully annulled before the Board of Appeal. Furthermore, the team has defended consortia on the inclusion of respiratory sensitisers in the candidate list as well as the inclusion of chromium trioxide in the authorisation list.
Moreover, we assist clients with regulatory compliance and data sharing, including breaches of contractual and legal requirements, dispute resolution concerning REACH, biocides and agrochemicals.

Agrochemicals/pesticides/fertilisers/biostimulants

We advise major pesticide manufacturers on the European re-registration programme laid down by Directive 91/414 and its replacement Regulation 1107/2009, including the renewal programmes under the so-called AIR regulations.
We provide legal assistance on a variety of issues ranging from initial notifications of pesticide active substances, joint and individual company dossier preparation and submission, including zonal applications and mutual recognition across jurisdictions, the creation of Task Forces and related data protection issues, including compliance with European competition laws. These issues are addressed at both an EU-wide and member state level. Our practice has been particularly active in challenging regulatory restrictions and negotiating data compensation agreements during the re-registration process, including relevant arbitration proceedings in several EU countries, as well as the re-submission of dossiers. We have negotiated many data sharing/ compensation agreements and successfully handled arbitration and litigation cases in various EU countries relating to data access. We also have a significant expertise on the new Regulation on fertilisers/ biostimulants.

Biocides

The biocides team provides legal advice on data protection, data sharing, dossier submission and evaluation, regulatory requirements under the biocidal products Regulation (BPR) as well as overlap with other legislation, such as the REACH Regulation and legislation on medicinal products, cosmetics or medical devices.
The team frequently provides expert advice on the national member state regulations of biocidal active substances/product type combinations during the review programme. Its expertise encompasses all EU member states. It also helps and provides advice on making biocidal product authorisation applications in the member states. The team provides expert advice on data sharing/compensation agreements, as such or in the context of distribution/purchasing or other arrangements. It has an in-depth knowledge of the free-rider and EU competition law issues at stake. The team is also guiding a number of active substance/ product type combinations through the EU review programme for existing active substances, including counselling and representation before the European Commission and Echa.
The team has represented clients in judicial proceedings with Echa, members states courts and EU courts.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2007	Fieldfisher's office and EU Regulatory practice established in Brussels
2010	The team won an interim Order from the President of the EU General Court to suspend an Echa decision regarding the REACH candidate list – the first of its kind. This extended the suspension of the Commission decision not to include napropamide in Annex I to the PPPD until the conclusion of the assessment of new data on napropamide under the so-called "re-submission" procedure.
2011	The team filed the first ever appeal before the Echa Board of Appeal (regulatory authority under REACH) and successfully obtained reversal of the Echa decision thereby maintaining client details as confidential.
2012-2015	The team filed groundbreaking annulment actions before the European General Court against commission regulations adopted under REACH (for clients such as PPG, Hitachi, Polynt, VECCO, EEIG or the International Cadmium Association).
2016	The team manages about 30 consortia under REACH, BPR and pesticides renewals and acts as financial trustee and legal secretary.

ACCREDITATIONS

The Legal 500

Equally adept in contentious and non-contentious matters, Fieldfisher leverages its '***deep knowledge of chemicals and the chemicals industry***' to deal with issues such as product defence, EU market access and consortia formation.

Chambers & Partners

Clients remark that Claudio Mereu "understands the business and tries to bridge the gap between business needs and legal requirements." Interviewees describe Koen Van Maldegem of Fieldfisher as "great at contextualising EU environmental regulations." Sources also admire his negotiation skills."

CLIENTS

We advise and represent both private clients, including major chemical/ pesticides/biocides, medical devices and pharma companies, small innovative companies, as well as groups of companies (industry associations, task forces or consortia) and have more than15 years' experience in consortia and task force management. We represent clients in the field of product regulation, advising them on issues pertaining to the classification, packaging, and labelling of chemical substances and preparations, including safety data sheets, marketing and use restrictions, workplace regulations, and product liability related issues, as well as questions relating to the free movement of goods and parallel imports.

CASE STUDY 1: Hitachi & Polynt

The General Court of the European Union handed down in May 2015 two judgments in the cases initiated by Polynt, Hitachi and others (Applicants) against the European Chemicals Agency (Echa) concerning the identification of HHPA and MHHPA as substances of very high concern (SVHC) on grounds of "equivalence of concern" (respiratory sensitisation). Polynt and Hitachi were represented by Claudio Mereu. The parties have lodged a new appeal before the EU Court of Justice. This case raises critical aspects for the inclusion of respiratory sensitisers in the list of SVHC and therefore will constitute a landmark judgment. Judgment is expected at the beginning of 2017.

CASE STUDY 2: Solutia

On 27 July 2015, the Echa Board of Appeal adopted an important decision on behalf of client Solutia with regards to the legal nature of so-called Statements of non-compliance (Sonc)". Solutia challenged the Sonc arguing that is was both procedurally and substantively flawed. Fieldfisher's team led by co-Managing Partner Claudio Mereu submitted Solutia's arguments and defended them orally before the Board of Appeal in an unprecedented and rather complex case. In its decision, the Board of Appeal ruled in favour of Solutia and annulled the Sonc.

CASE STUDY 3: Biocidal product consortia

The team is actively involved in the establishment and running of several biocidal product consortia for biocidal products containing permethrin, sodium hypochlorite, salt, peracetic acid and hydrogen peroxide. The consortia involve competing companies coming together to share costs in the development of biocidal products dossiers, and membership numbers typically range from 4-35 companies.

STAFF SELECTION

Claudio Mereu – Joint Managing Partner, EU Regulatory partner, Belgium

Claudio's practice focuses on European Union law, with an emphasis on the chemicals (REACH), pesticides, biocides and life sciences industry sectors. He advises on regulatory compliance issues, task force/ consortia formation, product defence strategies and product circulation across the EU. He handles product approval processes in the EU, related litigation before European courts and Echa Board of Appeal, and advises companies on business law and antitrust matters relating to their international agreements. He regularly represents chemical companies before the European institutions, member state authorities, scientific committees, and the European courts.

Koen Van Maldegem – EU Regulatory Partner, Belgium

Koen's practice focuses on EU regulatory, business and competition law, with an emphasis on chemicals, pesticides, biocides and cosmetics. He advises international and Belgian companies on regulatory compliance and free movement of products throughout the EU. His expertise covers regulatory counselling at the EU and member state level regarding data protection, data sharing and data compensation, task force formation and management, distribution and supply agreements for pesticides, biocides and chemicals, and he is specialised in solving the antitrust issues that may arise in these areas. He also handles product defence litigation before European and national courts.

CONTACTS

Website	www.fobig.de
E-mail	info@fobig.de
Head office	Klarastraße 63, 79106 Freiburg i Br, Germany
Tel	+49 761 386080
Fax	+49 761 3860820
Contact	Klaus Schneider
Directors	Klaus Schneider, General Manager
Ownership	Private company
Locations	Germany
Founded	1992

OVERVIEW

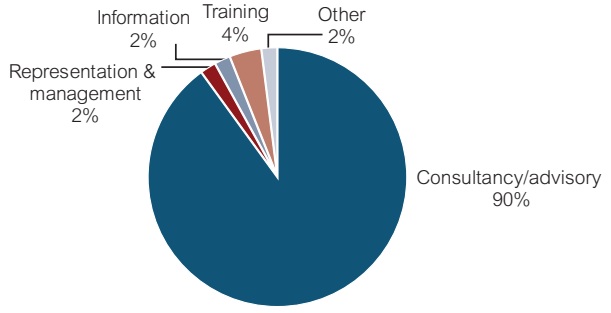
FoBiG is a privately owned consultancy specialising in toxicological and ecotoxicological risk assessment, with now 25 years of experience in exposure assessment and risk characterisation. FoBiG's REACH experience dates back to 2001 with participation in RIP projects, the Cefic-sponsored SPORT project, the REACH baseline study and its updates and VCI projects on exposure-based waiving and the practical guide on exposure assessment and communication in the supply chain. Together with partners, FoBiG is involved in studies, which are relevant parts of the European Commission's REACH reviews.

FoBiG successfully prepared numerous registration dossiers for the first and second REACH registration deadline. Furthermore, we provide ample experience in authorisation under REACH: FoBiG successfully prepared many authorisation dossiers for threshold and non-threshold Annex XIV substances and is involved in further authorisation projects at various stages of the application. Further projects deal with providing support for Corap-listed substances ("substance evaluation") and for substances targeted by Echa dossier evaluations.

VITAL STATISTICS

	2015/16
Turnover, group	-
Turnover, chemical service provision	€1m
No of offices	1
No of countries represented	Europe-wide
Staff, group	13
Staff, chemical service provision	13

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

REACH registration

FoBiG provides full-scale scientific support to meet industry's REACH obligations:

- Iuclid 6 files (including literature searches, data gap analysis, evaluation of reliability, application of read-across and category approaches and inquiry dossiers for new substances) / all endpoints (physico-chemical properties, human health, environmental fate and ecotoxicity);
- classification and labelling according to CLP Regulation;
- PBT/vPvB assessments; and
- (Chesar-based) chemical safety reports (including hazard assessment, derivation of DNELs, DMELs, and PNECs, exposure assessment and risk characterisation).

REACH authorisation

Together with partner RPA Ltd, FoBiG prepares complete dossiers for application for authorisation with:

- CSRs according to authorisation requirements, including a refined exposure assessment to demonstrate acceptable remaining risks;
- analysis of alternatives;
- socio-economic analysis;
- complete application for authorisation dossier (Iuclid 6);
- support for communication with Echa during the process (eg in PSIS meetings)
- and provides post-submission services (eg communication with Echa and Rac/Seac on submitted dossiers, trialogue meetings).

REACH dossier and substance evaluation and restrictions

FoBiG provides scientific support to companies whose substances are targeted in dossier and substance evaluations and are affected by restriction proposals. Services include problem analysis, dossier refinement and communication with competent authorities/committees.

Biocidal product authorisation

Together with RegisGate partners (see www.regisgate.eu) FoBiG offers full-scale services for authorising biocidal products according to the new BPR scheme, including data gap analysis, preparation of the Iuclid-based dossier and communication with competent authorities/Echa. FoBiG provides ample experience eg on authorising disinfection products and biocidal products with in situ-generated active substances.

Cosmetics ingredients and products

FoBiG prepares cosmetic ingredients assessment reports for ingredient suppliers and performs cosmetic products safety evaluations.

Pharmaceuticals and medical devices

Scientific services for pharmaceutical companies and for manufactures of medical devices include:

- derivation of PDE (permitted daily exposure) according to EMA guidelines for residual substances (eg for use in cleaning validation); and
- assessment of impurities, including application of TTC (threshold of toxicological concern) approaches.

Consumer products

Potentially harmful substances in consumer products such as textiles and toys rank high in public awareness. FoBiG prepares hazard assessments and develops exposure scenarios to derive scientifically sound product evaluations.

Occupational toxicology

(Company-specific) occupational exposure limits for threshold and non-threshold substances (the latter based on an analysis of exposure-risk-relationships according to a German methodology) support companies in their internal evaluations with regard to occupational safety and health.

Other services

FoBiG provides regulatory support and (eco)toxicological risk assessments in various other areas such as food safety, environmental contaminants and effects assessment for industrial plants requiring permissions.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1986	Founded as personal company by Fritz Kalberlah.
1992	Reorganised as private company (GmbH) with partners Fritz Kalberlah, Klaus Schneider, Martin Hassauer.
2009	New company partner Jan Oltmanns.

PARTNERS

FoBiG established a successful partnership with RPA Ltd for authorisation projects, providing full-scale services for preparing applications for authorisation.
Together with partners Battelle, Hydrotox and ECT FoBiG formed RegisGate (www.regisgate.eu), a sophisticated consortium providing services for biocidal product authorisations.

CLIENTS

- Chemical and pharmaceutical companies (from multinational to small- and medium-sized).
- EU institutions (eg Efsa, several Directorates General (DG) of the European Commission).
- (German) federal and other authorities (eg BfR, Baua, UBA).
- Stakeholder organisations (eg VCI, trade unions).

CASE STUDY 1: Specific REACH requirements in 2018 for substances in the 1-10tons/year band

According to REACH Art. 12 phase-in substances up to ten tons/year can benefit from reduced information requirements, if they do not fulfil the criteria of REACH Annex III. This could help to avoid costly toxicity and ecotoxicity tests when registering these substances in 2018. In order to do so, FoBiG applies adequate prediction tools such as the Qsar Toolbox to demonstrate that substances:

- are not likely to possess hazardous properties: and
- are not likely to be CMR or PBT/VPvB substances.

To respond to the second Annex III condition (which requires demonstrating that the substance does not have a wide dispersive use), FoBiG provides support for gathering supply chain information and exposure information on downstream uses.

CASE STUDY 2: Read-across for filling data-gaps

Application of read-across and category approaches for filling data gaps in registration dossiers:
Read-across proved to be the most successful strategy during the first two REACH registration phases for filling data gaps. Cases, where FoBiG successfully applied read-across in registration dossiers include:

- category formation/grouping based on structural relationship;
- read-across from metabolites to parent compounds or vice versa; and
- read-across along homologous structural changes.

At the same time Echa (see Echa's RAAF – Read-across assessment framework) asks for detailed justifications for applying read-across approaches, which require in-depth analyses of toxicokinetic and other available data. Read-across hypotheses and justifications need to be carefully documented as part of the registration dossiers. Approaches used for read-across are one of Echa's focuses in dossier evaluation.

CASE STUDY 3: Application for authorisation: refined CSR

For non-threshold substances such as carcinogens key to a successful application for authorisation is:

- use of exposure-risk relationships, which are scientifically sound and acceptable to RAC; and
- refinement of the exposure assessment to derive realistic exposure estimates.

in order to be able to demonstrate minimisation of risks and to conclude on low remaining risks associated with the use for which application is sought.
RAC may provide exposure-risk relationships and/or applicants may provide their own dose-response assessments. Deviations from linear dose-response extrapolation may be justified even for genotoxic carcinogens, if sufficient information is available to conclude on a sublinear dose-response behaviour. A methodology developed under participation of FoBiG and accepted in Germany in a regulatory context allows developing quantitative estimates also for sublinear dose-response data.
Experience from authorisation projects clearly shows that CSRs from registration dossiers need to be improved with regard to exposure assessment. Detailed descriptions of the technical processes and the conditions of use and availability of measured data (eg air and/or biomonitoring measurements), which may be supported case-by-case byTier II exposure modelling (eg by ART, RISKOFDERM, ConsExpo etc.), are key to a successful application. In addition to workers exposure characterisation, assessment of exposure of humans via the environment is an essential part of the authorisation CSR.

CASE STUDY 4: Dossier and substance evaluation: refinement of CSR and supply chain information

With more and more substances being added to the Corap list, substance evaluation becomes an additional important activity within REACH. Companies, whose substances are concerned, should adopt a proactive position, communicate with the competent authority, and try to reduce existing concerns. Often, reasons for selecting a substance for evaluation include:

- aggregated tonnages;
- insufficient supply chain information; and
- wide-dispersive use situations.

At the same time companies may receive Echa decision letters as a result of dossier evaluation and are requested to update registration dossiers. Improved and more detailed use descriptions, elaborated exposure scenarios and detailed justification of parameters used in the assessment (eg environmental release rates, RMM efficiencies) are often required in both REACH areas.

STAFF SELECTION

Klaus Schneider, PhD, DABT

Klaus Schneider is the general manager of FoBiG and responsible project coordinator for all REACH-related services. With more than 20 years of experience in toxicological risk assessment he provides expertise in many areas, among them risk assessment methodologies, dose-response modelling and exposure assessment. He is member of the BfR expert group on exposure assessment and standardisation.

Ulrike Schuhmacher-Wolz, PhD, ERT, Fachtoxikologin DGPT

Ulrike Schuhmacher-Wolz is a senior scientist at FoBiG and acted as project leader in various projects related to REACH, food safety and other work areas. She provides special expertise in reproductive toxicology and the assessment of endocrine disruptors.

Jan Oltmanns, MSc, PgDip

Jan Oltmanns, senior scientist and company partner, is especially experienced in the assessment of physical hazards and in supply chain mapping and exposure sciences (worker, consumer and environmental exposure).

Karin Heine, PhD, ERT, Fachtoxikologin DGPT

Karin Heine, a biologist and toxicologist, provides ample experience in hazard assessment and DNEL derivation as well as in gathering supply chain information and in exposure assessment, drawn from many REACH registration projects in recent years.

Markus Schwarz, PhD, Fachökotoxikologe (GdCh/SETAC)

Markus Schwarz is a certified ecotoxicologist with in-depth experience in assessing environmental fate and ecotoxicological properties of chemicals and in performing PBT/vPvB evaluations as well as environmental exposure assessments.

Eva Kaiser, PhD

Eva Kaiser is a biologist and toxicologist, whose key areas are hazard assessment, dose-response modelling, DNEL derivation and preparation of Chesar-based exposure assessments with special expertise in consumer exposure modelling.

GAB
A Global Services Company

CONTACTS

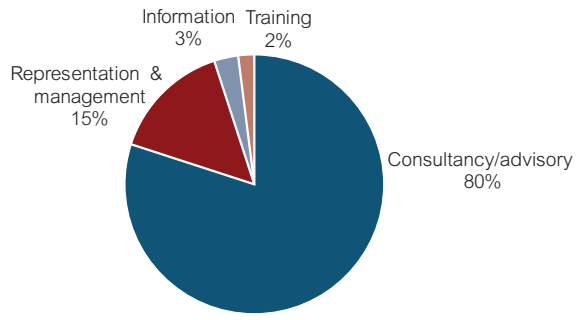
Website	www.gabconsulting.de
E-mail	info@gabconsulting.de
Head office	Ottenbecker Damm 10, 21684 Stade, Germany
Tel	+49 4141 80010 0
Fax	+49 4141 80010 20
Contact	Dr. Wolfgang Häußler (direct line -110)
Directors	Dr Wolfgang Häußler Dr Götz Neurath Dr Rüdiger Hauschild Dr Manuel Barrada Jose Luis Juanes
Ownership	GAB Global Services GmbH, Private shareholders, Partnership
Locations	Germany, Spain, Italy, Poland, Slovenia, Cyprus
Founded	1998

OVERVIEW

GAB Consulting is a leading consulting company offering global registration services for the chemical industry in Europe and worldwide (US, Canada, Mexico, Brazil, Argentina, Chile, China, Japan and Australia). We meet your needs by providing competent and flexible regulatory and scientific expertise to ensure that your product gets registered.
Our full range of services includes initial data gap analyses and dossier preparation, as well as risk assessments, expert statements, high tier refinements and dossier defence.
We can help you with a global approach to target several markets with the highest level of synergism for your dossier registration data-package.

VITAL STATISTICS	2016/17
Turnover, group	€10m
Turnover, chemical service provision	€7.5
No of offices	6
No of countries represented	35
Staff, group	50 – 100
Staff, chemical service provision	70

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Office in Stade (Germany), Heidelberg (Germany) and Valencia (Spain).

SERVICES PROVIDED

GAB Consulting is a team of experts offering global regulatory services at very high quality for agrochemicals, bio-pesticides, biocides, nanomaterials, feed additives, animal pharmaceuticals, pharmaceuticals (ERA) and chemicals (REACH) in compliance with the latest worldwide legislations. We support you in developing sustainable and global registration strategies in Europe and overseas. We have achieved a substantial track record over almost the last 20 years.
Our one-stop service concept provides cost-effective tailored solutions to meet your needs for your global market business.
We have available for you enough full time equivalence (FTE) resources on demand according to your necessities.
Our commitment is the preparation of high quality dossiers with a full time project manager team dedicated to you, as well as with our senior scientists group.
These teams in combination with our robust and safe in-house database are key elements to achieve timely approval of active substances and related products.
Additionally, an ad-hoc senior team for dossier defence and high tier solutions is available for a prompt and competent follow-up.
You, as customer, can track the status of our activities and archive your documentation properly with our IT tools, with the possibility to have a clear communication day by day with our project managers.

Agrochemicals

With almost 20 years experience in registration of pesticides, our expertise spans from providing you with up-to-date information on your regulatory obligations and evaluation of data gaps to the preparation and submission of complete dossiers for active substance and product approval according to Regulation (EC) No 1107/2009 and in compliance with national regulations. Expert toxicological analysis of the substance profile as well as tailored high tier refinements are also part of our global portfolio.

Bio-pesticides

We are the world leading consulting company in the field of bio-pesticides and have submitted dossiers for 41 strains or isolates from 35 microbial species for approval or renewal as active substances in the EU. We are also engaged in the revision of guidance documents for dossier preparation for biopesticides containing microorganisms, botanicals or semiochemicals as active substances and frequently participate in the OECD Bio Pesticide Steering Group, EU Commission Biopesticide working group, IOBC and IBMA – ensuring that we are always at the forefront of knowledge in regulations for bio-pesticide registration.

Biocides

With over a decade of experience in registration of biocidal substances and a dedicated biocides expert group, we can assist you with scientific and regulatory support for biocidal active substances and products (disinfectants, preservatives, pest control and other biocidal products).
In addition, we can provide you with strategies – tailored to your product portfolio – to meet the new regulatory challenges.
We can offer you our expertise and support with R4BP3 and Iuclid 6.0

Environmental risk assessment – pharmaceuticals

With almost 20 years of experience in the fields of environmental fate and ecotoxicology of crop protection and biocidal products and a dedicated environmental expert group, we can assist you with scientific and regulatory support for the environmental risk assessment of your pharmaceuticals (human or veterinary drugs) and to generate data or – if applicable – waiver which will successfully meet the regulatory requirements of Europe.

Feed additives

We offer support for the authorisation of chemicals or microbials as feed additives according to European regulations. We provide you with effective and timely solutions related to the characterisation, efficacy and safety aspects of feed additives. All the regulatory aspects related to your feed additive are in safe hands with us, making sure that your products can be placed on the market.

REACH

GAB Consulting will help to identify and fulfil your obligations as importer or producer of chemicals in the EU.
Classification and labelling according to the new CLP system is a requirement for all products since 2015. We offer our assistance in preparation of updated safety data sheets and CLH reports as well as communication with national authorities and the European Chemicals Agency (Echa) as well as defence of the submitted dossiers.

Nanomaterials

As a member of the European Nanotechnology Association we are glad to offer you scientific and regulatory support in the developing market of nanotechnologies. Our contribution spans from providing you with up-to-date information on your obligations, to the preparation and submission of complete registration dossiers.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1998	Company founded by Dr Wolfgang Häussler
1999	First A-I inclusion submission (91/414/EEC)
2000	Office relocation to Lamstedt, Germany
2002	Opening of Valencia Office, Spain
2003	Principles of Good Consulting Practice
2004	Expansion of Lamstedt Office, Germany
2006	Opening of Heidelberg Office, Germany
2007	Introduction of GAB Expert Groups
2009	New business area: veterinary medicines
2010	REACH submissions / representation in France
2011	Representations in Poland and Slovenia
2012	Introduction of GAB Roadmap Consulting Excellence
2013	New business area: nanomaterials
2014	Move of Valencia Office, Spain
2015	Implementation of new positions: SRAM and SSE
2016	GAB prepared and submitted biopesticide dossiers for 15 AIR for microbials
2017	Launch of 2021 Global Partner Business Development Project, Opening of Consultancy Offices in the US and Brazil

PARTNERS

We work with representation and cooperation in several European countries (France, Poland, Czech Republic, Cyprus, Hungary, Slovakia, Slovenia, Romania, Bulgaria, Greece and Italy) and other countries around the world (Russia / CIS, US, Argentina, Brazil, Chile, China, Japan and Australia). We always try to find solutions for our customers and we are always open to starting collaborations with new partners in order to get a closer follow up of the management of our clients´ needs.

CLIENTS

Broad spectrum of companies searching for professional assessment (global and/or locally) for their substances and products in the following areas: agrochemicals, nanomaterials, biocides, bio-pesticides, environmental risk assessment-pharmaceuticals, REACH, feed additives. We aim a win-win relationship in order to build a partnership of long term duration with our customers.

TESTIMONIALS

During the past 19 years GAB has developed and maintained a reputation for professionalism, adaptability, resourcefulness and, above all, for getting the job done. This has helped our clients trust us from the very beginning to the present day. Our closeness and commitment with the client success is one of our distinctions.

CASE STUDY: General remarks

- 84 chemical and 41 microbial active substances for EU Annex-I inclusion or approval/re-approval under Regulation (EC) 1107/2009
- Over 20 dossiers for biocidal product authorisation
- More than 700 product registrations supported all over EU and overseas
- Secure electronic client access database
- In-house quality assurance unit
- Good consultancy practice
- We guarantee satisfied customers by always keeping you informed about the status of your registration process. We provide you with a dedicated project manager contact to ensure permanent communication and service.

STAFF SELECTION

Dr Hanna Skarpos
Physical Chemistry and Analytical Methods

Experience with plant protection products (Annex II & III / dRR), biocides, CLP, REACH. Main focus: plant protection products, biocides and Iuclid Individual expertise: PPP, biocides, expert statements, regulatory issues, study monitoring.

Prof Dr Wolfgang Pfau – Dr Christian Bieler
Toxicology

Experience with plant protection products, biocides, REACH, feed additives, CLP. Main focus: plant protection products (including microbial PCP), CLP, Head of Expert groups GAB-REACH and GAB-feed additives Individual expertise: toxicological hazard evaluation, exposure assessment, risk assessment, scientific BfR committee on consumer products.

Dr Martina Dunker – David Tena
Residues and Efficacy

Experience with plant protection products, biocides. Main focus: plant protection products. Individual expertise: study monitoring and regulatory services for agrochemicals, expert statements.

Dr Andreas Häusler – Kevin O´Brien
Environmental Fate & Modelling

Experience with PPP (Annex II & III / dRR), biocides, REACH, exposure assessment. Main focus: PPP, biocides, modelling. Individual expertise: modelling, expert statements, study monitoring, general regulatory issues, ITR.

Sascha Otto – José Ortiz González
Ecotoxicology

Experience with PPP (AIR Annex II & III / dRR), Biocides, REACH, CLP Main focus: plant protection products, biocides. Individual expertise: environmental risk assessment, study organisation and monitoring, project management, expert statements.

Dr Rüdiger Hauschild – Dr Jacqueline Suess
Biopesticides

Experience with active substances and plant protection products (Annex II & III / dRR) based on microorganisms, semiochemicals and botanicals. Main focus: biological plant protection products. Individual expertise: regulatory issues microorganisms, botanicals, semiochemicals, project management, expert statements. Partner in EU Policy Support Action REBECA. Participation OECD Biopesticide Steering Group since 2009 Member of EU Commission Biopesticides Working Group

Dana Wallschläger – Narges Moradi
Quality Assurance

Experience with chemicals and plant protection products (AIR Annex II & III / dRR), biocides. Main focus: plant protection products, biopesticides and biocides. Individual expertise: Review of documents created during preparation of dossiers including risk assessments, study summaries, literature review etc.

Brigitte Litzenberger
Head of Project Management

Thomas Kloeble
Customer Relationship Manager

GRADIENT®

CONTACTS

Website	gradientcorp.com
E-mail	info@gradientcorp.com
Head office	20 University Road, Cambridge, MA 02138, USA
Tel	1-617-395-5000
Fax	1-617-395-5001
Contact	Ari Lewis, alewis@gradientcorp.com
Directors	Manu Sharma, President Ari Lewis Tom Lewandowski, PhD Kim Reid Tim Verslycke, PhD
Ownership	Privately owned
Locations	US
Founded	1985

OVERVIEW

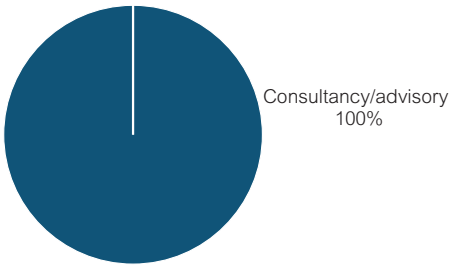
Gradient is an environmental and risk science consulting firm renowned for our specialties in toxicology, epidemiology, risk assessment, product safety, contaminant fate and transport, industrial hygiene, geographic information systems, and environmental/forensic chemistry. We assist clients in resolving their complex problems relating to chemicals in the environment, in the workplace, and in consumer products.

Gradient, together with international partners, has worked with clients across a variety of industries to develop best practices for managing global chemical compliance and product stewardship. We provide a full suite of services to ensure that regulatory requirements are identified, needed actions are executed, and outcomes are tracked and communicated to stakeholders, both within the company and externally. We support innovative product stewardship plans using our expertise in toxicology, chemistry, and risk assessment; extensive experience monitoring and tracking international regulations; and innovative IT solutions to manage chemical portfolio information.

VITAL STATISTICSa

	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	-
No of countries represented	Global
Staff, group	100-500
Staff, chemical service provision	50-100

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

20 University Road, Cambridge, MA 02138, US
600 Stewart Street, Suite 1900, Seattle, WA 98101, US

SERVICES PROVIDED

Global chemical registration and notifications

- Oversight of chemical registration across multiple jurisdictions (US, Canada, EU, Australia, New Zealand, Japan, China)
- REACH dossier preparation and registration
- Coordination with in-country representatives

GHS hazard assessment

- Comprehensive GHS human and ecological toxicity evaluation
- Toxicity study design and oversight
- Compliance with Osha and other international GHS-based schemes

Predictive toxicology

- Application of Qsar models to evaluate human health, ecological, and physical-chemical properties
- Read-across for testing waivers and hazard classification
- Safer product design

Product safety and risk assessment

- Toxicological evaluation
- Exposure assessment
- Testing design and implementation
- Liability and adulteration claims support
- Supply chain audits

Emerging global regulation

- Identification of existing and impending chemical requirements
- Impact of emerging regulations on portfolio (CA Safer Products, Prop 65; REACH authorisation, TSCA)

IT solutions

- Customisable database that efficiently organises product composition, toxicological data, hazard conclusions, inventory status and exemptions, and confidential business information per jurisdiction.
- Automated calculation of product-level hazards based on composition, component-level hazards, and jurisdictional mixture rules.

Safety data sheet (SDS) support

- SDS development, product labeling and packaging
- Chemical classification and hazard assignments for SDS completion
- Supplier communications
- Application of chemical disclosure requirements
- Classification of hazardous materials for transport in accordance with US DOT, ICAO, and IMDG Code

Green chemistry

- Alternatives assessment
- Hazard screening and prioritisation
- Third Party Certification via GreenScreen®

ACCREDITATIONS

- Gradient is a Licensed GreenScreen® Profiler and one of only four companies globally that hold this authority.
- Our toxicologists are certified in US EPA Sustainable Futures Programme.
- Technical experts on our staff hold a multitude of accreditations including: Diplomates of the American Board of Toxicology (DABTs); Fellows, Academy of Toxicological Sciences (ATSs); Fellow, American College of Epidemiology (FACEs); Registered Toxicologists in Europe and the United Kingdom (ERTs); Certified Industrial Hygienist (CIHs); Professional Engineers (PEs); Professional Geologists (PGs)

CLIENTS

Gradient provides services to all entities interested in receiving sound, science-based assessments and solution. We serve individual industrial clients (chemical, oil and gas, consumer, personal care); industry trade and research groups; non-profit public interest groups; and local, state, federal, and international government agencies.

CASE STUDY 1: GHS hazard evaluation and management

Gradient conducted and documented GHS-based hazard assessments for a chemical portfolio consisting of more than 2,000 chemicals used in the formulation of tens of thousands of products across the globe. Use of read-across and Qsar was an integral part of this process. The hazard assessments were used to understand product-level hazards and update US and international safety data sheets (SDSs) to meet GHS compliance requirements. To efficiently complete the task we also developed a comprehensive hazard information database that was used to document and track component-level conclusions, calculate product level classifications, and identify necessary ingredient disclosures across international jurisdictions. The hazard assessments we performed and the companion database tool we designed have become an integral part of our client's long-term product compliance sustainability plan.

CASE STUDY 2: Recommended best practices for assessing risks in baby products

Gradient partnered with a global safety certification company to develop recommended best practices for assessing chemical hazards and risks associated with personal care products, focusing on those used in infant care. We performed a comparative review of several existing health assessment frameworks and made best practice recommendations for numerous elements, including hazard assessment, toxicity endpoints, data requirements, filling data gaps, etc. Gradient then "benchmarked" the best practice recommendations against those currently utilised by the personal care product company. Our research is assisting in developing a hazard- and risk-based industry standard for assessing infant care products.

CASE STUDY 3: International chemical registration technical support and logistics

Gradient coordinated the chemical registration dossiers for a comprehensive portfolio of chemicals in a number of Asia-Pacific countries. The effort was multi-faceted involving technical input on physico-chemical properties; chemical hazard profiles; and expected exposures to workers, the public, and the environment. We filled data gaps using public literature, read-across, and new testing as needed. In addition to our technical role, we were part of a larger team that advised on the most appropriate registration type under the complex regulatory schemes for each jurisdiction. In addition, we developed a client database to track requests, submissions, and chemical and product hazard and registration data.

CASE STUDY 4: Alternative assessment

Focusing on potential ecological impacts, Gradient conducted a GreenScreen® hazard assessment for a wood preservative undergoing regulatory review and compared the identified product hazards with those for several other wood preservatives.

CASE STUDY 5: Derivation of Proposition 65 MADLs and NSRLs

Gradient derived safe exposure levels for chemicals added to California's Proposition 65 list in the absence of existing agency-established toxicity criteria. We developed criteria for several endpoints (including cancer and chronic, acute, and developmental effects) considering both US EPA and Proposition 65 guidance. Our specific efforts included compiling the relevant scientific literature, determining the appropriateness of route-to-route extrapolations, and assessing the toxicological mode-of-action considering potential metabolites. Our work included ethyl acylate, 1,3-dichloro-2-propanol (1,3-DCP), α-methyl styrene, and N,N-dimethyl-p-toluidine (DMPT). The manufacturer used our analysis to evaluate the safety of these products to office workers.

CASE STUDY 6: Development of occupational exposure limits

Gradient developed health-based inhalation occupational exposure limits (OELs) for compounds present in the workplace (eg, methyl methacrylate, manganese). We applied standard methods to derive the OELs, such as selecting read-across, making animal-to-human pharmacokinetic adjustments, and assigning uncertainty factors. The company used the values to ensure workers were adequately protected from chemical exposures.

CASE STUDY 7: Safety evaluation of consumer product material

Gradient assisted a client in establishing a product safety evaluation plan for a wearable consumer product. We established procedures for identifying chemical health hazards using both test data and predictive toxicology methods, determined proper analytical methods, and set appropriate detection limits for quantifying chemicals of concern in the product and its raw materials. We evaluated close to 3,000 chemicals for skin hazard, focusing on preventing adverse health effects associated with dermal contact. Our analysis assisted the manufacturer in deciding whether to move forward with release of new products.

STAFF SELECTION

Human Toxicology team

Gradient has a team of PhD and Master's level toxicologists and epidemiologists that use their expertise to conduct hazard evaluations, develop safe exposure levels for workers and the public, assess product liability and safety, and oversee and develop strategic animal testing plans. Our toxicologists are skilled at characterising chemical toxicity both by performing weight-of-evidence evaluation for data rich compounds with conflicting data, as well as for data poor compounds that require the use of predictive toxicology applications such as Qsar or read-across.

Chemistry and Environmental Sciences team

Gradient's highly trained PhD-level chemists and scientists coordinate and support chemical registration and compliance efforts worldwide. They design and oversee chemical characterisation testing, evaluate chemical fate and transport in the environment, and identify suitable chemical analogues for hazard read-across and data waivers. Our chemists can overcome the chemical registration and characterisation challenges of complex chemicals (UVCBs), such as chemical derivatives of naturally-sourced oils and resins. We have extensive experience evaluating chemical registration exemptions (eg, naturally occurring substances and polymers) and compiling data packages for registration of chemicals and polymers in the US, EU, Australia, New Zealand, Japan, China, and others.

Ecotoxicology team

Gradient has several PhD and Master's level ecotoxicologists who use their expertise to conduct environmental hazard evaluations, derive safe environmental exposure levels, assess product liability, evaluate product "green" claims, and oversee and develop strategic environmental fate and toxicity test plans. Our ecotoxicologists are skilled at characterising chemical environmental fate and toxicity for chemistries that have complex toxicity and biodegradation profiles. We use weight-of-evidence evaluations for data rich compounds with conflicting data, as well as predictive toxicology applications such as Qsar or read-across for compounds that lack specific testing data.

HOHENSTEIN

CONTACTS

Website	www.hohenstein.com
E-mail	info@hohenstein.de
Head office	Hohenstein Group, Schlosssteige 1, 74357 Boennigheim, Germany
Tel	+49 7143 271 908
Fax	+49 7143 271 51
Contact	Mr Jörg Diekmann, Head of International Sales
Ownership	Privately owned
Locations	Over 40 offices worldwide

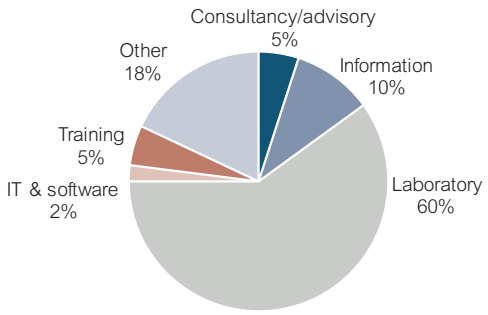
OVERVIEW

Hohenstein was founded in Boennigheim (Germany) in 1946. Currently, over 900 employees are working at its headquarters, laboratories and offices based in Europe, Asia and America. The international client base does not only include companies along the entire textile value chain but increasingly also customers from other branches such as the automotive industry, medicine and consumer goods. Today, Hohenstein is an innovative service partner for textile testing, inspection and certification. We combine our testing capacities and research activities to a unique service portfolio including third-party certifications such as OEKO-TEX®. Our Hohenstein mission is to help our clients develop and manufacture high quality products that succeed in the marketplace.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	54
No of countries represented	45
Staff, group	920
Staff, chemical service provision	368

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Hohenstein Group, Schloss Hohenstein, 74357 Boennigheim, GERMANY
Bangladesh, China, Germany, Hong Kong, India, Pakistan, Turkey, US and more.

SERVICES PROVIDED

Product and regulatory testing

In our state-of-the art laboratories, we are able to test a wide range of quality features and properties on all kinds of textiles and many other products. The focus is on ensuring an optimal performance, serviceability and marketability of the tested products, taking into account all relevant laws and standards. Based on our long-standing experience and our customers' specific requirements, we are able to draw up individual test programmes tailored to their individual needs

Product stewardship

Hohenstein offers companies an international network of expertise in textiles to assist them in the fields of social, environmental and economic sustainability along the textile supply chain. Apart from many other services, the OEKO-TEX® system provides a one-stop solution for implementing comprehensive product responsibility throughout the textile value chain. The product safety ensured by the STANDARD 100 by OEKO-TEX® remains a key element of this commercially well-established system and is supplemented by a range of other practical tools enabling companies to successfully implement sustainability, transparency and responsibility on all operational levels.

Product performance

Textiles and textile chemicals are used in a wide range of application areas today. As a consequence, our Hohenstein experts can provide support for a wide variety of branches, from the health care sector to the automotive industry and up to domestic appliances or the armed forces. We offer specific and targeted support when optimizing your products, and will work in close co-operation with you to develop innovative products and processes.

DETOX / ZDHC services

Hohenstein enables business partners along the textile chain to assess and verify the status of their chemical management systems including the quality of their wastewater and sludge with regard to the Detox goals of the Greenpeace campaign.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2013 Hohenstein developed a test programme to assess the aerobic breakdown of textile products over a defined period of time by burying them in the soil in controlled conditions. The Hohenstein Biodegradation testing services allow to evaluate the eco-toxicological safety of products.

2014 Hohenstein's HUMskin is based on a modified biopolymer and simulates the physiological, mechanical and topographic properties of healthy human skin. By using HUMskin to carry out ex vivo tests, all external influences can be completely excluded. The test conditions are standardised so that the results can be reproduced at any time.

2016 Hohenstein has been testing and verifying textile chemicals by means of the ECO PASSPORT by OEKO-TEX® since last year. This system verifies your formulations for chemicals of concern including many or all chemicals listed in currently existing manufacturing restricted substances lists (MRSL).

ACCREDITATIONS

Recognised test centre in compliance with DIN EN ISO/IEC 17025, and inspection centre in compliance with DIN EN ISO/IEC 17020, accredited by the German National Accreditation Body (DAkkS).

PARTNERS

- OEKO-TEX® Association

CONTACTS

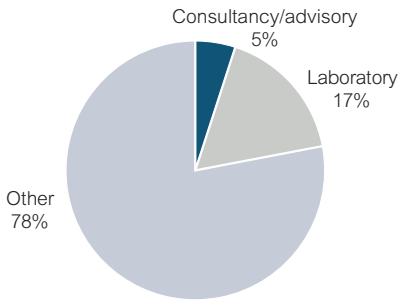
Website	www.icbpharma.com; www.icbpharma-analytics.com
E-mail	office@icbpharma.com; analytics@icbpharma.com
Head office	10 Lema Street, 43-603 Jaworzno, Poland
Tel	+48 32 74 54 700
Contact	Bartosz Łebek, Head of Analytical Laboratory
Directors	Tomasz Świętosławski Paweł Świętosławski
Ownership	Private ownership
Founded	2000

OVERVIEW

ICB Pharma is a family-owned company with long lasting, thorough expertise in the field of health care and protection against biological factors.
We are present in the fields of medical devices, professional pest control, agrochemicals for rural market and home and garden retail.
Our company is organised into five departments ie R&D, Analytics, Pest Innovations, Health Care and Crop Solutions. The heart of the company is R&D Laboratory, as a place where we have developed our most creative ideas such as a unique solid core micro and nano encapsulation method – Slow Release™Technology and just as innovative 3D IPNS™ (Immobilizing Polymeric Net Structure) Technology. Our patented products are successfully present on markets all over the world as a result of putting a great effort into a continuous development of formulation enhancements in our analytical and biological laboratories.

VITAL STATISTICS	2015/16
Turnover, group	€27m
Turnover, chemical service provision	€3.7m
No of offices	1
No of countries represented	-
Staff, group	105
Staff, chemical service provision	25

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

Analytical laboratory

The analytical division of ICB Pharma was established to conduct cost efficient studies for regulatory and quality control purposes. Our area of expertise is physico-chemical studies, technical properties of PPP (according to FAO) and biocidal products, as well as analytical determination of active ingredient contents, validation of analytical methods and residues testing. We offer studies conducted in compliance with the following: OECD Guidelines, OPPTS Guidelines, CIPAC methods, SANCO.
The laboratory is located in a brand new facility, equipped with renowned analytical systems (HPLC, GC-MS, GC-FID and many other study specific tools). Constantly building a team of highly experienced personnel we provide top-level quality results and excellent customer service.
The laboratory is fully compliant with GLP principles which assures that all reports will be respected by authorities worldwide.

Research and development

The R&D laboratory possesses highly advanced chemical processing equipment which enables creation of every cosmetic, agrochemical or medical product (for our own needs and also on client's request). Our laboratory is one of very few in the world where microencapsulated, biologically active solid and liquid cores products with extended release of active substance are manufactured.
Oil dispersions type of products are another unique subject of our researches. In this case biologically active substances are dispersed in non-vaporous oils, which allows to increase the safety of use and also to decrease commonly applied biocides usual doses.
The laboratory services aim at increasing the efficacy and reducing the threats for a man and the environment that come from pesticide usage.

Contract manufacturing

We provide our distributors and partners with thorough support during the process of placing the private label products on the target market.
This refers to medical devices, biocides and agrochemical products.
We offer registration process guidance or proceeding with the registration in the distributor's country, providing the dossier of all essential research and studies, graphic visualisation and marketing materials as well as production facility.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2000	ICB Pharma was founded
2003	Health Care Department was established
2004	R&D Department was established
2005	New Analytical Laboratory was established
2010	ICB Pharma was granted 20 worldwide patents
2013	New premises were opened (the area of over 5000 m^2)
2015	ICB Pharma was granted ISO 9001:2015 and PN-EN ISO 13485:2012 Certificates
2016	ICB Pharma was granted GLP (Good Laboratory Practice) Certificate

GLP
GOOD LABORATORY PRACTICE
CERTIFIED

We are the biggest provider of micro and nano-encapsulated formulations in Europe.

In the highest world class laboratories we conduct the full range of physico-chemical and analytical research, according to GLP.
We conduct tests stating pesticide residues for biocidal and agrochemical products.




ICBpharma

10 Lema Street
43-603 Jaworzno, PL
office: +48 32 74 54 700
office@icbpharma.com
analytics@icbpharma.com

www.icbpharma.com
www.icbpharma-analytics.com

INERIS
controlling risks for sustainable development

CONTACTS

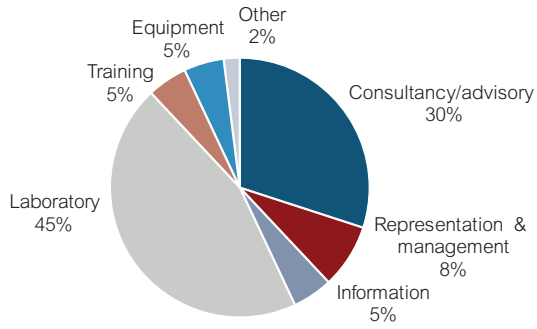
Website	www.ineris.fr
E-mail	prestaweb.dsc@ineris.fr
Head office	Parc Technologique Alata, 60550 Verneuil-en-Halatte, France
Tel	+33(0)3 44 55 67 81 (Reine LANDA)
Fax	+33(0)3 44 55 66 55
Contact	Reine LANDA, Business Development Manager Contacts for specific questions are included below
Directors	Hafid BAROUDI, Business Development and Certification Division Eric THYBAUD, Chronic Risk Division, Impact on Living Beings
Ownership	French public research body with industrial and commercial activities (EPIC), under the aegis of the French Ministry of Environment
Locations	France
Founded	1990

OVERVIEW

Established by the French government in 1990 as the National competence centre for Industrial Safety and Environmental protection, INERIS has developed broad expertise in the areas of chronic and accidental risks.
INERIS places its expertise as well as its scientific and technical experience at the service of companies in every industry, in order to guide them in their actions with regard to health, safety and environmental protection.
INERIS combines experimental approaches with expertise in modelling and risk methodology. It is equipped with physical/chemical analysis laboratories, GLP-compliant toxicology and ecotoxicology facilities, large scale fire gallery and explosion platform, and test facilities that are among the best in France, both for studying accidental phenomena and effects on living beings.
INERIS offers multi-disciplinary approaches with the capacity to conduct complex studies in many areas, including chemistry, *in vivo* toxicology, ecotoxicology, environmental fate and physico-chemical hazards in compliance with various regulatory needs (e.g. REACH, CLP and GHS notifications, biocides, waste (HP 14), transport of hazardous goods, ATEX, etc), or in response to research and development needs.

VITAL STATISTICS	2015/16
Turnover, group	€80m
Turnover, chemical service provision	-
No of offices	4
No of countries represented	Global
Staff, group	600
Staff, chemical service provision	250

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

France: main site in Parc Technologique ALATA, Verneuil-en-Halatte (60, North of Paris), Waste recovery platform ARDEVIE in Aix-en-Provence (13), Centre for Monitoring Ground and Underground Risks in Nancy (54), structural strength laboratory in Bourges (18).

SERVICES PROVIDED

Regulatory services

INERIS offers services according to REACH regulation and its implementation. The testing capabilities and the expertise permit a complete offer for the registration of substance in accordance with the requirements of REACH. It includes the development of Iuclid dossier and the chemical safety report according to the exposure scenario and management measures to ensure a high level of protection for workers, general population and environment. In the context of 3R strategy, INERIS can also provide with advice on the selection of the best alternative in integrated approaches for testing and assessment of your substance (Qsar, PBPK modelling and read-across).

Physico-chemical testing

INERIS has various equipments and facilities allowing an extensive range of experimental assays to study the physical and chemical properties of substances.
For chemical characterisation and determination of purity and stability of compounds, in-house analytical techniques available include:
GC-MS, GC with different detectors (FID, ECD, TSD, PFPD), LC with UV and fluorimetric detectors, LC-MS-MS, LC-HRMS, IC coupled to amperometric and conductometric detectors, ICP-OES and ICP-MS among others. INERIS also has expertise in developing and validating challenging analytical methods for a very broad range of substances in different matrices (water, air, soil, waste, biogas, etc.).
Physico-chemical hazard characterisation includes: flammability, explosivity of gas, liquid and dust materials by means of standard testing and specifically designed test methods, calorimetric study of hazardous chemical reactions, and standard testing of self-reacting substances and explosives.
INERIS can also study the thermal degradation of substances and materials by using tubular furnaces (from 50 to 1600°C).

Toxicological testing

INERIS provides *in vivo* (rat and mice) regulatory studies, in general toxicology, and with extensive expertise in pulmonary toxicology. All routes of administration are performed, with specific expertise in nose-only and whole body inhalation, and intratracheal instillation. Studies are performed in compliance with GLP and following OECD test guidelines, with a particular attention towards animal welfare (Directive 2010/63/EU):

- acute toxicological studies (OECD 402, 423 and 436);
- sub-acute repeated dose toxicity preliminary studies (range finding assays);
- short-term repeated dose toxicity studies (OECD 407 and 412); and
- screening for developmental and reproductive toxicity (OECD 421 and 422).

Research experience and expertise can also be provided in *in vivo* and *in vitro* pulmonary toxicology of environmental pollutants including nanoparticles, as well as on health effects of physical agents like electromagnetic fields.

Ecotoxicological testing

INERIS provides experimental assays and expertise in general ecotoxicity of chemicals and environmental matrices. It develops and performs biological assays to characterize the hazards towards the aquatic, benthic and terrestrial compartment, as well as an expertise for the environmental fate of chemicals. The study design, including test item preparation, test design and analytical phase is adapted to each specific requirement.

The following acute and chronic tests are performed routinely, according to European test methods or OECD test guidelines:

- aquatic tests: short and long-term toxicity on invertebrates (*Daphnia magna*, OECD 202 and 211; *Ceriodaphnia dubia*, ISO 20665), growth inhibition test on aquatic plants (algae, OECD 201; duckweed, OECD 221), fish lethality test (OECD 203) and activated sludge respiration inhibition test (OECD 209);
- terrestrial tests: deshydrogenase activity of *Arthrobacter globiformis* (ISO 18187), lethality and reproduction tests on earthworms (OECD 207 and 222), emergence and growth of higher plants (OECD 208), and growth, fertility and reproduction of nematodes (ISO 10872);
- sediment tests: Chironomids (OECD 218 and 219), Hyalella azteca (ISO 16303) and Myriophyllum (OECD 239, ISO 16191) toxicity tests; and
- environmental fate: ready biodegradability (OECD 301) and inherent biodegradability (OECD 302).

INERIS has also developed an expertise in the ecotoxicity of emerging substances including nanoparticles (sample preparation, nanoparticles characterisation, etc), ionic liquids and drugs residues.

Nanoparticles hazard assessment

INERIS has a complete *in vivo* (rat models) nose-only inhalation system (HCT) to expose animals to nanoparticle aerosols, with associated metrology, TEM and physico-chemical characterisation of nanoparticles. It participates also in the development of standardised technologies and assays for regulatory use in toxicology and ecotoxicology (eg assessment of air-liquid interface (ALI) exposure system for *in vitro* pulmonary nanotoxicology).

The S-NANO platform offers operational solutions for risk management throughout the lifecycle of nanomaterials: determination of safety parameters of combustible powdered nanomaterials (flammability, explosiveness, static electricity), use and development of the most effective instruments for testing, metrology and characterisation for use on nanomaterials, analysis and modelling of the behaviour of powders at the nanometric scale (rheology, suspension, dispersion potential) and investigation of granulation and agglomeration mechanisms, assessment of the emissivity of nanoparticles by materials in ambient air (dustiness) and by manufactured products containing nanomaterials when subject to external mechanical (abrasion, use), thermal (combustion, incineration), ultra-violet or chemical aggressions throughout their lifecycle.

Multi-disciplinary approach

INERIS services include various areas of expertise: characterisation of products, substances and materials, and capacity to generate an ATEX (physico-chemical properties, physical hazards related to substances, mixtures and to explosion of flammable liquids, vapours, gases, dusts and powders, explosive rapidity, etc), transport of hazardous materials, authorisation to operate application hazards study (industrial sites and ICPE-class facilities).

INERIS also has more than ten years' experience in nano-safety for the assessment of chemical and toxicological hazards of nanomaterials, workers and population exposure and the evaluation of associated risks.

Regulatory expertise on behalf of companies consists in appraising the compliance of equipment or systems with regulations, standards or frames of reference, particularly through certification, or providing, at the request of the authorities, an independent expert opinion (third party expert appraisals) on the validity of regulatory dossiers. Expertise, consultancy and training aim to transfer know how to those concerned by risk management (companies, local authorities, stakeholders, etc.) through a comprehensive and narrowly targeted range of services.

ACCREDITATIONS

INERIS is ISO 9001 certified by AFNOR for the following activities: research and development, consulting, appraisal, certification, product testing, development and also training in occupational hazards and industrial environment.

INERIS is compliant with Good Laboratory Practice (GLP) in the areas: toxicity testing, environmental toxicity studies on aquatic and terrestrial organisms, studies of behaviour in water, soil and air, bioaccumulation, analytical and clinical chemistry testing.

INERIS is accredited by COFRAC in compliance with NF EN ISO/CEI 17025 (testing and calibration body), 17043 (interlaboratory comparisons ILC), 17065 (certification body), cf. www.cofrac.fr, under n°1-0157, 2-1251, 1-2291, 5-0045.

CLIENTS

INERIS works with more than 2,000 clients around the world from various industry sectors and disciplines: chemistry, paints and coatings, cosmetics, food, oil, gas and petrochemicals, automotive and heavy equipment manufacturers, construction, marine, consumer electronics, nanotechnology, etc.

CASE STUDY: Accompanying client for a REACH dossier

Unique importer of a substance, at a tonnage above 1T/year (Annex VII), then above 10T/year (Annex VIII):

- validation of existing assay reports; *in silico* (read-across) feasibility evaluation and bibliographic expertise; guidance in providing physico-chemical identification data on the substance for Annex VI;
- definition and proposal of assay strategies for the development and validation of physico-chemical analysis methodology to quantify the test item in different media; for toxicology, ecotoxicology and physico-chemical characterisation;
- realization, at the same geographical site, of required physico-chemistry, *in vivo* toxicity and ecotoxicity experimental assays
- guidance along the process, on the assay strategy based on obtained results; for example, guidance for mutagenesis *in vitro* assays, and selection of the necessary follow-up *in vivo* assay for proposal to Echa; and
- reporting and preparation of all sections of the Iuclid file, including the chemical safety report (when applicable).

STAFF SELECTION

Anne BRAUN – experimental toxicology and REACH dossiers
anne.braun@ineris.fr

Pascal PANDARD – expertise and testing ecotoxicology
pascal.pandard@ineris.fr

Hugues BIAUDET – analytical resources
hugues.biaudet@ineris.fr

Adrien TROISE – regulatory expertise in toxicology and ecotoxicology
adrien.troise@ineris.fr

Bruno DEBRAY – accidental and ATEX risks
bruno.debray@ineris.fr

Emeric FREJAFON – hazards of nanomaterials
emeric.frejafon@ineris.fr

Lionel AUFAUVRE – transport of hazardous materials
lionel.aufauvre@ineris.fr

Reine LANDA – business development manager
reine.landa@ineris.fr

International Cosmetics
The service you don't think you need...until you do!
Regulatory Specialists, LLC (USA)
Chemical Services, Ltd (UK)
Intlcosmetics.com

CONTACTS

Website	www.intlcosmetics.com
E-mail	info@intlcosmetics.com
Head office	947 Manhattan Beach Boulevard, Suite A, Manhattan Beach, CA 90266, US
Tel	+1 310 545 3223
Contact	Georgia@intlcosmetics.com
Directors	Janet Winter
	Georgia Boehm
Ownership	Private company
Locations	USA, UK
Founded	1997

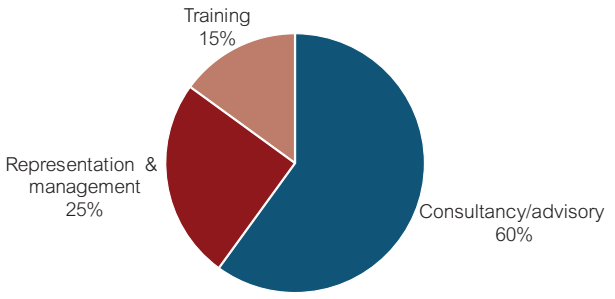
OVERVIEW

ICCS Ltd – UK, and ICRS LLC – US, are comprised of experienced technical professionals. Each provides expertise in regulatory compliance for the cosmetic and chemical industries worldwide. These companies specialise in: only representative services for companies needing chemical registrations and SDS under REACH; US agent services for FDA registrations; FDA and ISO GMP training, audits and manufacturing standards; EU RP services for cosmetics CPNP notifications and PIF. The company has offices in the US and the UK.

VITAL STATISTICS

	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	2
No of countries represented	35
Staff, group	10
Staff, chemical service provision	4

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

UK: International Cosmetics and Chemical Services Ltd
US: International Cosmetics and Regulatory Specialists LLC

SERVICES PROVIDED

Only representative (REACH), CLP notifications (sole representative) and safety data sheets (SDS)

Only representative services for companies needing chemical registrations for the EU scheme under REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). Late pre-registration and full registrations have already been successfully provided for many clients. CLP notification services are also available, in addition to safety data sheets (SDS) to meet the requirements of REACH and CLP.

US agent, cGMP audits and training, electronic US FDA registrations

Products such as Acne and any product containing SPF ingredients must be registered with the FDA. We can act as the US agent for foreign manufacturers (which is mandated by FDA) and provide the mandatory facility, distributor and product FDA electronic registrations.
FDA registrations must now be done electronically, which is a service we provide. We provide cosmetic and over-the-counter drug label reviews to the FDA monograph, training and 21 CFR 211 or ISO 22716 cGMP facility and standard operating procedure audits.

Training for GMPs and ISO manufacturing standards

A wide variety of experience facilitates custom services for international needs with the intricacies of each individual organisation in mind. Focus is given to tailoring these skills to fit the client needs for entire projects, multiple countries, or for an individual project for one country. We provide GMP training and audits to the newly-required ISO 22716 as well as FDA cGMP gap analysis to 21CFR211 for USA compliance. Foreign and US location audits performed.

EU responsible person (RP) for cosmetics CPNP notifications, Product Information Files (PIF)

2009 December
1223/2009 EC cosmetic Regulation published.
2013 July
1223/2009 EC cosmetic Regulation enforcement begins.

We provide full regulatory services in Europe, including labelling requirements, to meet 1223/2009 EC cosmetic Regulations for 28 EU member states.
Responsible person (RP) services. RP is responsible for:

- cosmetic safety reports;
- safety assessment by qualified safety assessor;
- product information file (PIF) for each product;
- EU physical location to hold PIF;
- EU address as required for all product labelling;
- label direction to meet EU requirements;
- access for the competent authorities (28 countries) for PIFs;
- holding and maintenance of PIFs for legally required access by competent authorities.

If a company does not own their formulas, we provide an agreement between the brand owner, the contract manufacturer and our company to provide confidentiality. With the agreement in place we only share information with an EU authority through access at our UK office.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

	REACH
2007	Formed REACH Chemical Consulting, Ltd now known as International Cosmetics and Chemical Services, Ltd.-UK.
2008	Filed pre-registrations for US and international companies to meet the EU Regulation.
2009	Among the first only representatives to successfully complete a cosmetic ingredient full registration in 2009 prior to the first 2010 deadline. This resulted due to a company who missed the pre-registration phase while importing finished product using the ingredient at one ton or more the previous three years.
2010	Preparation of safety data sheets (SDS) to meet the REACH and CLP requirements.
2011	Continuing with SDS creations, REACH late-preregistrations, Sief coordination for clients and their chemicals, continue with CLP notifications.
2013	Provided assistance to companies with mid-range registrations.
2014-2016	Assisting clients with meeting CLP deadlines and with preparations for the 2018 deadline.
2015-2016	Assisting clients with strategic planning for 2018 deadline
	ISO
2006	Designated expert in the Cosmetic ISO workgroup for TC-217, Cosmetic GMP, Sunscreens and Microbiology in Paris.
2006	Designated expert in cosmetic GMP and Sunscreen workgroup in Den Haag, the Netherlands.
2008	Designated expert Cosmetic GMP and Microbiology workgroup in Paris.
2009	Designated expert Cosmetic GMP and Microbiology workgroup in Baltimore, MD, US.
2010	Designated expert Cosmetic GMP, Microbiology and Sunscreens workgroup in London
2011	Designated expert Natural and Organic Terminology workgroup in Kyoto, Japan
2014	Staff members participated as Designated Experts in Microbiology and Terminology Working Groups.
2003-present	**cGMP audit**
2003-present	ICRS continues to excel in meeting cGMP compliance training and audits in the US as well as internationally. These activities are designed to meet the individual companies and their unique cultures. Staff use ISO GMPs, FDA cGMPs as well as country specific regulations depending on the market and or country needs. International OTC GMP audits: Switzerland, Germany and Poland

ACCREDITATIONS

- Personal Care Products Council (Formerly CTFA)
- Society of Cosmetic Chemists (SCC)
- Regulatory Affairs Professionals (RAPS)
- American Society for Quality (ASQ).
- Vrije University of Brussels (VUB), qualified safety assessor training and certificate from the department of Pharmacology and Toxicology
- Chartered biologist, Royal Society of Biology, UK

PARTNERS

Manhattan Repro (graphic design for labelling)

CLIENTS

Our client base consists of a wide variety of chemical companies, cosmetics and personal care companies and companies in related industries, of all sizes.

STAFF SELECTION

Janet Winter, Chief Technical Officer

- BA biology, University Redlands
- CEO of International Cosmetics & Regulatory Specialists LLC.
- CEO and founder US, and managing director of International Cosmetics and Chemical Services Ltd in the UK, serving the consumer products and chemical industries.
- 30 years of experience as a product formulator and regulatory expert has given her unique expertise in both the European and US regulatory schemes.
- Founder, instructor and lecturer for cosmetic science programme at UCLA (University of California at Los Angeles). Topics include: regulatory acceptance of cosmetic ingredients in individual countries; R&D and manufacturing for the global market; microbiology and quality control of cosmetic products.
- Past chairman, Society of Cosmetic Chemists; member, board of directors, Society of Cosmetic Chemists; regulatory affairs chairman, contributing author to SCC publications.
- Chartered biologist, Society of Biology, UK.
- Post graduate certificate in REACH management, University of Hull, UK.

Georgia Boehm, Vice President, Regulatory Affairs

- AA business management, Glendale College
- VP of Regulatory Affairs – International Cosmetics & Regulatory Specialists LLC, expert in yield and accountability documents for compliance with REACH regulations.
- 30+ years of experience in cGMP compliance, regulatory and quality systems, international registrations, FDA registrations, FDA drug compliance for claims and labelling and facility.
- Corporate experience: ten years at Neutrogena Corporation, six years at Herbalife International, and contract manufacturing management.

Deborah Rediet, Senior Manager, Regulatory Affairs

- BA French and minor in international studies, CSULB
- 11 years' experience in regulatory affairs in Canada, the US, Europe and Asia.
- Expert in labelling compliance and PIF requirements.
- Certificated from California State University, San Diego (CSUSD) in regulatory affairs, College of Science.
- Fluent in French, working proficiency in Spanish.

Robert Blaschke, Regulatory Systems Supervisor

- BA French and philosophy, Loyola Marymount University
- Regulatory affairs specialist – Seven years' experience in FDA compliance in the USA.
- Expert with FDA electronic registrations and IT portal.
- IT specialist.

Silvia Yoc, Regulatory Specialist, EU

- BA international business administration and marketing, CSULB
- Four years' experience in the US.
- European document compilation – Product Information File.

Adam Minc, Regulatory Associate

- BA business marketing, Spanish, Endicott College
- Two years' experience in the US.
- Database coordinator.
- Government submissions.

intertek

Total Quality. Assured.

CONTACTS

Website	www.intertek.com/green/chemicals/
E-mail	regulatoryaffairs@intertek.com
Head office	33 Cavendish Square, London W1G 0PS, UK
Tel	+44 161 245 8071
Contact	Jeremy Ramsden
Directors	Sir David Reid, Chairman; André Lacroix, Chief Executive Officer; Edward Leigh, Chief Financial Officer
Ownership	Public
Locations	Intertek is the industry leader with more than 1,000 laboratories and offices and over 40,000 people in more than 100 countries.
Founded	The Intertek story starts at the inception of the modern testing industry. The history of Intertek spans more than 130 years, and evolved from the combined growth of a number of innovative companies.

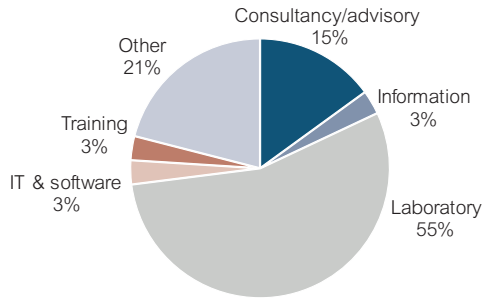
OVERVIEW

Intertek helps organisations across a wide range of industries to sharpen their competitive edge by providing advanced measurement, expert consulting related technical support services, and sustainability solutions. Our experts and laboratories provide critical support to our clients in their global trade, not just with data, but with essential knowledge to accelerate development of their next generation products, to improve their manufacturing, products or production processes or to enhance their efficiencies.

VITAL STATISTICS

	2015/16
Turnover, group	£2.20m
Turnover, chemical service provision	£175m
No of offices	1,000+
No of countries represented	100+
Staff, group	40,000+
Staff, chemical service provision	2,000+

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Germany: Stangenstr 1, 70771 Leinfelden-Echterdingen, +49 711 27311 152
UK: Bainbridge House, 86-90 London Road, Manchester, M1 2PW, +44(0)161 245 8071
Italy: Via Quasimodo 46, Castel Maggiore, Bologna, 40013, +39 051 0562930
US: 1060 Holland Drive, Suite G, Boca Raton, FL 33487, +1 561-989-7294
Canada: 2233 Argentia Road, Suite 201, Mississauga, ON, L5N 2X7, + 1-905-542-2900
China: Room 106 Comalong Building, Shanghai Comalong Technology Service Park, No. 889 Yi Shan Road, Shanghai, 200233, +86 (21) 6073 7735

SERVICES PROVIDED

Quality assurance – services that move beyond physical quality control to help provide you peace of mind through our assurance that your operating procedures and operating systems are functioning.

Advisory – services to help you advance your business

Inspection/auditing – services to help you control operations

Certification – services to help you reach new markets

Outsourcing – services to help you focus on core activities

Training – services to help you improve your performance

Testing – services to help you ensure you meet your quality standards

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2013	Intertek partnered with Decernis in order to provide research, content and information systems that supply a comprehensive service to help companies manage global regulatory compliance across the entire supply chain in a wide range of industries and products.
2013	Intertek expands testing capabilities through the addition of: granulometry to complement their comprehensive suite of REACH physico-chemical property tests and chemical characterisation; and, commercial materials and surface analysis laboratory capabilities in Australia with a scanning electron microscope with energy dispersive x-ray analyser (SEM-EDXA).
2013	Intertek announced that all obligations and agreements with clients pertaining to the 31 May 2013 REACH deadline were successfully fulfilled.
2015	Intertek Scientific & Regulatory Consultancy (formerly known as Cantox Health Sciences International) celebrates 30-year Anniversary of delivering valued service.
2016	Intertek expands chemical regulatory services to meet ongoing demands of TSCA Reform with the opening of an office in Washington, DC.
2016	Intertek Partners with Assent Compliance to address challenges in restricted substance management.
2016	Intertek aligns chemical regulatory and scientific consultancy under Global Health, Environmental and Regulatory Services business line.

ACCREDITATIONS

As a company, Intertek believes that acquiring the appropriate quality accreditations and maintaining membership (and in many cases) chairing industry regulatory groups and standards organisations is key to not only our development but to providing quality assurance and insight to our customers; and while the company holds membership to these organisations; individually Intertek has employees that represent the company on different boards. Examples of these would be:

Mr Naeem Mady – industry segment council board member and a national board council member at the Plastics Industry Trade Association (SPI), and a member of the America Chemical Society and Society of Plastics Engineering;

Ms Joyce Borkhoff – active member of the Industry Coordinating Group (ICG) for the Canadian Environmental Protection Act (Cepa), Responsible Distribution Canada (RDC), the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), and Canadian Paints and Coatings Association (CPCA); and

Dr Michael Leise – Board member of Only Representative Organisation (ORO) AISBL, representing credible REACH only representatives active within the European Economic Area.

CLIENTS

Our clients include: Behr, Bosch, BP, ChevronTexaco, Citgo, ConocoPhillips, Haier, Lubrizol, Petrobas, Siemens.

TESTIMONIALS

Director of Quality Engineering with Instrumentation Laboratory, Jim Richard, said "Intertek assisted us in the successful execution of a complex RoHS exclusion request. Throughout the process, Intertek experts were quick to respond, highly professional and knowledgeable in the legal and political processing of our request. In addition, Intertek acted as the liaison between authorities and Instrumentation Laboratory to ensure smooth and continuous progress of the application, as well as, the successful facilitation of in-depth communication with external stakeholders."

"I would like to let you know that I appreciate the high quality work and speed your team has worked to generate e-SDS for Braskem. You made us feel important by responding with a sense of urgency to our requests. I also wanted to inform you that Braskem Netherlands BV were inspected by Dutch government in regards to OR scope for all Braskem companies and all e-SDS checked were in compliance with REACH / GHS rules. Thank you so much!" – Braskem SA

CASE STUDY 1: Incorrect definition of substance can lead to unnecessary registration

One of the first major hurdles in the preparation of the technical dossier for REACH is to ensure the registrant is certain that the substance is well defined. The better the knowledge of the substance definition, the easier it is to decide on a registration strategy. In one case our client was uncertain about the handling and interpretation of the product-by-process definition, so our expert spent several hours discussing the problem. As the descriptions became quite complicated our expert was invited to the plant to better define the case. After a few hours of explanations onsite, it became quite evident that the substance in question was not eligible for registration and hence was exempted. Looking back this process was a minor investment compared to a full registration dossier. The client easily saved millions in consulting charges and multiples thereof in testing costs.

CASE STUDY 2: Intertek's global network of experts helps clients achieve cost-effective registrations worldwide

Keeping up with changes in regulatory landscapes and differences in pre-market approval programmes for new products, novel ingredients, and unique raw materials is challenging. Add a need for reliable safety assessments while protecting confidential information, and challenges seem insurmountable. Recently, Intertek was asked by a chemical company located in the UK for help with accessing new markets in South Korea. Sending chemicals into this region would require compliance with the new K-REACH programme, typically requiring submission of sensitive product information by the local importer to the government agency for safety assessment and pre-market clearance. Although the UK company agreed to provide the necessary information, they were reluctant to submit confidential information through the local customer. Intertek's global team worked seamlessly with the chemical company and its customer, to prepare and submit a robust dossier, and obtained approval directly for the UK company, using Intertek's South Korea-based only representative (OR) service, mimicking Intertek's highly successful OR service for EU-REACH compliance. Intertek solutions go beyond addressing scientific and regulatory challenges; we protect our customers' competitive advantage in global markets.

STAFF SELECTION

Joyce Borkhoff – Senior Director, NA Chemicals Group, Intertek Scientific and Regulatory Consultancy Services

As a regulatory chemist with more than 20 years' experience, Joyce Borkhoff helps the chemical industry understand and comply with global regulations controlling the manufacture, importation, distribution, and use of new and existing products. Her technical and regulatory acumen and strong communication skills enable Joyce to develop and deliver health, environment, safety, security, and stewardship programmes that address all regulatory obligations and contribute to the development and success of corporate business strategies. Joyce's leadership and advanced mediation skills enabled her to successfully represent the interests of the chemical industry in bilateral and multi-stakeholder regulatory forums that tackle the development and evolution of a wide variety of legislative and regulatory amendments.

Torben Nörlem, Esq – Chief Legal Counsel Regulatory Services

Torben Nörlem has an LLM in law from the legal faculty at Copenhagen University and 16 years' experience working with product related legislation and regulatory framework. Torben has been working as chief counsel for health and environment with Intertek since 2008. Torben was responsible for legal affairs related to the REACH legislative process and was a participant of the Danish government negotiation team during the negotiations in the European Union. He was also responsible for implementation and administration of EU rules regarding chemicals in electronics in Denmark.

Naeem Mady, Vice President, Regulatory Services

Naeem Mady's responsibilities include worldwide notification of U.S. products, and regulatory compliance for food contact substances. Prior to working for Intertek, Naeem was with Ciba Specialty Chemicals since 1980. His responsibilities included the design and implementation of Good Laboratory Practices (GLP) and Quality Management Systems programmes; the design and development of migration studies for FDA submissions; and ensuring FDA and EPA regulatory compliance for Ciba. Naeem expertise is evident through his contributions as an author and participation as an invited speaker for industry.

Dr Michael Leise – Senior Expert Consultant, Regulatory Affairs

Dr Michael Leise's responsibilities include consulting on notification strategies for chemicals worldwide, test-programme development, chemical risk assessment, negotiations with authorities and scientific bodies. He studied at Heidelberg, researched in Boston at MIT and acquired environmental expertise at TÜV Rheinland before he joined Ciba Specialty Chemicals in Lampertheim as head of product safety in 1995.

Helen Xue – General Manager, Chemicals & Pharmaceuticals, China

Helen Xue has 20 years of experience in pharmaceutical, public health and environment area. She worked as the medical research scientist of FDA China Office, Health and Environment specialist of the US Consulate Shanghai Economic and Political Department. Helen worked at Intertek from 1998 to 2006 and re-joined in 2013. She is in charge of C&P China which provides services for GMP compliance and EHS compliance programme for pharmaceutical, medical device and cosmetic industry, chemical regulatory support (registration, consulting etc), cosmetic chemical testing and safety assessment, cosmetic efficacy study.

CONTACTS

Website	www.jsci.co.uk
E-mail	enquiries@jsci.co.uk
Head office	The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, UK
Tel	+44 (0)1423 520245
Fax	+44 (0)1423 520297
Contact	Dr Samantha Wright or Dr Richard Elsmore
Directors	Richard Elsmore, Managing Director
Ownership	Wholly owned subsidiary of ERM Limited
Locations	UK
Founded	1992

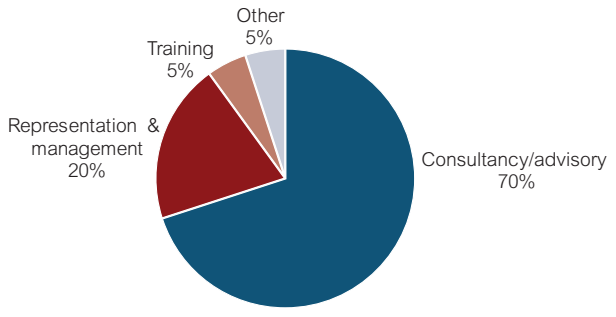
OVERVIEW

JSC International Limited is a wholly owned subsidiary of ERM Limited providing European regulatory consultancy to the chemical, agrochemical and biocides industries.
At JSC we have a dedicated team of highly motivated people with backgrounds from government, industry and contract research. Our integrated, cross-discipline working practices enable us to provide novel and innovative approaches to problem solving, supported by our excellent contacts with regulatory officials and scientific experts throughout the world.

VITAL STATISTICS

	2014/2015
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	30+
Staff, group	33
Staff, chemical service provision	26

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

JSC International Limited, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom

SERVICES PROVIDED

Biocidal active substances and biocidal products

JSC offers regulatory support for both active substances and biocidal products. We have experience of submitting active substance dossiers for a wide range of product types under the BPD/BPR. For biocidal products we routinely submit national registrations and have good contacts with regulatory authorities in all member states within the EU. We are also active in submitting BPR product dossiers following inclusion on the Union list of approved active substances. We are able to offer support on a diverse range of biocidal products.
JSC can also offer more general regulatory support to biocide manufacturers and formulators in areas such as scope issues, efficacy testing, claim support and risk assessment.

REACH services

JSC consultants have significant experience in all aspects of REACH. We have prepared a large number of registration dossiers (lead and member dossiers) and chemical safety reports (CSR's) and have provided expert advice on specific areas of REACH such as data evaluation and study monitoring. JSC have Sief/consortium management experience and ensure that the deadlines of your project are met. We are able to help with the preparation of consortium agreements, communication within the consortium and ensure an effectively running consortium. JSC are able to help downstream users identify their obligations and provide training to ensure continued compliance.

CLP/GHS

JSC experts are able to assist with classification, labelling and safety data sheet creation including the extended safety data sheet containing exposure scenarios.

DGSA

JSC can offer dangerous goods safety adviser services for the transport of hazardous goods. Our experts can act as your company DGSA, provide support, auditing and training.

Agrochemical products

JSC has extensive experience in the preparation, submission and regulatory support of EU dossiers and national draft registration reports. We have an excellent track record of successful EU approvals and national authorisations, and are well placed to assist you in the development of strategies to support your compounds in Europe.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1992	EU offices of JSC formed – US owners
1996	Offices relocated to Harrogate
2004	Management buy-out
2005	Biocides expertise consolidated
2006	Development of expertise in REACH
2008	Consolidation of REACH capability
2010	Preparation and submission of a large number of REACH dossiers/CSRs
2014	Office relocation within Harrogate
2016	Acquired by ERM Limited

ACCREDITATIONS

All technical staff are qualified to degree level or higher (MSc and or PhD). Our senior toxicologists are Society of Biology / British Toxicology Society and Eurotox registered and a certified DGSA in our parent company. We employ a number of chartered biologists (CBiol) including two fellows of the Royal Society of Biology (RFSB).

PARTNERS

Network of locally recognised regulatory contacts across the globe, as well as the ERM network of offices which comprise more than 160 offices in over 40 countries.

CLIENTS

Our clients range from large international companies to SMEs located worldwide.

TESTIMONIALS

We are unable to identify our clients due to client confidentiality constraints.

CASE STUDY 1: Biocidal active substance approval

JSC has successfully developed and submitted a wide range of active substance dossiers under both the BPD and now the BPR. These active substance dossiers have included uses in the majority of product types (PTs).

CASE STUDY 2: Biocidal product authorisation

JSC has successfully submitted a large number of biocidal product dossiers. This has involved national submissions (where relevant) in most member states within the EU as well as BPD and BPR biocidal product dossiers. Product dossier submission has included most of the BPR product types.

CASE STUDY 3: REACH dossier preparation

JSC has provided REACH dossier preparation for a number of complex and hazardous chemical substances. These substances have required the identification of data gaps and where necessary, placing and monitoring of studies. JSC has also been responsible for the production of the registration dossiers for the lead registrants and members of the consortia in Iuclid and for developing the chemical safety report and working with the consortia members to identify downstream user descriptor codes. The project was a success culminating in the successful submission of substance dossiers for the 2010 and 2013 deadlines.

During the development of these dossier and safety assessments JSC has had to work with consortia members and downstream users to identify relevant use patterns and in the development of appropriate RRM and in the production of meaningful extended SDS.

STAFF SELECTION

Dr Samantha Wright – Regulatory Affairs: Biocides and REACH

Samantha Wright is an experienced REACH manager with previous responsibilities for tracking and implementing worldwide legislation to ensure global regulatory compliance. Samantha has experience in the preparation and submission of REACH dossiers and consortium management, as well as a number of years authoring safety data sheets and determining classification and labelling. Samantha has been involved with strategy planning for business compliance and delivering training for REACH and CLP.

Samantha has experience of submitting a number of biocide active substance and product dossiers, and provides support and guidance for companies under the BPR.

Samantha's background in regulatory affairs was gained through working with clients in the cosmetic, pharmaceutical and industrial sectors.

Dr Richard Elsmore – Managing Director

Richard Elsmore has held a number of senior roles with speciality chemical manufacturers and formulators and has experience of working with a wide range of product chemistries; he has a practical background of operating within the global chemical market and with FMCG's.

Richard has worked in technical, regulatory and business management positions and has been involved with a number of industry bodies at EU level. He is also a director of the British Association for Chemical Specialities (BACS).

Richard has experience of submitting a number of dossiers under REACH (1907/2006), BPD (98/8/EC) and BPR (528/2012) as well as submissions to national regulatory authorities. He has been actively involved with a number of industry bodies on the implementation of the EU legislation and in the area of efficacy testing and claim support. He additionally sits on the BSi Technical Committee on disinfectant standards (CH/216) and has represented BSi within CEN. He has also worked on both method development and the assessment of individual chemicals in the human and environmental risk assessments programme (HERA).

Peter Chapman – Director of Regulatory Affairs

Peter has many years' experience in pesticides registration matters having previously held senior roles in the UK regulatory authority both in a national and international capacity. He has worked extensively with the European Commission, the European Food Safety Authority and most EU member states. His main focus is on providing up to date advice on regulatory matters relating to pesticide active substances and plant protection products.

KÆLTIA COMPLIANCE SERVICES

CONTACTS

Website	www.kaeltia.com
E-mail	info@kaeltia.com
Head office	Edificio CRISTASA. Av. de la argentina, 132. 33213. Gijón, Spain.
Tel	Line 1: +34 984391044 / Line 2: +34 984391280
Fax	+34 985308228
Contact	Dr Elisa Capellán, elisa.capellan@kaeltia.com
Directors	Dr Elisa Capellán
Ownership	Private company
Locations	Spain
Founded	2011

OVERVIEW

KAELTIA is an enthusiastic and motivated consultancy company formed by experienced and highly-skilled PhD and MSc scientists with a chemistry, toxicology, environmental and agronomic profile. Our experience in the chemical regulatory framework has allowed us to deal efficiently with several projects on time, within budget and to the required standards.

KAELTIA's managing director as well as the project managers have extensive experience of regulatory affairs gained in industry, contract research and consultancy.

We offer a qualified and efficient regulatory service to chemical industry with the help of our valuable, highly-experienced, proactive and committed staff, which is continuously updated on the regulatory requirements, with fluid communications with our clients and the relevant competent authorities.

We strongly believe that the effective project management is the key to offer a good service, so we invest great part of our time to train highly-qualified scientists and to improve our services for the benefit of our clients.

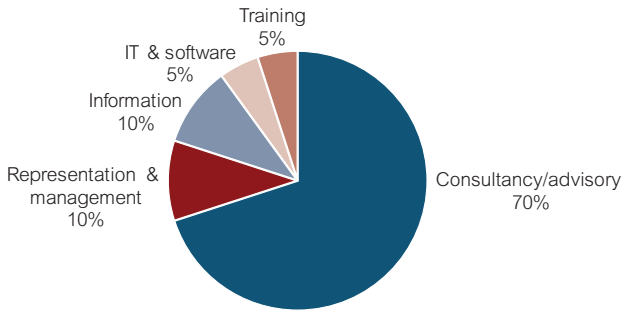
We offer our regulatory services in the areas of plant health, animal health, environmental and human health. We believe that this wide expertise across related regulatory areas enables us to offer a greater service value to our clients.

KAELTIA has developed a worldwide network of partners that allows us to provide our clients with up-to-date knowledge in the country legislation, establishing good relations with local competent authorities.

Our core values are efficiency, honesty, reliability and professionalism.

VITAL STATISTICS	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	Global
Staff, group	<10
Staff, chemical service provision	<10

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Spain

SERVICES PROVIDED

KAELTIA offers an effective and experienced support in managing the complex and constantly evolving regulation on the following areas:

Plant health

Areas of expertise:

- plant protection;
- fertilisers;
- biostimulants;
- basic substances;
- botanical extracts;
- microorganisms; and
- pheromones.

Services that KAELTIA offers in the plant health area:

- strategic advice and guidance;
- data gap analysis: data available vs data required;
- preliminary risks assessments for human and environmental health;
- pre- and post-submission meetings;
- preparation of EU dossiers for authorisation and renewal;
- preparation of EU mutual recognition applications;
- preparation of national registration dossiers in Europe (during the transitional period);
- preparation of National registration dossiers in North and South America, Asia, Australia and Africa;
- technical equivalence dossier for new active substance source;
- toxicological, environmental and consumer risk assessments;
- modelling and development of exposure scenarios;
- expert judgments to avoid unnecessary testing;
- read-across and Qsars;
- study commissioning and monitoring with accredited laboratories;
- CONSORTIA creation and coordination ;
- CLP/GHS classification of substances and mixtures;
- preparation of SDS and commercial labels according to local requirements;
- data sharing;
- liaison with the authorities;
- follow-up of the registration process until the product approval;
- third party representative services; and
- literature review.

Animal health

Areas of expertise:

- biocides;
- veterinary products; and
- feed legislation.

Services that KAELTIA offers in the animal health area:

- strategic advice and guidance;
- data gap analysis: data available vs data required;
- preliminary risks assessments for human and environmental health;
- pre- and post-submission meetings;

- preparation of EU dossiers for authorisation and renewal;
- preparation of EU mutual recognition applications;
- preparation of National registration dossiers in Europe (during the transitional period);
- preparation of national registration dossiers in North and South America, Asia, Australia and Africa;
- technical equivalence dossier for new active substance source;
- toxicological, environmental and consumer risk assessments;
- modelling and development of exposure scenarios;
- expert judgments to avoid unnecessary testing;
- read-across and Qsars;
- study commissioning and monitoring with accredited laboratories;
- CONSORTIA creation and coordination for biocides;
- CLP/GHS classification of substances and mixtures;
- preparation of SDS and commercial labels according to local requirements;
- data sharing;
- liaison with the authorities;
- follow-up of the registration process until the product approval;
- third party representative services; and
- literature review.

Environmental and human health

Areas of expertise:

- biocides;
- medicinal products;
- cosmetics;
- REACH;
- CLP/GHS;
- nanomaterials;
- endocrine disruptors;
- medical devices;
- food additives;
- food contact materials;
- detergents and surfactants; and
- toy safety.

Services that KAELTIA offers in the environmental and human health areas:

- strategic advice and guidance;
- data gap analysis: data available vs data required;
- preliminary risks assessments for human and environmental health;
- preparation of cosmetic and chemical safety reports;
- pre- and post-submission meetings;
- preparation of EU dossiers for authorisation and renewal;
- preparation of EU mutual recognition applications;
- preparation of national registration dossiers in Europe (during the transitional period);
- preparation of national registration dossiers in North and South America, Asia, Australia and Africa;
- technical equivalence dossier for new active substance source;
- toxicological, environmental and consumer risk assessments;
- modelling and development of exposure scenarios;
- expert judgments to avoid unnecessary testing;
- read-across and Qsars;
- study commissioning and monitoring with accredited laboratories;
- CONSORTIA creation and coordination for biocides;
- Sief and consortia management for chemicals;
- CLP/GHS classification of substances and mixtures;
- preparation of SDS, e-SDS and commercial labels according to local requirements;
- data sharing;
- liaison with the authorities;
- follow-up of the registration process until the product approval;
- only representative and third party representative services; and
- literature review.

KAELTIA offers their services in the following countries:

- EUROPE: Spain, Portugal, France, Italy, Greece, Cyprus, Germany, Belgium, Austria, Bulgaria, Croatia, Denmark, Hungary, Ireland, Lithuania, Norway, The Netherlands, Poland, UK, Czech Republic, Romania, Sweden, Turkey, Ukraine.
- AFRICA: Algeria, Tunisia, Morocco, South Africa.
- AMERICA: US, Canada, Brazil, Argentina, Chile, Colombia, Costa Rica, Ecuador, Mexico, Peru, Venezuela, Bolivia, Panama, Guatemala, Honduras, El Salvador, Nicaragua, Dominican Republic.
- ASIA: UAE, South Korea, Kuwait, Qatar, China, Israel, Indonesia, Malaysia, Thailand, Russia.
- OCEANIA: Australia.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2011	Foundation of KAELTIA.
2012	Expansion of the team and further development of services on biocides and plant protection products.
2013	Further development of services on plant health products and human health.
2014	Further development of services on animal health products: veterinary area.
2015	Expansion of the team.
2016	Expansion of the team and development of a consortia IT System for EU biocides.
2017	Development of a consortia IT System for EU plant protection products.

PARTNERS

KAELTIA has a worldwide network of partners that allow us to offer efficient regulatory services with the most updated local/country rules at any time.

CLIENTS

KAELTIA supports a global client database of chemical, biocidal, agrochemical and veterinary companies, ranging from SMEs to large multinational corporations. Our client list is maintained on a confidential basis and we cannot disclose their identity.

STAFF SELECTION

Elisa Capellán – PhD – Director

Founder of KAELTIA COMPLIANCE SERVICES.
Extensive international regulatory affairs consultancy experience.
Project management and team coordination.
Consortia management and data sharing.
Human and environmental health risk assessments.

The rest of the team

All the staff are professionally qualified and skilled in technical dossier preparation, risk assessments and modelling, and study design and monitoring.

KFT The CHEMICAL COMPLIANCE Company

CONTACTS

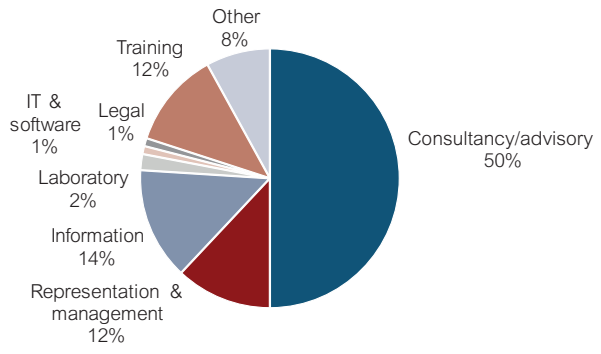
Website	www.kft.de; www.kft-academy.com www.kft-chemdoc24.com
E-mail	mail@kft.de
Head office	Im Leuschnerpark 3, 64347 Griesheim, Germany
Tel	+49 6155 8981-400
Fax	+49 6155 8981-500
Contact	Karl-Franz Torges (PhD), Karin Schmidt
Directors	Karl-Franz Torges (PhD) / Managing Partner, Angelika Torges / authorised officer
Ownership	Private company
Locations	Griesheim (near Darmstadt), Germany
Founded	1995

OVERVIEW

KFT Chemieservices' business is its competence in regulatory and product safety affairs. We ensure our customers' legal compliance for registrations, documentation as well as environmental exposures. Key elements are our experienced and well trained staff, modern, sophisticated software and fair compensation of our services. Our responsiveness to individual customer needs is well recognised in the market.

VITAL STATISTICS	2016/17
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	20
Staff, chemical service provision	16

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

Safety data sheets

Generation of safety data sheets (SDS) worldwide in accordance with GHS. SDS are generated according to national implementation of GHS and supplemented by country-specific requirements. Examples for countries and regions are EU, Switzerland, Canada, US, all of Asia, South America and South Africa. We generate SDS in all EU languages, also in Russian, Thai, Malay, and Mandarin Chinese. We also support specific national certifications as required in Turkey. A comprehensive concept of SDS maintenance packages has been successfully introduced allowing customer's permanent updating of safety data sheets (SDS) pursuant to statutory requirements. The total care service is completed by the latest innovation KFT SDS Control & Care, covering the management of supplier SDS. For our customers, we also offer creation and servicing for a specified number of SDS at a monthly fixed price.

Raw materials management

Many of our customers have entrusted KFT with the management of their raw material data. This involves the requisition and review of suppliers' safety data sheets, and communication with the supplier to eliminate possible deficiencies. We remotely enter the data of the suppliers' SDS into the customer's IT systems. In addition, we update the regulatory content data in the customer systems. Our many years 'experience with SAP EH&S allows us to guarantee proper and professional data maintenance also in these systems.

Generation and maintenance of exposure scenarios

We generate exposure scenarios according to legal requirements and the agreed exchange format (EsCom). Furthermore, we create the necessary information for mixtures based on the methods LC ID (lead component identification) and SUMI.

Notification according article 45 CLP

Notification of products and articles pursuant to Art. 45 of CLP, the German detergents and cleaning agents Act (WMRG) and product notification in all European countries, Turkey, the US and many other countries.

REACH

KFT Chemieservice has been working with REACH since 2001. Since that time we have prepared a number of companies for REACH, devised practical solutions by deploying taskforces, and we have assumed numerous registrations for our customers. We offer you:

- only representative services pursuant to article 8 (REACH);
- registrations according to article 10/11 and 18/19; and
- preparations of I dossiers and CSR (chemical safety reports).

Our REACH and management services cover:

- impact analysis, strategic and operative REACH consulting, portfolio as well as supply chain communication consultation.

Our Sief management provides:

- project management, financial processing and settlement, trustee services, conducting studies and organisation of data sharing, communication with customers, authorities and competitors.

Cosmetics

We check your formulas regarding permissible ingredients or compliance with permissible concentrations and we create the legally required labelling information and the approval of finished labels on your behalf. In addition, we carry out the notification of the products, draw up and verify existing safety assessments or complete product information files and finally, we will guide you through the jungle of 'borderline' products.

Biocide substances

With an experienced team we handle registrations of biocide substances, coordinate study generation, prepare the dossiers and do the authority management.

Seminars, training and coaching

The very popular and appreciated coaching support has been continuously developed to a broad spectrum of seminars around the compliance aspects of REACH, SDS, GHS / CLP, cosmetics, and biocides. The available selection can be found at www.kft-academy.com. In-house training and customised coaching are available on demand at sales@kft.de. Monthly webinars can be accessed free of charge.
The launch of eBooks on legal aspects around compliance has started 2013.

Emergency numbers

Emergency numbers are important in two respects. First, they must be provided in safety data sheets according to the REACH Regulation (1907/2006/EC). Second, legal regulations on transport, particularly by airlines, absolutely demand emergency numbers – usually on a carriage document or label. At KFT, we offer companies an emergency number service through our partners Chemtrec and Giftinformationszentrum Nord.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1995	Foundation of KFT Chemieservice.
1998	First registration according to the existing substances regulation 793/93/EC.
2000	Relocation of the company to Griesheim, Germany.
2008	First only representative contract with Brazilian company.
2010	> 3,000 pre-registrations, > 60 substances registered, first biocide substance registered.
2010	Launch of KFT-ChemDoc24.de
2011	First substances in articles notified.
2012	Introduction of SDS Control & Care (raw material mgmt.)
2013	Launch of KFT Chemical compliance Life – a webinar about regulatory chemical compliance news and special topics.
2014	Emergency number service, notification service according to Article 45 of the CLP regulation.
2015	Chemical Compliance Services for cosmetics
2016	Co-operation with Lisam systems to market and implement ExESS software systems; launch of customer days

ACCREDITATIONS

VCH (association of chemical suppliers) subsidiary of FECC (European Association of Chemical Distributors)
Member of ENES (European network on exposure scenarios)
Member of SCHC (Society for Chemical Hazard Communication)

PARTNERS

Tradas Translations and Consulting Services
Laus GmbH (GLP certified testing laboratory)
Chemtrec/GIZ Nord (Security number services)
KTR Europe GmbH (China and Korea New Chemical Substance Notification Service)
LISAM Deutschland GmbH (ExESS chemical compliance software solution)
CRAD (Cevre Risk Analiz Denetim), Turkey

CLIENTS

Chemical manufacturers, distributors, importers of consumer goods, biocide substances, pharmaceutical raw materials, hygiene products for veterinary applications, household cleaner formulations and other products.

CASE STUDY 1: Marketability study

Consumer goods providers must pay particular attention to hazardous materials and hazardous cargo. A few traders have established a partnership with KFT Chemieservice GmbH, in order to verify product compliance. Together with the tender, suppliers of the consumer goods providers are asked to submit a confirmation from KFT Chemieservice GmbH that all documents and labels conform to legal regulations. KFT Chemieservice checks the requirements and legal conformity with regard to:

- chemical legislation;
- ordinance on detergents;
- cosmetics regulations;
- biocide regulations;
- environmental regulations;
- commodities regulations;
- transport law (hazardous materials) etc; and
- ultimately issues approval for marketing.

CASE STUDY 2: Notification service

According to Article 45 of the CLP Regulation, manufacturers, market launchers, and distributors must notify the appropriate national agencies of the formulations and contents of hazardous chemical mixtures. However, for companies operating in multiple EU countries it is costly because each country has a different notification process. We know the requirements and processes in all countries and handle the notifications for our clients.

CASE STUDY 3: REACH lead registrant support

We perform the Sief survey with the available data in consideration of the interests of other Sief participants, find the existing data and data gaps, undertake negotiations with data keepers and contract testing labs to close the data gaps. We create the luclid file and the CSR and take care of registration with the Echa. KFT markets the letter of access to other registrants. In addition, we create the SDS with appendix (exposure scenarios) in all EU languages. We provide one-stop service for the client.

STAFF SELECTION

Dr Karl-Franz Torges (PhD) – Managing Partner

Dr Karl-Franz Torges is founder and managing partner of KFT Chemieservice GmbH, heading the business unit REACH and registrations. Familiar with hazardous materials, hazardous goods, MSDS and registrations since 1989. Several years experience in working with software companies focusing on compliance software (SAP EH&S). Since 2001 instrumental participation for the development of software tools for REACH processes. Member of Cefic and VCI working groups. Consulting for the development of luclid 5.0. Consulting and training projects and workshops for hazardous materials management, registrations, and chemical compliance.

Angelika Torges – Member of the Board

Board member and heading the division hazardous materials, marketability study and MSDS. Experience and responsibilities in these segments since 1989. Certified dangerous goods officer for several companies. Expertise in toxicology, ecotoxicology, chemical compliance ie. for washing and cleaning agents and has expert certificate for §5 of Restriction Ordinance on Chemicals.

Other staff

Majority of staff are PhD chemists, biologists and experts in food technology with years of experience for material registrations and MSDS. In-house training is a strong focus and sustainable external training is obligatory.

LISAM SYSTEMS

CONTACTS

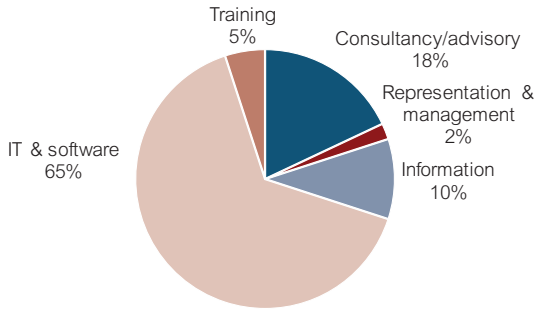
Website	Global: www.lisam.com Regulatory advisory: www.lisam-telegis.fr
E-mail	info.eu@lisam.com
Head office	Rue Jean Jaures 5, B-7190 Ecaussinnes, Belgium
Tel	+32 67 49 00 03
Fax	+32 67 49 02 11
Contact	Michel Hemberg
Directors	Michel Hemberg, Owner & CEO/CIO Lisam Global Thierry Levintoff, Owner & CFO Lisam Global Françoise Saint-Romain, Managing Partner Regulatory
Ownership	Private company
Locations	Belgium, France, Germany, UK, Romania, Lithuania, USA, Canada, India, Turkey, Brazil, China, Japan, Singapore.
Founded	1999

OVERVIEW

Founded in 1999, Lisam Systems is a global provider of Environmental, Health and Safety (EH&S) compliance management software solutions and services, operating from offices worldwide. By combining an easy-to-use, flexible technology built on the Microsoft .NET platform, with the latest regulatory content, Lisam brings innovative, affordable and timely solutions to solve EH&S challenges faced by manufacturers, distributors and users of chemical products. Working with industry associations and partners, Lisam has developed, proprietary, vertical EH&S solutions for the chemical, specialty chemical, cosmetics, aromas and flavourings, detergents, paints, coverings, coatings, plastics and energy industries. Today, more than 1000 clients in these industries rely on Lisam's flagship software, ExESS®, to manage their compliant safety data sheets and labels, designed for all major commercial markets and available in 50 languages. With the recent opening of offices in China and Singapore, Lisam now also holds the key to meet all the regulatory challenges of the Asian market.

VITAL STATISTICS	2015/16
Turnover, group	€15m
Turnover, chemical service provision	€15m
No of offices	13
No of countries represented	22
Staff, group	130
Staff, chemical service provision	110

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Belgium, France, Germany, UK, Romania, USA, Canada, India, Turkey, Brazil, Lithuania, Singapore, China

SERVICES PROVIDED

Regulatory advisory services

Lisam Services (Telegis) is the regulatory expertise department of Lisam Systems, partner of the chemical industry in regulations on health, safety and environment for 20 years. With pragmatic knowledge and experience they will guide you in making strategic decisions and bring support in the following areas:

- safety data sheets: issue of quality SDSs in compliance with REACH and other regulations specific to your activities;
- exposure scenarios authoring: preparation and translation of exposure scenarios in the latest standard format;
- consultancy and regulatory studies: compliance projects on REACH, GHS, CLP, (e)SDS, dangerous goods transport, notifications of hazardous substances, biocides … including preparation of chemicals' dossiers;
- regulatory monitoring and watch, general and on-demand;
- biocides: declaration of biocidal products and quantities, composition validation, monitoring of studies and environmental fate assessment, request for market authorisation, inclusion on list of authorised active substances, labels;
- hazard assessment by *in silico* methods: predictive evaluation of substance properties and hazards with computer models to guarantee cost and time savings compared to *in vitro* and *in vivo* studies;
- REACH only representative: REACH obligations for non-EU manufacturers; and
- REACH third party representative: Lisam acts in your name for data submission, data sharing and cost sharing discussions, while your identity remains confidential.

Our regulatory department also includes IT experts to advise you on the most adequate IT environment, install Lisam Systems' EH&S modules, train your teams and support you with change requests and incidents.

ExESS® EH&S packages

ExESS EH&S applications are easy to use and flexible to configure. The system provides a powerful, open strategy for integrating with customer and third-party content. It allows for real-time API integration with a broad range of enterprise systems, and batch integration with built-in integration tools:

- SDS and labels authoring and distribution: user-friendly, comprehensive and globally compliant solution for authoring and distribution of safety data sheets and labels, installed on single workstations, over worldwide corporate networks or accessed and used via the cloud;
- chemical management: efficient and effective management of all materials information relating to regulatory compliance, hazard communication, environmental reporting and inventory management;
- safety management: workplace safety information managed from one centralised database. Easy generation of documents to describe advised handling of chemicals and adequate protective and emergency measures;
- substance volume tracking: simplification and automation of regulatory volume tracking and reporting, for EU REACH (including SVHC), US inventory update reporting and chemical data reporting, and Japan Chemical Substance Control Law;
- regulatory content: cost effective, integrated regulatory content such as OEL lists, EU GHS and REACH libraries, US state/federal lists, and choice of fully integrated third-party regional libraries, including BIG for EU, JCDB for Japan, SRICI for China, or ChemADVISOR's LOLI® for global content; and
- more solutions for waste management, risk assessment, detergents, fragrances, cosmetics, gas…

Training, services and support

Our services are proposed in several languages:

- regulatory training: REACH, GHS, CLP, Iuclid, (e)SDS…;
- introduction and extended trainings on ExESS applications;
- regional trainings: EU, US, China, Japan;
- technical trainings: API, ERP integration, customisation…;
- a helpdesk answering you on the phone or via email; and
- version patches and updates of ExESS issued three times a year guarantee a system aligned with latest regulatory changes.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1999	Creation of Lisam Systems in Belgium
2002	Acquisition of Belgian company ESI (Protheus Software)
2006	Acquisition of Telegis, France, to offer support and regulatory consultancy services
2007	Lisam India opens in association with Kalosoft Systems Technologies
2009	Acquisition of Hemmis, reinforcing development team and integrates ExESS software
2009	Start partnership with EMORI (Japan) to develop the ExESS modules and interface in Japanese
2010	Lisam America opens in Houston, Texas
2012	Lisam UK opens in Hartlepool
2013	Lisam Canada opens in Montréal, Québec
2014	Lisam Deutschland opens in Berlin
2014	Wikichemia, start-up of LISAM dedicated to the sole management of regulatory lists, opens in Luxembourg
2015	Lisam opens offices in Turkey, Romania and Brazil
2016	Lisam opens offices in Singapore, China and Lithuania

ACCREDITATIONS

REACH Ready certification
Full member of ORO (REACH Only Representative Organisation)
EIGA preferred solution
Microsoft Gold Partner

CLIENTS

With premises and partners around the globe, Lisam applications and regulatory advisory services are adopted by more than 1000 medium and large clients worldwide, in all industry sectors.

TESTIMONIALS

"Lisam's ExESS® software centralises all our needs regarding REACH and GHS, and this on a worldwide scale. Employees from 28 offices around the world are connecting to the ExESS software to generate compliant SDS, labels or other documents. We chose the Lisam solution for their worldwide compliance and support, and for their commitment to keep track of legislation changes and implement future GHS whenever released," – Vice President, Corporate QSHE of a multinational consumer goods manufacturer

"After a comprehensive selection process, we chose to work with Lisam Systems and his software, ExESS®, for a number of reasons. Their system offered all functionalities expected and no other system we looked at could match its usability. The people of Lisam Systems fully understood our needs and our process flow. We didn't need to adapt our way of working to the new system, for it's so flexible that it adapted itself to our way of working," – Senior Director HSEQ of a global actor in the petrochemical Industry

For confidential reasons, testimonials on our regulatory services will gladly be provided on request.

CASE STUDY 1: Gas industry centralised SDS/label software

Context:

- multiple tools used for SDS and labels authoring;
- some subsidiaries using the same tool, but with different approach;
- some subsidiaries sharing a centralised database whilst others use independent ones;
- no synergy, SDS and labels layouts all different, no efficient working way.

Achievements:

- unification of the software's patchwork under Lisam ExESS®;
- central unique database for all subsidiaries;
- limited migration of data: interface ExESS® with ERP/lab software;
- work done by one is benefiting to all;
- one corporate standard for all compliance documents.

CASE STUDY 2: Global regulatory success stories

Lisam Services has been supporting successfully global actors in cosmetics, detergents, fine chemicals, industrial and specialty gases etc with their:

- ingredients, raw materials and products compliancy under REACH
- under other regional regulations;
- early regulatory qualification processes;
- preparation and submission of inquiries as well as individual and joint REACH registration dossiers;
- creation of thousands of (e)SDSs, meeting different regional GHS implementations.

STAFF SELECTION

Michel Hemberg, CEO

Michel is a founder and majority owner of Lisam Systems. Since June 2012, Michel took over the CEO position, managing the global expansion of the company. Michel got a civil engineer degree in 1986 and worked for 25 years as IBM mainframe consultant in the financial market.

Dirk Stevens, R&D Director

Dirk is head of the ExESS R&D development at Lisam systems.
He got a civil engineer degree in 1985 and has more than 20 years' experience in software engineering, consultancy and product management in EH&S.

Maxime Juste, Ch.E., Head of Delivery and Support

Maxime got a civil engineer degree in chemistry and is head of delivery and Support. He has experience in the management and distribution of SDS/Label as well as data and product management in the EH&S domain. Since 2010, he has been working as technical lead for the gas industry, represented in the EIGA association and is active in other industrial associations.

Françoise Saint-Romain, Managing Partner Lisam Service Telegis

After working in industry then in continued training, Françoise has created and developed a wide regulatory affairs competence centre over 20 years. She is acting as auditor of ORO (REACH Only Representative Organisation) and is cultivating the synergy between the ExESS EHS software and her regulatory consultancy activities.

Magaly Courtois, Senior Consultant (e)SDS authoring & CLP

With 17+ years' experience in chemicals' compliance, Magaly is expert in the development of safety data sheets and GHS/CLP classification and labelling questions. She has prepared and submitted registration dossiers at an early stage of REACH, and is an experienced Iuclid trainer.

Aude Carton, Senior Consultant Regulatory dossiers

Together with strategic advice, Aude has been providing her pharmacy and toxicology skills for six years. From test monitoring and label or technical document drafting, to final product compliancy, Aude's unique blend of scientific, regulatory and business knowledge is supporting our customers in meeting the necessary regulatory requirements in Europe (REACH, biocides) and abroad (Australia, Canada, …).

RAMBOLL ENVIRON

CONTACTS

Website	www.ramboll-environ.com
E-mail	sbullock@ramboll.com
Head office	Artillery House, 11-19 Artillery Row, London, SW1P 1RT, UK
Tel/ Fax	+44 20 7808 1420
Contact	Sue Bullock
Directors	137 partners worldwide including: Sue Bullock (UK) Dr Martina Vosteen (DE) Reinhard Joas (DE) Anke Joas (DE) Dr Bob De Mott (US) Dr Salvatore Giolando (US)
Ownership	Private limited company
Locations	130 offices worldwide
Founded	1982

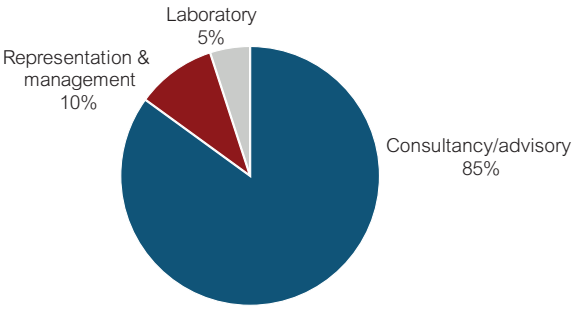
OVERVIEW

Ramboll Environ is the environment and health business of leading global engineering, design and consultancy company Ramboll, formed by the integration of Ramboll's environment and health specialists with independent environment, health, safety and sustainability consultancy ENVIRON at the end of 2014. Together we address some of the most important issues facing our global community, including the environmental and health implications of urbanisation, climate change and resource scarcity. Our global team helps companies gain regulatory approval for products to comply with chemical regulations around the world. We help industry leaders and innovators engage with policy makers and regulators, and provide effective product stewardship programmes to manage risk, reduce liability and enhance support from stakeholders. At the leading edge of science, we deliver thoughtful and innovative solutions in product safety. Clients around the world benefit from our unique ability to bring clarity to issues at the intersection of science, business and policy. We provide a single point of support for chemical regulation and risk management.

VITAL STATISTICS 2015/16

Turnover, group (2016)	$297.8m (unaudited)
Turnover, chemical service provision	-
No of offices	130
No of countries represented	26
Staff, group	2,100
Staff, chemical service provision (dedicated)	90

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Hong Kong, India, Italy, Malaysia, Mexico, Myanmar, New Zealand, Norway, Poland, Russia, Singapore, South Africa, Spain, Sweden, the Netherlands, UK, US

SERVICES PROVIDED

Risk management, strategic support and regulatory compliance (REACH, CLP, biocides, PPP, cosmetics, food contact materials)

Ramboll Environ works in partnership with clients to develop and support product regulatory compliance strategies and prepare robust technical dossiers and risk assessments for substances in industrial, agricultural, biocidal and consumer applications such as cosmetics and food contaminants. We balance clients' technical, regulatory and commercial interests through sound science and strategy. Clients trust us with their most critical problems. We provide strategic, scientific and regulatory support for substances targeted for substitution including impact assessment, applications for authorisation under REACH, supply chain management and audit of product regulatory compliance systems. We help our clients influence development of practical policy, regulation and guidance and communicate effectively with the EC, Echa and MSCA. Ramboll Environ also acts as consortium manager and only representative, and is independent from testing facilities.

Global chemical notifications and regulatory compliance support

Ramboll Environ evaluates obligations and provides support for regulatory approvals required to market products across Asia Pacific, America, Europe and Africa. We assess new market opportunities, substance notification and regulatory obligations, classification and labelling (GHS) and packaging. Our established global network covers Argentina, Australia, Brazil, California, Canada, China, Egypt, Europe, India, Japan, Korea, Malaysia, Mexico, Myanmar, New Zealand, Philippines, Russia, Singapore, South Africa, Switzerland, Taiwan, Turkey and the US.

Product stewardship, substitution and troubleshooting

We have tremendous breadth and depth of expertise as well as extensive hands-on process experience, covering:

- toxicology (and toxicokinetics);
- epidemiology;
- exposure modelling, measurement and reconstruction;
- risk assessment and mitigation;
- ecotoxicology;
- environmental fate;
- chemistry;
- occupational health;
- regulatory affairs;
- supply chain and stakeholder management;
- product vigilance; and
- advocacy.

We are ideally placed to advise clients on problems across the spectrum of product safety and stewardship including product substitution and sustainable chemistry. We couple internationally recognised expertise and a reputation as a leader in risk management with client-focused solutions.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1982	Environ founded in Washington, DC, USA
2010	Chemical Industry Association (CIA) REACH service provider of the year
2014	Ramboll Environ formed by the integration of Ramboll's environment and health specialists with ENVIRON.
2016	Ramboll acquires specialist chemical, product, health, sustainability and environmental performance consultancy BiPRO

CLIENTS

Clients span all industrial sectors including industrial and specialty chemicals, petrochemicals, agrochemicals, food and food packaging, cosmetics, medical devices, electronics, manufacturing, aerospace and defence, apparel and consumer products.

TESTIMONIALS

"We are working with Ramboll Environ in a constructive and successful manner on various REACH projects, covering the entire processes (ie preparation of technical dossiers, exposure estimation and hazard and risk assessment)" – Dr Hans Certa, manager, global product safety, SASOL.

"Ramboll Environ has been, and is, an essential element in the success of our on-going REACH programme. Their seamless integration into our team and systems creates an unprecedented collaboration that enables high quality, cost effective and timely solutions. Our dossiers have been consistently ahead of schedule and have been fully satisfactory when reviewed by the competent authorities. Ramboll Environ's professionalism, expertise, and organisational excellence has and continues to contribute to our compliance goals and commercial success." – James V Hagan, global director, product stewardship and regulatory affairs, Elementis Specialties Inc.

"This is just perfect. I will never again be influenced by site arguments in other countries that we should hire local firms to perform risk assessments! If they had agreed to use Ramboll Environ in the first place this whole process would have been so much cleaner and easier. Thank you for all of your hard work on this and in the short time frame requested" – Michelle T Quinn, associate general counsel, regulatory affairs and general litigation, Catalent Pharma Solutions.

CASE STUDY 1: REACH registration and evaluation

Comprehensive REACH dossiers and CSRs for numerous, challenging substances, reliably characterising chemical fate and effects on humans and the aquatic environment and setting out practical exposure scenarios to deliver safe use for the environment, workers and consumers.

CASE STUDY 2: Application for authorisation under REACH

A cross-sector consortium asked us to prepare an upstream application for authorisation under REACH to support the authorisation of chromium trioxide in various critical surface treatments. Regarded as the most complex application to date, it received a positive recommendation from Echa's committees.

CASE STUDY 3: Advocacy for SVHC under REACH

Technical support to help an industry sector develop and justify to policy makers a more credible and effective risk management option for a chemical than inclusion on Annex XIV REACH, and active engagement with stakeholders to inform policy development.

CASE STUDY 4: Assured global compliance of new product

A company launching a new consumer product worldwide had overlooked product regulations. We advised on regulatory obligations in 50 countries, considering chemical notification, packaging and labelling requirements and optimising the formulation and market claims.

CASE STUDY 5: Comprehensive exposure assessment

A food packaging producer was concerned when residual levels of a contaminant were unexpectedly found in a key product. We could show that consumer exposure from handling the packaging and ingesting the packaged foods was safe, avoiding regulatory action.

CASE STUDY 6: Regulatory action related to product contamination

An industry association asked Ramboll Environ to review all available and relevant evidence in order to comment on the basis and technical merits of EC proposals to re-classify the substance as a carcinogen.

CASE STUDY 7: Proposal to reclassify as CMR

An industry association asked Ramboll Environ to review all available and relevant evidence in order to comment on the basis and technical merits of EC proposals to re-classify the substance as a carcinogen.

STAFF SELECTION

Sue Bullock – Principal, product safety and stewardship

Sue provides strategic, regulatory and technical support for chemical compliance and stewardship, advocacy and policy, as well as risks from chemicals in the environment, the workplace and consumer products.

Dr Martina Vosteen – Principal, chemist and product safety

Over 15 years' experience as a consulting chemist. She is experienced in product related regulatory support including registration of and authorisation applications for chemicals, biocides and cosmetics.

Dr Joe Rodricks – Principal, toxicologist

Joe is an internationally recognised expert in the field of toxicology and risk analysis in chemical regulation, management and stewardship.

Juliana Ding – Managing Director, Asia

Twenty years' experience in environmental and health consultancy, including regulatory advice, health, safety and environmental assessments, product stewardship and supply chain management.

Dr Salvatore Giolando – Principal, product safety and stewardship

More than 28 years' experience directing product stewardship programmes for global supply chains and chemical products and is a leading expert on EU REACH and REACH implementation.

Dr Reinhard Joas – Managing Principal, global chemical policies

Thirty years of experience consulting with governments and international bodies on global policies. His expert advice includes process optimisation, environmental technologies and risk management.

Dr Anke Joas – Principal, environment and health policies

More than 20 years experience with environment and health policies. She is an international expert in biomonitoring and persistent organic pollutants, and an expert on chemical risk management.

Mike Padgham – Senior Manager, toxicology and regulatory affairs

A chemist and toxicologist with 30 years' experience working in regulatory affairs and toxicology, providing strategic, regulatory and technical support for compliance with EU legislation such as REACH.

Thomas Birk – Principal Consultant, exposure assessor

An epidemiologist, with more than 20 years' experience and expertise in the areas of occupational and environmental health, exposure assessment and exposure reconstruction.

Dr Thomas Rücker – Principal Consultant, toxicologist

More than 15 years' experience in biochemistry and toxicology consulting including the hazard and risk assessment of chemicals, and support for products under REACH and related legislation.

Dr Thomas Sendor – Manager, ecotoxicologist

A biologist with ten years' experience in regulatory support for chemicals regulated under the BPR, REACH and the PPP Regulation, specialising in risk assessment of chemical substances.

Samantha Deacon – Manager, ecotoxicologist

An ecotoxicologist with 20 years' experience in environmental regulation, consultancy and research in the assessment of chemicals in the environment, particularly agricultural products.

Dr Gavin Thompson – Principal Consultant

More than 20 years of experience advising industry on characterising chemical exposures from consumer products, food, food packaging, household items and environmental media.

CONTACTS

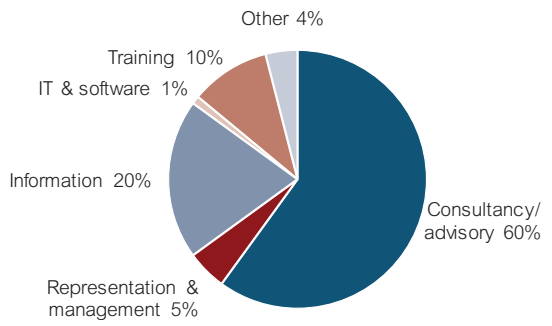
Website	www.reach-chemadvice.com
E-mail	info@reach-chemadvice.com
Head office	Am Marktplatz 5, D-65779 Kelkheim / Taunus, Germany
Tel/ Fax	+49 6195 96 199 0/ +49 6195 96 199 33
Contact	Dr Rudolf Staab
Directors	Dr Rudolf Staab, Managing Partner
Ownership	Privately owned company
Locations	Germany, US, India, Portugal, Sweden, China
Founded	2007

OVERVIEW

REACh ChemAdvice GmbH is a sister company of ChemAdvice GmbH. It was formed by a group of senior executives with many decades of experience in the chemical industry, in collaboration with a team of REACH specialists. Originally founded to help Non-EU manufacturers to comply with the REACH legislation as only representative, the company meanwhile supports EU manufacturers and importers as consultant and/ or as third party representative and downstream users as consultant in all REACH matters. Unlike most advisers, we offer the complete scope of REACH related services in-house and through our network. We also support manufacturers, importers, distributors and users of chemicals on the implementation of CLP and BPR (biocidal products Regulation). Our services for non-EU manufacturers include also EU representative for Article 95 of the biocidal products Regulation.

VITAL STATISTICS	2015/16
Turnover, group	c €1.5m
Turnover, chemical service provision	c €1.5m
No of offices	6
No of countries represented	6
Staff, group	10
Staff, chemical service provision	10

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

REACh ChemAdvice GmbH, Germany
Regional offices: Portugal, Sweden, USA, India, China

SERVICES PROVIDED

REACH services

- identification of obligations under the REACH Regulation
- implementation of strategy for REACH compliance
- only representative (Art.8 of the REACH Regulation)
- third party representative (Art.4 of the REACH Regulation)
- late pre-registration
- Sief communication management
- import certificates for REACH compliance
- creation and submission of luclid dossiers (registration, inquiry, PPORD notification, authorisation, substance in articles notification, downstream user report) to Echa in REACH-IT
- consortia management / consortia representation
- toxicological evaluation / studies / tests / reports
- SVHC inventory and monitoring
- SVHC testing and screening
- creation of chemical safety reports (CSR)
- strategy development for the registration
- REACH and luclid workshops
- customised training
- REACH due diligence
- data gap analysis
- project management
- support on the purchase of letters of access
- audits to suppliers concerning REACH compliance
- audits / REACH compliance verification (preparation for inspections)
- creation and review of REACH-compliant SDS/ e-SDS (safety data sheets) in all EU-member states languages
- analysis of exposure scenarios and implementation of risk management measures

CLP services

- identification of obligations under the CLP Regulation
- implementation of strategy for CLP compliance
- CLP workshops and customised training
- CLP due diligence
- project management
- classification and reclassification of substances and mixtures in accordance with the CLP Regulation
- safety data sheets (SDS) authoring and review
- CLP notifications dossiers / CLP-group notifications dossiers

Biocides services

- identification of obligations under the BPR
- implementation of strategy for BPR compliance
- preparation of luclid dossiers (approval of active substances and authorisation of biocidal products) and submission in the R4BP
- EU representative for Article 95
- support on the purchase of letters of access
- data gap analysis
- studies / tests / reports (physico-chemical properties, efficacy, environmental fate, ecotoxicology and toxicology)
- risk assessments
- liaison with authorities and post-submission support
- classification and labelling of biocides according to the DSD/DPD and CLP
- creation and review of REACH compliant safety data sheets
- BPR and luclid workshops

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2007	Start up in Frankfurt am Main, Germany
2007	Opening regional office in USA
2008	Opening regional office in India
2009	Relocation to new offices in Kelkheim/Taunus
2011	Opening regional office Sweden

2012	Expansion into the Iberian peninsula (Portugal and Spain)
2013	Start China REACH consultancy with the establishment of strategic partnership
2014	Start Korea REACH consultancy with the establishment of strategic partnership
2015	Start acting as Sales Representative of Telematic Safety Data Sheets Software Epy in Portugal and UK

ACCREDITATIONS

REACH ChemAdvice GmbH is a member of ORO, the Only Representatives Organisation in Brussels and complies with the quality standards of this trade association.

PARTNERS

Our partners can be viewed on our website.

CLIENTS

Our clients are located in Europe, United States of America, Latin America, Africa, Middle East and Asia.

TESTIMONIALS

Testimonials or references will be provided upon individual request.

CASE STUDY 1: REACH only representative

The company started offering only representative services for NON-EU clients in 2007. We represent more than 100 companies with sizes ranging from SME to multinational firms. We also represent European clients as third party representatives and offer consultancy work under REACH.

CASE STUDY 2: Consortia management

We successfully managed consortia or represented our clients in consortia. We support our clients throughout the whole REACH registration process from registration strategy development, data generation, and dossier preparation to dossier submission.

CASE STUDY 3: Biocides industry

REACh ChemAdvice supports clients all over the EU with defining the best strategy for compliance with the BPR as well as preparing dossiers for article 95, technical equivalence and chemical similarity, active substance approval and biocidal products authorisation.

STAFF SELECTION

Dr Rudolf Staab – Managing Partner

Dr Staab has held many senior jobs in the industry including: senior vice president Masterbatches Clariant International, responsible for the reorganisation and re-engineering of business processes and the introduction of new marketing approaches for key accounts. He was vice president additives within Hoechst AG and Clariant International and vice president specialty chemicals within Hoechst AG in charge of strategy development and implementation, business re-engineering, efficiency improvement activities and relocation efforts. He looked after the development of new markets and applications M&A transactions, and has been a member and chairman of the board of several companies within the chemical, food ingredients and plastic processing industry. He has an MSc in inorganic chemistry (Diplom-Chemiker – Saarbrücken, Germany, and a PhD in inorganic chemistry (Dr rer nat – Saarbrücken, Germany).

Carlos Fazendeiro – Director Regulatory Affairs, Regional Head Portugal

Mr Fazendeiro has worked in regulatory compliance in industry and has considerable experience in classification, labelling and packaging of chemicals, safety data sheets and giving regulatory support to clients and business units on REACH, CLP and biocides legislation. He has worked in consultancy on REACH implementation, with extensive experience of pre-registrations and REACH registration dossiers, assessment of test data reliability under the biocidal products Directive and gave support to business development activities.
He has a Master's degree in industrial chemistry (University of Beira Interior, Portugal) and has practical education and extensive training on REACH, CLP/GHS, biocidal products Regulation, Iuclid, REACH-IT, R4BP and SDSs, keeping always up-to-date with the latest developments related with chemicals legislation.

Silvia Teige – Finance and Administration

Ms Teige's experience includes working as a management assistant at both ChemAdvice GmbH and to the head of regional business unit Europe, NME, Africa, Clariant Masterbatches. She has been executive assistant to head of division pigments and additives, Clariant, and executive assistant to head of business unit additives, Hoechst AG and Clariant, fulfilling the same role to the head of division chemicals, Hoechst AG.

Dr Sebastian Hoffmann – Scientific Consultant

Dr Hoffman has extensive experience as a REACH consultant (TÜV Rheinland BioTech GmbH), as well as project management and scientific consulting and hazard and risk assessment. He is an expert on human health hazards and *in vitro* toxicological methods, having worked as a scientific officer at the European Commission's Joint Research Centre in Italy). His speciality is assessment (validation) of *in vitro* test methods and management of scientific projects. He is qualified to assess data reliability and relevance, and has 25 peer reviewed publications to his name.

Jim DeLisi – Regional Head, North America

Jim DeLisi is a president of Fanwood Chemical, Inc, where he looks after the sale of organic intermediates in North America, South America and Europe, as well as tariff and trade affairs, monitoring of imports and exports and REACH. He has been chairman of Socma's International Trade Committee, and chairman of the Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services.
He has a BA in business administration (Rutgers College, USA), and an MBA in chemical marketing (Fairleigh Dickinson, USA).

Barbara Fertl – Regional Head, Sweden

Barbara Fertl has extensive experience having worked at: the Institute for Physical Biochemistry, Munich; Munich Municipal Hospital Group; Linde AG, Munich; DQS Deutsche Gesellschaft zur Zertifizierung von Managementsystemen, Frankfurt; Sasol, Hamburg. She has been a chemical consultant for Kemikalierådgivare in Sweden and has experience of safety data sheets, registrations, national and international regulations on chemicals.
Ms Fertl has an MSc in biology (Diplom-Biologin, Ludwig-Maximilians-University, Munich, Germany), and is a certified auditor for quality management systems.

RGS REACH Global Services

CONTACTS

Website	www.reach-gs.eu
E-mail	info@reach-gs.eu
Head office	Rond Point Schuman, 6 Box 5, B-1040 Brussels, Belgium
Tel/ Fax	+32 (2) 234 77 78/ +32 (2) 234 79 11
Contact	Dr Yaprak Yuzak Kucukvar
Directors	Global Offices Managing Director Mr A Ecmel Yorganci Chairman of the Board Ahmet F Bitlis
Ownership	Private company owned by Chemicals and Chemical Products Exporters' Association
Locations	Headquarters: Brussels, Belgium; Offices: Istanbul, Turkey
Founded	2008

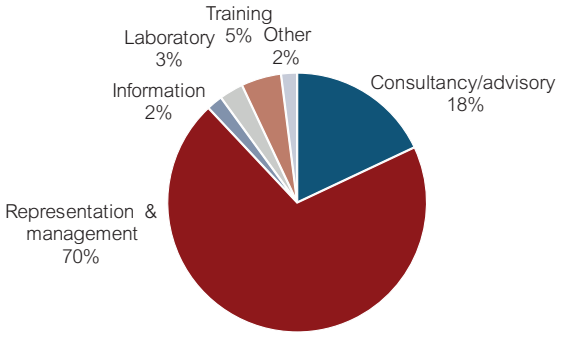
OVERVIEW

Brussels-based REACH Global Services SA (RGS) and its Turkish branch RGS Danışmanlık AŞ are professional regulatory consulting companies advising clients in the chemicals and allied industries to comply with EU and Turkish chemicals legislations. RGS Group's experienced staff, based in the EU and Turkey consults to a diverse array of chemical companies, both international and Turkish, operating across a range of chemical industry sectors.
Through experience, in-depth knowledge and understanding of the regulations and governments' regulatory processes, associated policies and guidance documents, RGS offers a wide range of cost-effective services ranging from OR services to; company-specific consultancy services, general consultancy on regulatory compliance issues, training on specific EU REACH and cosmetics legislation compliance, audits or due diligence projects, as well as on Turkish chemical by-laws and Turkish-REACH (KKDIK) compliance services.
RGS's core competencies include only representative (OR) and responsible person (RP) services for non-EU manufacturers assisting them to comply with EU REACH and cosmetics Regulations. RGS also acts as a representative for many national and multinational chemical companies to comply with Turkish chemicals regulations.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	3
No of countries represented	2
Staff, group	14
Staff, chemical service provision	12

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

REACH Global Services SA Brussels, Belgium

REACH Global Services Istanbul Liaison Office Istanbul , Turkey

REACH Global Danışmanlık AŞ Istanbul, Turkey

New branch offices starting in 2017 in Russia, US, UEA, Iran

SERVICES PROVIDED

EU REACH compliance services

According to Article 8 of the EU REACH Regulation it is compulsory for non-EU manufacturers, who export chemicals on its own or in preparations to the EU, to appoint an OR for compliance. The EU importer benefits from being a downstream user and RGS acting as an OR fulfils the obligations of the manufacturer and the importer under the REACH regulation. RGS provides a wide range of services to comply with REACH legal requirements. Our only representative services cover:

- late pre-registration;
- registration dossier submission;
- Sief/consortia representation;
- ensuring compliance of the downstream user (DU)/ importer under the substance registration via specialised tonnage tracking IT system and certification;
- inquiry dossier submission;
- general REACH consultancy services for EU based companies in complex cases impacting substance registration dossiers, and interactions with regard to the authorities' requests and inspections; and
- audit and certification services assisting non-EU manufacturers and their EU importers covering compliance evidence.

EU cosmetics Regulation compliance services

According to the Regulation (EC) No 1223/2009 notification of a cosmetic product must be submitted prior to placing the cosmetic products into the EU market. Companies manufacturing outside of EU must appoint an RP. RGS acts as an RP and notified hundreds of products to the CPNP portal since 2013. RGS's experienced team of consultants assists manufacturers to compile cosmetic product information files (PIFs) to comply with the legal requirements. Our cosmetics compliance services cover:

- EU legal representation (responsible person);
- preparation and verification of PIF;
- cosmetic product safety report parts A&B (CPSR);
- formulation and claims review;
- review and guidance on borderline cases;
- review and guidance on necessary corrections on labelling;
- cosmetic product notification;
- scientific and laboratory services (mandatory and claim tests); and
- regulatory compliance support.

Turkish REACH (KKDIK) only representative services

REACH is the most complex chemicals regulation so far. There is a new challenge ahead of companies in 2017; Turkish-REACH abbreviated as KKDIK. KKDIK is almost a copy/paste of the EU REACH Regulation translated into Turkish, but unavoidably there are slight differences to pay attention to, and all implementation and compliance processes are in Turkish language. However, The spirit of Article 8 of the EU REACH remains identical in the Turkish KKDIK regulation and the responsibilities of an OR are similar to the art 8. RGS acts as a Turkish OR through its Turkey-based branch office with its consultants highly experienced in the EU REACH Regulation fluent both in English and Turkish. It is critical for non-Turkish manufacturers to choose a well-experienced professional OR in Turkey in order to properly comply with the Turkish national legislation.

Turkish chemical regulations representative services

Companies putting chemical substances alone or in mixtures into the Turkish market must notify these chemical substances to the Turkish Ministry of Environment and Urbanism (MoEU) database and update data as required or requested by the competent authority according to the By-Law on Inventory and Control of Chemicals(CICR). Classification and labelling of hazardous substances put into the Turkish market should also be notified separately to the MoEU. REACH Global Services, through its Turkish operations acts as a Representative (trustee) alleviating companies of this regulatory compliance burden. Only an importer in Turkey or a representative located in Turkey can notify. Therefore, many companies located outside of Turkey placing substances and preparations on the market choose to work with RGS to protect their companies' confidential business information with professional consultancy services for compliance.

General consultancy services

RGS also offers tailored made training sessions on REACH, EU cosmetics and Turkish chemical regulations (KKDIK and SEA) compliance. Should your company require expertise in regulatory compliance to chemicals or related industry legislation then please do not hesitate to contact us. RGS consults to a diverse array of chemical and allied industry companies, both international and Turkish, operating across a range of industrial sectors. Auditing and certification services are also offered to companies in difficulty to prove compliance during exports into the EU.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2008	REACH Global Services SA. established in Brussels, Belgium Istanbul Liaison Office established in Turkey Appointed as an OR for over 220 companies by the end of the year with hundreds of pre-registrations completed, representing 80% of the Turkish chemicals exportation volume in addition to manufacturers from US, Japan, India, China, Indonesia etc.
2009	Representing hundreds of non-EU companies over five continents as an OR after the pre-registration deadline.
2010	Registered more than 100 substances before the first EU REACH registration deadline.
2011	Notified over 2000 substances under the Turkish By-Law on Inventory and Control of Chemicals on behalf of +100 worldwide manufacturers.
2013	Successfully completed REACH registrations in 2013 Started providing product information file (PIF) preparation services and introduced responsible person (RP) services according to the EU cosmetics Regulation.
2015	Notified 800 hazardous substances under the Turkish CLP (SEA) regulation.
2016	Established REACH Global Services Danışmanlık A.Ş. in Istanbul, Turkey. Successfully notified more than 2000 cosmetics products into the cosmetics products notification portal(CPNP) by 2016.
2017	Preparing for 2018 REACH registrations Extending chemical compliance services with regard to South Korea, China and the new Turkish-REACH (KKDIK) legislation. Opening new branch offices in Russia, USA, UAE, Iran

ACCREDITATIONS

RGS is a founding member of ORO (Only Representative Organisation), the unique European association, established in 2008 in Brussels, gathering all professional OR companies under the same umbrella, and guaranteeing common standard service quality to their non-EU clients.

PARTNERS

See our website

CLIENTS

RGS' client portfolio ranges from multinational Fortune 500 leading worldwide chemical and allied industry companies up to small and medium enterprises. RGS is working for sectors including but not limited to;
Petrochemicals, paint, cosmetics, fertilisers, cement, welding, textile agents predominantly pigments, adhesives, iron and steel, metals and ores, plasticisers, automotive, industrial and household chemicals etc.

TESTIMONIALS

References can be provided upon request.

CASE STUDY 1: REACH registrations

RGS successfully submitted registrations of a range of substances from oil refineries, petrochemicals, metals, ores, monomers, chemicals used in iron and steelworks, plasticisers to Echa in 2010. 2013 proved to be a successful year with registrations of medium sized companies as well as large companies. RGS also represents its clients at the consortia and Siefs. RGS works with the largest petrochemical and oil refinery companies in Turkey to comply with REACH obligations and assessed numerous borderline cases including exemptions since 2008. RGS assists non-EU manufacturer to understand a very complicated regulation by offering tailor-made solutions.

CASE STUDY 2: Cosmetic product notifications and PIF preparation

Several non-EU cosmetic product manufacturers were unaware that only submitting a labelling artworks and formulations to a distributor/importer in the EU for CPNP notification was not sufficient, and neither the right way to follow for compliance. RGS raised awareness among non-EU companies to choose the right path forward, and to appoint a trustworthy RP to comply with their legal obligations. Several companies that initially worked through their distributors, and faced tricky headaches, contacted RGS to seek for professional assistance. RGS assessed each company's obligations, advising manufacturers on how to correctly update their registrations through a professional RP. With a written mandate, manufacturers were also able to export their products successfully to the EU and importers could benefit from the notifications done by the RP.

CASE STUDY 3: Wrong substance registrations leading to non-compliance

A non-EU manufacturer contacted RGS, complaining about lack of feedback from their OR in Sief communications and 2018 registration roadmap. An OR change procedure was initiated by RGS at the company's request. Following the change, RGS realised that initial substance-definitions were made poorly as most of the pre-registrations have never been registered, and in addition wrong substances were pre-registered. RGS evaluated and assisted the company to properly redefine the substances to register by contacting the relevant consortia, associations, and more importantly the company's own production units. RGS took the corrective compliance actions on behalf of the company as our team has years of experience in defining manufacturers' REACH obligations accurately.

STAFF SELECTION

RGS Board Members and management have 30+ years of chemical industry experience and international regulatory affairs practice.
RGS technical team consists of chemists, chemical engineers, and environmental engineers with masters and PhD degrees from five to 15 years of experience. Our consultants are experienced within the areas of regulatory management of chemicals both in the EU and Turkey, with extensive practices in preparing and submitting luclid REACH registration dossiers as well as representation of our clients in consortia and Siefs. Our consultants have worked on numerous cosmetic products and labelling, gaining comprehensive knowledge to properly reflect the compliance criterion according to the manufacturer's needs.
RGS team of experts assesses manufacturers current regulatory status and supplies solutions and corrective actions to the companies in urgent need for compliance.

REACH mastery

Know the rules, play your market.

CONTACTS

Website	www.reachmastery.com
E-mail	info@reachmastery.com
Head office	Via Giovio 16, 22100 Como, Italy
Tel	+39 031 269513
Contact	monicalocatelli@reachmastery.com
Directors	Monica Locatelli
Ownership	Private company
Locations	Italy
Founded	2008

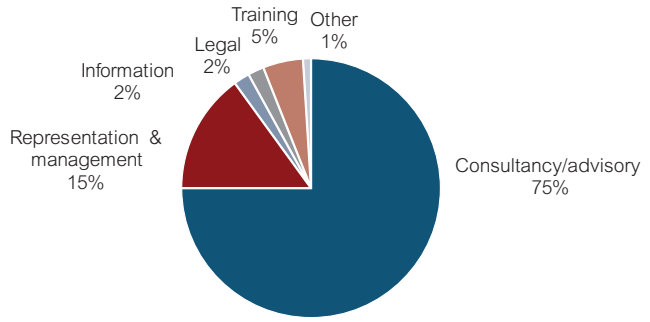
OVERVIEW

REACH mastery is a provider of a wide range of services in the area of chemical regulatory affairs. The staff is a highly motivated team, skilled in different scientific areas: chemistry, biology, human health and environmental toxicology. Our commitment is to assist clients along the supply chain with our industrial experience and to help them in the cost efficient implementation of the European regulations. Our mission is to look for innovative solutions and to develop strategies using, when applicable, alternatives to animal testing like *in vitro* and *in silico* methods, through the high quality of our services and the expert support.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	4
Staff, group	15
Staff, chemical service provision	15

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

General consulting services

- **Supply chain communication**

Importers and manufacturers, downstream users and manufacturers/ importers of article, are all responsible for the effective communication flow of information. We provide all the necessary support by distributing standard templates or customised forms to properly manage the communication flow between customers and suppliers.

- **Strategic implementation of European regulations**

Participation to consortia, co-registrants agreements, data sharing, deadline and tonnages for registration are decisions that are managed in order to find the most cost-effective solution and the most convenient choice on the market.

- **Chemical management and product stewardship**

The market will constantly evolve over time. Companies will face new challenges to strategically select secure suppliers and to identify growing sector markets. Our business development experts will support companies with the most effective advice, in compliance with the provisions of the regulation.

- **Implementation of IT systems for chemical management**

Companies will internally develop new management systems to integrate existing tools to monitor the presence of chemical substances, including deadlines, total amounts, risk management measures etc.

REACH services

- **Consortia management**

A lot of experience has been gained on consortia rules and management. We provide also legal advice, agreement documents, meeting location, cost calculation, managing of LoAs.

- **Data gap analysis and data collection**

Gathering existing information is the first step in the preparation of any registration dossier, but is not enough. All these data have to be really collected, in respect to the right to use. The latter requires the negotiation of the conditions for use according also to the quality of the data. Each single study is evaluated and rated to check relevance and adequacy to fill the requirements.

- **Testing strategy development, *in vitro* strategies development, Qsar modelling, read across evaluation.**

An integrated testing strategy is the first step for cost reduction and building rationale for waiving. International well known partners are helping us in focusing on the right choice. The expertise in Qsar modelling (OECD Toolbox, VEGA, customised models) has been often successful in discussion with the national authorities and scientific working groups

- **Managing of analytical identification and inquiry dossiers**

Our great expertise in analytics and experience in enquiries let us face without problems one of the most critical aspect of REACH regulation.

- **PPORD dossier**

REACH mastery can assist in the preparation of PPORD dossiers

- **Test monitoring**

In case new tests are required, REACH mastery will take care of selecting the most appropriate lab, will review the protocol and check the results.

- **Dossier preparation (luclid compilation)**

Dedicated experts are managing luclid compilation and informatics tools for submission (REACH-IT).

- **Human health and environmental risk assessment**

The focused experience and the support of high experienced toxicologists let us make of the risk assessment the core part of the developing registration dossier.

- **Exposure modelling**

Exposure modelling can be performed with most of the recognised official tools like EUSES, Ecetoc TRA, EASY TRA, ART, CONS EXPO, RISKofDERM

- **CSA-CSR**

REACH mastery is part of the consultation group of Chesar in Echa. We followed the development of the tool since the beginning and we are among the first experts in Europe to use it. The tool is also used to develop translated exposure scenarios and extended safety data sheets

- **Authorisation dossiers**

REACH mastery acquired the expertise to develop authorisation dossiers complete with analysis of alternatives and socio-economic analysis

- **CLH dossiers**

REACH mastery can prepare CLH dossiers for re-classification on behalf of industry to be discussed and presented to the member states authorities and within the Member State Committee

CLP/GHS services

- Data collection and assessment of classification and labelling
- CLP notification
- MSDS compilation

- Extended safety data sheets
- Exposure scenarios scaling and translation

BPD services

- Full dossier preparation for active substances and placing a biocidal product in the market
- Testing strategy development
- Study monitoring
- Risk assessment
- Finalisation and discussion with national and EU authorities.
- Post-submission support

Pharma services

- REACH mastery offer assistance in drug development from discovery to registration. We have competence in the toxicology review for new chemical entities
- Review of toxicological in new drug discovery (new chemical entities)
- Contracting and monitoring of new tests
- Human health risk assessment
- Environmental risk assessment
- Dossier strategy evaluation
- Authorisation process and dossier
- Determination of the PDE (permitted daily exposure)
- Assessment of mutagenic impurities

FEED and FOOD registration

- Dossier preparation
- Risk assessment
- Test monitoring
- Assistance to customer for Efsa calls for data

EU cosmetic directive

- Regulatory compliance support
- Product notifications
- Assistance in GMP certification
- Cosmetics ingredient profiles
- Product information files
- Clinical studies: design and monitoring
- Cosmetic product safety reports
- Product labelling review and support

PPP

- Full dossier preparation for active substances and placing a plant protection product in the market
- Testing strategy development
- Study monitoring
- Risk assessment
- Finalisation and discussion with national and EU authorities.
- Post-submission support

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2008	Foundation of REACH mastery within HBJ consultancy group
2010	About 120 successful registrations for the 2010 deadline
2014	Preparation and submission of the first application for authorisation
2015	Implementation of the group to comply with the needs of the biocidal products Regulation and pharma industry. Presentation of the first accepted CLH dossier and of the first family dossiers for biocidal products to the Italian member state.
2016	Implementation of the group to comply with the needs of the plant protection products Regulation. Presentation of two dossier after Article 95 disputes in biocides and two authorisation dossier.

PARTNERS

RTC, Qsar group of Bicocca University, Vitroscreen, REACH & Colours, CAAT Europe as preferred cooperations.

CLIENTS

We are working for about 100 customers around Europe; they are manufacturers, distributors, downstream users, from SMEs to international chemical companies involved in many different industrial fields: fertilisers, leather, textile, paper, pharmaceuticals, galvanic, food, cosmetic, polymers and many others.

CASE STUDY 1: TIER 3 REACH registration

The group has proved itself as one of the most professionally prepared in the European scenario to manage all different aspects of a REACH dossier. REACH mastery prepared about 20 lead dossiers for the 2013 second Tier registration, many of them with a full study plan ordered and monitored, 40 intermediate dossiers and actually about 40 joint registrations. UVCBs and difficult substances are the main specialisation area. The group has gained a great expertise in substance identification and difficult inquiries and is timely preparing his customers to the 2018 Tier 3 registration with over 100 lead dossiers.

CASE STUDY 2: Two dossiers after Article 95 disputes

During 2016 REACH mastery prepared and submitted two active substance dossiers for biocides for customers that put forwards a Article 95 dispute and received partial data access from Echa.

CASE STUDY 3: Authorisation dossiers

REACH mastery implemented internally the group in order to compose successful authorisation dossiers, complete with risk assessment, analysis of the alternative and socio-economical analysis.

STAFF SELECTION

Dr ssa Monica Locatelli – Founder and Director

After a degree in chemistry, ten years in R&D and a specialisation in toxicology applied to risk assessment, she has been working in regulatory and implementation of REACH regulation since 2001, when it was still a proposal. The cooperation with many specialists within international companies and universities let her specialise in consortia management and dossier preparation.

Dr ssa Costanza Rovida – REACH Regulatory Specialist

Graduated in chemistry, after 15 years' experience in the field of analytical chemistry, she worked for three years at the European Commission, participating in two groups of RIP 3.3 (REACH Implementation Project, Technical Guidelines to Industries) and as a leader of a work package in a European project focused on integrated development of alternative toxicological methods to animal testing. She is responsible for the management of individual projects and global customer assistance.

Francois Busquet – Ecotoxicologist

François Busquet studied Biotechnologies at the ENSTBB in France. He graduated from the TU Dresden, completing his PhD at the MerckSerono group in Germany on the development of a new screening assay to detect proteratogenic compounds using zebrafish embryos. After his studies, he worked in Ecvam at the Joint research Centre (European Commission) in Italy on the coordination of the OECD validation study of the zebrafish embryo toxicity test. Since 2012, he has been responsible for the CAAT-EU policy programme in Brussels.

Dr Daniele Ferrario – Toxicologist

Graduated in biological science, he earned a PhD in toxicology in 2009. He gained knowledge in cellular and molecular biology techniques, as well as having a strong background in metal toxicity on mammalian immune and haematopoietic systems. While working for five years at the laboratory of European Centre for The Validation of Alternative Method of the European Commission he was actively involved in the validation of CFU-GM as alternative to animal testing to evaluate immunotoxicity. He is now responsible for the evaluation of toxicological outcomes of testing in compliance with REACH Regulation.

CONTACTS

Website	www.reachcentrum.eu
E-mail	info@reachcentrum.eu
Head office	Avenue E van Nieuwenhuyse 6, B-1160 Brussels, Belgium
Tel/ Fax	+32 26767400/ +32 2 6767499
Contact	Francesca Furlan
Directors	Emma Farthing, Managing Director Laurent Beuselinck Jean-Francois Bolduc
Ownership	Private company
Locations	Brussels, Belgium
Founded	2006

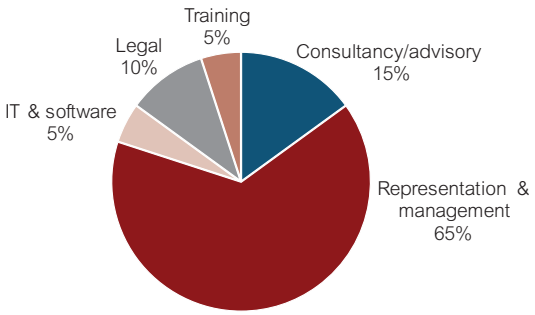
OVERVIEW

ReachCentrum was established in 2006 by Cefic, to help companies fulfil their EU-REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) Regulation requirements through their value chain. It was acquired by ERM, in May 2015 and forms a core part of the product stewardship offering from ERM. ReachCentrum supports clients in relation to chemical regulations including EU-REACH, classification, labelling and packaging of substances and mixtures (CLP) and biocidal products Regulation (BPR). Services include: consortia and project management, lead- and co-registrant support, consultancy and brokerage of data for use in product compliance in other jurisdictions. Together, ReachCentrum and ERM provide global support to clients for product compliance with respect to K-REACH and other global REACH-like legislation.

VITAL STATISTICS

	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	Global
Staff, group	20
Staff, chemical service provision	20

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Global coverage as part of ERM group

SERVICES PROVIDED

Business solutions

ReachCentrum offers expert consultancy to support REACH implementation within companies and stakeholder groups, assisting customers with effective strategies to fulfil REACH requirements.
Lead registrant, consortia and co-registrant support comprises project management, Sief communication, finance and data management, legal support, letter of access management (LoAShop www.loareachcentrum.eu), co-registration and training. Post-registration activities include dossier update, evaluation and authorisation support.
Beyond EU-REACH regulation:

- CLP Regulation;
- biocidal products Regulation (BPR) – use of the consortia approach to promote joint submission for product families with same active ingredients and individual company support;
- non-European chemicals regulations – eg K-REACH, Taiwan REACH. In addition to data brokerage and consortia support, technical provision may be made by local ERM offices.

REACH consortia and registrant support

Dedicated staff manage consortia and support lead- and co- registrants in meeting their regulatory obligations under EU REACH. This experience has been gained through the 2010 and 2013 REACH registrations, with currently more than 100 consortia and 1,500 substances under management.

Authorisation support

ReachCentrum and staff have been involved in authorisation activities since the first applications (DEHP). ReachCentrum has deep knowledge of the processes, steps and potential pitfalls in approach. From the time of inclusion in the substances of potential concern list clients benefit from updates via ReachCentrum's extensive network and contact to industry associations, REACH authorities in member states, the European Commission and Echa.

Training, workshops and e-learning solutions

ReachCentrum organises tailored training courses and workshops for individual Companies, trade associations or conference events covering all aspects of REACH legislation, CLP and BPR. The courses offer flexibility and convenience to participants – classroom, web-based, virtual and e-learning.

Project management for biocides

ReachCentrum supports companies in the preparation of their authorisation application dossiers for product(s) containing certain active substances within certain product types (PTs) under the biocidal product Regulation. Activities include customised training for BPR compliance, dossier preparation and risk assessment.

Data brokerage and global chemical regulations

ReachCentrum actively supports data owners to provide access to data for use in compliance in chemical regulation globally (eg K-REACH or Taiwan REACH). Together with ERM, we assist clients prepare their dossiers for substance registration; using our network of 140 offices, we are able to cover all aspects required for project, technical and legal management. Secured IT-systems, including our data brokerage platform, and processes are in place to support joint registration, access and purchasing data from Europe, data sharing and cost sharing for a successful dossier registration.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2006	Founded by Cefic (European Chemical Industry Council).
2010	LoA e-shop successfully launched.
2010	Through the LoA e-shop 342 lead registrants allowed their SIEF members to access the registration dossier.
2010	About 900 people attended ReachCentrum events (about 90 events).

2012	Set up of three authorisation consortia.
2014	Submission of the first joint application for authorisation (HBCDD).
2014	Creation of the first biocidal product family (BPF) pre-consortium, sodium hypochlorite.
2015	Acquired by ERM.
2015	Launch of K-REACH activities.
2016	Launch of Data Brokerage Platform for K-REACH.
2016	ERM acquisition of JSC (UK). Full technical and administrative support for biocidal products authorisation according to BPR and to non-European Regulations.

PARTNERS

- An ERM Group Company
- Cefic list of preferred partners

CLIENTS

ReachCentrum offers its services to a wide range of companies, from major multinationals to SMEs and only representatives (OR) from all over Europe and beyond, including downstream users and distributors.

TESTIMONIALS

"As a REACH substance coordinator at BASF I very much value the support of REACHCentrum for efficient project organisation, coordination and support of meetings, where a neutral party is needed. We also have good experience with general REACH activities such as handling REACH-Dossier sales. " 2017, Dr Carina Johansson Manderbach, Product Stewardship REACH BASF.

"ReachCentrum was selected first as consortium secretariat based on its experience with consortia management, more particular relating to in financial and communication aspects but also due to their knowledge of REACH authorisation process as such. During preparation for application, ReachCentrum has proven to be very supportive in translating between the language of pure technical service providers and the understanding of our group. Also in reviewing documents for application, ReachCentrum's input is very helpful." – Ingrid Brassart, chairperson of the Sodium Dichromate authorisation consortium, Akzo Nobel.

CASE STUDY 1: Biocidal product authorisation support

ReachCentrum worked with a multinational company to support it in launching biocidal products on European and non-European markets. ReachCentrum provided strategic advice – a global action plan with timelines and costs – for optimised placement of products in the relevant markets. Activities included legal and regulatory advice, technical dossier preparation, and cooperation with local authorities before and after submission of specific documents.

CASE STUDY 2: Support consortia on data sharing for K-REACH

ReachCentrum is currently supporting consortia members with a comprehensive strategy to share existing EU data for K-REACH purposes. Consortia can benefit of legal support, including advises and verification of current EU agreements. An assessment of the financial value of data and studies is managed by ReachCentrum, together with communication with potential registrants in South Korea and analysis of data to be shared. The data is brokered via the data-brokerage platform.

CASE STUDY 3: Analysis of alternatives listed as good example by Echa

A downstream user analysis of alternatives (AoA), figures among a list of good examples published by Echa. ReachCentrum and ERM worked together and the analysis, submitted by DOMO Caproleuna GmbH for trichloroethylene, was used by Echa as an example of a downstream user analysis of alternatives. Since ReachCentrum's acquisition in May 2015, ReachCentrum and ERM have combined their technical and management expertise to support industry in REACH authorisation. Services include regulatory advice, strategic planning, communication facilitation (supply chain, data access), application for authorisation and review of documents, analysis of alternatives and socio-economic analysis, and also setting up interest groups, taskforces and consortia to serve a common goal for registration and evaluation and authorisation.

STAFF SELECTION

Emma Farthing – Managing Director

Emma was appointed Managing Director of ReachCentrum in July 2015 and is a Partner at ERM. Emma is responsible for the day to day operations and strategic development of the company. She has 25 years of environmental and sustainability consulting experience in a number of technical fields including transactions, EHS and more recently REACH and REACH-like regulations within Europe and other regional jurisdictions.

Inneke Claes – Project Manager

Inneke joined ReachCentrum in October 2014. Prior to that, she worked for almost 15 years in European industry associations representing the interests of paper, cement and non-ferrous metals industry sectors. She handled topics related to REACH and CLP, as well as environmental issues and helped cement companies with REACH implementation. Inneke holds a PhD in physics and a degree in environmental sciences.

Aggie Kotze – Project Manager and Authorisation expert

Aggie joined the ReachCentrum team in January 2017. Subsequent to her product stewardship activities in-house for chemical companies between 2011 and 2015, Aggie was the REACH manager at the International Lead Association Europe. Her experience is broad having worked with other member associations (eg Eurometaux) and regulators (member states and Echa) covering aspects of substance identification, evaluation and authorisation under REACH. Her advocacy track record is strong and as such, Aggie is the lead for this type of work in ReachCentrum.

Magdalena Urbanowska (nee Kornacka) – Project Manager

Magdalena has several years' experience in consortia management. During her career, she has been involved in REACH at different levels – administrative, regulatory and technical. As Director of an Industry Association, she has been also responsible for the regulatory affairs and participated in the legislation process for wastes and environmental regulations. At ReachCentrum, Magdalena is responsible for REACH consortia and for authorisation of biocidal products.

Willi Muenninghoff – Project Manager

In addition to consortia management, Willi is responsible for data brokerage and global regulatory support at ReachCentrum. Willi has over 30 years' experience in the chemical industry having started his career in R&D then moved to Technical Customer Services, Business Development and finally Compliance. Since 2006 he has been involved in all sorts of regulatory issues on an international scale, such as REACH, GHS, biocides, transport classification, import and export regulations.

Adam Shahin – Financial Controller

Adam is a qualified chartered management accountant (CIMA) and has 15 years industry experience. Adam leads the finance team at ReachCentrum that manages the consortia finances. The team has developed a consistent and robust approach to enable clients meet their data sharing obligations under the data implementing regulations.

REACHLAW
COMPLIANCE. SUSTAINED.

CONTACTS

Website	www.reachlaw.fi
E-mail	sales@reachlaw.fi
Head office	Vänrikinkuja 3 JK 21. FI-02600 Espoo. Finland
Tel/ Fax	+358 (0)9 412 3055/ +358 (0) 9 412 3049
Contact	Mr Frederik Johanson, Partner, Sales
Directors	Mr Jouni Honkavaara, CEO, Partner Mr Frederik Johanson, Sales, Partner Dr Ying Zhu, COO, Partner Mr Riku Rinta-Jouppi, Head of Global Compliance, Partner
Ownership	Private company
Locations	Finland, Belgium, India, Turkey
Founded	2006

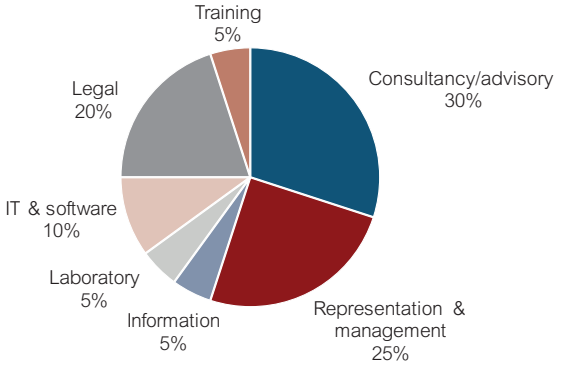
OVERVIEW

REACHLaw provides chemical regulatory compliance and product safety solutions to fit each customer and their needs. We help companies and organisations to gain market access for their chemical products and we support them with different chemical regulations such as: EU REACH and CLP, Turkey KKDIK, SEA, & GBF, K-REACH and GHS, China REACH and GHS and many more. Furthermore, our out-tasking EHS services as well as our digital solutions will help you manage and control your chemicals and your supply chain globally.
Having a multicultural team, REACHLaw is able to serve its clients in the following languages: English, Finnish, French, German, Spanish, Swedish, Chinese, Hindi, Russian, Ukrainian and Turkish.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	4
No of countries represented	40+
Staff, group	30+
Staff, chemical service provision	25+

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Helsinki, Brussels, New Delhi and Istanbul.

SERVICES PROVIDED

2018 REACH registration services

We help co-registrants and lead registrants as their service provider or as only representative (OR) in fulfilling all REACH requirements. We have vast experience in taking companies through the different phases of the registration process including Sief and consortium. We provide resources and expertise for the hazard assessment, exposure assessment and risk characterisation, when needed. We provide the customer with a complete chemical safety report and necessary collection of information in the supply chain, handling of third party access rights and financial transactions, completing the technical dossier and submitting it to Echa.

REACH authorisation and advocacy support services

REACHLaw combines the best expertise and a deep understanding of your business and regulatory requirements to provide you with a full set of services for authorisation. Our support covers the overall strategy and scope of the authorisation to performing the work needed in the different stages of the authorisation process (eg, analysis of alternatives, socio-economic analysis, chemical safety report and full authorisation application). Furthermore, through our advocacy support services we also assist you before authorisation and restriction decisions are made. We help you to achieve the best possible outcome for your business by supporting you in the public consultations phase, as well as with the RMOAs, exemption studies and legal consulting.

Out-tasking services

For companies to keeping up the long term of REACH and CLP regulatory compliances is a big challenge as the regulatory contents change and evolve. Using our out-tasking solutions ensures you continued REACH and CLP regulatory compliance that saves your time, resources and money. We help you to stay focused on your core business while we take care of all your regulatory compliance tasks.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2006	Established in Helsinki.
2008	Partnerships with 20+ local partners in Asia, Europe, Latin America, US and India established. 3,000+ REACH pre-registrations submitted.
2009	REACHLaw received internationalisation award from the president of Finland. Customers in 40+ countries. Brussels and New Delhi offices opened. REACHLaw delivered more than 50 events globally, having 1,500+ attendees in total.
2010	300+ REACH registrations submitted. REACHLaw launched global compliance services outside the EU. The attendees to our events increased considerably reaching more than 2,500+.
2011	Istanbul office opened. REACHLaw supported large companies to ensure compliance with global chemical regulations.
2012	20+ REACH lead registrant cases. First authorisation cases. Several global notifications were completed. REACHLaw became shareholder in eSpheres Ltd: www.espheres.com
2013	REACHLaw launched www.compliantsuppliers.com. REACHLaw supported several hundred REACH registrations, numerous authorisation projects, 20+ lead registrant and BPR cases.
2014	Delivering several REACH lead registrations and a large number of authorisation projects. Providing SDSs for mixtures. Providing IT management solutions especially related to supply chain compliance and risk management.

2015	Supporting companies in creating strategies for biocides product authorisation. Acting as EU representative related to Article 95. REACHLaw launched THEBLOG: www.reachlaw.fi/theblog
2016	Supporting several companies with advocacy projects. Working on different authorisation cases and supporting 2018 lead registrations and co-registrations.
2017	Supporting several REACH 2018 lead registrations and co-registrations. Working on different advocacy support cases and EU country specific product notifications.

ACCREDITATIONS

Internationalisation award from the president of Finland in 2009. Innovative – Growth sustainable company by Europe Innova in 2011. Among 200 fastest growing companies in Finland by Kauppalehti in 2011. Young Innovative Growth Company Programme by TEKES completed in 2012.

PARTNERS

REACHLaw collaborates with several industry associations and has partners in different continents.

CLIENTS

Major industry sectors served: oil, chemicals, specialty chemicals, pulp and paper and metals. Downstream users in the electronics and space sectors. Our customers are manufacturers, importers, traders, downstream users, retailers and governmental organisations.

TESTIMONIALS

"Over the years REACHLaw has advised Freeport on several strategic REACH and CLP issues and in the planning of our 2010 registrations. For one substance REACHLaw managed the whole lead registrant registration process in 2010. We are very pleased with REACHLaw service" – Dr Thomas Slotte, Freeport Cobalt Oy.

CASE STUDY 1: Authorisation application

In 2015-2016, REACHLaw was commissioned by the world No 1 lock maker Abloy to conduct an authorisation project for chromium trioxide. The material is an integral part of Abloy's unique lock design. REACHLaw was responsible for conducting all three parts of the authorisation dossiers, CSR, AoA and SEA. In addition, REACHLaw played an important role in the post-submission activities to assure that Abloy will obtain the authorisation with the right review period. In autumn 2016, Echa's SEAC committee gave their supportive opinion for the Abloy application with a review period of 12 years.

CASE STUDY 2: Lead registration of magnesium compound as the only representative

One of REACHLaw's North American clients was looking to register a magnesium compound and found that no-one else had submitted a joint submission for the substance to join. Therefore, the company, through REACHLaw as the only representative, opted to become the lead registrant for the substance. After a pre-Sief lead registrant election process by the OR (REACHLaw) confirming the lead registrant elect status, the actual dossier creation work started. After careful examination of routes of exposure, some additional waiving of tests could be justified saving in the total costs for the client and the Sief members thereof. The result is a robust and cost efficient dossier which will be submitted during 2017 in due time for co-registrants to join the joint submission ahead of the May 2018 deadline. Special attention has also been given to the itemisation of all costs related to the registration work in light of the recent Commission implementing Regulation (EU) 2016/9 on joint submission of data and cost-sharing.

CASE STUDY 3: REACH impact studies – European Defence Agency

In 2016 the European Defence Agency (EDA) commissioned REACHLaw Ltd to carry out a study "*REACH and CLP impact on the Defence Sector*". To gather the study input, more than 100 stakeholder organisations including EU ministries of defence (MoDs), EU and non-EU defence industries, the European Commission, Echa and REACH member state competent authorities were consulted. Based on the impact assessment REACHLaw elaborated recommendations for the EC REACH review 2017 and for European defence stakeholders. The study was supported by the EDA REACH Task Force (comprised of MoD REACH experts).

STAFF SELECTION

Mr Tim Becker, MA (Law) – Chief EU Compliance Officer

Tim has been a consultant at REACHLaw since 2008. He also worked previously with Echa in its guidance team. His track record includes legal analyses, key account and project management (eg REACH authorisation consortia and impact studies) for various industries and governmental organisations. Since 2011 he has been advising key stakeholders in the European Space Sector on REACH related issues. In 2016 Tim was REACHLaw's project leader and main contributor for the study "*REACH and CLP impact on the Defence Sector*", commissioned by the European Defence Agency.

Dr Ying Zhu, PhD (Biochemistry), MSc in Economics, COO-Partner

Dr Zhu has both a scientific and economic educational background. She has also worked in various management positions in industry for more than 15 years. Her unique educational background and work experience enable her to act as a leading expert in the area of REACH authorisation and advocacy services. Dr Zhu has advised companies from four different continents on REACH compliance issues since 2008. In addition, she also has in-depth knowledge on global chemical regulations and compliance issues.

Mr Riku Rinta-Jouppi, MA (Law), MSc – Head of Global Compliance-Partner

Graduate of Cambridge University. He is widely recognised as one of the leading European legal experts in chemicals regulations. In addition to his legal qualifications he holds a masters degree in bio-information technology. Mr Rinta-Jouppi is responsible for REACHLaw global compliance services.

Mr Sami Vesikansa, MSc (Biochemistry) – Specialist in human health hazard assessment

Mr Vesikansa is working as a toxicologist for REACHLaw. His responsibilities include management of lead registrant projects, chemical safety assessment and consortium/Sief management. He specialises in the field of human health hazard assessment and risk characterisation of chemicals and products. He has over ten years of experience in toxicity tests of pharmaceutical and industrial chemicals.

Sini Suomela (MSc in Organic Chemistry) – Head of OR and registration practise

Ms Suomela has been responsible for REACH member registrations since 2010 and has successfully completed hundreds of registrations during this time. She has extensive knowledge of all kinds of REACH registrations and inquiries. She has also worked with the physico-chemical part of the REACH lead registration projects and has been involved in REACH authorisation work.

RRA
Redebel Regulatory Affairs

CONTACTS

Website	www.redebel.com
E-mail	info@redebel.com
Head office	Rue de Chassart 4, B-6221 Saint-Amand, Belgium
Tel	+32 71 853 392
Fax	+32 71 853 618
Contact	Ir. Jean-Yves Lontie – Business Development Manager MIB. Olivier Balhan – Business Development Manager
Directors	Sebastien Dumont de Chassart – Managing Director Tanguy Dumont de Chassart – Managing Director
Ownership	Redebel Holding SA, a private family company, 100% private shares
Locations	Belgium
Founded	1988

OVERVIEW

The REDEBEL Group offers the full range of services for the registration of plant protection products, biocides and chemicals. For about 30 years now, our experts have been helping companies to obtain authorisation for marketing their products in all 28 EU member states. Located in Belgium, our team offers tailor-made solutions for the resolution of regulatory issues with the European Commission as well as with any of the 28 European national authorities in order to obtain the approval of active substances and the registration of products.

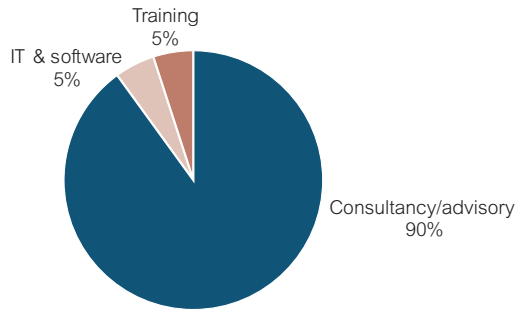
Why choose us?

- a team of 60 experts built on about 30 years of existence;
- full confidentiality;
- flexibility, human-scale, with easy direct contact, for a privileged and personalised relationship;
- numerous success stories with tangible results;
- ongoing training of our team of experts leading to continuous improvement and a drive for progress and excellence;
- presence at all major international conferences;
- a European network: close working relationships and partnerships with service providers and laboratories all over Europe; and
- privileged relationships with European Commission and all the 28 national competent authorities .

VITAL STATISTICS

	2015/16
Turnover, group	> €6.5m
Turnover, chemical service provision	> €6.5m
No of offices	1
No of countries represented	28
Staff, group	> 60
Staff, chemical service provision	> 60

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

For the chemical, agrochemical and biocide industry, the REDEBEL Group offers a broad scope of support services that meet the international regulatory requirements and include the following:

- registration of agrochemicals (1107/2009), biocides (EU 528/2012) and REACH (1907/2006);
- risk assessment for such substances and products;
- dossier writing;
- data gap analysis;
- liaison with the competent authorities (EU and national);
- project management – study direction – study monitoring;
- testing of efficacy, selectivity, residues of plant protection products (GLP and GEP certifications);
- research and development of agrochemicals; and
- European field trial projects.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1988	Foundation of Redebel SA (staff two people) which specialised in agricultural field trials.
1988-2000	GEP certification. GLP certification. Creation of the Regulatory Affairs Department. New offices in family farm. Continuous internal growth from two to 20 persons, without any acquisition.
2000-2014	Development of the company, with a staff increasing from 20 to 55 persons, and the turnover from €1.5m to € 5.5m.
2014-2016	Building of new offices linked to a ten year expansion project
2016	Creation of Redebel Regulatory Affairs SCRL to separate the field trials business from the regulatory affairs business

ACCREDITATIONS

Good Laboratory Practice (GLP)
Good Experimental Practices (GEP)
Toxicologists, ecotoxicologists, environmental fate specialists

PARTNERS

We have a long-term and well established network of partners in all European countries, among laboratories and field trial stations. All partners are rated annually based on several factors (expertise, respect of deadline, communication,…) for an optimal selection process.

CLIENTS

Chemical companies, agrochemical companies, biocides industry. From SMEs up to multinationals.

STAFF SELECTION

A team of 60 persons with more than 400 years of experience. 85% of our people are highly educated (master degree, engineer or doctor), divided into chemists, agronomists, biologists, microbiologists, plant pathologists.


RRA
Redebel Regulatory Affairs
Redebel
We turn your ideas into value
www.redebel.com

CONTACTS

Website	www.refac.eu
E-mail	Rachel.Green@refac.eu
Head office	Group House, Southmere Court, Electra Way, Crewe, Cheshire, CW1 6GU, UK
Tel	+44 (0)1270 258530
Fax	+44 (0)1270 258444
Contact	Rachel Green
Directors	Peter Newport MD Neville Prior Chairman Andrew Mitchell FD Kate Mingay Reg Warren
Ownership	Wholly owned subsidiary of CBA
Locations	UK
Founded	2007

OVERVIEW

ReFaC provides regulatory assistance to companies, within Europe and from across the world, who seek to comply with regulatory schemes such as REACH, CLP, BPR etc. Our team of regulatory professionals provide efficient and expert services to SME companies, multinational organisations, industry associations and consortia. Wherever possible ReFaC aims to reduce the burden imposed by regulation and provides tailored support to clients in order to maximise the value of our contribution.

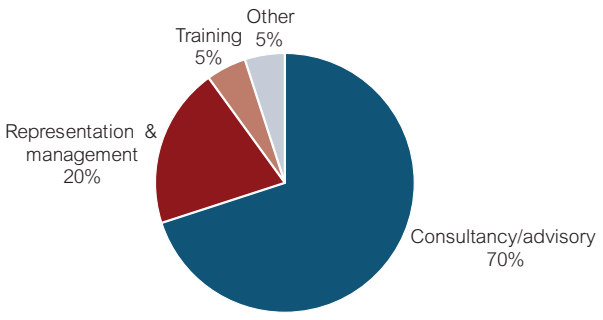
ReFaC delivers REACH compliance solutions using its own staff and a select group of industry partners, including Bibra, Charles River Laboratories, WIL Research, Intertek and AMG Analytical Services.

ReFaC is owned by the Chemical Business Association Ltd.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	11
Staff, chemical service provision	4

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Crewe, UK

SERVICES PROVIDED

ReFaC provide a complete range of services for those seeking compliance with chemicals regulations. Our services include: REACH dossier development and submission; data gap analysis; hazard and exposure scenario development and CSR authorship; consortium and Sief management; consultancy and study monitoring; PPORD notification; OR and TPR services; SDS and eSDS authorship; CLP compliance management; toxicology consulting and study monitoring; worldwide notifications; dangerous goods consultancy and DGSA service and compliance with the biocidal products Regulation.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2007	ReFaC established by leading professionals in the chemical distribution industry
2010	ReFaC acquired by the Chemical Business Association Ltd. (CBA)
currently	12 OR clients 7 TPR clients 19 regulatory compliance consultancy clients

PARTNERS

- ReFaC has a network of partners with whom we work, including Bibra, Charles River Laboratories, WIL Research, Intertek and AMG Analytical Services

CLIENTS

- ReFaC supports SMEs and large organisations from across the chemical industry, both within Europe and worldwide. In addition, ReFaC assists a number of industry associations and consortia that require compliance management, consultancy and study monitoring services.

CASE STUDY 1: Technical management for a large consortium

ReFaC provides support and services for a large consortium with a number of substances on a range of technical issues. This includes preparing REACH registration strategies, lead registration dossiers and chemical safety reports, advising on classifications and liaising with lead and member registrants.

CASE STUDY 2: REACH and biocides compliance management

ReFaC has created and implemented a compliance management plan for a formulator/distributor of industrial chemicals and biocidal products

- REACH compliance of products supplied are confirmed annually through correspondence with suppliers and cross-checking (pre-) registration numbers provided within the Echa database
- Article 95 list status of biocidal active substance suppliers checked and list of approved active substances reviewed at regular intervals to allow a plan for biocidal product authorisation to be prepared if required

STAFF SELECTION

Peter Newport DMS, FCILT, MCIM – Managing Director

Peter was educated in business and management to postgraduate level and has 35 years' experience in supply chain operations and managing chemical industry regulatory compliance. He has been involved with ReFaC from its inception

Rachel Green BSc (Hons), PgCert, MSc – Technical Manager

Rachel holds a BSc (Hons) degree in biochemistry and biological chemistry from the University of Nottingham, a post-graduate certificate in REACH chemical management from the University of Hull and an MSc in applied toxicology from the University of Surrey.
Rachel has extensive experience with advising clients on REACH and CLP requirements, identifying data needs; preparing regulatory strategies for compliance; preparing and submitting lead registration dossiers and preparing chemical safety reports. In addition, Rachel has considerable experience in preparing read-across strategies for inorganic chemicals.

Rachel Hill MChem (Hons) – Regulatory Affairs Officer

In her role Rachel provides regulatory assistance to UK and overseas companies in relation to the REACH Regulation, the classification, labelling and packaging Regulations (CLP), biocides regulations, toxicology consulting and testing management.
In particular, Rachel has experience preparing lead and joint REACH registration dossiers, managing only representative responsibilities and providing CLP advice.
Rachel holds a first class MChem degree in chemistry (with environmental and sustainable chemistry) from Edinburgh University. She graduated in 2013.

Kim Shillington BSc (Hons) – Technical Officer

Kim holds a BSc (Hons) degree in chemistry from the University of Liverpool.
Since graduating in 2013 Kim has worked as a formulation chemist for a printing sciences company helping to expand their pigmented ink range and as a development chemist assisting customers develop chemical processes in flow reactors. Kim joined the ReFaC team in April 2016 and has gained experience with REACH and CLP Regulations.

REGULATORY SERVICES INTERNATIONAL

CONTACTS

Website	www.rsireg.com
E-mail	andy@rsireg.com
Head office	Suite 1009 Tongguang Tower, 12 NongzhanguanNali, Chaoyang District , Beijing, 100125, China
Tel	+44 7810 863 748
Contact	Andy Burgess
Directors	Yang Ni and Andy Burgess
Ownership	Private company
Locations	China, UK and US
Founded	2010

OVERVIEW

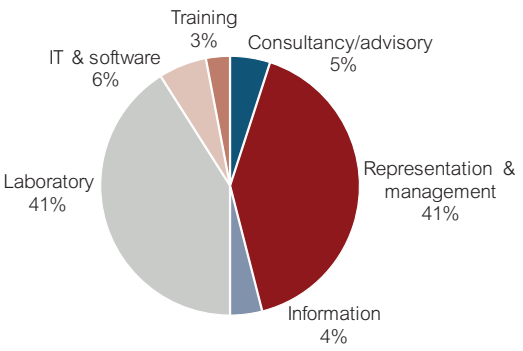
Regulatory Services International is a privately owned chemical regulatory services company, set up in 2010 and focused on delivering a range of integrated high quality and reliable regulatory services for less. We have built up our presence in core jurisdictions, initially in China and subsequently expanding into EU and US. With our network of partners we deliver a depth of expertise in our core jurisdictions and also expanded coverage to other in-demand geographies.

We provide an integrated set of services covering regulatory/dossier work, registration agent, study arrangement/monitoring and regulatory consultancy. We deliver reliable quality regulatory services for less by harnessing our regulatory knowledge to reduce study costs, matching regulatory and laboratory resources with requirements to reduce study costs, leverage authority relationships to ensure reliability and quality of registration strategies, and manage our integrated services through internal management systems.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	6
No of countries represented	3
Staff, group	20
Staff, chemical service provision	20

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

China: Suite 1009 Tongguang Tower, 12 NongzhanguanNali, Chaoyang District, Beijing, 100125.
UK: PO Box 1280, Peterborough, PE2 2NG, UK
US: Suite 100-1212, 1024 Iron Point Road, Folsom, CA 95630, US

SERVICES PROVIDED

EU REACH registration

In the EU focus is on meeting the 2018 registration deadline, which is the final deadline for existing chemicals. We have long-term in-depth knowledge of the EU chemicals legislation going back for 20+ years. Through this we have successfully handled hundreds of registration dossiers, with significant numbers of these as lead registrant. We support companies by:

- submission of late pre-registrations;
- submission of inquiry dossiers;
- Sief communications;
- performing literature searches for existing data;
- existing data evaluations;
- identification of data gaps;
- explore ways of fulfilling data gaps without testing (eg read-across, Qsars);
- manage all elements of studies covering contracting, sample delivery and acting as study monitor;
- build chemical safety assessment/report (CSA/CSR); and
- preparation of registration dossier in Iuclid.

Study contracting, arrangement and monitoring

The registration of substances requires a wide range of studies and often leads to data gaps being identified. Arranging and monitoring these studies takes time and specialist knowledge.

Our service that saves you money and time by contracting, arranging and supervising the performance of studies. We scour the world to identify and vet suitable laboratories to work with and have developed long-term relationships with key laboratories in a range of cost geographies. We match your requirements and needs with a range of labs to identify the most cost effective qualifying solution and then take care of contracting, operational arrangements and study monitoring activities to deliver a completed study package.

EU REACH post registration services

Under EU REACH registration is just an initial regulatory obligation, from which several further regulatory pathways can be followed. In coordination with our network partners we provide a comprehensive set of post-registration support services including:

- registration dossier updates;
- substance evaluation support;
- dossier evaluation support;
- pre-authorisation monitoring/interventions; and
- authorisation dossier preparation and support.

Chinese New Substance Notifications (MEP Order No. 7)

The Chinese legislation for new chemicals (MEP Order No 7) is a challenge for all: data requirements are high, approvals are time consuming, requirements are not explicit, and a number of environmental studies need to be performed in-country.

We have successfully gained approval for hundreds of new substances under new chemicals legislation in China at all notification levels including Level 4 (>1,000 t/a).

We understand the challenges in China and start by guiding you through the business options available, so you can determine if pursuing a registration is viable or even necessary.

Where a registration is required, we then identify and explain your options, handle the required work including studies to meet the registration and work with all parties in the supply chain to deliver your approval on-time. This includes:

- undertaking data gap analysis;
- submitting inventory searches;
- preparing registration dossiers;
- compiling risk assessments;
- managing studies;
- translating submission package into Chinese;
- submission to authorities and handling of authority communications.

Testing: We arrange and monitor all studies to support a new substance registration in China, using OECD GLP or national GLP laboratories.

Chinese hazardous chemical services

We have an evolving range of services for companies meeting the challenges of State Order Decree 591 and its supporting legislation including registrations under SAWS Order No 53 and SAWS Order No. 60. These services include:

- strategic review and analysis of obligations;
- regulatory guidance and investigations;
- chemical inventory searches;
- testing of hazardous chemicals/products in SAWS approved laboratories
- registration of hazardous chemicals;
- SDS and label preparation; and
- emergency 24 hour hotline service as required for Chinese SDSs (using a local partner in China).

Regulatory compliance problem solving in China

We provide a specialist service to assist solving chemicals regulatory compliance issues in China. We leverage expertise from a pool of technical experts within China along with our connections with Chinese government agencies including MEP, SAWS, MOA, MOH, SFDA and CIQ, and accredited Chinese laboratories in order to investigate, analyse and solve your chemical regulatory compliance challenges.
This has ranged from queries on SDS formatting, investigating scope of precursor chemical regulations in China through to maintaining regulatory compliance from sale of business assets.

US TSCA reform

In the US 2016 was a year of change with the coming into force of TSCA reform, which will present a range of challenges to industry in maintaining their compliance. A major initial driver within TSCA reform is to complete the inventory reset obligations which are projected for second half of 2017.
We offer the following:

- TSCA inventory reset service;
- ensuring production material TSCA compliance;
- preparation of EPA PMN application;
- preparation of polymer exemption certification;
- preparation of article exemption certification;
- notification of EPA before manufacturing or importing an 'inactive substance';
- assessment of product development TSCA compliance issues; and
- fulfilment of commercial obligations and assure customers of product TSCA compliance.

We can provide the tools, and tracking systems your company needs. Avoid inadvertent TSCA violations and their commercial implications.

Restricted substances tracking services

We offer a service that constantly tracks the emergence and spread of regulatory restricted substances delivered as either a regulatory service or as a SaaS product. Targets of our service are:

- minimising the health and environmental impacts of products, while maximising economic benefits of products.

Our database contains:

- 50+ of the major restricted substance listings and early warning listings from EU, US, China and others;
- >20,000 entries containing >9,000 unique substances; and
- hidden entries of >300 chemical categories linked with specific chemicals.

Other in-demand registration services

Through our network of partners we provide a range of further registration services.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2010	Company founded with team of three, opening of Beijing office and UK office
2011	Opening of US and Shanghai offices
2012	Opening of Nanjing and Xian offices
2013	Expansion of services to include EU REACH
2014	Restricted substances tracking service established
2015	Expansion of services to include China Food Contact Notification
2016	Expansion of services to include US TSCA reform

PARTNERS

Our partners include Beijing RuiYuan, Apeiron Team, Verdant Law and Advintess. We work closely with a range of laboratory testing, regulatory and legal service providers.

CLIENTS

Our clients include manufacturers, formulators and users involved in a wide range of market sectors including chemicals, agrochemicals, pharmaceuticals, cosmetics, paints and coatings, electronics, medical devices, petrochemicals, plastics and many others.

TESTIMONIALS

Specific references can be provided to potential clients upon request.

CASE STUDY 1: Development of cost effective registration programme

We worked for a chemical manufacturer who had received a proposal from a service provider for global registration of a new substance. Our brief was to develop a cost effective registration strategy while maintaining high quality and reliability of service. We reduced the number of studies required to be performed by integrating in-depth regulatory knowledge of EU and Chinese legislation. We then matched the client objectives and concerns with substance properties and identified a testing programme utilising laboratories in different cost geographies. Through this set of approaches we were able to save the client more than 40% of their study costs while meeting the regulatory requirements, while maintaining reliability through use of "tried and tested" partner laboratories.

STAFF SELECTION

Andy Burgess – Managing Partner

Extensive experience (>20 years) in directing global chemical registration and testing services. Wealth of experience with practical strategic support in anticipating and complying with regulatory requirements.

Yang Ni, JD – CEO

Over ten years of experience in Chinese chemical registration and testing services, coordinating the development and maintenance of professional working relationship with Chinese regulatory authorities and Chinese GLP laboratories. Educated in China and the US with expert knowledge in both Chinese and US legal matters. Rich and extensive experiences in transnational business transactions, IP protection, and cross-cultural conflict management and resolution.

Renke Dai, PhD – Chief Scientist

Extensive and wide ranging experience in chemistry, biosciences and environmental toxicology coming from a PhD from the University of Nebraska-Lincoln and background in the US National Cancer Institute, Chinese Academy of Sciences Guangzhou Institute of Biomedicine and Health as well as industry experience.

Susan Sun – Regulatory Specialist

Six years of Chemical Registration and compliance experience with detailed knowledge of chemicals legislation as well as a strong network of contacts with authorities and laboratories. Graduate of QingDao University of Science & Technology with a master degree in BioChemical Engineering.

Cliff Shen – Manager

Five years of experience in managing teams of regulatory and IT professionals as well as industrial experience as technical support engineer. Graduate of Northwestern Polytechnical University with a master degree in computer technology.

RPA
Risk & Policy Analysts

CONTACTS

Website	rpaltd.co.uk
E-mail	post@rpaltd.co.uk
Head office	1 Beccles Road, Loddon, Norfolk, NR14 6LT, UK
Tel	+44 1508 528465
Fax	+44 1508 520758
Contact	Panos Zarogiannis
Directors	Pete Floyd Meg Postle
Ownership	Private
Locations	UK, Belgium
Founded	1990

OVERVIEW

Risk & Policy Analysts Ltd (RPA) was established in 1990 as an independent specialist consultancy. RPA has gained extensive experience in undertaking impact assessments and evaluations, including the development of quantitative and qualitative methodologies to assess policy impacts, chemicals policy, chemical risk assessment and management. RPA is the market leader in the development and application of socio-economic analysis (SEA) to chemical risk management and is particularly proud of its reputation for preparing applications for authorisation of SVHCs under REACH for industry clients.

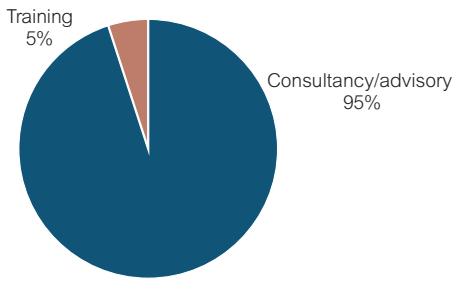
RPA has been working with industry clients since 2001 on the implications of the new EU regime for chemical risk management. We have also been working closely with the European Commission (EC) and the European Chemicals Agency (Echa) on the development and implementation of REACH and many other directives relating to chemical risk management.

Our experience covers a wide range of industry sectors including bulk chemicals, ferrous and non-ferrous metals, paints and coatings, oil and gas, speciality and novel chemicals (including nanomaterials), etc, and this has resulted in detailed studies on over 50 high profile chemicals. RPA's multi-national staff routinely undertakes detailed analysis and consultation with industry and regulators in most European languages.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	3
No of countries represented	Focus on EU-28, EEA and candidate countries
Staff, group	25
Staff, chemical service provision	17

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

UK, Belgium

SERVICES PROVIDED

REACH authorisation

RPA assists industry clients with the development of applications for authorisation of SVHCs under REACH, as well as REACH authorisation strategies more broadly. These studies involve detailed analyses of supply chains, of alternatives and the preparation of SEAs.

REACH restriction and CLP classification

RPA assists both industry clients and regulators with the collection and analysis of use/exposure data of chemicals and their alternatives and the preparation of SEAs, which may be used to inform the development of a restriction dossier or support industry in defending substances for which harmonised hazard classifications are proposed.

Regulations and impact assessment

RPA advises industry clients and regulators on the (potential) impacts of regulations and regulatory change. Recent examples include work on REACH, nanomaterials, OELs, WEEE/RoHS, CMRs at work, toy safety, cosmetics, biocides, drinking water and WFD.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1992	RPA develops a risk-benefit analysis methodology for chemical risk management for the UK authorities.
1998	RPA wins major framework contract for the UK authorities on chemical risk management leading to numerous risk reduction strategies under the existing substances Regulation.
2000	OECD publishes guidance documents on SEA and chemical risk management prepared by RPA.
2004	RPA wins major framework contract for the European Commission on chemicals.
2009	RPA contracted by industry clients to support applications for authorisation under REACH with a focus on SEA work.
2011	RPA leads consortium for the second Echa REACH framework contract.
2012	RPA completes three studies for DG Environment reviewing the first years of REACH implementation.
2013	RPA leads the market in supporting seven applications for authorisation of SVHCs under REACH.
2014	RPA clients obtain the first granted REACH authorisations.
2015	RPA supports the submission of another nine applications for authorisation.
2016	RPA leads the EC fitness check for chemicals legislation (excluding REACH).

PARTNERS

RPA works with FoBiG, Ökopol, TNO Triskelion, Milieu, DHI, RIVM, Arche, IEH Consulting, ReachCentrum, Anthesis and Acta among others.

CLIENTS

- European Commission (including DG Grow (previously Enterprise) DG Environment, DG Employment and DG Justice and Consumers).
- National authorities (including those in the UK, Germany, Sweden, Denmark, France and the Netherlands).
- European Chemicals Agency.
- Numerous European/international industry/trade associations and groups (including AISE, Apeal, Cefic, Cosmetics Europe, DEHP ATF, Etinsa, Eurocommerce, Eurometaux, European Plastics Recyclers, ICMM, IMnI, International Zinc Association, Lead Development

- Association, Nickel Institute, Titanium Dioxide Industry Consortium and UKWIR).
- A range of companies (from multinationals to SMEs) and consortia, including Bayer Pharma AG, Deza a.s., Dow Chemicals, Eli Lilly, Grupa Azoty, Grupa Lotos, H&R Group, Lanxess, Rolls Royce.

TESTIMONIALS

"We would like to express personally how much we appreciated your work and your help during the whole authorisation process. Not only the high level of expertise and the extremely efficient and flexible organisation were noteworthy, but the very friendly and warm work atmosphere..." – REACH authorisation client.
"My thanks to you for successful accomplishing of the very ambitious survey programme, as well as the equally challenging work on developing the model for the 2018 registration costs." – European Commission client.
"They are committed to the job, responsible, punctual, reliable and always ready to assist and help" – industry client.

CASE STUDY 1: Provision of analysis of alternative and socio-economic analysis support services

RPA has been providing REACH authorisation support to several consortia of manufacturers and users of SVHC substances. The work includes preparation of an analysis of alternatives (involving an assessment of the technical and economic feasibility of alternative chemicals and techniques), supply chain communication to develop information on uses and users' responses to the loss of the SVHC in question and preparation of socio-economic analyses of the impacts of the loss of the SVHC. As part of this work, we are managing the services of specialist toxicology and risk assessment consultants. RPA has recently started the preparation of a new round of applications for substances with complex SVHC profiles that have been added to REACH Annex XIV.

CASE STUDY 2: Undertaking a regulatory fitness check of the legislative framework of chemicals

RPA is currently assisting the European Commission in undertaking a study of the regulatory fitness check of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation. The purpose of this study is to identify and evaluate the impact and consequences of implementing the CLP Regulation and to evaluate the interface with other related chemicals legislation. This is based on the criteria of effectiveness, efficiency, coherence, relevance and EU added value in accordance with the Commission's evaluation and fitness check guidelines.

CASE STUDY 3: Dioxins and furans

RPA was contracted by Efsa in 2016 to undertake an extensive literature search, followed by selection for relevance and extraction of relevant data for consideration in the (human) risk assessment of dioxins, furans and dioxin-like PCBs. Over 6,000 references were identified which were progressively screened down to the 257 most relevant papers for detailed data extraction.

STAFF SELECTION

Meg Postle – Director

Meg is an environmental economist and policy analyst with more than 20 years' experience of consultancy. She has led RPA's work for the European Commission, the UK government and a range of industry bodies on business, health and environmental impact assessments of REACH and of proposed restrictions and other controls on the use of hazardous chemicals within the EU. As a leading expert on socio-economic analysis (SEA), she guides the preparation of SEAs to support authorisation and restriction activities.

Panos Zarogiannis – Technical Director, Chemicals Policy

Panos is a chemist with extensive experience of developing risk reduction strategies for chemical substances under the Existing Substances Regulation as well as SEA-related studies and in the development of TGDs for REACH. He has managed studies in support of the development of Annex XV dossiers by Echa and is leading our work for major industrial clients on the development of authorisation dossiers.

Linda-Jean Cockcroft – Technical Director, Business, Industry and Growth

Linda-Jean has almost 20 years' consulting experience, with most of the last six years focused on sustainability, REACH and chemicals regulation. She has a unique combination of both inside-industry and consulting experience and has worked in a number of EU countries.

Dave Fleet – Principal Consultant, EU Policy

Dave is an economist with wide project management experience and socio-economic analysis expertise. He has extensive experience of managing RPA's impact assessments and evaluations for the European Commission. He is currently co-ordinating consortium-wide and company- specific SEA outputs for applications for authorisation.

Anthony Footitt – Principal Consultant, Chemicals

Anthony has 19 years of experience and undertook a great deal of the risk and economics work underpinning the EU REACH chemicals strategy on behalf of the European Commission where this included work on all of the business impact assessments (BIAs) and many subsequent analyses/impact assessments. He was also responsible for much of the modelling work that RPA carried out for the EC on the impacts of introducing the GHS. Most recently, he has been working on REACH impact assessments and on nanomaterials.

Marco Camboni – Principal Consultant, Chemicals

Marco specialises in the evaluation of the European chemicals legislation and its synergies with the occupational health and safety, product safety and environmental legislation. He has been involved in numerous studies looking at how to better regulate nanomaterials and he is currently managing RPA work for the European Commission on the strategy for a non-toxic environment of the 7th Environment Action Programme and for the Danish EPA on the development of the Danish society towards a circular economy.

Tom Persich – Senior Consultant, Chemicals

Much of RPA's work on REACH authorisation for industry clients benefits from Tom's detailed research and analysis into their uses of the SVHCs for which authorisation is being sought. Tom has also prepared core AoA and SEA arguments at sector level for a key set of downstream users. He has also undertaken extensive supply chain mapping activities to assess potential vulnerability of downstream user groups to the loss of key substances.

Royaltain Research COMPANY

CONTACTS

Website	royaltainresearch.com
E-mail	contact@royaltainresearch.com
Head office	2 rue René Truhaut – 26300 ALIXAN, France
Tel	+33 4 82 48 00 31
Contact	Célia Cavaignac
Directors	Jean-Claude Ricomard Bruno Combourieu
Ownership	Private Company
Locations	France
Founded	2014

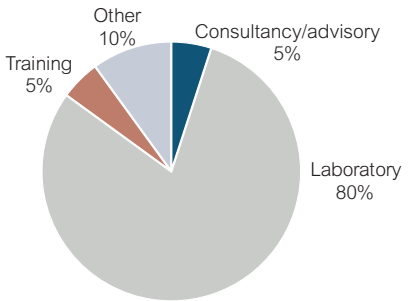
OVERVIEW

Royaltain Research Company is a global expert service and contract research organisation for ecotoxicology and environmental toxicology. We are a company that specialises in providing a distinctive blend of innovative and classical approaches to evaluating the potential risks of chemical and biological contaminants for researchers and industrial clients. We offer a range of services from fundamental research, applied research, and experiments to more classical studies concerning environmental toxicology and ecotoxicology.
We support our clients answering to tomorrow's concern as we define and realize customised projects that meets their expectations. We also offer more conventional tests following ISO, ASTM and OECD guidelines.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	25
Staff, chemical service provision	15

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

2 rue René Truhaut – 26300 ALIXAN, France

SERVICES PROVIDED

Ecotoxicology

We offer acute and chronic ecotoxicity regulatory tests, particularly tests from the series 2xx in static, semi-static or dynamic version. Tests can be realised according to OECD/ISO international guidelines or adapted on client's specific requests.

Environmental toxicology – environmental fate

We offer substances properties analysis – relevant physical chemical properties and regulatory studies on biodegradability and bioaccumulation. Tests can be realised according to OECD/ISO international guidelines or adapted on client's specific requests.

Analytical and bioanalytical chemistry

We provide services in analytical chemistry alone or in combination with ecotoxicology and environmental toxicology tests. The combination between our fields of expertise and our analytical platform (including equipment such as LC-HRMS, LC-MS/MS, GC-MS/MS…) proves to be a powerful and complete tool that help client in their R&D approach as well as in regulatory dossier.

Studies in mesocosm

We offer to assist our clients in their projects and studies that need specific environmental control.
Our installations, unique in Europe, permit to follow and regulate environmental variables as humidity, temperature or irradiance. We can thus provide a range of innovative services custom-made in ecotoxicology, ecology and environmental chemistry. We also offer the possibility to work in climatic chambers with biosafety level two or three to handle potentially dangerous substances and/or organisms and invasive species.

Maldi-Tof imaging

We offer analysis via MALDI-TOF Imaging. This technic involves to realise histological cut of 12µm thickness in an organism or in a target organ and then to analyse the cut through a succession of laser impacts. We thus obtain information on the spatial repartition (2D) of the molecule in the cut that can provide valuable information in the context of bioaccumulation studies or histopathological analyses.

Efficacy Trials

We offers assistance to test the efficacy of your pure substances or your formulated products. From the experimental protocol design to its analysis and data interpretation, the expertise of the RRCo team as well as the facilities and the equipment are available and dedicated to efficacy trials.
These tests can be conducted as part of product homologation or following authorities request (ANSES, European or US regulation…) in order to obtain a pre-market approval.

Screening and other activities

With a surface area of more than 6,700m^2 of laboratories, we can design with our clients, tailor-made protocol answering to their request. We offer to realise experiments outside the regulatory framework in the field of agrochemicals (biocontrol), chemistry, and pharmaceutical industry and in various other fields of environmental sciences.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

April 2014	Foundation of Royaltain Research Company
July 2016	Integration in our new facilities
2017	New offer for *in vitro* testing and genotoxicity

ACCREDITATIONS

Good Laboratory Practice

PARTNERS

Rovaltain Research Company is 100% privately owned.

CLIENTS

General chemical industry, human and animal pharmaceutical industry, biocides industry, plant protection products industry, 'biocontrol' industry, plastics industry, personal care products industry, flavours and fragrances industry. Research institutes and universities, government bodies, NGOs.

TESTIMONIALS

Testimonials can be provided on request.

CASE STUDIES:

- Our clients and their studies are protected by our strict confidentiality agreements; therefore, we are unable to describe in details specific case studies. However in the case studies below you will find general description of studies we have already provided.
- Thanks to our installations, our highly qualified team of scientists and our in-house expertise, we are able to provide high quality science and services.
- We put the emphasis on quality through regular internal audit programme.

CASE STUDY 1: Regulatory tests as part of marketing authorisation

As requested by the French authorities for file submission as part of marketing authorisation for an organic fertiliser; we have provided the ecotoxicologic data (equivalent ISO of the OECD tests 201, 202, 208, 222).

CASE STUDY 2: MALDI TOF imaging – R&D support

As part of R&D study, client wanted to locate three different molecules (with molecular weight included between 150 Da and 20 000 Da) in a plant. In different histological cut of 12µm thickness we have located the three target molecules with a spatial resolution of 20 µm. This allowed our client to better understand the mechanisms of defence of the plant against its aggressors.

CASE STUDY 3: Dedicated study in climatic chambers

We have designed specific experiments to assess biocontrol product. The regulated environment allows us to simulate specific climatic conditions and to avoid any external perturbation or contamination on tests in progress. With our four halls of 225 m^2 each we have enough area to create replicates and specific environment.

CASE STUDY 4: Analytical method development

For an industrial client, we have developed, validated and implemented different analytical methods allowing them to analyse their effluents. The main constraint for the RRCo team was to provide analysis methods easily implemented (with standard equipment), internationally (in the different plants of our client).

STAFF SELECTION

Dr Bruno Combourieu – General Manager

Bruno Combourieu is an experienced environmental chemist with key strengths in measuring and interpreting the fate and ecological effects of organic substances in terrestrial and aquatic systems. He also hold a position of professor of ecotoxicology and bio-analytical chemistry at the University of Lyon (department of microbial ecology) until the end of 2016 with a specific remit within his work to bring together the disciplines of ecology, ecotoxicology and environmental chemistry.

Dr Marie-Laure Bayle – Organic Analysis Section Head

Marie-Laure has a strong experience in analytical chemistry and especially chromatography coupled to mass spectrometry applied to environmental and biological samples. Also expert in metabolomics, she has experience in large sets of samples and various preparation techniques.

Mr Aymeric Bellemain – Regulatory Ecotoxicology Section Head

Aymeric has an extensive experience within ecotoxicological and biodegradability testing of substances in aquatic and terrestrial systems. Expert in good laboratory practice (GLP); he is in charge of the regulatory tests.

Mr Yann Gouriou – Cell Biology and Biochemistry Section Head

Yann is in charge of the cell biology and biochemistry unit. He manages all the activities regarding cell biology, biochemistry and histology. And he also has a huge experience within Maldi-Tof imaging.

Dr David Lejon – Efficacy/Experimental Ecology Section Head

David is dedicated to support our clients with all specific enquiries. He is in charge of all tailor-made protocol answering to clients issues. Thanks to his scientific background he helps in tests design and analysis to answer to clients problematic.

Mr Alex Guesne – Quality Assurance Manager

Alex is in charge of the different quality system implementation in our company. He also inspects regularly studies/tests in progress. Thanks to his experience background he supports our teams to respect scrupulously quality system guidelines.

Royal HaskoningDHV
Enhancing Society Together

CONTACTS

Website	www.royalhaskoningdhv.com
E-mail	IB-NL.Secretariat.Health.Safety.and.Environment@rhdhv.com
Head office	HaskoningDHV Nederland BV, Laan 1914 nr. 35, 3818 EX Amersfoort
Tel	+31 88 348 69 18
Fax	+31 24 323 93 46
Contact	Mr Christiaan van Daalen / Mr Tjeerd Bokhout
Directors	Mrs Mirjam van der Velde, Director Advisory Group – Health, Safety & Environment
Ownership	Private company
Locations	100 Locations worldwide. Key locations: Nijmegen, Amersfoort (NL), Peterborough (UK), Mechelen (Be)
Founded	1881

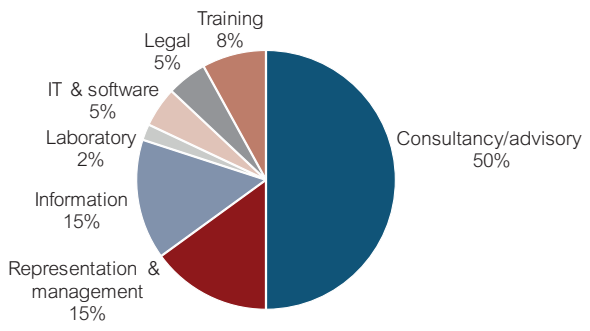
OVERVIEW

The firm was founded in 1881 in the Netherlands. In 2012 Royal Haskoning and DHV merged to the current organisation. Our employees combine a wide range of knowledge and experience. Rooted in a technical background, our consulting services focus on the broad field of interaction between people and their environment. We are committed to working enthusiastically with our clients to achieve sustainable solutions in an increasingly complex society. The expertise and experience of our professionals in a variety of disciplines allows us to consider all technical, logistical, legal, organisational, social, environmental and economic aspects of the projects of our clients, in order to subsequently develop sustainable and practical solutions.
We have been working with the industry on chemicals management for several decades and contributed to the implementation of numerous legislative programmes.

VITAL STATISTICS 2015/16

Turnover, group (2015)	€654 m
Turnover, chemical service provision	-
No of offices	100
No of countries represented	35
Staff, group	6,065
Staff, chemical service provision	50 – 100

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

HaskoningDHV Nederland BV:
Jonkersbosplein 52, 6534AB Nijmegen, The Netherlands
Haskoning UK Ltd:
Rightwell House, Bretton, Peterborough, PE3 8DW, UK
Haskoning Belgium SA:
Schaliënhoevedreef 20D, B-2800 Mechelen, Belgium

SERVICES PROVIDED

REACH

Royal HaskoningDHV provides a full range of REACH services, varying from consortium management to preparation of the technical dossier and the chemical safety report. Royal HaskoningDHV experts prepare and submit both lead and individual registration dossiers and support clients with both their regulatory strategy and day-to-day practical questions, both in the EU and Turkey. Although Royal HaskoningDHV does not provide laboratory services, it provides support in laboratory selection and study monitoring. Royal HaskoningDHV has good working relations with many laboratories.

GHS/CLP

Royal HaskoningDHV can assist you with services varying from technical support to total solutions for implementation of GHS. The services include, but are not limited to: regulatory consultancy and compliance checks, GHS/CLP implementation, CLP notification, (re-)classification of substances and mixtures, training on GHS/CLP.

Safety data sheets

Royal HaskoningDHV provides a full safety data sheet service including the preparation of the annex of the extended SDS (eSDS). In addition to these services advice is provided on the organisational and technical implementation of information from the eSDS.

Chemicals management

Royal HaskoningDHV provides a unique combination of knowledge on (eco)toxicology, chemical control legislation, safety and engineering to deliver lean and mean organisational and technical solutions for both these challenges. The key challenges for chemicals management: Effective communication of (REACH) information on hazards of substances and their safe use up and down the supply chain, is the key issue for the next years. Based on this information companies will need to reassess their working practices and habits.
Improvement of the risk management of SVHCs and the demonstration that the control is at the appropriate level.

Storage of chemicals and (external) safety

Royal HaskoningDHV can assist you with assessing, designing and permitting of storage facilities for hazardous chemicals, modelling of external safety (SEVESO) and assessing aspects such as explosion safety (ATEX).

Other services

Royal HaskoningDHV provides a wide range of services that provide solutions for multidisciplinary challenges to industry, such as engineering/ design of installations and buildings, responsible care and environmental impact assessments.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1881	Founding fathers Johan van Hasselt and Jacobus de Koning start their business in Nijmegen.
1917	Founding fathers Dwars, Hederik en Verheij start their business in 's Gravenhage.
1981	Haskoning is granted the designation 'koninklijk' (Royal) at its 100th birthday.
1991	EaSI is developed by Royal Haskoning: a database with hazard information from legislation all over the world

1994	Royal Haskoning developed Rosetta, one of the first programs able to produce multilingual safety data sheets.
2005	RIP 3.10 on characterisation and checking of substance identity is prepared by Royal Haskoning.
2007	Royal Haskoning joins the organisation of ChemCon Conferences.
2012	Merge between Royal Haskoning and DHV.
2013	Royal HaskoningDHV completes a three-year EU-project impact assessment and training for the implementation of REACH in Turkey.
2014	Royal HaskoningDHV submits first full supply chain REACH application for authorisation of two pigments

ACCREDITATIONS

ISO 9001/ ISO 14001/ OHSAS 18001

PARTNERS

ChemCon Conferences, EPPA SA, The Wercs

CLIENTS

The clients of Royal HaskoningDHV are located in many different industries. Because Royal HaskoningDHV provides more services than chemicals management alone, it has service relations with clients covering a wide variety of solutions. Clients are, for example, in pharma, flavours and fragrances, plastics, petrochemicals, paints and coatings, minerals and metals.

CASE STUDY 1: Application for authorisation of two pigments

For a producer of inorganic pigments Royal HaskoningDHV prepared an application for authorisation in collaboration with EPPA SA. The application covered the entire supply chain complicating the risk assessment and socio-economic analysis. To determine actual exposure conditions site visits were performed at downstream user sites throughout Europe. The information gathered was used to extensively describe the uses applied for and to refine the risk assessment and demonstrate safe use using higher-tier modelling (ART). The application for authorisation was supported by an analysis of alternatives showing no suitable substitution candidates. Other project activities included updating the existing lead registration dossier, official meetings with Echa (PSIS and Trialogue) and meetings with Member States and EC to explain the case. These efforts combined resulted in granting of an authorisation by the European Commission in 2016.

CASE STUDY 2: Preparation for substance evaluation (REACH)

For a consortium of producers of cosmetic product ingredients we have reviewed the dossier to see whether indubitably it can be said that the substances are not PBT and are not to be assessed as endocrine disrupting. Based on the results of the review we have provided several options to strengthen the statement of the dossier which will help the involved companies to defend their substances vital to the human health, protecting European consumers from thousands of serious illnesses per year.

CASE STUDY 3: Supply chain communication

For a client who formulates over 1,000 different products from over 350 substances we created a tool that allows the formulator to make informed decisions on the lead substances used for the assessment of the risk. After a pilot we were able to prepare sets of only eight different risk management measures for over 30 mixtures prepared from more than 80 hazardous substances. Based on this pilot we estimated that for the entire product portfolio a maximum of 30 sets of safe operational conditions and risk management measures were needed to inform the downstream user on safe use. Our method also allows downstream formulators to determine the contribution of these mixtures to the secondary mixtures produced without having to reveal the exact composition. This will help protect the client's confidential business information.

STAFF SELECTION

Berend Mensink, PhD ERT – Senior Expert Ecotoxicology

Berend Mensink studied environmental sciences and is a registered toxicologist (EuroTox). Although interested in the hazards and impacts of chemicals on humans and the environment, he is specialised in ecotoxicology and environmental fate and behaviour of chemicals. He holds over 15 years of experience in the chemical industry, including overall management of a laboratory studying properties, fate and effects of chemicals in the aquatic environment and endocrine disruption. He was responsible for a wide range of product and substance registrations for applications and markets within Europe in the chemical industry, including assessing hazards and risks.

Chris Rietveld PhD, ERT – Senior Expert Toxicology

Chris Rietveld is a senior toxicologist at Royal HaskoningDHV who has worked as a toxicologist in both research institutes and various branches of industry. He has ample experience with regulatory toxicology, technical consultancy and REACH dossier preparation and has been responsible for regulatory and product safety departments in previous positions.

Ing. Manon van Kuijk – GHS/CLP and SDS Expert

Manon van Kuijk is lead expert in the field of classification and labelling and safety data sheets. For ten years she has been involved in consultancy on classification and labelling issues and safety data sheets services. She also has experience with data collection, processing and interpretation. As a consultant and project manager she participates in multiple projects for various industries and authorities and provides (inhouse) training courses.

Tjeerd Bokhout, MSc MBA – Consortium Manager

Tjeerd Bokhout is an experienced consultant and project manager on environmental and chemicals management projects in Europe and abroad (mainly Asia). Tjeerd holds both an MSc and MBA and has a strong focus on the business case of his clients. Tjeerd has a vast network in the global community on chemicals legislations. He has experience in the support of chemical industry and governmental bodies with requirements of REACH. Tjeerd manages several REACH consortia and provides strategic advice on REACH implementation. Tjeerd is also active as director of ChemCon Conferences, the world's leading conference on chemical control legislation and trade aspects.

Leo van der Biessen, MSc – Senior Expert Occupational Exposure

Leo van der Biessen has more than 25 years' practical experience in controlling and managing chemical exposure risk in the chemical process industry and its downstream users. In 1990 he joined a leading health and safety service provider in the Netherlands where he devised chemical risk assessment and control strategies as well as worker protection regimes. He joined Royal HaskoningDHV in September 2002. Since 2008 he has focused on creating realistic risk assessments under REACH, assisting companies with authorisation and the communication of REACH results in the supply chain. Leo was a board member for chemical safety of the Dutch Industrial Hygiene Association.

Christiaan van Daalen, MSc – Project Manager

Christiaan van Daalen is trained as an environmental scientist, specialising in both regulatory toxicology and business communication with a focus on REACH. He has been involved in the production of several large dossiers under REACH and advises on various REACH implementation processes. Besides the preparation of technical dossiers Christiaan acts as project manager in many REACH registration projects for individual companies and consortia.

RTC Research Toxicology Centre

CONTACTS

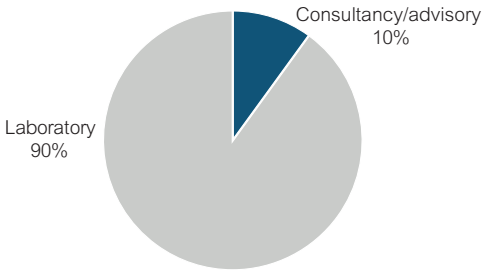
Website	www.rtc.it
E-mail	mkt@rtc.it
Head office	RTC – Research Toxicology Centre S.p.A., Via Tito Speri 12/14, 00071 Pomezia (Rome) Italy
Tel	+39 06 91095263
Fax	+39 06 9122233
Contact	Danilo Bucci, Head Business Development
Directors	Germano Oberto, Scientific and Productive Process Director Stefano Villa, General Services Director
Ownership	I.F.R. Menarini
Locations	Italy
Founded	1972

OVERVIEW

RTC is a fully fledged contract research laboratory located in Pomezia near Rome (Italy) with a track record spanning more than four decades. RTC collaborates with a large range of industrial clients including the pharmaceutical, biotech, chemical, agrochemical and biocide industries. Our research staff is composed of a highly qualified team specialised in different areas of toxicological research. In our international and multilingual environment we work in compliance with all relevant international guidelines. We are proud to say RTC was awarded the full AAALAC accreditation in 2012 and has since worked to the highest standards for animal welfare. Our research centre works according to the principles of Good Laboratory Practice and holds the GLP Certificate achieved from the Italian health authorities. Furthermore, RTC has repeatedly been inspected by FDA and by the Japanese Ministry of Health and Welfare, our GLP compliance being confirmed on all occasions. RTC can support its clients from a very early stage of the project, offering a full range of experimental and consultancy services in order to ensure a tailored approach. Scientific and technological expertise, combined with skills in project management and communication, qualify RTC as the partner of choice for any product development. Serving our clients is our utmost priority. That is why RTC is deeply committed to serving your needs and attending to every detail of your project. We will guide you during the selection of the experimental design and provide tailored solutions. RTC will ensure close monitoring of each study phase to respect quality and timing. Our staff will constantly keep you informed of progress, every step of the way, since communication and collaboration are essential to achieve success.

VITAL STATISTICS	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	1
Staff, group	155
Staff, chemical service provision	-

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Our facilities are located in Pomezia (Rome), Italy. In addition, we have sales representatives in Germany, France and Switzerland.

SERVICES PROVIDED

Genetic toxicology

Genetic toxicology studies fall within our core competences as this study type has been established in RTC since 1972.

In chemico and *in vitro* toxicology

Many *in vitro* studies are already available and further alternative methods are being implemented in order to be in line with the most recent regulatory requirements.

General toxicology on rodents, from acute to oncogenicity studies

Hundreds of these studies have been performed over the years and this number will increase considering all feedback from Echa relating to the previous REACH deadlines.

Reproductive toxicology and juvenile toxicology

Reproductive and developmental toxicity studies in rats and rabbits are performed at RTC on a routine basis. The Eogrts (all cohorts) has been established as well.

Analytical support

All tox studies are supported by our internal analytical chemistry department. Experienced scientists are available to set up and validate new analytical methods (for both formulation analysis and TK sample analysis) from scratch or to transfer existing methods.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1972	Foundation as CRF
1979	Acquisition by the Menarini Group
1987	GLP certification
2007	Ready for REACH
2014	Full AAALAC accreditation

ACCREDITATIONS

AAALAC
GLP
FDA approved
ISO 14001:2004
BS OHSAS 18001:2007
EcoVadis

PARTNERS

We collaborate with partner laboratories for ecotoxicology, physico-chemical properties, inhalation studies and regulatory support.

CLIENTS

We serve a wide range of clients, from SMEs to global corporations, consortia and industry associations worldwide. Confidentiality agreements preclude the possibility of naming them.

TESTIMONIALS

Testimonials can be provided upon request.

CASE STUDY

Both our clients and their testing programmes are protected by confidentiality agreements. Over the years many different types of compounds have been tested and many customers have qualified RTC as preferred supplier, contributing to the positive outcome of the client's testing programmes. RTC is committed to comply with currently applicable scientific, legal, regulatory and ethical requirements, guidelines and policies to ensure animal welfare. All studies are carried out by well-trained, duly qualified and experienced personnel. RTC is committed to the 3Rs principles and shall actively pursue their promotion.
In November 1998 an Ethical Committee for Experimentation on Animals was created in order to evaluate the experimental protocols which involve the use of animals and to ensure that experimentation on animals carried out in RTC is performed according to current laws and regulations. A specific SOP regulates the activities of this committee.
As RTC claims to be a right-size CRO, flexibility and proactive attitude are among our core characteristics. Having one location is a positive factor as all laboratories and facilities are close to each other.
Our long experience with demanding clients has taught us that on-time delivery is a must. In order to meet our clients' requirements, a specific project management system has been set up. Within REACH projects a study director is assigned to each single study and a project leader is appointed as central reference point for the specific testing programme. At certain intervals of time, agreed upon with the client, an overview of the project is prepared and may include also subcontracted studies.

STAFF SELECTION

Silvana Venturella – Associate Scientific Director, Head Business Unit *In Vivo* Toxicology

- Responsible for the Study Director Group and Operational Departments of *in vivo* studies
- Biology degree
- Joined RTC in 1991
- Oversees the design and the conduct of the studies for non-clinical development ensuring the up-dating and scientific validity and compliance to national and international guidelines.

Serena Cinelli – Associate Scientific Director, Head Business Unit Genetic and *In Vitro* Toxicology

- Joined RTC in 1984
- Responsible for improvement of methods and techniques to meet current standards in genetic and *in vitro* toxicology, providing the best up-to-date solutions for safety evaluation of products.
- Responsible for the experimental conduction of non-clinical safety studies in compliance with GLP regulations.
- Invited professor (specialising master) in environmental mutagenesis.
- Author of several peer reviewed publications.
- Member of the American, European, British and Italian Environmental Mutagen Societies (EMGS, EEMS, UKMS, SIMA) and the European Society of Toxicology *In Vitro* (ESTIV).

Rosaria Cicalese – Expert in Reprotoxicity Studies, Senior Study Director

- Scientific expert in reproductive, juvenile and neonatal toxicology
- Biology degree
- Joined RTC in 1990
- RTC senior foetal morphologist
- Acts as Senior Study Director and/or Project Leader for designated clients in different areas of reproductive toxicology
- Defines the design of studies intended to support non-clinical development and act as a referee for internal scientific staff and for the client in the area of expertise.

Cristina Longobardi – Expert in Industrial Toxicology, Senior Study Director

- Scientific expert in industrial toxicology
- Biology degree
- Joined RTC in 1990
- Acts as Senior Study Director and/or Project Leader for designated clients in different areas of general toxicology
- Defines the design of studies intended to support non-clinical development and act as a referee for internal scientific staff and for the client in the area of expertise.

Francesca Calfapietra – Head, Analytical Chemistry Department

- Chemistry Degree
- Joined RTC in 2000
- Acts as Senior Study Director and/or Project Leader for designated clients in different areas of analytical chemistry
- Supervises new analytical method development and validations ensuring the up-dating of scientific, technological and regulatory matters providing support to meet client expectations in the area of expertise.

SCC
WE CARE FOR YOUR SUCCESS

CONTACTS

Website	www.scc-gmbh.de
E-mail	scc@scc-gmbh.de
Head office	Am Grenzgraben 11, 55545 Bad Kreuznach, Germany
Tel	+49 671 298 46-0
Fax	+49 671 298 46-100
Contact	Dr Werner Koehl (Chemicals / REACH, Consumer Products, Cosmetics, Feed & Food Additives)
Directors	Dr Friedbert Pistel, Owner and President Dr Albrecht Heidemann (Agrochemicals and Biopesticides) Dr Monika Hofer (Regulatory Science, Pharma Pre-Clinical) Dr Werner Koehl (Chemicals / REACH, Consumer Products, Cosmetics, Feed & Food Additives) Dr Hans-Josef Leusch (Biocides)
Ownership	Private company
Locations	Germany and Japan
Founded	1989/ regulatory experts for more than 25 years

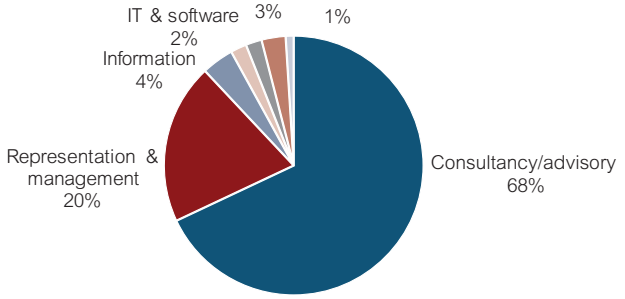
OVERVIEW

SCC – Scientific Consulting Company – was founded in 1989 by Dr Friedbert Pistel, and is today one of Europe's largest privately-owned and independent consulting companies for the registration of chemicals, cosmetics, consumer products, agrochemicals and biopesticides, biocides, feed and food additives, food contact materials and pharma pre-clinical.

VITAL STATISTICS 2014/15

Turnover, group	-
Turnover, chemical service provision	-
No of offices	3
No of countries represented	2
Staff, group	125
Staff, chemical service provision	50

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Headquarters Bad Kreuznach (Germany), Office Berlin and Liaison Office Japan

SERVICES PROVIDED

Registration of chemicals – REACH and international programmes

SCC has prepared hundreds of chemical notifications for new chemical substances (ELINCS) including high volume products of more than 1,000t/a) and successfully filed more than 250 dossiers for the first two deadlines. In addition, more than 50 PPORD and more than 50 inquiry dossiers were submitted. SCC has notified new chemical substances in China, Japan, Korea, Australia and Canada. Also, SCC has established a network with the competent authorities within the entire EU and abroad and is recognised as a reliable and competent partner by the authorities (eg Echa) and EU industry organisations (eg, Cefic or HERA). SCC can provide you with:

- only representative support;
- trustee service for supply chains (non-EU, EU);
- support in the (late) pre-registration process;
- support in prioritisation/advice on required action in your company for the 2018 REACH deadline and regarding international requirements for chemicals;
- literature (re)search and evaluation;
- data review and identification of data gaps;
- analysis of potential analogous/family category approaches;
- development of registration/ testing strategies for chemicals and polymers (including global programmes) as well as organising and monitoring of these studies;
- support with uses, use categories, PROCs, and (sp)ERCs;
- exposure modelling (eg EUSES, Risk of Derm, ConsExpo, EASY-TRA, ART);
- human and environmental risk assessments;
- preparation of the chemical safety report;
- submission/defence of the dossier at authority level;
- support in the Corap and SVHC/authorisation procedure;
- Sief and consortia support/management including trust account;
- C&L support (CLH dossier according to Annex XV, RAC evaluation);
- eSDS including annex;
- scientific/regulatory support at EU expert meetings;
- Qsar tools.

Regulatory science

The scientific experts of the SCC regulatory science department are the backbone of the company and the key to its success. SCC unites experts from all regulatory relevant disciplines, such as chemists, physicists, food chemists, biologists, geo-ecologists, toxicologists, eco-toxicologists, environmental fate specialists, agronomists, veterinarians, etc. This access to a wide spectrum of expertise ensures that clients of SCC can take advantage of a highly efficient service.

Registration of agrochemicals and biopesticides

The SCC agrochemicals and biopesticides department considers current and future regulatory and legislative needs and developments in the common agricultural policy of the EU, and stays up-to-date on the latest scientific research data. For this reason, the agrochemicals and biopesticides department is at the forefront in strategic planning and defence, negotiations with authorities, or task force support.

Registration of biocides

The SCC biocides department has successfully submitted dossiers for more than 20 existing biocidal active substances according to the biocidal products Directive 98/8/EC, covering nearly all product types. We have established good working relationships with many competent authorities in the EU and have become an acknowledged partner of authorities and industry. Currently, we are involved twofold: defending active substance dossiers already submitted and preparing dossiers for biocidal products under Regulation (EU) No 528/2012.

Registration of feed and food additives

The SCC Feed and Food Additives department successfully managed almost 50 application dossiers for re-authorisation of feed additives for the 2010 deadline, which is about 10% of all dossiers filed. Our expertise and connections with authorities and industries enable us to put together the optimal portfolio of scientific data and expert statements for your products. These portfolios will be as concentrated as possible and as extensive as necessary. In addition, we actively support our customers in the area of food contact materials.

Registration of consumer products and cosmetics

SCC has successfully supported the cosmetics and consumer product industry for more than two decades. Detailed knowledge of all relevant national and international regulatory directives and regulations are the basis to meet all challenges originating for example from the cosmetics Regulation (EC) No. 1223/2009 including the hurdles due to the ban on animal testing or detergents Regulation (EC) No. 648/2004. SCC has proven experience for exposure and risk assessments on different scenarios. Data gap analysis, dossier preparation as well as placement and monitoring of studies are other fields of expertise. SCC has successfully prepared more than 60 safety dossiers for challenging cosmetic ingredients like hair dyes, UV-filter, preservatives, nanomaterials, botanicals and CMR categorised substances.

GLP and regulatory/scientific archiving

SCC has more than 25 years' archiving experience. SCC offers a complete archiving concept for all regulatory needs (regulatory/scientific and GLP-compliant storage). Our EDDMS (Electronic Document and Dossier Management System) with versatile tools is a regulatory dossier management system with worldwide access to all regulatory and scientific information. SCC is also your partner for secure archiving of GLP raw data. In 2004, we were successfully certified as first GLP contract archive in Germany. Since then, SCC has been continuously recertified by the German GLP monitoring authority. SCC looks forward to becoming your European or worldwide central archive.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1989	SCC GmbH founded
1989	Establishment of Agrochemicals and Biopesticides department
1989	Establishment of Regulatory Science department
1996	Establishment of Chemical and Consumer Products department
2000	Establishment of Biocides department
2004	GLP archive certification
2007	Establishment Liaison Office Japan
2007	Establishment of Feed and Food Additives
2014	25 years of SCC
2014	Establishment Office Berlin

ACCREDITATIONS

GLP archive (since 2004)

PARTNERS

Along with our Headquarters in Bad Kreuznach (Germany), our Office Berlin and our Liaison Office Japan, we have a global network with CROs, governmental institutions, local regulatory experts and scientists. We can support our clients all over the world.

CLIENTS

Small to large (global) companies in the areas of chemicals and consumer products, agrochemicals and biopesticides, biocides, feed and food additives and food contact materials.

TESTIMONIALS

Many of our clients have been customers for a long time, some going back to the start of our company. New clients are often recommended to us via existing clients.

CASE STUDIES: General remark

All the names of our customers and projects are restricted under the highest level of confidentiality. Therefore we are unable to focus on individual case studies. Our consultancy has an excellent proven track record in all regulatory areas where we are active. Only one proof of our success is the fact that in the two decades of our existence, we have grown from a small national business to become a global player.

STAFF SELECTION

Dr Werner Koehl – Head of Chemicals/REACH, Consumer Products, Cosmetics, Feed & Food Additives

Dr Koehl has a PhD in food chemistry and is a certified expert for toxicology. He has been with SCC since 2001 and is head of Chemicals/REACH, Consumer Products, Cosmetics, Feed & Food Additives. He previously worked for the scientific committee on food safety and a large chemical multinational, and has gained many years of experience in the registration processes of consumer products and chemicals worldwide.

Isabel Kirbach

Mrs Kirbach has a master's degree in chemical engineering. She has been with SCC since 2004 and her focus is on Sief, Iuclid and consortia management since 2006.

Dr Karsten Schilling

Dr Schilling, head of the BU consumer products and cosmetics, has a PhD in veterinary medicine and more than two decades experience in this field.

Dr Ingo Walter

Dr Walter has a PhD in food chemistry. He has been with SCC since 2008, focusing on risk assessments, C&L and eMSDSs.

Dr Monika Hofer – Head of Regulatory Science, Pharma Pre-Clinical

Dr Hofer has a PhD in chemistry. She has been with SCC since 1998 as head of Regulatory Science, Pharma Pre-Clinical.

Dr Albrecht Heidemann – Head of Agrochemicals and Biopesticides

Dr Heidemann has a PhD in biology. He has been with SCC since 1994 as head of Agrochemicals and Biopesticides.

Dr Hans-Josef Leusch – Head of Biocides

Dr Leusch has a PhD in agronomy. He has been with SCC since 2000 as head of Biocides.

Dr Bernd Brielbeck – GLP Archive

Dr Brielbeck has a PhD in chemistry. He has been with SCC since 2001 and is responsible for our GLP-certified archive.

SMITHERS VISCIENT

CONTACTS

Website	www.smithersviscient.com
E-mail	info@smithersviscient.com
Head office	108 Woodfield Drive, Harrogate, UK
Tel	+44 (0) 1423 532 710 (UK) +1 508 295 2550 (US)
Contact	Fiona Brook-Rogers – Marketing Manager – Europe Hope Aubin – Director of Marketing – North America
Directors	Steve Dean – Managing Director – Europe Ron Biever – Vice President – North America Susan Shepherd – President
Ownership	Private
Locations	US, EU, Japan
Founded	1969

OVERVIEW

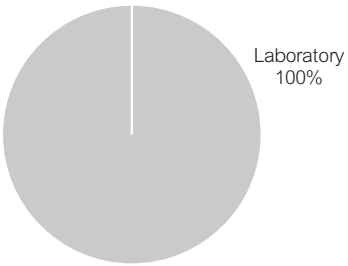
Environmental testing and regulatory services

Smithers Viscient performs environmental and consumer safety contract research and regulatory services for the crop protection, pharmaceutical, industrial chemical and consumer product industries. Smithers Viscient has performed standard guideline and higher-tiered environmental studies for over 45 years. We conduct studies that satisfy all global regulatory requirements. Smithers Viscient is a leader that delivers trusted testing services.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	-
No of countries represented	-
Staff, group	-
Staff, chemical service provision	-

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Smithers Viscient – Harrogate, United Kingdom
Smithers Viscient – Fresno, California, North America
Smithers Viscient – Wareham, Massachusetts, North America
Smithers Viscient – Snow Camp, North Carolina, North America
Smithers Viscient – Tokyo, Japan

SERVICES PROVIDED

Environmental fate

Environmental fate and metabolism studies include study designs to assess biotic and abiotic degradation, mobility in the environment, bioaccumulation in organisms, along with plant and animal metabolism.

Plant metabolism

Metabolism studies are conducted to determine the nature of residues and the test substance's metabolic pathways in plants and animals. In addition, confined rotational crop studies can be conducted under field conditions to assess the potential for accumulation and metabolism of soil residue.

Smithers Viscient has the capability to perform plant metabolism and confined rotational crop studies with radiolabeled test substances at dedicated sites in both the US and UK.

Ecotoxicology

Our scientists are knowledgeable in testing challenging (eg complex mixtures (UVCB), hydrolytically unstable, volatile, low solubility, adsorptive) materials and analytically confirming exposure levels in low parts per trillion (ppt) range in a variety of sediment, soil, diets and aquatic matrices. Smithers Viscient has experience in working with 150 species and has a well-deserved reputation for its work with honey bees, earthworms, arthropods, invertebrates and a variety of fish species. Some stocks of test organisms have been continuously maintained for thirty years.

Avian toxicology

Avian ecotoxicology programmes include toxicity testing, non-target organism pesticide exposure characterisation and avian endocrine disruption.

We offer poultry and catfish feeding studies to assess the nutritional equivalency and safety of feed developed from genetically modified plant material. We offer pesticide exposure characterisation and risk assessment as well as a variety of field studies. Field studies may be conducted on remote agricultural field sites or on study plots.

Honeybee and pollinator testing

Smithers Viscient conducts all Tier 1 laboratory pollinator studies at our Wareham and Harrogate facilities in addition to field pollinator studies throughout the United States with permanent locations on the East and West coast. Our North Carolina facility is the base of operations for pollinator health effects and residue/exposure studies. Our Fresno California facility allows for staff to be readily available for field studies that must be conducted in California under EPA/CDPR recommendation.

Pollination and field trial services guidelines:

- honeybee acute;
- acute oral (OECD 213);
- acute contact (OECD 214, 850.3020);
- honeybee 10-day chronic adult (OECD draft);
- honeybee larval;
- 7-day (OECD 237);
- 22 day OECD draft;
- bumble bee acute;
- acute oral (OECD 213, modified);
- acute contact (OECD 214);
- solitary bee;
- acute oral;
- acute contact
- honey bee toxicity of residues on foliage (850.3030);
- analytical support; and
- bumblebee chronic (queenless micro).

Residue, analytical and product chemistry

Smithers Viscient provides leading-edge technology and analytical support services for environmental compliance in the pharmaceutical, agricultural, specialty and industrial chemical industries. Our staff includes experienced scientists and technicians offering a broad range of skills and areas of expertise. Our scientists will work closely with you to develop procedures and protocols that produce effective and conclusive results.

About residue chemistry services:

Smithers Viscient provides GLP-compliant residue chemistry studies for registration and environmental monitoring needs.

Our analytical chemists have expertise in method development and method validation, and can design and implement fully customisable multi-residue testing programmes for both active ingredients and metabolites. Smithers Viscient has developed HPLC and GC methods for a wide variety of matrices, including plant materials, soil, water, air, and processed food, animal feed and animal tissues. These methods are fully validated according to the latest EPA and SANCO guidelines. Our experienced chemists quantitatively measure the active ingredient (AI) and its metabolites – or the degradation products produced from the AI.

About analytical chemistry services:

Smithers Viscient offers a wide range of analytical services using sophisticated analytical instrumentation. We have the expertise, personnel and equipment to provide clients with assistance in analytical method development in support of environmental toxicology studies, biotechnology, manufacturing support, compliant sample analysis, polymer analysis, and surfactant analysis.

Smithers Viscient's analytical chemistry team has experience with particular strengths in method development, chromatography and compound identification. This range of expertise when combined with the latest analytical instrumentation and techniques allows Smithers Viscient to develop, and validate methods for a very broad range of test articles.

About product chemistry services:

Smithers Viscient performs product composition investigation, identification and quantification of the contents in a technical grade product subject to registration. Our capabilities include screening of ingredients to 0.1% and lower. Smithers Viscient has considerable experience in trace level analysis for the detection and identification of toxicologically significant impurities for preliminary five-batch analysis, as well as experience in structure elucidation, in addition to having extensive experience with a very broad range of test article chemistries.

Endocrine disruptor testing

Smithers Viscient is active in the area of endocrine disruption in both the US and Europe. Smithers Viscient provides services that meet global regulatory endocrine testing requirements and is a recognised leading team in this field and conducts short-term reproduction assays (OECD 229, OECD 230), fish sexual development tests (OECD 234), the new medaka extended one generation reproduction test (OECD 240) and lifecycle tests.

Smithers Viscient has successfully conducted a significant number of FSTRA tests and AMA tests for Tier I studies and our leading ecotoxicology experts are participating in development of the testing guidelines for both US EPA Tier 1 and Tier 2 phases. Our staff can assist clients with other EDSP questions regarding fish, amphibian and avian testing guidelines proposed for Tier 2 testing.

REACH testing

Smithers Viscient serves a global client base and has all the required official accreditations necessary to provide regulatory studies to support product registrations in full compliance with Good Laboratory Practice Regulations. Our scientists are experts in the design and implementation of experimental protocols offering a wide variety of analytical services in physical and chemical properties, ecotoxicology and environmental fate using state of the art analytical instrumentation. We provide superior quality and value through expert advice, accurate and timely delivery and clear, concise communication.

Since only substances are registered under REACH, correct and unambiguous substance identification is essential. REACH environmental data requirements (Annex VII – VIII) include data on physico-chemical properties, ecotoxicological information, toxicology and environmental fate properties.

Toxicology

Smithers Viscient offers toxicology testing services for the agricultural and chemical industries. Smithers Viscient provides a portfolio of services with scientific expertise and project management capabilities that ensure the quality of the data with the convenience of working with one company. Services include:

- general toxicology;
- developmental and reproductive toxicology (DART) – includes Extended One Generation Reproductive Toxicity Study (EOGRTS);
- neurotoxicology studies; toxicokinetics;
- dietary exposure;
- subchronic and chronic toxicity studies;
- carcinogenicity studies; and
- Endocrine Disruptor Screening Program (EDSP) assays.

ACCREDITATIONS

GLP and AAALAC accredited

CONTACTS

Website	www.spherasolutions.com
E-mail	operationalexcellence@spherasolutions.com
Head office	130 East Randolph St, Suite 1900, Chicago IL, 60601, USA
Tel	1-514-337-2114 / 31 (0) 24 329 7424
Contact	Frank Arcadi
Directors	Paul Marshka, President and CEO
	Bob Hogue, Chief Financial Officer
Ownership	Privately held
Locations	United States, Canada, Paris France, Bracknell UK, Nijmegen The Netherlands
Founded	2016 (previous division of IHS)

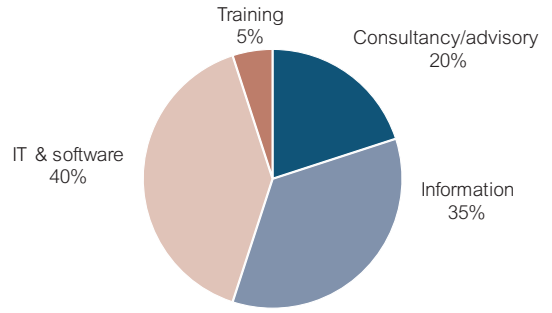
OVERVIEW

Sphera Solutions, formerly IHS Operational Excellence & Risk Management, is the largest, global provider of software and information services in the operational risk, environmental performance and product stewardship markets. For more than 30 years, we have served over 2,500 customers and a million-plus users in 70 countries to optimise workflows and navigate the complex and dynamic global regulatory structure. Our goal at Sphera is to help customers keep their people safe, their products sustainable and their operations productive. We do this by advancing operational excellence with innovation through software, information from our data and expert-driven insight.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	11
No of countries represented	Global
Staff, group	550+
Staff, chemical service provision	150

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Willoughby Road, Bracknell, West Berkshire RG12 8FB, UK
4777 Levy Street, St. Laurent, Quebec, Canada H4R 2P9
Oranjesingel 34, 6511 NV Nijmegen, The Netherlands

SERVICES PROVIDED

Sphera provides a complete solution to strengthen and enable companies to stay aligned with current and future legal requirements when managing chemicals. Sphera's solution is designed to integrate with key ERP and PLM systems enabling consistent support for business compliance processes.
Powered by Intelligent Authoring™ and Comply Plus® this comprehensive solution combines software, content and industry expertise, enabling organisations to efficiently monitor and manage product compliance with rigorous regulatory mandates at every stage of the product lifecycle, from product design through manufacturing, shipping and delivery.
Sphera supports your company's compliance programme with these powerful information management capabilities:

SDS authoring

Automates the production of compliant safety data sheets in nearly 50 languages, ensuring your customers and employees will have the information they need to ensure safe use of your products and continued access to global markets. This includes a powerful rule-based document generation engine with the ability to produce extended SDS and exposure scenarios with translated ESCOM Phrases. The solution also has functionality to allow easy tailoring of rules so that authors can effortlessly modify and enforce decisions about regulatory variables and grey areas affecting the content of safety data sheets. Furthermore the solution allows for GHS by Design, a unique functionality that allows SDS authors to configure user-defined GHS implementations for any area, country or region with no official GHS regulatory support.

Documentation and labels

Simplifies the process of designing, producing and printing labels for GHS, transport and consumer goods regulations.

Product compliance analysis

Enables product compliance specialists to proactively plan for and manage impacts of evolving requirements and gain insight into calculated classifications, quickly identify substances of concern in products, and make better decisions.

Chemical management

Allows for effective management of inbound and produced chemicals by using a consolidated platform for SDS management, chemical approvals, chemical inventory tracking, including SVT, and environmental reporting.

Managed regulatory content

Ensures efficiency in maintaining compliance in the ever-evolving regulatory environment by providing consolidated and validated regulatory data. Sphera continuously monitors global regulations, interprets changes, and delivers application ready updates to data, rules, templates and logic.

Integration with key business systems

Facilitates end-to-end business data flow by effectively connecting to other key systems, such as ERP, PLM, LIMS and formulation management applications. Based on many years of experience, we have developed tools that decrease the time-to-value for implementations and ease sustainability.

Sphera also offers a product compliance solution for SAP® EHS

Sphera provides a modular pre-packaged SAP® EH&S solution that delivers regulatory data, rule sets, phrases, templates and configuration tools to accelerate the benefits of your investment. The solution has a state-of-the-art content editor that regulatory experts can use to change the behavior of their core SAP® EH&S system rules and support company specific requirements. It enables the creation and/or modification of rules, viewing of phrases and mapping of rule outputs to a product property tree.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1989	Atrion International is founded
1991	Dolphin Software is founded
2008	IHS acquires Dolphin Software IHS acquires Environmental Software Providers
2009	IHS acquired Environmental Support Solutions
2010	IHS acquires Atrion International IHS acquires Syntex Systems
2011	IHS acquires Dyadem IHS creates Operational Excellence & Risk Management (EHS) Division
2015	Verdantix – Smart Innovators Badge
2016	Verdantix – Green Quadrant Leader
2016	Sphera Solutions founded from previous IHS EHS Division

CLIENTS

For more than two decades, Sphera's portfolio of solutions has been trusted by hundreds of enterprise-level clients worldwide across a vast array of industries, including chemicals, pharmaceuticals, energy, mining, manufacturing, transportation and consumer goods.

CASE STUDY 1: Drom Fragrances

Challenge: Drom Fragrances, one of the world's premier fragrance manufacturers, sought to ensure product compliance with regulations and industry standards in 43 countries – including REACH, CLP and Ifra.

Results: Drom consolidated seven systems into one centralised system for product compliance data, standardised material safety data and work processes and saved over ten weeks of cleansing and transforming material safety data. They also simplified data management and production of SDS documentation/labelling and were able to lay the foundation for proactively addressing future changes to product regulations/standards in order to maintain and expand access to markets.

CASE STUDY 2: Yara International ASA

Challenge: Yara, the world's largest fertiliser company and a leading chemical manufacturer needed to enhance safety data sheet authoring capabilities to comply with higher requirements from REACH, CLP and other mandates. Yara also wanted to establish a new integrated chemical compliance system compatible with their corporate IT environment and drive continuous improvement of SDS work processes and core business operations.

Results: Yara efficiently managed exponential growth of SDS volume to support their business expansion. In the European market alone, they increased from 3,000 SDSs in 2008 to 15,000 SDSs in 2012. Yara was also able to standardise and enhance the quality of SDSs across their global enterprise. The Sphera solution enabled them transparency and accountability for audits by offering the ability to track back to chemical composition and business decision justifications. Yara was also able to streamline work processes by automating distribution of SDSs.

CASE STUDY 3: Lanxess

Challenge: Meet the changing regulatory compliance needs on a global scale including GHS, Osha Hazcom, EPA Fifra and CLP. Author SDSs in dozens of languages for as many destination countries. Respond rapidly to customer requests for safety information

Results: Moved ahead of schedule for full compliance with GHS. Maintained and managed 4,000 products in the US, as well as a few thousand more products produced in Canada and distributed in Mexico in 39 languages for destination countries. Sent out 120,000+ SDSs companywide in 2013 and increased customer satisfaction by addressing new compliance challenges proactively.

CASE STUDY 4: Siemens Healthcare

Challenge: Meet US Osha and EU GHS compliance deadlines and maintain access to key markets. Train product stewardship managers about complex GHS requirements. Identify substances of concern in their products to create safer, more sustainable products and respond to customer inquiries

Results: Reassessed 3,500 reagents according to new GHS classifications and updated 70,000 safety data sheets prior to 2015 GHS deadline. Created GHS-compliant SDSs in 20 unique language formats. Avoided product interruption to customers in key GHS-affected markets. Effectively analysed product portfolio to identify substances of concern and respond effectively to customer requests.

STAFF SELECTION

Francis Trudeau, Solutions Manager

Francis Trudeau has worked for nearly 20 years in product compliance and chemical management. Trudeau has significant experience in solutions management and development, global regulations and industry standards enforced worldwide. He has worked on a wide variety of projects that support integrated information management solutions, and address legal compliance challenges and the implementation of regulations in databases and software applications.

Trudeau is a recognised industry expert, serving both as a featured speaker at international conferences and leading multi-organisation task forces in establishing industry best practices for regulatory compliance.

Mary Rudolph, Senior Manager – Global Content

Mary Rudolph has more than 25 years of international environmental, health and safety experience, including technical and business implementations of authoring services. She offers customers an in-depth and often sought after understanding of the needs of global EHS departments. She has also managed the development of EHS-related databases, including RTECS®, a recognised toxicology database.

Scott Harter, Director Regulatory Content

Scott Harter has more than 25 years of experience in EH&S. He has worked for 15 years in implementation, SDS authoring service, and content development. Previously he managed an EH&S department in a consulting business and worked for industry. In industry Harter managed extensive environmental investigations, the Industrial Hygiene Department, and the Radiation Protection Program for Eastman Kodak Company. He is a board certified industrial hygienist or "CIH".

Rosemary Feiter, Senior Manager – Authoring Services

Rosemary Feiter has over 25 years of experience in a variety of fields that are correlated to product stewardship activities such as R&D, production, quality control, distribution and EH&S assessments. Feiter leads the Regulatory Managed Services team that provides clients with safety document authoring and consulting services. The authors and project managers are regulatory experts that have substantial experience and knowledge of global regulations and industrial best practices having worked on multiple authoring projects for clients with diverse product portfolio.

CONTACTS

Website	www.ssseurope.org
E-mail	sk@reach-onlyrep.eu
Head office	IDEON Science Park, Beta 5, Scheelevägen 17, 223 70 LUND Sweden
Tel	+46 46 2850417 & +46 46 2114615
Contact	Shisher Kumra
Directors	Shisher Kumra and Mukta Kumra
Ownership	Private Limited Company
Locations	Sweden, India and South Korea
Founded	2008

OVERVIEW

SSS is one of the most sought after chemical regulatory compliance service provider based in Sweden. Today, SSS has diversified its service portfolio to also include conformity assessment and compliance management services. **SSS services have the distinction of being accredited as a third party inspection services for chemical regulatory compliance, with special focus on REACH; as per the ISO 17020 standard. All regulatory compliance activities of SSS are processed through this system.**

SSS also provides neutral third party inspection services to textile exporters for confirming adherence to the code of conduct of the European apparel brands. SSS has an extensive network of European, Indian and other Asian business intermediaries and has been working to facilitate businesses to comply with the requirements of REACH and various other European regulations as well as the chemical regulations in place in other countries like US, China, Japan, South Korea, Malaysia, Canada, etc.

SSS has a memorandum of understanding (MoU) with the following organisations, namely:

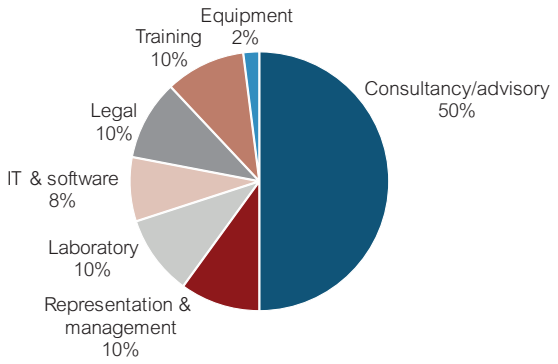
- TISAMAX Technical Co, Ltd;
- China Chamber of Commerce of Metals Minerals and Chemicals (CCCMC);
- China International Electronic Commerce Center (CIECC); and
- Randis ChemWise (Shanghai) Co,Ltd, China.

SSS is also actively contributing towards the finalisation of India's National Chemical Policy (NCP), Hazardous Substances (Classification, Packaging and Labelling) rules sometimes referred to as India GHS and the national chemical inventory, a demonstration of which has been recently presented to the Indian chemical ministry. SSS and its group company in India are all geared up to help companies comply with the Indian regulations when they become a law.

VITAL STATISTICS

	2015/16
Turnover, group	€3.2m
Turnover, chemical service provision	€2.9m
No of offices	3
No of countries represented	20
Staff, group	35
Staff, chemical service provision	25

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Sweden, with affiliates in India and South Korea

SERVICES PROVIDED

Late pre-registration (LPR)

SSS offers LPR services to help non-European companies, either new manufacturers or first time exporters of substances, to late pre-register their substances that were not pre-registered during the June-December 2008 period. Since the pre-registration deadline, SSS has successfully completed the LPR for over 1,800 substances, with more in the pipeline.

CLP notification

SSS provides the CLP notification services to non-European companies for which the company has to furnish the identity of the substance like the CAS No, EC No.

SSS has successfully completed over 1,900 CLP notifications.

Registration

Since 2011-12, SSS is working very hard to help its client companies successfully meet the last registration deadline of 31 May, 2018. SSS successfully registered around 225 substance; including 125 substances as the lead registrant by the end of 2014 and is expected to help its clients register around 500 chemicals by the last REACH registration deadline of 31 May 2018.

REACH and CLP compliant SDS

SSS is also engaged in compiling the 16 point REACH and CLP compliant SDS for the chemical substances and preparations meeting the criteria of classification as dangerous.

Extended SDS (e-SDS): SSS also provides e-SDS for the classified registered substances with the relevant exposure scenarios that have to be annexed to the SDS.

SDS translation: SSS also provides the service of translating the SDS into other languages of European member states (for example, German, French, Spanish, Dutch, or Italian).

SSS has till date prepared over 3,500 REACH and CLP compliant SDSs.

Compliance with K-REACH

The Act on the Registration and Evaluation of Chemical Substances (ARECS) regulation also known as K-REACH has come into effect in South Korea from 1 January 2015. Within this regulation, Non-Korean suppliers (through their OR) had the obligation of annual reporting of the use and tonnage for all phase-in chemicals for the calendar year 2015, to the Ministry of Environment (MoE), Korea, between 1 January and 30 June 2016. Here, SSS has acted as the OR and successfully completed the annual tonnage reporting for several of its clients.

SVHC applicability analysis

Companies exporting articles to European countries need to confirm the presence or absence of substances of very high concern (SVHC) and the REACH compliance obligations. SSS offers a very economical and technically sound solution to these companies for fulfilling their REACH obligations and certification requirement of their European buyers. This solution is in line with the guidance provided by Echa. So far, SSS has provided this service to many Indian and Asian companies exporting articles/substances to Europe.

SSS also provides compliance assistance on the following:

- GHS
- Proposed – Indian national chemicals policy and India GHS
- China REACH
- Compliance with chemical management in Malaysia (EHSNR)
- Responsible person service within European cosmetic regulation

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2008	Established and registered as a private limited company.
2008	Successfully pre-registered over 7,000 substances within REACH.
2009	Professionals trained in Iuclid from REACH Centrum.
2009	Trained over 100 industry professionals in use of Iuclid.
2010	35 REACH registrations successfully completed.
2010	Delivered 1,500 REACH and CLP compliant SDS.
2011	Acquired capacity in Chesar and Qsar.
2011	Mandated as lead registrant for 50 substances.
2012	Mandated as lead registrant over 60 additional substances.
2013	Successfully registered over 225 chemicals by the 2013 deadline.
2014	Over a dozen companies (20 companies) changed over to SSS as the OR from their earlier OR.
2015	Group company is accredited as a certified inspection body.
2016	SSS has an affiliate in S.Korea to offer services pertaining to K-REACH compliance.
2016	OR representation and successful completion of Annual reporting for several clients within K-REACH.

PARTNERS

- Confederation of Indian industry (CII), India
- China International Electronic Commerce Center (CIECC), China
- Tisamax Technical Co, Ltd (Tisamax), Taiwan
- Randis ChemWise (Shanghai) Co.,Ltd, China
- Associated with Ricardo's CareChem24 chemical emergency helpline services through its Indian group company NS Support Services Pvt Ltd

CLIENTS

SSS has clients in the industrial and specialty chemical and petrochemical industry, as well as the following industries: agrochemical, food colour, cosmetic, electrical and electronics, automotive industry, leather, garment and apparel, plastic and rubber, steel, writing instruments, polymers.

TESTIMONIALS

On the service quality criteria, 98% of our client companies have rated the REACH compliance assistance services being offered by SSS as very good.

CASE STUDY 1: SSS group company in India is accredited for an internationally recognised standard for inspection bodies

With a view to provide quality regulatory compliance services to its client companies, SSS has helped prepare its Indian group company in getting accredited to an internationally recognised standard for the competence of inspection and certifying bodies. This is probably a first of its kind global achievement for any OR service providing organisation wherein all its compliances shall be inspected and validated prior to completing the compliance process request of its clients. This shall ensure accurate regulatory compliance and conformance with the technical product standards.

CASE STUDY 2: SSS and its sister concern have jointly initiated a Forum for review of global chemical regulatory Updates

Problem: Indian chemical exporters were finding it difficult to keep themselves updated of the changing chemical regulations requirement and therefore needed SSS to provide a suitable solution for the same.
Solution: In October 2015, the inaugural meeting of the Forum was held in Mumbai, India, to discuss the upcoming REACH like regulation in South Korea. It was well attended by all the invited chemical companies. The SSS team briefed the company representatives on their roles and responsibilities to comply with this upcoming regulation. The Forum provides the companies the much-required platform for discussing global chemical regulatory updates to be prepared in time rather than facing difficult situations of non-compliance. It is envisaged that the Forum shall meet twice or thrice a year depending upon the need in order to help the companies understand the regulatory requirements and facilitate compliance.

CASE STUDY 3: Guidance to many Sief members for successfully completing their REACH registration in the 2013 deadline

Problem: SSS received requests from Sief members to provide know-how on how to complete the REACH registration process as they were unaware of the same
Solution: The technical team at SSS, provided the know-how to the Sief members relating to the finalisation of their registration dossiers, TCC clearance and submission of the member dossier on the REACH-IT by joining the joint submission (JS). Some of these requests were received very close to the deadline and the timely inputs from SSS helped companies meet their registration deadline.

STAFF SELECTION

Mr Shisher Kumra – Executive Director

Area of expertise includes specialisation in regulatory affairs, legal expertise, chemical assessment, toxicology.

Mr Shrirang Bhoot, Chief Technical Officer (CTO)

Area of expertise includes REACH data inventory, REACH registration process, environmental toxicology, bio-assay and other regulatory affairs. Also specialisation in softwares like Iuclid, Qsar, Ecosar, dossier preparation, Chesar.

Dr Martina Holst

Responsible for evaluation of toxicological reports and for dossier quality assurance for toxicological endpoints and CSR.

Dr Cecilia Hultin

Responsible for evaluation of Eco-toxicological reports and for dossier quality assurance for the Eco-toxicological endpoints and CSR.

Mr Mangesh Barbate

Area of expertise includes REACH data inventory, dossier preparation, eco-toxicology and specialisation in softwares like Iuclid, Qsar, Ecosar,.

Mrs Akanksha Nagpure

Area of expertise includes chemical safety assessment (CSA), chemical safety report (CSR), toxicology, SDS, CLP and Iuclid software.

Mrs Swati Gondhalekar

Area of expertise includes REACH and Articles, SVHC assessment and REACH compliance verification.

Mr Keith Yongho Jung, South Korean Regulation Executive

Manages activities related to K-REACH compliance and coordination with the Korean regulatory authorities as Korean representative at SSS.

CONTACTS

Website	www.thereachcentre.com
E-mail	enquiries@thereachcentre.com
Head office	Lancaster Environment Centre, Lancaster University, Lancaster LA1 4YQ, UK
Tel	+44 (0) 1524 510278
Fax	+44 (0) 1524 510588
Contact	Sandra Meijer
Directors	Jonathan Lutwyche Dr Kath Carr Dr Sandra Meijer Adam Rowntree
Ownership	Privately owned
Locations	UK, Italy, US, Japan, China
Founded	2007

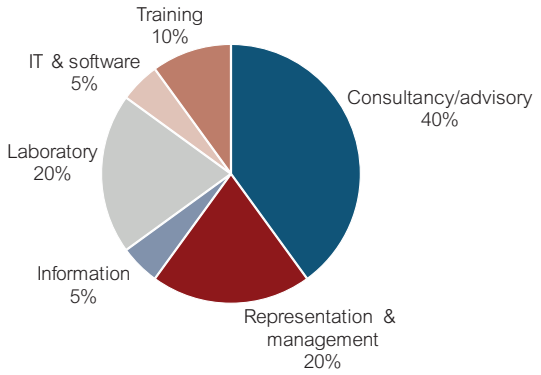
OVERVIEW

The REACH Centre is one of the leading international providers of regulatory guidance, scientific and analytical services, and training to industry in the field of chemicals management and risk assessment. Our integrated services ensure our customers are able to effectively manage and comply with current and future chemicals legislation.
The REACH Centre employs a team of experts in chemistry, (eco)toxicology, environmental and occupational exposure, offering services for EU REACH, equivalent global notification systems, GHS and the EU CLP implementation, cosmetics, detergents and biocidal products Regulations, RoHS and conflict minerals, and the developing nanomaterials regulatory framework.
Providing a global capability, the company has offices and representation in the UK, Europe, USA and Asia.

VITAL STATISTICS

	2015/16
Turnover, group	-
Turnover, chemical service provision	-
No of offices	-
No of countries represented	Global
Staff, group	37
Staff, chemical service provision	37

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

The company has offices and representation in the UK, Italy, the US, Japan and China.

SERVICES PROVIDED

EU REACH

- Lead registration
- Joint registration
- Late pre-registration
- Only representative
- Third party representative
- Non-phase-in substance inquiry
- PPORD notifications
- Sief and consortia management
- Iuclid
- Authorisation
- Support ongoing responsibilities such as; monitoring on tonnages and regulatory status, supply chain communication, management of Echa fees.

Regulatory services

- Global regulations including US TSCA, China MEP Order No. 7, Korea ARECS (K-REACH), Taiwan TCSCA and Osha, Japan CSCL and ISHL etc
- OSPAR
- Conflict minerals and RoHS
- Toys, cosmetics, detergents and aerosols

EU biocides

- Business impact assessment
- Member state notification
- Biocidal product authorisation
- Active substance approval
- Treated articles

Hazard communication

- Global safety data sheets
- Classification to GHS, and CLP and other global classification systems
- Exposure scenarios and eSDS
- Product labelling and packaging requirements
- Translation services: global coverage

Testing and analytical service

- Chemical characterisation
- Analysis of nanomaterials
- Chemical and physico-chemical testing for CLP
- Regulatory data acquisition and management

Chemicals management

- Impact assessment
- Policies, procedures and management systems
- Regulatory and supply chain audits
- chemtrac® chemicals management solution

Scientific expert service

- Substance identity and sameness
- Chemical safety assessment and reporting
- Expert assessments: CLP, polymer status, exemption from registration, regulatory endpoints, substitution strategies

Legal support

- Expert witness services
- Litigation support

Training

Classroom courses, virtual classroom, e-learning and bespoke in-house training on REACH, hazard communications, Iuclid, biocidal products Regulation, OSPAR, Asia-Pacific regulations and nanomaterials.

ACCREDITATIONS

Our training courses are approved by the Royal Society of Chemistry and by IOM3.

CLIENTS

Our global customer base across 35 countries incorporates manufacturers, distributors and retailers across several industry sectors along with multiple trade associations and government bodies.

CASE STUDY 1: REACH

A client has a portfolio of several hundred substances that potentially need to be registered in 2018. Working closely with the client, we have developed a robust strategy allowing them to ensure REACH compliance in the most cost-efficient manner. We first of all identified those substances that can be exempt from REACH as per Annex V. For the remaining substances, communication with the supply chain has been undertaken to explore the options for taking advantage of only representatives and re-imports. An action plan has subsequently been put into place to ensure all relevant substances are going to be registered, with the client acting either as joint or as lead registrant. Undertaking this work early on has been essential in order to ensure compliance throughout.

CASE STUDY 2: Sameness and substance identity

A client had developed a new hydrocarbon-based UVCB and needed to submit both an Inquiry and a lead registration dossier. The REACH Centre was able to demonstrate substance identity to Echa in the inquiry through rigorous analytical characterisation.
Using the analytical information, it was possible to identify similar substances for read-across purposes. This involved a considerable amount of background literature research, which identified a shortlist of options from which the most similar substance was identified. As a result, the client was able to purchase data for read across, thus avoiding unnecessary animal testing and reducing the overall cost of registration.

CASE STUDY 3: Biocides

A number of clients have developed devices which use *in situ* generated active substances to produce a biocidal effect. These devices are newly under the scope of the biocidal products Regulation (BPR). The REACH Centre's expertise has been used to determine the regulatory requirements associated with marketing the devices in the EU under the BPR. Collaboration between the scientific and analytical team and the regulatory management team allowed The REACH Centre to conduct thorough literature searches and data gap assessments to identify data which may be used in an active substance approval submission while keeping up to date with the latest information on the management of in situ generated active substances from the EU Commission. This has included representing clients at meetings with EU member state competent authorities, in particular with a view to understanding where data adapted in accordance with the provisions of the BPR. For example, exposure based waiving may be accepted by the evaluating competent authority, with a view to allowing those clients to build compliant dossiers with a significant cost saving against the cost of commissioning studies which may be scientifically unjustified.

CASE STUDY 4: OSPAR

Over the last few months The REACH Centre has supported several clients with all aspects of registration of offshore chemicals under OSPAR and REACH. A client needed support to register a new product under OSPAR HMCS while they had met all his REACH registration obligations for the substances contained in the new formulations. The REACH Centre was able to support the client with the data gap assessment, strategy to fulfil the endpoint required, submission of the HOCNF form and entertain discussions with the regulators to ensure that the product was registered successfully and in the timeline required by the client.

STAFF SELECTION

Sandra Meijer – Director of Business Development

As a recognised expert on REACH and chemicals management, Sandra has previously managed numerous lead registration projects, carried out REACH audits, and provided chemical management support to large manufacturers and retailers. Currently, Sandra is taking the lead on developing our Chemtrac® software solution for regulatory compliance and chemicals management. Sandra is a well-known speaker at industry events, and delivers classroom and bespoke REACH training. Sandra is an honorary fellow of Lancaster University's LEC.

Kath Carr – Director of Science

Kath established The REACH Centre's scientific service seven years ago and has built an extremely strong team of experienced chemists whose work is highly regarded across the chemical industry. One of Kath's particular strength's is her ability to resolve complex technical issues and she specialises in the characterisation of UVCB substances. She provides scientific support for The REACH Centre's lead and joint registration activities, for inquiries and for PPORD notifications. Her work is underpinned by her 18 years' industrial research experience in the speciality chemicals sector.

Alex Paul – Managing Regulatory Consultant

Alex oversees The REACH Centre's regulatory services including the management of lead and joint registrations for non-EU clients and the provision of only representative services. In addition to maintaining and further developing The REACH Centre's strong position in Japan through collaboration with our strategic alliance partner JEMAI, Alex is responsible for developing new partnerships and business in Asia as Asian countries implement REACH-like notification systems. Since 2014, The REACH Centre has established new partnerships in China, South Korea, Thailand and Taiwan. Alex formerly managed The REACH Centre's Hazard Communication Division which allowed him to become a leading expert in chemical classification regulations and is regularly invited to speak at workshops and seminars on the subject.

Rosalinda Gioia – Managing Regulatory Scientist

Rosalinda is an internationally recognised expert on ecotoxicology and is highly experienced in understanding chemical regulations. She has provided expert scientific advice and policy support to government regulators on chemical risk assessments relating to the oil and gas industry, for which she has authored technical bulletins and papers to the annual meeting of OSPAR's Offshore Industry Committee (OIC). Rosalinda project manages REACH lead registrations and biocides active substance approval and product authorisation dossiers. She also provides technical leadership and advice relating to the environmental fate of chemicals, persistence, bioaccumulation and toxicity (PBT) and risk assessments in the aquatic environments.

Siobhan Murphy – Senior Regulatory Scientist

Siobhan leads The REACH Centre's biocidal product consultancy services, including biocidal product authorisation and biocidal active substance approval applications, member state marketing approvals, and ensuring compliance of treated articles. In addition, Siobhan is part of the team responsible for the management of data for REACH Lead Registrations and the coordination of Iuclid 6 dossiers. Siobhan leads The REACH Centre's biocides training, along with Iuclid training for both REACH and biocidal regulatory applications.

Tarn Brown – Managing Regulatory Consultant

Tarn heads The REACH Centre's Hazard Communication department and manages our SDS scheduling and delivery services. Her focus is the development of services including SDS and eSDS compilation, and the full range of classification, labelling and packaging (CLP) services. Tarn also has extensive knowledge and expertise in REACH, DSD/DPD, the EU detergents Regulation, EU aerosols Directive and in UN Transport of Dangerous Goods.

toxminds
Product Safety & Regulatory Affairs

CONTACTS

Website	www.ToxMinds.com
E-mail	info@toxminds.com
Head office	116, Avenue de Broqueville, 1200 Brussels, Belgium
Tel	+32 (2) 762 91 45
Fax	+32 (2) 762 91 46
Contact	Ms Silvia Balletta
Directors	Dr Thomas Petry Dr Francesca Tencalla
Ownership	Private company
Locations	Brussels (Belgium); Düsseldorf (Germany)
Founded	2006

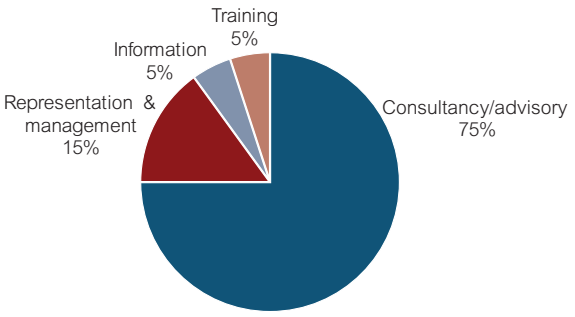
OVERVIEW

ToxMinds BVBA is a product safety and regulatory affairs firm located in Brussels, Belgium. Our passion and motivation is the use of good science, but we also understand the reality of our tightly regulated chemical world. With our broad industry experience, we support our customers in bringing safe, regulatory compliant and publicly acceptable products to the market.

VITAL STATISTICS

	2016/17
Turnover, group	-
Turnover, chemical service provision	-
No of offices	2
No of countries represented	4
Staff, group	10 – 25
Staff, chemical service provision	10 – 25

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Brussels, Belgium; Düsseldorf, Germany

SERVICES PROVIDED

Our core team of industry-experienced toxicology, environmental and regulatory affairs consultants and analysts provides chemical safety, regulatory and product stewardship assistance to the following industries:

- industrial chemicals;
- biocides;
- agrochemicals;
- cosmetics and consumer products;
- pharmaceuticals;
- green biotechnology.

We are up-to-date on the latest EU developments and regulatory changes. This, coupled with our access to experts in the European Institutions and member states, allows us to best represent the interests of our clients. Thanks to the international nature of our team, we interact with our clients in various languages including English, German, French, Italian, Portuguese and Hindi.

Chemical and product safety

Our chemical and product safety services include:

- literature and desktop searches;
- quality analysis, study summaries and presentation of information related to the effects of chemicals on human health and the environment;
- structure activity analysis (Qsar);
- analogue identification and chemical similarity assessments;
- data gap analysis under consideration of non-testing approaches;
- identification of intelligent hazard assessment and testing approaches (Iata) to fill information gaps, including:
  - non-testing hazard and safety assessment strategies;
  - hypothesis and mechanism-based *in chemico* and *in vitro* testing;
  - *in vivo* testing strategies.
- (eco)toxicology study monitoring and management;
- exposure modelling using REACH, BPR or PPPR recommended modelling tools;
- tiered human and environmental risk assessments;
- green chemistry and R&D candidate evaluations.

Regulatory strategy and compliance

Our team of regulatory experts assists and guides our clients through all the necessary steps to achieve regulatory compliance with European regulations for industrial chemicals, consumer and cosmetic products, biocides and agrochemicals. Our regulatory services include:

- portfolio review and regulatory strategy consulting
- registration dossier preparation under:
  - REACH Regulation (EC) No 1907/2006;
  - biocidal product Regulation (EU) No 528/2012 ('BPR');
  - plant protection product Regulation (EC) No 1107/2009 ('PPPR').
- preparation of SCCS-compliant cosmetic ingredient dossiers;
- post-submission support, including the preparation of responses to authority requests or advocating and defending scientific approaches with public authorities;
- cosmetic product information Files (PIF).

Product stewardship

We support our clients in their product stewardship activities with the following services:

- development of REACH-compliant extended safety data sheets;
- generation of ICCA-compliant product safety summaries;
- tailored trainings to PS and RA or product stewardship staff on, eg:
  - principles of human and environmental hazard, exposure and risk assessment of chemicals;
  - Qsar modelling and hazard-specific endpoint training;
  - regulatory frameworks and related IT tools (eg, Iuclid);
  - REACH exposure modelling and CSR/CSA creation software;
  - creation of REACH-compliant extended safety data sheets (eSDS).
- establishment and moderation of scientific review panels;
- science-based advocacy and client representation with regulatory authorities;
- hazard and risk communication to various audiences.

CORPORATE DEVELOPMENTS and ACHIEVEMENTS

2006	Creation of ToxMinds BVBA
2009	Opening of ToxMinds headquarters in Brussels
2014	Collaboration with Deskin Associates LLC to provide direct support to US-based clients
2016	Creation of ToxMinds GmbH affiliate in Düsseldorf

CLIENTS

ToxMinds provides (eco)toxicology, product safety and regulatory compliance services to a wide range of multinational fortune 100 companies, SMEs, and industry associations from the chemical, biocidal, plant protection, metal/mining, consumer product, biotechnology and pharmaceutical sectors.

TESTIMONIALS

"We have been working with ToxMinds BVBA for many years on various complex toxicology, ecotoxicology and regulatory issues. The professionals at ToxMinds are thorough, knowledgeable and always meet the demands and difficult timelines […]. We continue to rely on ToxMinds as experts in the fields of toxicology, ecotoxicology and EU regulatory compliance." – Senior regulatory manager, international specialty chemical company.

CASE STUDY 1: Consortium management and technical support to REACH consortia

ToxMinds provides REACH support to a number of consortia as well as individual chemical. So far we have developed more than 200 REACH registration dossiers. Our technical work includes:

- desktop research and data gap analysis;
- Qsar modelling, analogue identification and RAAF conform read-across justification;
- data gap analysis and identification/evaluation of suitable non-animal alternatives to fill existing endpoint gaps;
- development of Iuclid 6 registration dossiers, chemical safety assessments and reports (CSA/CSR);
- strategy advice and support during registration and evaluation phases;
- client representation in discussions with authorities;
- strategic and technical support during application for authorisation.

CASE STUDY 2: Human and environmental risk assessment

Our consultants have substantial experience in assessing hazards and risks associated with human and environmental exposure to chemicals. To date, our team has assessed more than 850 substances in the context of consumer use, food contact, exposure at the workplace or presence in the environment. In the pharmaceutical context, we have been involved in developing permitted daily exposure (PDE) values for cross-contamination in pharmaceutical production sites and safe exposure levels for process impurities and drug container leachables.

CASE STUDY 3: Non-animal testing based chemical safety assessments

ToxMinds supports chemical and consumer product companies in identifying non-animal testing based safety assessment approaches. We use a transparent rule-based SAR and analogue identification process to support business strategies and regulatory submissions. The process can also be applied in a general product safety or product stewardship context.

Our integrated process takes into account predicted chemical similarity and reactivity, structure activity, physico-chemical properties, metabolic pathways and toxicokinetic behaviour. In case toxicological data gaps are identified, a strategic testing approach to meet a regulatory purpose is proposed by taking into account the existing understanding of a chemical's mode of action along the adverse outcome pathway (AOP). This process allows for the prioritisation of candidate chemicals (eg biocidal actives, food contact materials, cosmetic ingredients) for further R&D qualification at early stages of the R&D cycle by considering hazard profile, predicted testing costs and expected time to complete the required testing programme. In a more regulatory context, available tools are used to support guideline-compliant read-across and/or grouping approaches or for REACH phase III chemical portfolio prioritisation.

CASE STUDY 4: Biocides

We work with manufacturers of biocidal actives and products to ensure chemical/product safety and regulatory compliance under the BPR. In this context, our activities include:

- portfolio review and strategic consulting;
- identification of data gaps and management of testing programmes;
- development of Iuclid datasets and documents required to register biocides under the BPR;
- human and environmental exposure modelling and risk assessment;
- determination of classification of substances and mixtures under the CLP/GHS;
- BPR registration management, including data sharing discussions
- post-submission support and client representation with EU regulatory bodies;
- consortium management and client representation in technical advisory groups;

STAFF SELECTION

Thomas Petry, PhD, ERT, DABT

Dr Petry, Managing Director of ToxMinds BVBA, is a product safety and regulatory affairs consultant with more than 20 years' industry, consulting and research experience in the human safety assessment of chemical exposures occurring at the workplace through their use or presence in consumer products or via the environment.

Francesca Tencalla, PhD, ERT

Dr Tencalla, Director at ToxMinds BVBA, is an (eco)toxicology and regulatory affairs consultant with more than 20 years of industry and research experience in the human and environmental safety assessment of chemicals, metals, agrochemicals and pharmaceuticals.

Sanghamitra Mishra, M. Pharm, ERT

Mrs Mishra is a toxicology and regulatory consultant at ToxMinds with substantial research and consulting experience in the human health hazard and risk assessment of chemical substances. Ms Mishra has been instrumental in developing our services in the area of non-animal alternatives, particularly SAR/analogue-based read-across justifications and the identification of mechanism-based testing programmes (AOP) to reduce remaining uncertainties in a proposed read-across approach. Mrs Mishra has a master's degree in pharmacology.

Sabyasachi Chakraborty, M.Pharm, DABT

Mr Sabyasachi Chakraborty is a toxicology consultant with more than 12 years of research and consulting experience in the human health hazard and risk assessment of chemical substances. He is experienced in the hazard and risk assessment of chemicals used or present in consumer products with focus on cosmetic products. Mr Chakraborty is also deeply involved in the development of chemical exposure and risk assessment outputs as required under REACH using relevant prediction and modelling tools. He has a master's degree in pharmacology.

Monica Autiero, PhD

Dr Autiero is a consultant at ToxMinds BVBA. Monica specialises and leads our efforts in non-animal based safety assessments with particular focus on Qsar modelling, analogue identification and justification as well as grouping-based hazard assessment approaches. Dr Autiero is a trained biologist with a PhD in biochemistry and molecular biology.

Daniela Jeronimo Roque, MSc

Ms Jeronimo Roque is a consultant at ToxMinds BVBA. She is specialised in the area of human and environmental exposure modelling, as for example required under the REACH, BPR and agrochemicals Regulation. She further supports the ToxMinds team in developing and compiling registration files, conducting (eco)toxicological hazard and risk assessments as well as providing ad-hoc regulatory analyses.

TOXSERVICES
TOXICOLOGY RISK ASSESSMENT CONSULTING

CONTACTS

Website	www.toxservices.com
E-mail	info@toxservices.com
Head office	1367 Connecticut Avenue NW, Suite 300, Washington, DC 20036, US
Tel	+1 202-429-8787
Fax	+1 202-429-8788
Contact	Margaret H Whittaker, PhD, MPH, CBiol, FRSB, ERT, DABT
Directors	Margaret H Whittaker, PhD, MPH, CBiol, FRSB, ERT, DABT
Ownership	Limited Liability Company
Locations	US, UK
Founded	2003

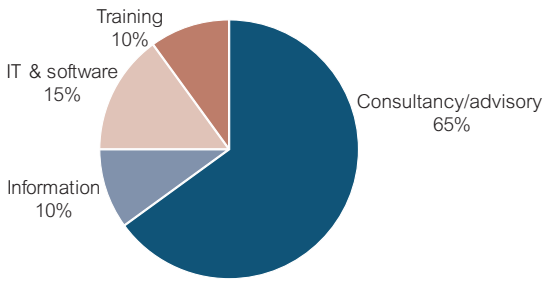
OVERVIEW

ToxServices is a global provider of scientific consulting services designed to resolve complex human health, environmental health, and regulatory compliance issues. ToxServices excels at providing toxicology, sustainability, alternatives assessment, and risk assessment consulting services to private and public sector clients. We strive to advance chemical optimisation throughout the supply chain.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	3
No of countries represented	Global
Staff, group	22
Staff, chemical service provision	17

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

ToxServices is located in the US and the UK and is headquartered in Washington, DC.

SERVICES PROVIDED

Cosmetic, personal care products, and consumer products services

ToxServices LLC provides clients from around the world with expert technical and regulatory support services in formulating, labelling, manufacturing, and marketing cosmetics, personal care products, and consumer products. Our PhD level, board-certified toxicologists include Diplomates of the American Board of Toxicology (DABT) and U.K.//Eurotox Registered Toxicologists (ERT), ensuring that your cosmetics and personal care products are safe and comply with applicable regulatory requirements.

Litigation support services

ToxServices provides litigation support services to attorneys involved in product liability or toxic tort cases:

- critical literature reviews and preparation of white papers assessing biological and technical feasibility of allegations;
- preparation of detailed toxicology reviews, exposure assessments, and human health risk assessments;
- assessing potential human health hazards and risks associated with exposure to substances in occupational and non-occupational settings; and
- California Proposition 65 – related services, including NSRL and MADL development, exposure assessments, and safe harbor determinations.

Medical device biological evaluation services

ToxServices performs ISO 10993 biological evaluations of medical devices and combination products, including materials characterisation, assessing health risks of extractables and leachables, and evaluating results of biocompatibility assays under for submissions intended for the US, the EU, and the Asia/Pacific region.

Food additives, medical foods, GRAS determinations, dietary supplements, and food contact substances services

ToxServices assesses exposure and health risks associated with food additives, GRAS ingredients, food contact substances, and dietary supplements marketed in the US, Canada, and the EU. We prepare petitions, notifications, and provide advice regarding the regulatory status of food additives, GRAS ingredients, and food packaging substances. We evaluate, substantiate, and recommend specific label claims, and serve as experts in claims-related disputes.

Sustainability services

Manufacturers, designers, retailers, and consumers are now seeking products that are eco-friendly, are formulated with chemicals that are not toxic to human health or the environment, and are designed and produced responsibly.

Cradle to Cradle Certified™ Products Programme

As an authorised assessor, ToxServices evaluates healthy and sustainable products under the Cradle to Cradle Certified™ Products Program managed by the Cradle to Cradle Products Innovation Institute. The ultimate goal of the program is to encourage continuous improvement, innovation, and formulation of products that benefit humans and the environment.

US EPA Safer Choice Programme

ToxServices has partnered with the US EPA Safer Choice Program as a third-party profiler to evaluate a wide range of products for Safer Choice recognition.

GREENSCREEN® for Safer Chemicals

ToxServices is an authorised third-party evaluator of Clean Production Action's (CPA) GreenScreen®, which is a leading chemical hazard assessment tool. CPA's GreenScreen® supports informed substitution of chemicals and materials.

CLEANGREDIENTS®

GreenBlue®'s CleanGredients® is an online database for green formulations of cleaning ingredients and products. This resource provides an opportunity for manufacturers and producers of cleaning products to showcase their ingredients and products while protecting their intellectual property.

Health Product Declaration™

Developed by the HPD Collaborative, Health Product Declarations (HPD) are a mechanism for consistent and transparent disclosure of product contents and the associated health information for individual building materials and products.

Alternatives assessments

Alternatives assessments are used to assess a chemical's impact on human health and the environment. The goal is to find a science-based solution that promotes the selection of less hazardous ingredients through informed substitution.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2003	Company established
2012	Company added staff in Ann Arbor, MI
2013	Company added staff in Oxford, UK
2016	Launched ToxServices's ToxFMDTM third-party certification programme that is used to promote safer chemical selection throughout the supply chain, particularly in the textile and apparel industry.

PARTNERS

Although ToxServices is a privately-owned corporation, we actively work with law firms, CROs, testing laboratories, and certification organisations around the world to serve our client's needs.

CLIENTS

ToxServices clients include Fortune Global 500 companies, consumer products companies, construction and built environment companies, cosmetics and personal care products companies, chemical companies, national, state, and local government bodies, non-governmental organisations, trade industry associations, and law firms representing plaintiffs or defendants.

TESTIMONIALS

"Levi Strauss & Co nominated ToxServices as a third- party assessor and technical advisor for LS&Co's screened chemistry programme. ToxServices' toxicological capabilities and expertise in hazard assessment methodologies, along with their professional and collaborative work ethic, make them an ideal partner for LS&Co." – Linda Gallegos, Innovation Manager,Levi Strauss & Co.

"ToxServices exceeded expectations for all deliverables, communicated frequently with the contracting officer on progress and developments, worked stringently to meet all deadlines, and provided a high quality final report." Dr Alex Stone, Safer Chemicals Alternatives Chemist Washington State Department of Ecology

CASE STUDY 1: Screened chemistry support services

For almost four years, ToxServices has provided toxicology and regulatory support services to Levi Strauss & Co (LS&Co) as part of their corporate-wide goals of eliminating hazardous chemicals in the supply chain and eliminating hazardous factory wastewater discharge to waterways by 2020. ToxServices screens textile and apparel processing formulations for human health and environmental hazards as part of ToxServices's Full Materials Disclosure™ Program. Since launch in August, 2013, ToxServices has performed comprehensive hazard screens for >800 chemicals used in hundreds of formulations supplied by formulators located in 26 different countries.

CASE STUDY 2: Worldwide cosmetics safety and regulatory compliance services

For more than six years, ToxServices has provided continuous scientific support services to a major US-based cosmetics/personal care products company.

- Prepared safety assessments and product information files (PIFs) for >750 cosmetics/personal care products marketed throughout the EU and China, including safety assessments of intentional ingredients and impurities, and evaluation of clinical, safety-in-use, and *in vitro* test data supporting safety of formulated products.
- Provided reformulation recommendations to replace chemicals of concern (such as preservatives and UV filters) and, as needed, recommended additional preservative efficacy or clinical safety testing on revised formulations.
- Prepared quantitative risk assessments for >1,500 cosmetics raw materials to ensure compliance with the EU Cosmetics Regulation, as well as the Chinese Safety and Technical Standards for Cosmetics.
- Conducted bi-annual training courses to instruct client's staff in regulatory requirements for cosmetics (EU, US, Canada, China, Asean, Gulf States), practical application of risk assessment methods for cosmetics raw materials and their impurities, and instruction in clinical and toxicological test selection strategies.

CASE STUDY 3: Preparation of CLP and Osha-compliant SDS

ToxServices provides clients with safety data sheets (SDS) prepared according to the Globally Harmonised System of classification and labelling of chemicals (GHS), including SDSs that comply with EU Regulation No 1272/2008 on classification, labelling, and packaging of substances and mixtures (CLP) and SDSs that comply with US Osha's hazard communication standard regulations (HCS).

- ToxServices prepared CLP-and HCS-compliant SDSs for proprietary peptide mixtures formulated by a client. This required careful redaction of trade secret formulation data while still communicating hazards associated with the formulations, along with correct application of GHS mixtures rules.

STAFF SELECTION

Margaret H Whittaker, PhD, MPH, CBiol, FRSB, ERT, DABT

Margaret Whittaker is the Managing Director and Chief Toxicologist of ToxServices. She manages ToxServices projects for the US EPA Safer Choice Program, Clean Production Action's GreenScreen for Safer Chemicals, and Cradle to Cradle Certified Program. As project manager and technical lead, Dr Whittaker has contributed to and/or managed the development of hundreds of human health risk assessments, chemical hazard assessments, exposure assessments, as well as hundreds of product-specific toxicology evaluations. Dr Whittaker is one of the pioneers in the field of chemicals alternatives assessments and drinking water risk assessment methods, and is a key contributor to advancing these methods around the world. Dr Whittaker is a Diplomate of the American Board of Toxicology who earned a PhD in toxicology from The University of Maryland, Baltimore and an MPH in environmental health from The University of Michigan. Dr Whittaker is a UK/EuroTox Registered Toxicologist, as well as a Chartered Biologist and Fellow of the UK Royal Society of Biology.

Dr Jennifer G Fleischer

Jennifer Fleischer is a senior toxicologist, risk assessor, and project manager who earned her PhD in toxicology and MHS in environmental health sciences from Johns Hopkins University. Dr.Fleischer prepares, reviews, and manages quantitative human health risk assessments, exposure assessments, product and ingredient safety assessments, and regulatory compliance evaluations for a diverse range of substances within a variety of national and international regulatory contexts, including food allergens, food additives, food contact materials, medical devices, consumer/household products, personal care products/cosmetics, pharmaceuticals, and dietary supplements, among others. Recent work has focused on quantitative exposure assessments, particularly for Proposition 65-listed substances, nanomaterials, and impurities, often in response to actual or potential litigation. Dr Fleischer advises clients on key technical issues, such as clinical and nonclinical testing strategies, study design and monitoring, and data interpretation; the scientific merit of test data provided by claimants or other parties; regulatory compliance requirements for US, EU, and other markets; and comprehensive interpretation of test data and literature.

Senior toxicologists specialise in the assessment of human health and environmental risks posed by chemicals or biologics, including six Diplomates of the American Board of Toxicology (DABT)

Multi-lingual scientists and engineers fluently speak and write Mandarin, Arabic, French, German, and English, allowing ToxServices to prepare multi-language work product for countries around the world.

Product safety specialists are trained in US, Canadian, and EU regulatory requirements, and excel at the interpretation and application of GHS and CLP, including classification of mixtures.

TRADE WIND

SDS Authors

CONTACTS

Website	www.twnl.com
E-mail	info@twnl.nl
Head office	Haagsche Hof, Parkstraat 83, 2514 JG The Hague, Netherlands
Tel	+31 70 214 3040
Fax	+31 84 747 24 99
Contact	Mrs Daniëlle Nuijten-Dijns
Directors	Mr Harro Elsborg
Ownership	Elsborg Holding B.V.
Locations	The Hague, Holland
Founded	1998

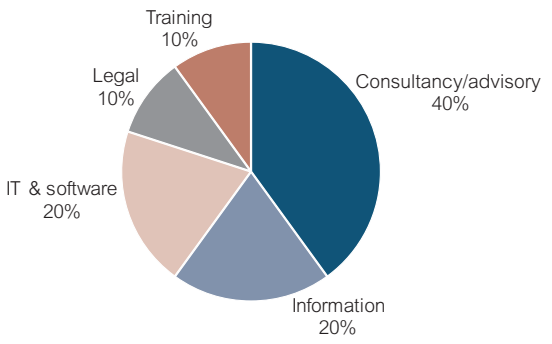
OVERVIEW

Trade Wind helps companies to fulfil their obligations with regard to drafting, translating and distributing safety data sheets. We can provide you with a state-of-the-art software system (ExESS) that will create and translate your SDSs into more than 48 languages and according to all local GHS-varieties. ExESS can also help you to manage your volume tracking, inventories, your complete H&S, maintenance etc. Any documents such as labels, work instruction cards and overviews can be created with just a few clicks of the mouse.
Our internet solution DeDoks helps companies distribute their SDSs in pdf-format or be linked to URLs without any software needing to be installed. With the use of FTP or a web service the process can be completely automated. If required all SDSs can be published on the internet within any website.
Companies can outsource their SDS-authoring to SDS Authors (a Trade Wind brand). We will assess your raw materials and, on the basis of your formulations, draft your SDSs, translate them and even distribute them to your customers.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	2
No of countries represented	2
Staff, group	8
Staff, chemical service provision	6

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

The Hague, The Netherlands
New York, 30 Wall Street, 8th Floor,USA

SERVICES PROVIDED

Chemicals management software

Implementation, optimising, supporting and training on ExESS of Lisam Systems, one of the leading software solutions for SDS-drafting, translating and distribution of safety data sheets, exposure scenarios, volume tracking, health and safety, incident management and waste management.

SDS-distribution management through DeDoks

Our internet (SAAS) solution will take care of SDS distribution to your downstream users. It can be documents in a pdf-format, or links to SDSs already on your website. According to REACH art.31 you have to provide your recipient with an SDS when it concerns a classified substance or a classified preparation. DeDoks will take care of this and will also send new versions of the SDS to recipients that have received a previous version less than 12 months before. DeDoks will also allow you to publish your SDSs on your website from where they can be downloaded. This will be registered in order to be able to resend new versions.

SDS authoring

Our SDS-outsourcing service will take care of all your worries as it comes to creating, translating and distributing your SDSs. Our team is able to draw up your documents according CLP and most of the other GHS dialects in the world. We have 48 languages available. SDSs can be designed according to your wishes; fonts, colours and layout can be adjusted to your needs. Documents are available in PDF of Word-format.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1998	Establishment of Trade Wind B.V.
2002	Distributor agreement with Lisam Systems Belgium
2011	ExESS becomes part of the portfolio
2011	Reach Annex II and CLP seminar (120+ attendants)
2012	DeDoks for SDS-distribution is operational
2013	Dutch paint industry implements DeDoks for all members (VeiligmetVerf)
2015	Establishment of SDS Authors, New York

PARTNERS

- Lisam Systems Belgium
- Lisam Telegis, Paris

CLIENTS

- Dutch Paint Association (VVVF), AKZO, PPG, 3M, L'Oreal, Nestlé,Total, P & G, Ducros, Holland Colours Apeldoorn, Vlisco and many small to medium sized companies
- ExESS users in the Netherlands and Switzerland: IMCD, Dunlop, Hunter Douglas, Vlisco, Helichem, Alpheios, Van Dam Bodegraven, Mardenkro, Mibelle (Migros) (250+ in the Netherlands, Lisam ExESS 1000+ worldwide).

TESTIMONIALS

"Trade Wind has provided us with a state of the art solution 'VeiligmetVerf' which enables the Dutch paint industry and its distributors to fulfil their REACH obligations to send SDSs and SDS updates to their downstream users electronically. The underlying solution DeDoks saves our industry at least € 700,000 each year." – Martin Terpstra, managing director VVVF, Netherlands

"Our SDS Software ExESS has enabled us to speed up the process of creating SDSs tremendously. Not only has the process been simplified, but also our possibilities have increased enormously: CLP, GHS (all area's), 45 languages, all European OELs, labels, work instructions, detergent reporting, interfaces etc. All available within one system and easy to manage." Herbert Meier, manager Dangerous Goods and Regulatory Affairs, Switzerland

CASE STUDY 1

The Dutch Association of the Paint and Printing ink industry (VVVF), the Dutch Association of Adhesive and Sealants Manufacturers (VLK) and the Dutch Association of Paint Distributors (VVVH) have more than 200 company members .

The Ministry of Economic Affairs was aware of the big administrative burden of distributing SDSs and launched a project to reduce this and its costs. The ministry, together with Trade Wind and the VVVF developed a solution by implementing additional functions to DeDoks to make it compliant with REACH and to tackle the problem of the wholesalers at the same time.

The solution which was created has two main benefits. First of all, the new DeDoks (implemented as VeiligmetVerf or VmV) enables VVVF and the VLK members (paint and adhesive manufacturers) to distribute SDSs through the so-called ERP link. This can be done manually, by uploading an MS-Excel sheet with order information, or an FTP-service, or through a completely automated web service. At the same time, it allows downstream users (distributors and wholesalers) to use VmV for distributing SDSs to their customers in the same way as the manufacturers distribute their SDS to them. All they need to do is refer to the products that have already been uploaded by the manufacturers. When customers buy a product for the first time, they automatically receive an email with a deep link to the SDS (or the SDS in pdf-format). This means that they don't need to look for their SDS on a website. By just clicking the deep link they immediately open the SDS. When a revised version of an SDS is published by the paint supplier, they receive a new deep link or a pdf-document (12 months period). The use of deep links has been approved by the inspectorates. By introducing VeiligmetVerf, the Dutch paint industry complies with REACH, reduces its costs and contributes to a saver workplace by getting the SDSs to the workplace faster and easier.

CASE STUDY 2: Alpheios

Alpheios is one of the largest companies in the field of professional cleaning products, systems and strategies in the Benelux. When Alpheios was looking for a software system to help them to create high quality SDS's, complying with the detergent Regulation (REGULATION (EC) No 648/2004), it chose ExESS. Not only are more than 1,000 substances, classified by Aise, in the database, but also all relevant functionalities (labelling of contents in Chapter 15 of SDS, ingredient data sheet on website, full listing of all ingredients for medical personnel) are available in the system. Exposure scenarios can be included and 48 languages are available.

CASE STUDY 3: Van Meeuwen Lubrication BV outsources SDS-authoring to Trade Wind

Since 2011 Van Meeuwen Lubricants and Van Meeuwen Chemicals have outsourced the drafting of SDSs. On the basis of formulations, supplier SDSs and physical properties we create the SDSs, with the Van Meeuwen corporate identity, in the languages that are required. SDSs are supplied within fifteen days, or within 48 hours depending on urgency.

STAFF SELECTION

Harro Elsborg – Managing Director

Harro has a law degree from the University of Leiden and has been working in the industry since 2002. Previously he was a consultant and sales director at Cap Gemini.

ChiHo Tang (Bio-Pharmaceutical Sciences, Leiden) – Consultant

Chris Meijboom (AMBI, IT and Organisation) – Consultant

MeiBo Cheng (Life Science and Technology, Leiden and Delft) – Consultant

Mehenash Alidjan (BASc Life Science Research, Rotterdam) – Consultant

Niqui van Olphen - Marketing Manager

Daniëlle Nuijten-Dijns – Office Manager

Valery Tjoeng (Bio-Pharmaceutical sciences, Leiden) - Consultant

TRISKELION
RESEARCH FOR BETTER LIVING

CONTACTS

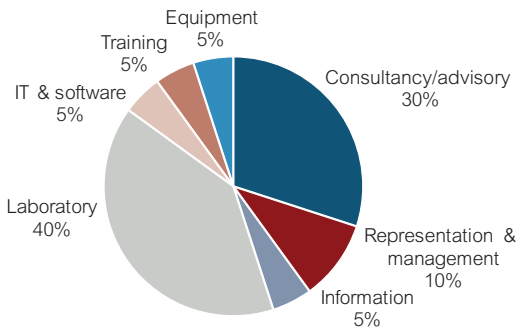
Website	www.triskelion.nl
E-mail	chemistry@triskelion.nl
Head office	Utrechtseweg 48, PO Box 844, 3700 AV Zeist, The Netherlands
Tel	+31 88 866 1628
Fax	+31 88 866 6970
Contact	chemistry@triskelion.nl
Ownership	Private company
Locations	Zeist, The Netherlands
Founded	TNO, 1933; TNO Triskelion, 1/1/2011

OVERVIEW

It is important for you to unequivocally demonstrate the quality and safety of your products. This is at the heart of our business. Triskelion safeguards the use of chemical products through individual attention, personal advice and excellent research. Our chemical risk assessment services combine research-driven excellence in the classical disciplines of toxicology and advanced analytical chemistry, with new developments in risk assessment, in order to produce intelligent testing strategies and thereby, cleaner, safer, chemical products.

VITAL STATISTICS	2015/16
Turnover, group	€30m
Turnover, chemical service provision	€15m
No of offices	7
No of countries represented	4
Staff, group	200
Staff, chemical service provision	150

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Headquarters group TNO: The Hague, The Netherlands
Headquarters Triskelion: Zeist, The Netherlands
Sales Offices: Japan, USA, Canada

SERVICES PROVIDED

Risk assessment and chemicals management

Our focus is on REACH and its implementation. Besides registration, authorisation and building exposure scenarios, we support the evaluation of risk management options. We can audit your own implementation and communication under REACH and its eSDS's. Additionally, we support biocides and the safe use of nanoparticles. TNO and Triskelion have together developed a range of assessment tools to help evaluate human exposure and to avoid and reduce health risks. Our expertise is available to address your regulatory issues as well as to solve your day-to-day chemicals management problems.

Experimental toxicology

We offer high quality toxicology studies, specifically tailored to the needs of REACH, biocides, pesticides and nanomaterials customers. Our toxicological research centre provides new and improved methods in toxicology, especially inhalation, reproduction, immuno-toxicology and (*in vitro*) skin adsorption. We have been developing novel methods to reduce, refine and replace animal testing for nearly two decades and are proud of our performance record in this field, especially resource saving combined *in vivo* studies such as repeat-dose (28/90d), repro screening and *in vivo* genotoxicity (also Comet assay) in the same study. We can offer the OECD 443 guideline for an extended one-generation reproduction toxicity (EOGRTS) study, with already several studies performed in our laboratories.

Analytical chemistry

Triskelion's analytical research centre, with its history of TNO R&D excellence, has expertise in developing challenging analytical chemical methods for a very broad range of substances including: organotins, fluorocarbons, formaldehyde, biocides, pesticides, fragrance materials, to name but a few. At the interface of the fields of toxicology and risk assessment, our tailor-made services can make a difference, for example:

- test substance identification and characterisation;
- mechanistic studies of toxic compounds *in vivo* using sophisticated analytical techniques;
- human and environmental exposure studies in various settings (industrial, agricultural).

Food packaging petitions, migration testing and plastics recycling

Triskelion offers regulatory affairs services, migration and toxicity testing of food contact materials (FCM) for petitions to the European Food Safety Authority (Efsa) and for food contact notifications (FCN) to the US Food and Drug Administration (FDA). Examples are monomers and additives used in plastics described in Directive 2002/72/EC. We sharpened our knowledge by participating in the technical committees of the Efsa.

How we work

Project management – your assignment with Triskelion is always led by one of our experienced project managers, your primary contact person, who manages your project, interacts with the scientific team, and ensures you that deadlines are met and that the assignment meets your needs. Your project manager maintains contact with you during phone and/or conference calls (scheduled as and when you require), and also provides regular update reports.

Quality assurance and reporting – our GLP reports are consistently subjected to the required auditing and control procedures to ensure compliance. All the documentation you receive (proposals, reports, analytical results, Iuclid files, chemical safety reports, eSDSs) is reviewed by a senior staff member before being sent out to you.

Relationship management – in addition to strong project management, our sales and account managers are also there to assist you. Our customer services department is there to guide you to the correct technical contacts within Triskelion, who will help you find the right solution. We are specialised in multidisciplinary projects where our

consultative skills, knowledgeable expertise and personal care all contribute to tailor made study designs and reliable project management. It is our people that make the difference.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1932	TNO The Netherlands Organisation for Applied Scientific Research is founded.
1946	Founding of the Central Organic Chemistry Institute in Zeist.
2004	Completion of five-year HPV programmes on various chemical groups including organotins.
2006	Participated in REACH implementation projects (data requirements, exposure assessment).
2007	Commenced REACH partnership with Sabic Europe.
2010	Successful completion of 325 full and partial REACH dossiers.
2011	Incorporation of TNO Triskelion as a private company.
2011	ReachCentrum and TNO Triskelion join forces to offer REACH workshops and training courses.
2012	Extensive application of our exposure experience to the evaluation of risk management options for SVHCs.
2013	AAALAC accreditation obtained; REACH 2013 dossiers submitted on time!
2014	First EOGRTS study accommodated in our laboratory.
2015	Substantially expanded our animal facilities and made some mayor steps in becoming a larger global player.
2016	Launching our new branding campaign with new logo, name and slogan: Research for Better Living.

ACCREDITATIONS

In compliance with GLP (toxicology and analytical chemistry); ISO 9001 and AAALAC certified; Some analytical services under ISO 17025.

PARTNERS

TNO Quality and Safety (R&D): we work together with TNO on development of alternative toxicological methods and (bio)analytical methods.
Where needed we supply additional services like ecotoxicology, physico-chemical testing and special evaluations (as SEA) through our network of co-operators.

CLIENTS

Three top ten and 15 top-50 global chemicals manufacturers are our clients.
We have provided long-term chemical safety services to the following chemical sectors: fluorochemicals, hydrocarbon distillates, organotins, biocides, chlorinated solvents, fuel oxygenates, organic peroxides, formaldehyde, amines, polyols and isocyanates, silicates and mineral oxides (micro and nano grades), coal chemicals, fragrances.

TESTIMONIALS

“Triskelion has been supporting BASF SE in a variety of registration activities since the beginning of REACH. We were and we are impressed by the broadness and depth of the expertise, the professionalism in conducting complex projects and their flexibility to adhere to our time requirements.” – Edgar Leibold, BASF SE

CASE STUDY 1: Successful registration within REACH, post-2010 2013 follow-up and 2018 preparations

With Phase II REACH registration completed by mid-2013, within 2014 and 2015 a number of our customers already started with REACH 2018. We can combine the necessary data searches, propose testing where needed, perform a chemical safety assessment, and prepare chemical safety reports and eSDS, all under the same roof.
Results from several 2010 substance evaluations are coming in and it’s clear that authorities may have in-depth questions on specific parts of your dossiers, for example the DNEL derivations, exposure assessment and read across justifications. We will support you in the communication with Echa and take care of your dossier update.
Based on our extensive experience, Triskelion will help you plan the registration, guide you through the process, and work with you to ensure timely and successful registration for 2018 as well. Grouping and read across will be needed to keep costs down. Feedback of Echa and member states on 2010 and 2013 dossiers has shown that more data development is needed to support this.

CASE STUDY 2: Echa test proposal evaluations including EOGRTS

REACH requires that for substance volumes of 100-1,000t and >1,000t, missing higher tier safety studies be included in the registration dossier in the form of a test proposal. Echa is in the process of evaluating these proposals and (draft) decisions are being sent to lead registrants. Many have already been published on the Echa website and were open for public comment for several weeks.

- Our advice to clients faced with an Echa test-proposal that diverges from their own, is to enter, as far as possible, into a dialogue with Echa. We can help develop and support the scientific arguments to support your case to Echa.
- Should testing be needed, Triskelion is specialised in higher tier testing with difficult test materials. Our inhalation toxicology skills cover gases, volatile liquids, solids and nano-grade materials, while our reproduction toxicology skills are second to none and include the EOGRTS (OECD 443). We were involved in the guideline development of OECD443. Therefore several EOGRTS studies were already performed. Triskelion is well equipped to perform several OECD443 studies with the most challenging substances; for example by inhalation.

CASE STUDY 3: Authorisation

Is your substance included in the candidate list or even already prioritised for authorisation? Based on our substantial experience in dealing with consortia and sector groups, including downstream user communication, and our strong expertise in exposure and risk assessment, we will support you with:

- advocacy and strategic support, including communication;
- appropriate responses to candidature or Annex XIV prioritisation;
- formal replies to Echa notices;
- revision and optimisation of the chemical safety report and exposure scenarios;
- socio-economic analyses and report writing;
- analysis of alternatives;
- preparation of substitution plans; and
- application for authorisation.

STAFF SELECTION

Our key staff members have long experience in the analysis, testing and risk assessment of a wide diversity of substances for the chemical, pharmaceutical and food industry. This solid background is applied to your substances as well. A steady inflow of young academics ensures that we remain vigorous and up to date.

Choose certainty. Add value.
Más seguridad. Más valor.

CONTACTS

Website	www.tuv-sud.es
E-mail	info.es@tuev-sued.es
Head office	Ronda Can Fatjó nº 13 08920 Cerdanyola del Vallès, Spain
Tel	+34 935 922 633
Contact	Montserrat Fernández (REACH Technical Leader)
Directors	Jordi Campos (Business Unit Manager Process Safety)
Ownership	TÜV SÜD
Locations	Spain, Taiwan
Founded	1945

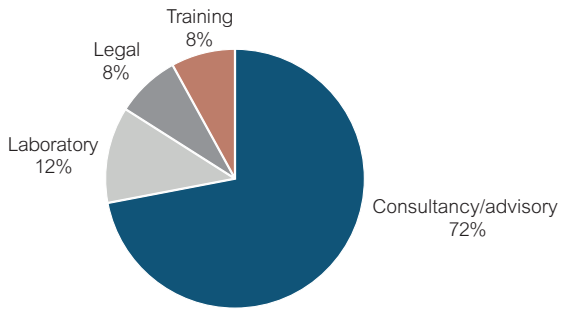
OVERVIEW

The Business Unit Process Safety of TÜV SÜD in Spain and Portugal offers consulting and training services on process safety (chemical, petrochemical, pharmaceutical and food industries). It works to promote safety in the industry and particularly in the industry dedicated to chemicals and chemical processes. Its commitment to industrial, process and labour safety is its top priority. It works hand with hand with clients, but it also participates in research institutes, international safety organisations and standardisation committees. Its activities focus on three main areas: consulting, laboratory testing and training.

VITAL STATISTICS 2015/16

Turnover, group	€12m
Turnover, chemical service provision	€2.8m
No of offices	6
No of countries represented	Global
Staff, group	220
Staff, chemical service provision	46

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

TÜV SÜD Iberia S.A.U.: Ronda Can Fatjó nº 13 08920 Cerdanyola del Vallès, Spain
Taiwan Sales Office: 13F, No 83, Jian Sing Rd., Sanmin Dist, Kaohsiung 807, Taiwan, R.O.C.

SERVICES PROVIDED

REACH and product safety

We assist a high number of companies outside the European Union by taking over the tasks and responsibilities of their importers for complying with REACH. Our core service is to act as a REACH only representative: we prepare registration dossiers of their substances, submit them to Echa and provide the necessary documentation to their downstream users. We also act as third party representative, offering consultancy services to European companies, preparing their registration dossiers and SDS adapted to the REACH and CLP Regulations. We are members of ORO (Only Representative Organisation).

Laboratory testing

We offer more than 150 different tests in the fields of thermal process safety, fire and explosion protection, electrostatics, physico-chemical REACH and GHS tests and also those related to substances of very high concern. We offer these services thanks to the TÜV SÜD Schweiz laboratories located in Switzerland which are certified in accordance with ISO/IEC 9001, and tests accredited under ISO/IEC 17025. The Business Unit Process Safety of TÜV SÜD can offer all kind of REACH test thanks to good relationship with international laboratories (GLP).

Process safety and loss prevention

We conduct audits and risk analysis in our fields of expertise: process safety, ATEX, electrostatics, environment, thermal process safety, occupational risk prevention and machine directive. We apply recognised methodologies such as HAZOP, ZHA, FTA, LOPA and FMA and propose cost-effective solutions. We belong to the EPSC – European Process Safety Centre.

Environment consultancy

We perform environmental risk analysis, quantify the consequences of possible damage, help companies to integrate their activities in the environment, and perform administrative procedures associated to each regulation and to environmental licenses. We also implement safety management systems

Crisis management

We are accredited to prepare emergency plans and also help companies to implement them with training and emergency exercises aimed at both management and staff. As part of the global services we give to our clients, we develop crisis management and communication manuals to minimise negative publicity.

Behavioural safety

Companies and TÜV SÜD Iberia create a challenge together to influence the culture and behavioural safety of a company. Reaching challenging goals is the only way for a commitment and to solve critical situations. In our methodology all the org chart is included in the behavioural safety, from upper-top management to operator.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1945	Company founded in Switzerland.
2004	Company established in Barcelona, Spain.
2008	REACH department is set up.
2008	Sales company in Taiwan.
2012	Delegation in Murcia, Spain.
2013	TÜV SÜD acquires the company.
2015	TÜV SÜD Process Safety (legal entity name Instituto Suizo para el Fomento de la Seguridad, Swissi-Espana S.L.U.) merges into TÜV SÜD Iberia S.A.U.
2016	TÜV SÜD Process Safety has been integrated into TÜV SÜD Iberia S.A.U. as the Business Unit Process Safety under the division of Technical Assistance.

ACCREDITATIONS

Our laboratories in Switzerland are certified in accordance with ISO/IEC 9001 and our partner test laboratories are accredited under ISO/IEC 17025.

CLIENTS

In the service field REACH, the majority of our clients are companies that produce or handle chemicals and chemical products. They belong to the chemical, pharmaceutical, petrochemical and agrifood sectors, among others. We work for all kinds of companies, from multinationals to small and medium-sized local companies.

CASE STUDY 1: REACH management platform and customer care

TÜV SÜD Iberia developed in 2009 an IT tool for our REACH clients so that they are able to manage all the information related and linked to REACH processes, specifically the registration. The information is made available both to our clients and to their respective supply chains. That way their European clients can access the IT tool to download relevant documentation related to the substances they import (only representative certificates, tonnage certificates, SDS, etc). We also have a close relationship with our REACH clients. We visit them on a yearly basis to provide them with updates on the latest issues related with the registration process. We organise REACH and product safety seminars and train them depending on their specific needs.

CASE STUDY 2: Tailor-made proceedings

Companies are increasingly concerned by safety, health and environment. To meet its clients' needs, TÜV SÜD Iberia provides consultancy services to develop tailor-made proceedings to help companies to manage its procedures and thus increase effectiveness and reduce costs. This service is the fruit of years of experience in consulting.

STAFF SELECTION

Jordi Campos – Business Unit Manager Process Safety

Jordi Campos has been the Business Unit Manager Process Safety since 2016. Before this appointment, Campos was the business manager of TÜV SÜD Process Safety and worked as consultant specialised in emergency plans, major accidents (Seveso) and safety management systems.

Jaume Sagarra – Operational Manager – Process Safety

Jaume Sagarra holds a degree in chemical engineering and is specialised in electrostatics, process safety, accident investigation and risk analysis.

Montserrat Fernández – REACH consultant – Technical Leader

Montserrat Fernández holds a degree in chemistry. She is a consultant specialising in REACH Regulation, safety data sheets (SDS), classification, labelling and packaging (CLP).
She also worked at the R&D department of Clariant Spain, where she held various positions.

Gema Fernández – REACH consultant – Project Manager

Gema Fernández holds a PhD in chemistry and masters in environment and occupational risk prevention. She is a consultant specialising in REACH. Her tasks are related to registration dossiers, supply chain communication, web service and testing solutions provider.

Joan Marc Juncosa – REACH and Machine Directive consultant

Joan Marc Juncosa is chemical engineer. He is a consultant specialising in REACH, classification, labelling and packaging (CLP), explosive atmospheres (ATEX) and machinery safety.

Dolors Vinyoles – REACH, ORP and environment consultant

Dolors Vinyoles holds a degree in chemistry. She is a consultant specialising in REACH Regulation, environmental safety, safety management systems, and occupational risk prevention.
Before joining the company, she worked at Clariant Spain, where she used to be ESHA (environment, safety, and health affairs) country head.

Ester Pellicer – REACH and Crisis Management consultant

Ester Pellicer holds a degree in communication science. She is a consultant specialising in crisis communication and management, and emergency exercises. As part of the REACH team, she keeps up to date clients in topics related to REACH through newsletters and updating the REACH IT tool.

Industrie Service

CONTACTS

Website	www.tuev-sued.de/plants_buildings_technical_facilities
E-mail	REACH@tuev-sued.de
Head office	TÜV SÜD Industrie Service GmbH, Westendstr 199, D-80686 Munich, Germany
Tel	+49 / 89 / 5791-1004
Fax	+49 / 89 / 5791-1174
Contact	Dr Dieter Reiml
Ownership	TÜV SÜD Holding AG
Locations	TÜV SÜD Group employs more than 24,000 people in 80 countries in ca. 850 locations
Founded	1866

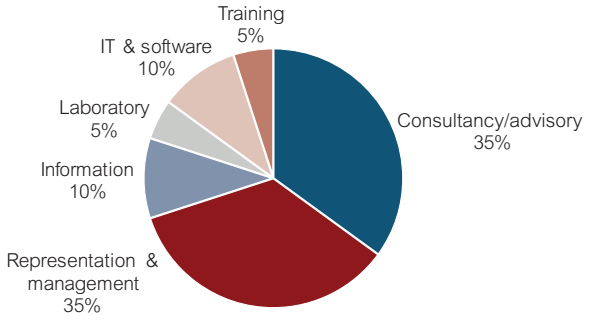
OVERVIEW

The principle of REACH, "No data, no market", may seem alarming. Additionally, comprehensive obligations governing the provision of information along the supply chain and to Echa have came into effect. As a globally recognised expert in all chemical law issues, TÜV SÜD continuously pursues the reform process in the EU and supports companies throughout all steps of REACH and GHS implementation.
To assist the companies affected by REACH, TÜV SÜD has established an international REACH network. Our environmental experts are tracking REACH implementation in the EU on an ongoing basis. And in addition, we also help to maintain business secrets of our customers in spite of mandatory data sharing provisions.
In view of the 2018 registration deadline TÜV SÜD developed a service package custom tailored for small and medium-sized enterprises (SME) as well as for global players.
Since 2013 we have expanded our range of services to biocides.
An increasing focus is to support companies in securing their supply chain management in conjunction with chemicals legislations.
Our maxim is "REACH – Made easy with TÜV SÜD expertise."

VITAL STATISTICS 2016/17

Turnover, group	€2,220m
Turnover, chemical service provision	-
No of offices	850
No of countries represented	80
Staff, group	24,000
Staff, chemical service provision	80

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Japan, Singapore, China, India, Croatia, Indonesia, Thailand, Vietnam, Serbia, Russia, Ukraine, South Korea, USA

SERVICES PROVIDED

Only representative

TÜV SÜD Industrie Service acts as reliable and impartial OR to numerous manufacturers of substances established outside the community. The obligations of an OR outlined in Article 8 of the REACH regulation comprise not only registration but also all obligations for importers under REACH. Calling in an OR has the following advantages: importers need not become active themselves, and manufacturers established outside the EU can bundle notifications and do not have to address each importer individually. We experience that often manufacturers address to us when their previous OR failed to act to their satisfaction or did not fulfil its obligations.

REACH initiative for mid-sized and small companies

All companies must register their chemicals by mid-2018 at the very latest – which is especially challenging for small and mid-sized businesses! TÜV SÜD aims to help these companies ensure that REACH is not a threat, but a path to safeguarding business. With the special needs of small and mid-sized companies in mind, TÜV SÜD has created a service package that provides these companies with assistance in all questions related to chemicals. The spirit of initiative: focus on your core competences, not on REACH.

Authorisation

The authorisation procedure aims to assure that the risks from SVHC are properly controlled and that these substances are progressively replaced by suitable alternatives. SVHC may be included in the authorisation list and become subject to authorisation. These substances cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Our support extends from the management of authorisation consortia to supporting individual companies in fulfilling their duties in a cost-saving and effective manner.

In-house training and seminars

Companies affected by REACH or CLP are seeking advice on how to deal with the challenges caused by REACH in a timely effective manner. Desired training events vary depending on participants' existing knowledge:

- introductory training courses to gain an overview of REACH and CLP;
- seminars on selected topics of REACH;
- workshops to create solutions under the guidance of an experienced expert;
- in-house consulting for the ad-hoc solution of characteristic problems.

Any other activities concerning REACH and CLP

REACH and CLP shift most of the responsibility for the safe handling of chemicals from the regulatory bodies to producers, importers and downstream users and retailers. The relevant requirements and consequences, however, are not clear at first sight. Consequently we offer all kind of services related to REACH and CLP, from the starting point to implement REACH via testing in our own GLP accredited laboratory to long-term compliance with chemicals regulations.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1866	Established in Mannheim
1926	Introduction of the "TÜV SÜD mark / stamp" in Germany
1960	Establishing chemical services
1990	Conglomeration of TÜVs from the southern part of Germany to form TÜV SÜD and the expansion of business operations into Asia. Best brand of technical services, testing, consulting, training, certification in all industries worldwide – energy producers and providers, nuclear power plants, chemical industry

2006	Expansion of services in Asean by acquiring Singapore-based PSB Group
2007	Establishing REACH services. Founder member of the "BUSINESSEUROPE REACH Implementation Network".

ACCREDITATIONS

GLP

CLIENTS

Due to client confidentiality individuals cannot be named. Our clients from more than 30 countries are active in all fields of industry and professional sectors. We support a network of chemical plants. Company size varies from worldwide operating entities to SMEs. We support clients in all their roles under the REACH regulation and for all types of substances. In 2013 we expanded our range of services to biocides as to the biocides products Regulation.

CASE STUDY 1: Consortium management

A consortium with representatives from five countries took over to register a series of substances with registration deadlines from 2010 to 2018. The duty to act as lead registrant was shared among the individual consortium members. The main bodies of the consortium are the steering committee, the technical committee and the secretariat. TÜV SÜD rendered consortium management to all bodies. Technical REACH consultancy and financial consultancy was part of the services to be delivered.

CASE STUDY 2: Support in REACH implementation

An EU manufacturer of articles and substances required support in implementing a REACH system for the entire company. The tasks focused on communication in the supply chain, registration, SVHC, training and organisational building. A team was formed for continuous assistance; the core team was fully integrated in the client's activities on-site.

CASE STUDY 3: Complete service package for lead registrants

Several clients from the chemical industry lacked capacity to prepare lead dossiers. TÜV SÜD prepared and submitted the lead dossiers on behalf of the clients. Additionally, all accompanying steps were performed as well: Sief communication, data-gap analyses, testing, expert statements, Qsar modelling, communication within consortium, preparation of safety data sheets, cost calculation of letter of access, handling of letter of access.

CASE STUDY 4: Testing strategies and testing

The lead registrant of four substances had to conduct studies in order to fulfil the information requirements under REACH. Two of the substances were classified as hazardous according to CLP, the classification of the others was not yet clarified. TÜV SÜD performed all steps to comply with the information requirements.
All available information that had been gathered was assessed for its adequacy for classification and labelling. Cost for data sharing is one of the crucial issues of negotiations in Siefs. High quality data outsell a higher price than data of low quality.
Some data gaps were closed by Qsar and read-across. Other data gaps had to be closed by testing following to a meaningful test strategy.
TÜV SÜD operates its own GLP testing laboratory capable of performing all testing required by REACH.

CASE STUDY 5: SVHC

A EU-based group with legal entities in several member states was seeking support in making an inventory of SVHC of the articles put into market, as well as in implementing a system to comply with the duties to communicate information on SVHC in articles. TÜV SÜD offered an integrated approach over all affected legal entities in order to avoid duplication of work. Representative articles were selected for chemical testing in case of uncertainty on the presence or concentration of SVHC. Testing was performed in TÜV SÜD's own chemical laboratory.
As a result of the investigation and consulting, a unified system was implemented in the entire group. The system ensured full compliance with REACH Art. 33 to 36. Furthermore, supply contracts were amended to increase legal certainty, to avoid the risk of lawsuits and to avoid image problems.

CASE STUDY 6: Only representative

TÜV SÜD acts as OR for many non-EU manufacturers. In several countries this is performed by involving local TÜV SÜD offices. This approach guarantees direct contact to the end-client and avoids language barriers where applicable. Thus, also smaller non-EU manufacturers can benefit from OR services which are not sufficiently conversant with English and technical terms.

STAFF SELECTION

Dr Fritz Prechtl

Fritz Prechtl is a chemist and certified REACH multiplicator with more than 30 years' professional experience. His core activities are

- only representative;
- preparing registration dossiers;
- communication up and down the supply chain;
- communication in Siefs and with authorities;
- complex role analyses; and
- regulatory affairs.

Dr Dieter Reiml

Dieter Reiml is a molecular biologist and certified REACH multiplicator with more than 30 years' professional experience. His core activities are

- consortium management;
- authorisation;
- only representative;
- preparing lead dossiers;
- CSA / CSR; and
- consultancy on REACH and CLP.

Javier Castro

Javier Castro is a chemist and certified REACH multiplicator with 18 years' professional experience. His core activities are

- downstream users;
- legal monitoring;
- supply chain communication;
- strategic support;
- consultancy on REACH and CLP.

Ing. Rupert Scherer

Rupert Scherer is an engineer and certified REACH multiplicator with 15 years' professional experience. His core activities are

- implementing REACH systems;
- full material declaration;
- RoHS;
- management systems and IT;
- biocides and
- downstream users.

Dr Yvonne Fery

Yvonne Fery is a food chemist, European Registered Toxicologist and certified REACH multiplicator with more than ten years' professional experience. Her core activities are

- toxicology;
- authorisation;
- supply chain communication;
- dossier preparation;
- finance management and
- consultancy on REACH and CLP.

Other staff

Other REACH experts are located in offices in the EU and outside EU. Additional staff are active in testing for REACH and CLP as well as chemical testing.

CONTACTS

Website	www.ul-scs.com
E-mail	environment@ul.com
	23 British American Blvd, Latham, NY 12110, US
Tel	+1 800 572 6501
Fax	+1 518 640 9299
Contact	Bridget Millen
Directors	Lou DeSorbo Tom Carter Eric Vangarderen Adam Sawyer Karen Lintz Alberto Uggetti Jim O'Keefe Doug Lockard Tony Worthan Anne Bonhoff Craig Rowlands
Ownership	UL, LLC
Locations	44 Countries
Founded	1894

OVERVIEW

UL provides leading and comprehensive software tools and services for:

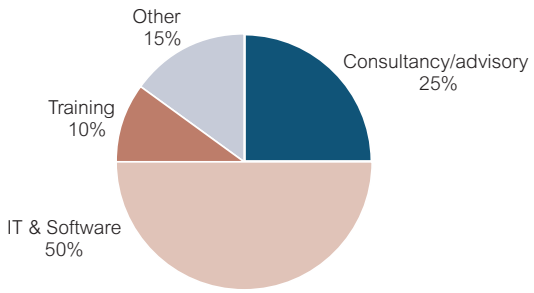
- GHS SDS authoring, managing and distribution;
- retail and Industrial manufacturing supply chain compliance and data management solutions;
- REACH compliance software;
- predictive toxicology software; and
- green chemistry and sustainability solutions.

After nearly 30 years in operation, in November 2013, The Wercs became part of the UL family, a trusted company, with a 120-year tradition and over 150 offices around the globe. UL's principles are deeply rooted in science and dedicated to innovation for complex global supply chain challenges, holistically and efficiently.

Today, UL software products and services are considered the gold standard in global regulatory and sustainability compliance solutions.

VITAL STATISTICS	2015/16
Turnover, group	US $2bn
No of offices	159
No of countries represented	113
Staff, group	11,000
Staff, chemical service provision	160

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

UL offers a unique mix of leading software automation tools and professional services to help clients achieve global hazard communication requirements, regulatory compliance, chemical data management and distribution, as well as supply chain risk mitigating solutions.

EHS and SDS chemical data management solutions

Utilised by regulatory departments worldwide, our flagship software, WERCS, is a robust hazcom solution to author, manage and distribute safety data sheets, labels and other chemical documents according to all local, national and international regulations, including GHS, EU-CLP and other global formats. As a true global, scalable and automated solution, WERCS compares regulatory rules against 5,300 monitored regulatory lists and results can be distributed in over 45 languages comprised of 21,000 credentialed phrases.

Self service SDS – ULGHS.com

Designed to meet the needs of customers with small inventories, ULGHS.com is a self-service tool that allows users to quickly and accurately create an SDS through a secure web interface. Our proprietary logic tree of questions encodes everything you'll need to be GHS-compliant, updating alongside evolving regulatory guidelines.

Supply chain compliance

The Wercs Supply Chain Compliance solutions uniquely combine regulatory content, localised expertise, and technology that provides customers with the ability to identify and manage risk within their supply chain.

REACH compliance

UL REACH Across software enables automated read-across for regulatory compliance through rapid, high throughput screening of chemicals to multiple end points. The tool is designed to help companies meet approaching REACH deadlines without the use of traditional testing methods such as animal testing, reducing cost and increasing speed.

Predictive toxicology software

UL's chemical safety prediction software combines the world's largest database of chemical health endpoints and **predicts** a chemical's likelihood to produce adverse human health effects such as skin sensitisation, eye irritation, acute oral toxicity, and mutagenicity. The tool can estimate chemical toxicity prior to chemical synthesis and provide data for chemical substitution choices.

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

1984	WERCS global hazcom software launched
2003	Wercs Professional Services founded
2006	WERCSmart Retail Platform created.
2013	The Wercs acquired by UL
2016	UL partners with Johns Hopkins researchers to develop UL REACH Across software

PARTNERS

ChemAdvisor, DHI, JCDB Japan, Brandywine Drumlabels, Royal Haskoning, SAP, Oracle

CLIENTS

More than 11,000 customers worldwide using various UL products and services. Major industry sectors served: adhesives, consumer products, flavour and fragrance, life sciences, paints and coatings, consumer electronics, building products, petrochemical, pharma, retail, and specialty chemicals.

CASE STUDY 1: Replacing traditional SDS outsourcing with automation.

Due to recent GHS regional requirements, a company had 1,500 out-of-date or missing SDSs. With limited in-house regulatory resources, SDS authoring demands were historically outsourced to regulatory experts within respective regions around the globe. Time and accuracy were critical for the company to achieve compliance and it was realised that traditional outsourcing was not an option.

The Wercs solution began with porting component level data from the company's SAP system into UL Secure Connect (ULSC), a lightweight WERCS application that is designed to leverage the powerful hazcom automation capabilities of the WERCSmart Platform.

Once the company's new product library was mapped within ULSC, new SDSs were created and reviewed via WERCSmart automation. Data and documents were delivered back into the company's ULSC library for global distribution.

Benefits:

- increased accuracy. No manual data entry. Increased control of product data and documents;
- speedy turnaround for SDS creation;
- documents created for multiple regions simultaneously via WERCSmart automation;
- ULSC became a centralised repository for all product data and documents; and
- added comfort of a UL-approved GHS SDS template.

CASE STUDY 2: Supply chain compliance with WERCSmart

Due to increasing regulatory demands, a leading retailer was looking for a solution to bridge the gap between the chemical data provided by suppliers and the data required to assure the correct handling, transportation, storage and disposal of the chemical containing products on their store shelves. The WERCSmart Retail Platform created a portal where suppliers can enter required data as part of the on-boading process with the retailer. Through logic automation, WERCSmart then determined the data points necessary for the retailer to correctly handle, transport, store and dispose of the chemical-containing products on their shelves. With advanced access to data beginning at procurement, the retailer now manages their entire supply chain before products arrive at the dock – switching from reactive to proactive and establishing real control over compliance issues. Today, WERCSmart has over 40 leading retailers participating in the programme.

Benefits:

- create a trusted third party portal for suppliers to input product composition data without disclosing critical confidential business information; and
- WERCSmart Platform allows retailers to convert legacy MSDS's to the Osha GHS standard seamlessly.

CASE STUDY 3: Global substance volume tracking

For one WERCS customer, the process of generating a final substance volume report for just one EU REACH regulation was taking approximately two man months. With growing regional substance volume tracking requirements, the customer needed a more efficient method of creating reports that would allow them to calculate quantities of substances across geographies over various time spans. The Wercs Substance Volume Tracking solution allowed the company to use the material data already available in their WERCS software, then married the data with the associated sales volumes within their ERP systems. The solution now calculates quantities of substances by geography and time at unprecedented speeds. What once took them two man months to complete can now be accomplished within minutes.

Benefits:

- no more manual calculations;
- real time global trade compliance; and
- one person with five years of data can now create a full EU REACH SVT calculation in ten minutes.

STAFF SELECTION

Lou DeSorbo – VP and Managing Director

Lou DeSorbo is the Managing Director of UL i&i, The Wercs, a company he spearheaded in 1993 with the creation of a MSDS (material safety data sheet) system. Today, Lou and The Wercs provide software solutions to thousands of chemical companies across Europe, Asia, North America, the Middle East and Africa. Prior to The Wercs, Lou consulted for North American Technical Consultants and was assigned to General Electric. It was during this assignment as a computer programmer that he developed the commercial software that would become the basis for The Wercs. Lou is a global leader with a flair for business development, visionary leadership and dynamic technology foresight. Lou holds a BS and a MS from the University of Albany – State University of New York.

Karen Lintz – Director of Regulatory Services

Karen Lintz is the Director of Regulatory Affairs for UL i&i, The Wercs, and has been since 2005. Ms Lintz came with experience in toxicology and regulatory affairs, previously from GE Silicones, and The Carborundum Company, a division of BP Chemicals. In these previous positions she directed toxicology testing for new materials, FDA compliance efforts, and MSDS and labelling programmes. She holds a master's degree in pharmacology, toxicology, and therapeutics from the State University of New York at Buffalo. She has been working on regulatory data solutions for supply chain management for nine years.

Christine Lepisto – Senior Regulatory Specialist

Christine Lepisto offers over 25 years of industry experience. Mrs Lepisto holds honours degrees in chemistry and mathematics and built her career managing global compliance and best practice systems for HES (health, environmental, safety), product stewardship, and sustainability.

Anne Bonhoff, PhD – Global Head of Chemistry

Through her vision and over 25 years of expertise Dr Anne Bonhoff develops targeted business solutions to ensure the standardisation, harmonisation, and quality of chemical testing for consumer goods throughout UL's state-of-the-art laboratories. An industry thought leader, she is a recognised global expert on the topics of restricted substances, toxicology, environmental issues, ecological trends and eco-legislation.

Craig Rowlands, PhD, DIBT – Senior Toxicologist

Dr Craig Rowlands is Senior Toxicologist with UL Supply Chain and Sustainability where he provides leadership in the development of new approaches and capabilities for safety assessments of chemicals and consumer products. His research has focused on systems biology and toxicology applications to chemical risk assessments, sustainability and toxicant modes of action.

chemicals compliance consulting UMCO

CONTACTS

Website	www.umco.de
E-mail	umco@umco.de
Head office	UMCO GmbH, Georg-Wilhelm-Straße 187, 21107 Hamburg, Germany
Tel / Fax	+49 (0)40 / 555 546 300 / 49 (0)40 / 555 546 357
Contact	Jan Mönster
Directors	Hubert Oldenburg Peter Duschek Ulf Ch Inzelmann
Ownership	See directors
Locations	Germany
Founded	1982

OVERVIEW

Everything from one source

Compliance for substances, plants and processes along the chemicals value added chain – worldwide.

UMCO has been offering compliance solutions for the worldwide distribution and handling of chemicals over the last 35 years. We provide complete and high quality advisory services to our customers on substances, plants, organisations and transport. Our 60 employees in Hamburg, Cologne and Rottweil provide consultancy services for more than 1,000 enterprises in the chemicals, pharmaceuticals, logistics and processing industries worldwide.

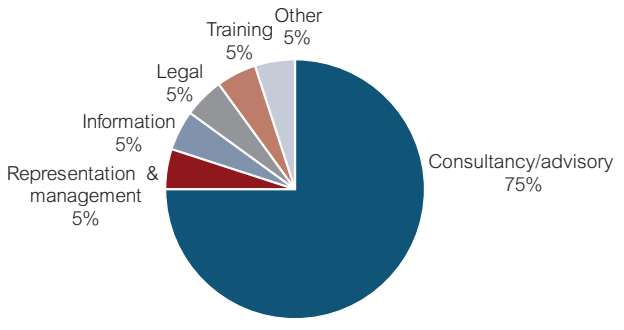
Our service portfolio includes:

- chemicals management;
- REACH;
- SHE management;
- dangerous goods; and
- emergency services.

VITAL STATISTICS 2016/17

Turnover, group	–
Turnover, chemical service provision	–
No. of offices	3
No. of countries represented	1
Staff, group	65
Staff, chemical service provision	30

SERVICE AREA BREAKDOWN



GLOBAL OFFICES

Germany: Hamburg, Cologne, Rottweil

SERVICES PROVIDED

Chemicals management

- determination of the status of all the substances used or traded by your company with regard to their worldwide marketability;
- auditing and advising regarding chemicals management at company or corporate level and the integration of responsibilities and documentation into management systems;
- determination of classification and labelling in accordance with chemical and dangerous goods legislation, water hazard classification or VOC;
- authoring and monitoring of SDS and exposure scenarios (for all European regions/languages using UMCO SDS software UHCS); international SDS compilation and monitoring performed in conjunction with our network partners;
- support with regard to worldwide chemicals management, including analysis of national requirements for marketing of chemicals and notification/registration in cooperation with our network partners;
- permanent monitoring of substance and product data with regard to legislative amendments or changes in the formulation, including the updating of all necessary documents;
- customised interfaces to generate the automatic import and export of data in standard XML format into/from UMCO SDS software UHCS;
- web services for customer specific evaluations, for example current stock or dangerous goods lists and functions; online calculation tool in accordance with the CLP Regulation;
- automated export of data for compiling CLP/GHS labels;
- company-internal hazardous material management;
- compliance service for restricted / banned substances in mixtures / articles.

REACH management

Registration management for co-registrants:

- support in joint registration: communication regarding substance sameness and letter of access (LoA);
- compilation of dossiers and submission to the European Chemicals Agency (Echa); and
- only representative (OR) for non-EU manufacturers according to article 8 of the REACH Regulation.

Comprehensive support for lead registrants:

- Sief management: communication with co-registrants and preparation of contractual arrangements for data and cost sharing;
- dossier management: collection and evaluation of information for technical dossier and chemical safety report; and

Communication in the supply chain:

- strategies for the communication with suppliers and customers;
- integration of registration information in the eSDS;
- support regarding the identification of uses (use mapping);
- implementation of exposure scenarios in daily practice; and
- consultation regarding substances of very high concern (SVHC).

Strategic consulting:

- consultation and evaluation of organisations and structures in order to ensure REACH compliance;
- support related to participation and argumentation in public consultations and other communications with authorities;
- support for manufacturers and downstream users of substances subject to authorisation.

Biocide services (biocidal product Regulation (EU) No 528/2012)

Strategic consulting:
- consultation and evaluation of organisations and structures in order to ensure BPR compliance.
- advising regarding borderline and dual use products

Biocidal product authorisation:
- definition of the appropriate authorisation strategy;
- preparation of dossiers according to national legislation, in case the transitional period for actives is applicable;

- preparation and submission of luclid-dossiers for biocidal products;
- conduction of literature research, data evaluation and data gap analysis;
- monitoring of studies and toxicological evaluations;
- communication with authorities and laboratories.

Safety health environment management

- provision of a SHE manager;
- provision of external company advisors for the fields of occupational safety, emission protection, water pollution control, waste, hazardous incidents, fire protection;
- carrying out of approval procedures;
- advice on storage of dangerous materials;
- explosion protection consultation;
- preparing operating instructions and risk assessments;
- compiling safety reports and further hazardous incident documentations such as safety management systems and corporate alarm and hazard control plans;
- training and instruction;
- management systems: ISO 14001, 18001 (OHSAS), 50001;
- compliance organisation;
- compliance checks;
- conducting internal audits.

Dangerous goods

- provision of an external Dangerous Goods Safety Advisor (DGSA);
- establishment of a company individualised dangerous goods organisation and analyses for optimising procedures;
- inventory and dangerous goods audit;
- dangerous goods consulting;
- checklists, working and operating instructions;
- verification of correct classification and labelling;
- instruction and training courses;
- preparing and checking of documents;
- information about legislative changes; and
- project organisation.

Emergency services

- emergency telephone number for safety data sheets according to REACH Regulation (together with "GIZ Göttingen"); and
- GlobalChem24 – 24 hour emergency number for chemicals transport worldwide (together with the NCEC).

Training

- training, workshops and seminars in all services provided
- in-house seminars
- working and process instructions

CORPORATE DEVELOPMENTS & ACHIEVEMENTS

2006	Co-founder of the Global Chemical Consulting Network (GCCN), an entity which provides further services regarding foreign legal regulations.
2012	New development of an independent, proprietary software solution – UMCO Hazard Communication System (UHCS) – for monitoring products and compiling documents for hazard communication.
2013	Customised interfaces for the automatic import and export of data per XML transfer from our UMCO SDS software (UHCS) to ERP systems of our customers.
2015	Development of a proprietary software, in conjunction with the Haufe – Lexware – Group in Freiburg, designed to internally update legal and liability compliance regulation information in the areas of environmental protection and occupational safety. This software allows for a more up-to-date, precise and complete understanding of specific operator obligations.
2016	Customised online training for employees about occupational safety and related areas in cooperation with AS-Trainer. These trainings can be adapted to suit the needs of individual company requirements.

PARTNERS

- NCEC
- GIZ
- GCCN
- Haufe – Lexware -Group
- AS-Trainer

CLIENTS

Our clients include over 1,000 national and international companies, ranging from the chemicals and pharmaceutical industry, traders, warehouses and logistics companies to the manufacturing industry. All along the chemicals value added chain.

CASE STUDY 1: Chemical product management

- compilation of SDS for different chemical traders and producers of chemical mixtures; and
- more than 60,000 SDS compiled and regularly updated.

CASE STUDY 2: Business process outsourcing

- assumption of product stewardship and legal chemical product service for paint companies, including determination of classification and labelling for products in all EU regions and languages; and
- compilation of SDS and CLP / GHS labels.

CASE STUDY 3: REACH consortium management

- secretariat of the REACH Selenium and Tellurium consortium;
- financial management, management of subcontractors, trustee;
- registration management, Sief- and LoA-management; and
- representation of the consortium in the Eurometaux REACH Forum.

STAFF SELECTION

We support our customers with 60 engineers, scientists and legal experts, working on an interdisciplinary basis, to ensure the economic viability, quality, adherence to deadlines and success of projects.

VERDANT
VERDANT LAW, PLLC

CONTACTS

Website	www.verdantlaw.com
E-mail	inquiry@verdantlaw.com
Head office	Verdant Law, PLLC, 1025 Connecticut Ave, NW Suite 1000, Washington, DC 20036, US
Tel	+1 202 828 1233
Contact	Philip Moffat – pmoffat@verdantlaw.com Kurt Blase – kblase@verdantlaw.com Irene Hantman – ihantman@verdantlaw.com Danielle Schreiber – dschreiber@verdantlaw.com
Directors	Philip Moffat, Principal
Ownership	Private
Locations	US
Founded	2009

OVERVIEW

Verdant concentrates our practice on the global regulation of products across their lifecycles, from materials sourcing through manufacturing, marketing, use, and end-of-life management.

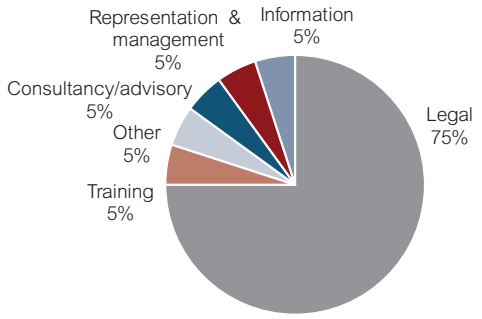
- The firm focuses on statutory, regulatory, and related requirements affecting the making, marketing, or using of consumer, industrial, and commercial products.
- The firm's principal areas of practice emphasise sustainability and the environment, and associated legal concerns.

Verdant has a strong commitment to delivering value. We work with clients to learn their business and strategic objectives and apply that knowledge to deliver timely, practical, and actionable advice.

VITAL STATISTICS 2015/16

Turnover, group	-
Turnover, chemical service provision	-
No of offices	1
No of countries represented	>25
Staff, group	6
Staff, chemical service provision	6

SERVICE AREA BREAKDOWN



SERVICES PROVIDED

Green chemistry and chemicals management

Governments globally have adopted regulatory frameworks to manage the risks that chemicals may pose. These regulations control chemical manufacture, importation, use, and marketing. Verdant helps clients achieve their objectives with product registrations and defence, compliance counseling, audit support and enforcement defence under TSCA, FIFRA, REACH, and similar programmes.

Green marketing

The number of "green" marketing claims and procurement programmes continues to increase globally. Important standards define acceptable marketing. Verdant reviews proposed advertising claims to help clients enjoy the benefits of compliance and avoid reputational harm as well as defends them against government investigations and enforcement.

Classification and labelling of chemicals and right-to-know

Right-to-know laws and requests for transparency are growing in response to demands for more access to information on chemicals. Green chemistry initiatives, implementation of the Globally Harmonised System of Classification and Labelling of Chemicals, and the proliferation of private stakeholder initiatives place a substantial burden on business. Verdant can help clients meet these challenges.

Nanotechnology

The development and commercialisation of nanotechnology-enabled products poses many risks for companies, including noncompliance with chemical and product regulatory requirements, legal liability for damages to human health and environment, and loss of market acceptance. Verdant has substantial experience helping clients manage these risks.

Regulatory policy

Successful campaigns to influence regulatory policy often require multi-faceted strategies involving Congress and the courts, as well as federal regulatory agencies. Verdant attorneys specialise in planning and execution of sustained efforts to attain regulatory policy goals.

ACCREDITATIONS

Please see our website for bar admissions.

PARTNERS

Advintess (Advanced Integrated Stewardship Services)
Regulatory Services International (RSI)

CLIENTS

The firm represents clients in a wide variety of sectors including:

- agriculture;
- chemicals;
- coatings;
- consumer products;
- cosmetics and personal care products;
- electronics;
- energy, including fuels;
- food;
- glass;
- manmade mineral fibres;
- mining;
- pharmaceuticals;
- retail;
- rubber;
- telecommunications, including wireless;
- trade associations;
- transportation; and
- voluntary standards.

CASE STUDY 1: Environmentally-friendly marketing claims and compliance with Federal Trade Commission regulations

Verdant attorneys manage responses to Federal Trade Commission (FTC) investigations regarding environmental marketing claims governed by the FTC's "Green Guides" for clients.

- We work with technical experts to develop substantiation for "free-from" and other environmental marketing claims for these matters.
- The team guides clients through internal audits to identify environmental claims in product labeling and marketing materials, identifies appropriate substantiation for such claims, and revises product labels and other materials to limit risk.

CASE STUDY 2: Compliance audit for EPA statutes and audit policy disclosure

The Verdant team guides clients through a step-wise assessment of their compliance with TSCA requirements related to R&D, manufacturing, processing, import and export, and sales; developing SOPs to address compliance gaps; and preparing declarations, as necessary, to EPA under the agency's Audit Policy Disclosure Program.

Audit activities include tasks such as:

- training staff on TSCA requirements;
- working with technical experts to evaluate reaction chemistry for the formation of new substances and whether those substances are on the TSCA inventory or eligible for an exemption;
- assessing compliance with SNUR requirements;
- working with technical experts to determine the inventory status of all substances within raw materials; and
- supporting communication up and down the value chain.

CASE STUDY 3: Food contact material notification in the EU, China and Canada

Verdant provides strategic support to clients seeking to enter the global market for a food contact materials. These clients need expeditious notification for proprietary food contact substances in the European Union, China, and Canada in order to sell the product to customers within global supply chains. For these matters, the firm identifies the common and unique legal and technical requirements of each jurisdiction, and the relevant policies and practices of competent authorities, as well as generally accepted industry practice where regulation is nascent or inchoate. Verdant then implements a multi-prong strategy including preparating dossiers to meet the common core requirements of all jurisdictions concerned, and marshalling cross-border resources and agency contacts to strengthen the individualised notification strategies tailored to attain compliance within each of the targeted countries.

CASE STUDY 4: Preventing product (chemical substance) ban under TSCA

Since 1991, one of our attorneys has represented an industry group initially threatened with a product ban pursuant to TSCA Section 4(f). The 4(f) proceeding was settled on the basis of a voluntary consent order, the first ever in which an industry party agreed to monitor customer exposures, and a product stewardship programme (PSP) which we assisted the industry in developing. Negotiating a continued commitment to implement the PSP subsequently formed the basis for four five-year agreements with OSHA, under which the agency has agreed not to pursue a permissible exposure limit (PEL). The PSP also has served as a model for similar programmes employed by the industry in Europe, South America and Japan, and is now being introduced to industry operations in China.

STAFF SELECTION

Philip Moffat

Mr Moffat founded Verdant Law to address the growing need for sustainability-related legal services and respond to the demand for greater value in the delivery of legal services generally. His practice has encompassed a variety of environmental, health, and safety-related matters, although he focuses on the environmental regulation of products under laws such as TSCA, FIFRA, FTCA, CPSC, FHSA, REACH, and California Proposition 65. Mr Moffat provides compliance counselling, transactional support, defence against enforcement actions, and support for internal compliance audits.

Kurt Blase

Mr Blase has a wide range of experience under state and federal health, safety and environmental laws. His practice focuses on administrative approvals, rulemaking and related litigation, as well as legislation, permitting, enforcement and counseling in these areas, including all major provisions of TSCA and rulemakings pursuant to the recent TSCA amendments. Mr Blase concentrates on strategies for management of complex regulatory issues involving multiple agencies, Congress, and related toxic tort or product liability litigation. He has appeared in over 30 federal cases primarily involving judicial review of agency regulations and other actions. He also has substantial experience with matters abroad.

Catherine Lin

Ms Lin practices comparative environmental law in the areas of complex, cross-border transactions, host country regulatory compliance, and product stewardship – particularly, in connection with supply chain continuity, products and chemicals regulation, and extended producer responsibility. She focuses on analyses and harmonisation of the environmental laws and liability regimes of multiple jurisdictions in order to achieve regulatory compliance and protection against liability exposure risks. Ms Lin's practice includes the EU and the Asia-Pacific region.

Sylvia Chi

Ms Chi focuses on green marketing, TSCA, and EPCRA, as well as compliance with California's Safer Consumer Products programmes. Her practice includes compliance counseling and enforcement defence for companies that manufacture chemicals and those that use chemicals in the manufacture of industrial and consumer products. She helps clients manage regulatory obligations up and down the value chain. Ms Chi has worked extensively on VOC issues related to indoor air quality (IAQ) under green marketing regulations. Ms Chi previously was a visiting attorney with the Environmental Law Institute. She is writing on IAQ for the American Bar Association's Natural Resource Law journal.

Irene Hantman

Ms Hantman advises clients on the domestic regulation of chemicals and has written extensively on these issues. She steers clients through the complexities of auditing and enforcement defence. She also advises clients on the practical implications of state and federal legislation and regulations. Ms Hantman joined Verdant after working at the US EPA in the Waste and Chemical Enforcement Division. She serves in a leadership position for the American Bar Association's Pesticide, Chemical Regulation, and Right-to-Know Committee.

Danielle Schreiber

Ms Schreiber's practice focuses on the environmental regulation of industrial, commercial, and consumer products. This includes compliance counseling, litigating, defending against enforcement actions, and supporting internal audits under TSCA, FIFRA, CAA, RCRA, green marketing under the FTC Act, and providing strategic advice under EU's REACH programme. Ms Schreiber also advises companies on compliance with hazard communication regulations under both the OSHA and the FHSA.

scivera

sciveraLENS
rapid screen

Delivering instant results, SciveraLENS Rapid Screen helps you make chemicals management decisions quickly and with confidence. Select one of four subscription plans for every need and budget that all come with an easy to use web browser interface and backed by board-certified toxicologists and professional tech support.

COMING SPRING 2017

SCIVERA.COM

1cc • compliance consulting

CONTACTS	
Website	www.1cc-consulting.com
E-mail	compliance@1cc-consulting.com
Head office	GEO PARK I, Max-Eyth-Straße 35, 71088 Holzgerlingen, Germany
Tel/ Fax	+49 7031 4 39 38 – 0/ +49 7031 439 38-222
Contact	Ms Nadiia Kaiun, Consultant Mr Christian Ege, Consultant
Ownership	Private
Locations	Germany, US, Italy, China
Founded	1996

OVERVIEW

1cc GmbH offers consulting and compliance services for chemical legislation in EMEA, North and South America and Asia-Pacific region. Our REACH related services focus on identification of legal requirements and administrative handling of obligations such as co-registration or LoA administration, workshops and training. Our customers benefit from our: consulting expertise, specialist knowledge concerning specific compliance issues, multilingual members of staff and long standing experience in the fulfilment of producer obligations.

SERVICES PROVIDED

Our consulting and compliance service portfolio in the area of chemical legislation encompasses following areas and service elements.

REACH/CLP (GHS) services:

(co-)registration: dossier creation and handling; only representative for non–EU suppliers; communication services (Sief, Echa, supply-chain); LoA (letter of access) administration services: handling, cost-sharing models and reimbursement system; testing (in collaboration with partner laboratories); and consulting on individual questions on REACH and CLP.

Supporting services:

monitoring of regulatory developments; impact assessment on legal obligations; workshops and trainings; audits, compliance-checks; and communication, SDS, supply-chain.

CLIENTS

We provide our consulting services to more than 130 customers, across various industries many of which are globally active companies, and assist industry associations' members in fulfilment of legislative requirements.

3S Safely Serving Science

CONTACTS	
Website	www.3s-chem.gr
E-mail	info@3s-chem.gr
Head office	133, El Venizelou Str, 16343 Athens, Greece
Tel/ Fax	+30 2109901150/ +30 2109901151
Contact	Panos Drougas
Ownership	Private
Founded	2/01/2007

OVERVIEW

3S–SafelyServingScience is a distinctive company providing specialised advice and guidance at each stage of a chemical's lifecycle. Our mission is to contribute with knowledgeable care and best practices to our customers' efforts to:

a) identify and harmonise with compliance requirements governing the production, supply and transport of chemicals; and

b) conscientiously fulfil their environmental, health and safety duties.

Our +24y of practical experience in the global supply of chemicals, supported by certified knowledge on Transport-HSEQ management systems, enables us to deliver quick and cost-effective solutions. Aiming to provide efficient, reliable, high value-added services, we practice the modern project management principles supported by the latest technology software. We are passionate about creating and sharing value and look forward to offering you the best possible customer experience!

SERVICES PROVIDED

Here's a detailed listing of the out-of-shelf deliverables and services we offer:

- CHEMICAL MANAGEMENT AND REGULATORY COMPLIANCE (SDSs/C&L/ studies-reports-notifications/SEVESO III inventory-classification);
- ENVIRONMENTAL PERMITS (EIAs/ISO14001*/ HazWastes classification [WFD-EWC/ADR-IMDG]);
- HEALTH AND SAFETY AT WORK (safety officer outsourcing services/ISO18001*/ risk assessments of chemical hazards/ business conduct policies [EH&S]); and
- DANGEROUS GOODS SAFETY ADVISER (DG transport classification/transport documentation (ADR/IMDG/IATA-DGR)/ independent supplier audits [EH&S, SQAS]).

*implementation guidance and internal auditing

A.S.C. PART OF Staphyt

CONTACTS	
Website	www.ambrosiconsulting.com
E-mail	contact@asc-consult.eu
Head office	A.S.C., 23, rue de Moeuvres, 62860 Inchy-en-Artois (France)
Tel	+33 (0)6 26 14 64 99 / +33 (0)6 84 85 21 42
Fax	+33 (0)3 20 88 85 92
Contact	Aurély Béghin / Sophie Aviron-Violet
Ownership	Private company part of STAPHYT
Locations	France and Poland
Founded	1999

OVERVIEW

Whatever your activity in the chemistry area, you are necessarily subject to numerous and complex regulations, whose non-compliance can be fatal to your business.

Since 1999, A.S.C. is consulting company, expert in regulatory chemistry. Our mission is to inform you about the regulation that applies to your activity, and to help you providing the authorities with the necessary dossiers in order to be authorised to produce, import or sell your substance or product, either new or existing.

Our teams currently pool 35 scientists, whose backgrounds cover all areas related to chemical risk assessment: physico-chemistry, analysis, toxicology, ecotoxicology, biological efficacy, etc

SERVICES PROVIDED

- luclid dossiers (REACH, biocides)
- Risk assessments for human and environment
- Regulatory advice and strategy
- Classification, labelling and SDS
- Transitional registrations of biocides in all Europe
- Building or update of PIF, online notification through CPNP for cosmetics
- Study monitoring
- Expert statements, literature search on chemical substances
- Regulatory support in all European countries, including answer to authorities
- Regulatory watch on chemicals/REACH, biocides, cosmetics, PPP and fertilisers

CLIENTS

From SMEs to large companies, our clients have businesses in chemicals (CLP, REACH), biocides, cosmetics, PPP… A.S.C. can assist chemical manufacturers, formulator, importers, distributors...

Altox

CONTACTS	
Website	www.altox.dk
E-mail	altox@altox.dk
Head office	Tonsbakken 16-18, DK-2740 Skovlunde, Denmark
Tel/Fax	+45 3834 7798
Contact	Pernille Hjaltalin
Ownership	Private limited company
Locations	Denmark
Founded	1991

OVERVIEW

Altox is a service provider assisting private companies (SMEs as well as large companies), authorities and trade organisations. We aim at finding practical solutions based on science and regulatory requirements. Altox is widely recognised for the development of helpful desk tools to ease implementation of C&L and preparation of SDS. Being independent from software solutions (C&L, SDS) and test laboratories (CRO) it allows for a more flexible approach towards regulatory changes. We also offer extensive and well recognised education programmes, open courses and tailor-made company courses, seminars etc.

SERVICES PROVIDED

Altox is a consultative company that provides counselling within:

- REACH and CLP requirements of chemicals and articles (C&L, SDS, ECHA registrations and communication);
- toxicological end ecotoxicological evaluations and reviews;
- biocides (BPR);
- cosmetics (safety assessment, Product Information File, labels, CPNP etc);
- other registration services (eco labelling, national product registers, poison centres);
- general HSE counselling (on-site handling, storage, ATEX etc); and
- Scandinavian regulations (eg MAL codes and order on carcinogenic substances)

CLIENTS

Importers, downstream users and manufactures of chemicals primarily in Europe. Altox also provides counselling to trade organisations, universities and other professionals within the chemical area.

Anthesis Incorporating Caleb

CONTACTS	
Website	www.anthesisgroup.com
E-mail	contact@anthesisgroup.com
Head office	The Stables, Somerset House, Church Road, Tormarton, Badminton, Gloucestershire, UK
Tel/ Fax	+44 (0)1454 269330/ +44 (0)1454 216030
Contact	Stuart Burrow
Ownership	Private company
Locations	Europe (UK, Germany, Sweden, Finland), North America, Asia Pacific
Founded	1994

OVERVIEW

Anthesis-Caleb is a policy and regulatory consultancy that has been active in the field of chemical regulation since 1994, and part of the sustainability specialist Anthesis Group since 2014. Anthesis's clients range from governments, multinational companies and worldwide consortia to small companies with a single substance. Anthesis tailors its support to take account of a client's internal resources in order to maximise the value of our contribution. The company has a considerable track record in sustainable management recently adding a sustainable procurement support service for our clients.

SERVICES PROVIDED

- Consortium and Sief management
- REACH – dossier development for registration, evaluation and authorisation/ restrictions
- OR and TPR services
- CLP compliance management
- SDS authoring and management
- Sustainability strategy development and implementation
- Sustainable procurement
- Supply chain mapping, design and implementation
- Environmental due diligence

CLIENTS

Anthesis-Caleb supports SMEs and large corporations, European and global industry associations and global taskforces across a range of industrial sectors and retailers. Currently the company is OR or TPR for about 20 companies and provides consultancy support for many more. Anthesis-Caleb also supports more than ten REACH consortia as managers and advisors.

arcerion

CONTACTS	
Website	www.arcerion.com
E-mail	info@arcerion.com
Head office	Gabrielenstr 15, 80636 München, Germany
Tel	+49 89 38899797
Fax	+49 89 38899798
Contact	Dr Michael Piber (Managing Director)
Ownership	Private
Locations	Germany
Founded	2009

OVERVIEW

Arcerion is an experienced service and consulting provider aimed to assist companies in complying with chemical control legislation. Our main activities deal with the implementation of European control legislation like the REACH and CLP Regulations, as well as the Seveso II/III-directives. Our regulatory consulting is aimed to support our clients through the regulatory duties and to enable them to maintain a secure market access for their products. Our objective is to facilitate the most efficient and cost-effective implementation of the requirements of all applicable control legislation.
All of our consultants have a solid background in chemical industry, management consulting and academia – combining strong commercial experience and technical expertise. Arcerion's industry specialists have been dealing with the implementation of REACH and CLP since these regulations came into force in 2007, and have been supporting the implications of the Seveso-III directive since 2012.

SERVICES PROVIDED

Arcerion's services include:

- regulatory compliance assessment (including certificates of compliance);
- REACH registrations (including inquires, notifications, Sief representation, completion of data requirements and dossier creation);
- CLP implementation (including authoring of eMSDS, CSA/CSR);
- only representative tasks (pursuant to REACH article 8);
- supply chain management and communication;
- fulfilling task for products that contain SVHC; and
- preparation and submission of applications pursuant to Seveso-directives.

CLIENTS

Arcerion serves more than 100 clients in Europe, North America and Asia across multiple industry sectors including industrial- and petrochemicals, electronics and consumer products.

ARROW REGULATORY

CONTACTS	
Website	www.arrowregulatory.com
E-mail	elicia@arrowregulatory.com
Head office	6th Floor, City Gate East, Toll House Hill, Nottingham, NG1 5FS
Tel	01159 352243
Contact	Dr Sara Kirkham / Dr Carlo Poncipe / Dr Virginia Gretton
Ownership	Limited company
Locations	UK
Founded	2016

OVERVIEW

Arrow Regulatory has extensive knowledge of chemical legislation, particularly in the EU biocidal products Regulation, REACH, CLP and ADR. The company has considerable experience in the development of regulatory strategies, designing test programmes and providing tailored advice, in addition to the preparation of dossiers and risk assessments. Working with both international consortia and global partners Arrow Regulatory has experience in obtaining worldwide registrations for chemicals and biocides. Together the Arrow Regulatory team has over 40 person-years of experience in regulatory compliance during which time we have prepared over 40 REACH lead dossiers and worked on over 30 biocide active substance inclusion dossiers.
Arrow Regulatory Limited is able to offer an integrated and tailored service with our experts adding value by applying their thorough understanding of separate pieces of legislation to each company-specific enquiry. Our aim is to provide a high level of service to all of our clients, irrespective of their size.

SERVICES PROVIDED

Arrow Regulatory services: REACH registration and authorisation; preparation of vulnerability reports for REACH phase-in dossiers; biocides; product authorisation and active substance Union list inclusion; human and environmental risk assessment; Sief and consortium management services; data gap analysis, data evaluation (reliability and acceptance), data-sharing and cost compensation; project management and study monitoring; worldwide product compliance; EU ORR and biocide EU representative functions; Dangerous Goods Safety Advisor (DGSA); CLP, GHS and labelling advice; preparation of safety data sheets (SDS).

CLIENTS

Manufacturers, importers or downstream users of industrial chemicals, biocides, veterinary drugs, plant protection products or cosmetic ingredients.

AYANSAN

CONTACTS	
Website	www.ayansan.com
E-mail	info@ayansan.com
Head office	Ikitelli Org San Bol Hurriyet Bul Saraclar San Sit 5. Blok Kat:2 No:41-42, 34490 Basaksehir/Istanbul, Turkey
Tel/ Fax	+90 (212) 4855059/ +90 (212) 4855087
Contact	Mr Burak Ayan
Ownership	Limited company
Locations	Turkey, Hungary
Founded	1986

OVERVIEW

AYANSAN is a consultancy organisation providing services to the chemical industry on regulatory affairs, chemical management and analysis services complying to Turkish and EU legislation. Our team of experienced professionals supports clients by providing them with the most essential and the best knowledge. AYANSAN keeps up with the changes in the regulations. We pride ourselves on delivering the best quality work, always on time at affordable prices. AYANSAN has been active within the industry on chemical management for several years, successfully satisfying its clients' demands.

SERVICES PROVIDED

- follow up on national and international regulations
- TR&EU CLP and GHS compliance
- E-SDS/SDS/MSDS authoring and management
- Turkish biocidal registration services
- KKDIK (Turkish REACH) services
- Ministry of Health, CLP and chemical notifications
- REACH, SVHC and RoHS compliance
- only representative (REACH, biocidal)
- TR&EU cosmetic responsible person services, CPNP notification
- cosmetic product information file (PIF) and cosmetic safety assessment by qualified safety assessors
- Turkish detergent notifications, laboratory and analysis services

CLIENTS

Our clients include manufacturers, importers and downstream users from all around the world. Clients are included in chemical, pharmaceutical, cosmetic and personal care, medical, plastic, household cleaning, textile, metal, petrochemicals and mineral industry.

CONTACTS	
Website	www.big.be
E-mail	info@big.be
Head office	Technische Schoolstraat 43A, 2440 Geel, Belgium
Tel/Fax	+ 32 14 58 45 47 / +32 14 58 35 16
Contact	Zita Snellinx
Ownership	Non-profit organisation
Locations	Belgium
Founded	1979

OVERVIEW

BIG is an independent information and emergency call centre for dangerous goods (substances, mixtures). Information is gathered on physico-chemical and (eco)toxic properties, as well as regulations on safety, health, environmental protection and transport related to hazardous materials. Based on these data BIG delivers a large number of products and services to clients from diverse sectors, including: industry, emergency services, governmental and inspection services, healthcare and academia.

SERVICES PROVIDED

BIG offers expertise concerning information on hazardous products. For REACH and CLP this means assisting our clients in determining what their role and obligations are, the complete registration process from A to Z (including CSA/CSR), notifications, communication up- and downstream (compilation of ext-SDSs, CLP compliant labels), onsite training in REACH and/or CLP, onsite REACH audits, only representative and third party representative services. BIG also specialises in downstream user CSA/CSR/ES for non-identified uses.

CLIENTS

BIG acts as only representative, third party representative, implementing partner and consultant for European and global players, providing customised services to large international companies and SMEs. Our clients are in many sectors, such as: raw chemicals, fine chemicals, polymers, adhesives, plastics, healthcare, pharmaceuticals, coatings and paints, article manufacturers.

CONTACTS	
Website	www.boeijeconsulting.com
E-mail	boeijeconsulting@telenet.be
Head office	Meersstraat 44, B-9830 Sint-Martens-Latem, Belgium
Tel	+32-468.15.41.08
Contact	Geert Boeije
Ownership	Geert Boeije
Locations	Belgium
Founded	2012

OVERVIEW

Boeije Consulting provides tailor-made solutions in the areas of safety-related product stewardship, regulatory compliance, environmental science and sustainability. Dr Geert Boeije is an environmental engineer with more than 15 years of experience in product stewardship, risk assessment, regulatory affairs, and organisational management.

SERVICES PROVIDED

- Product stewardship: assessment and management of vulnerabilities for chemicals/products; stakeholder engagement; poison control centres interaction; scientific and layman communication; expert panels; overall project management; organisation management.
- Regulatory compliance: strategic advice and execution for: classification and labelling (eg CLP); registration and compliance in the EU (eg REACH, BPR) and beyond; artwork compliance.
- Environmental science and sustainability: risk assessment; lifecycle assessment; holistic review of opportunities / vulnerabilities; claim strategies and claim support; product qualification for eco-labels or other environmental credentialing.

CLIENTS

- Detergents sector: several individual companies (eg CLP classification, artwork compliance), as well industry association (eg product stewardship of laundry capsules; sustainability and hygiene of low temperature washing; consumer research on safety label understanding).
- Metals sector: coordination of REACH strategies for the antimony industry (focusing on data cost sharing); industry association management ad interim.
- Other examples include environmental risk assessment of pesticides; contribution to new EU ecolabel criteria as independent expert.

CONTACTS	
Website	www.bootmanchem.com
E-mail	info@bootmanchem.com
Head office	Diss Business Centre, Diss, Norfolk, IP21 4HD, UK
Tel	+44 (0)1379 640534
Contact	Chris Lewis
Ownership	Limited company
Locations	UK
Founded	1994

OVERVIEW

Bootman Chemical Safety Ltd is an established UK-based consultancy, offering a wide range of scientific and regulatory services to support our clients through the process of chemical safety assessment. We have in-depth knowledge of REACH, CLP and other chemical regulations, in combination with expertise in industrial toxicology and risk assessment to serve a worldwide client base.

SERVICES PROVIDED

We are focused on providing the best service to our clients whatever the size of project. REACH forms a major part of our work and highlights a number (but not all) of the areas where we provide expertise:

- registration strategy, dossier preparation, prior-registration inquiries, PPORD application, chemical safety assessment including exposure assessments and risk characterisation, only representative/third party representative services, SVHC product statements, study monitoring, support on classification and labelling, safety data sheet authoring or review, preparation of CLP notifications and the list continues!
- we also offer technical support to major Sief/consortia on behalf of clients or as an independent contractor, discussing strategies for registration or evaluation; literature searches and other critical data reviews are also undertaken.

CLIENTS

Client confidentiality precludes our naming them, but we serve a wide range from SMEs to global corporations. All our clients expect high-quality service and this can be provided to you.

CONTACTS	
Website	www.chem-academy.com
E-mail	info@chem-academy.com
Head office	Hauptstrasse 54, CH-8280 Kreuzlingen, Switzerland
Tel	+41 71 677 8700
Fax	+41 71 677 8701
Contact	Dr Bjoern Nehls
Ownership	Private company
Locations	Switzerland, Germany
Founded	2003

OVERVIEW

The Chem-Academy organises high-class conferences, congresses and professional training courses covering topical news from the chemical industry. The events distinguish by practical orientation and premium speakers from relevant authorities, science and industry. You will meet executives from leading companies of the chemical and pharmaceutical industry such as manufacturers, distributors, downstream users and service providers.

SERVICES PROVIDED

Conferences and courses on regulatory topics, both for domestic and international target groups.

CLIENTS

A wide variety of clients and delegates from industry, authorities, and service providers.

chemtrac

CONTACTS	
Website	www.chemtracglobal.com
E-mail	info@chemtracglobal.com
Head office	Lancaster Environment Centre, Lancaster University, Lancaster LA1 4YQ, UK
Tel/ Fax	+44 (0) 1524 510278/ +44 (0) 1524 510588
Contact	Anna Holden
Ownership	Privately owned
Locations	UK, Italy, US, Japan, China
Founded	2007

OVERVIEW

chemtrac® is a complete online solution for chemicals management, regulatory intelligence, specialist training, custom IT development and hands-on support services.

SERVICES PROVIDED

Comprehensive database with essential and key information on more than 230,000 chemical substances.
Global regulatory obligations – comprehensive and concise overview of more than 500 regulations and lists, including listings on governmental, NGO and sector lists. **Manage business risk and compliance** – view and cross-reference information relating to chemical's regulatory status, hazard classification, common uses and chemical grouping. **Current and informed** – actively reviewed and managed by our in-house regulatory experts. **Alerts** – control and monitor the substances and regulations of specific interest to you and to stay on top of the latest amendments by receiving systematic updates in a clear and concise form into your mailbox. **Minimise product risk** – identify at-risk product and optimise testing strategies. **Share your knowledge** – share and store your information, lists and files to enhance internal communication. **Regulatory advice service** – access the expertise of our team of regulatory consultants, chemists, environmental scientists and toxicologists. **On-demand software development** – complex applications and systems integration requirements across various chemical management and regulatory topics.

CLIENTS

Global manufacturers, distributors and retailers along with multiple trade associations and government bodies from across all major industry sectors.

CHYMEIA

CONTACTS	
Website	www.chymeia.com
E-mail	info@chymeia.com
Head office	Universitetsparken 2, DK – 4000 Roskilde, Denmark
Tel	+45 72 40 16 22
Contact	Lars Bugge
Ownership	Private, limited company
Locations	Denmark
Founded	2006

OVERVIEW

CHYMEIA ApS' core business is software solutions for complying with the chemical legislation in an efficient and user-friendly way. CHYMEIA ApS is specialised in SDS-authoring with a very high degree of automation and a built-in CLP calculator. Our main product is the chemical management software AlphaOmega, which is an advanced solution for generating and updating SDS, chemical safety documents and inventory labels.

SERVICES PROVIDED

The **SDS-authoring software AlphaOmega** has an integrated CLP calculator that – combined with an intelligent phrase library – offers the user a unique automated SDS authoring process. In 2010, CHYMEIA ApS was among the world's first companies to introduce a completely auto-mated CLP calculator. The calculation engine was developed by CHYMEIA ApS and was initially tested in cooperation with the Danish Environmental Protection Agency, for which CHYMEIA ApS also developed a version of the CLP calculator. **AlphaOmega** includes comprehensive chemical management functions, control functions and smart update functions. SDS output is available in more than 25 languages. **AlphaOmega** can also be used for authoring of chemical safety documents like APB (DK), COSHH (EN), Skyddsblad (SE) Betriebsanweisungen (DE) etc. CHYMEIA also provides consultancy including lectures and seminars on chemical legislations.

CLIENTS

CHYMEIA ApS serves a wide range of companies, industries and sectors. AlphaOmega is used by the chemical industry, the pharmaceutical industry, schools, research facilities and manufacturing including paint and coating, flavours and fragrance, detergents, adhesive and sealants, ink and colours etc.

CSR

CONTACTS	
Website	www.csregulatory.com
E-mail	helpline@csregulatory.com
Head office	The Old Courthouse, St Peters Churchyard, Derby, DE1 1NN, UK
Tel/Fax	+44 1332380692/ +44 1332380692
Contact	Steven Green, Craig Deegan
Ownership	Privately owned
Locations	UK and Republic of Ireland with a global network of expert technical providers
Founded	2007

OVERVIEW

CS Regulatory Ltd is an independent, privately owned organisation accredited to ISO 9001:2015 successfully providing regulatory assistance to suppliers of industrial chemicals throughout the world. Staff at CS Regulatory offer a combined experience of more than 50 years of professional experience within the industrial environment; we have the expertise to assist you with whatever global chemical regulation requirements you may have. With a network of strategic partnerships throughout the globe we can assist with EU registration for REACH and CLP purposes, worldwide notification of chemicals, representation of clients within Europe, production of associated chemical safety documents, liaison with authorities and product defence, advice on testing strategies and project management of data packages, acquisition of existing data and product stewardship.

SERVICES PROVIDED

- REACH and CLP
- Worldwide notification of chemicals
- Representation of clients within Europe
- Production of associated chemical safety documents (MSDS, chemical labelling, hazard assessment, etc)
- Liaison with authorities and product defence
- Advice on testing strategies, including administrating and project management of data packages
- Acquisition of existing data
- DGSA Services

CLIENTS

A broad range of clients, from small niche suppliers to global multinationals with customers throughout the world.

DR. MACH
CHEMICAL COMPLIANCE & COMPETENCE

CONTACTS	
Website	www.mach-chemguide.com
E-mail	info@mach-chemguide.com
Head office	Boernsener Str 16f, 21039 Hamburg-Boernsen, Germany
Tel/ Fax	+49 40 729 10 933/ +49 40 729 10 934
Contact	Dr Bettina Mach
Ownership	Private
Locations	Germany
Founded	2011

OVERVIEW

We guide you through REACH and CLP and the cosmetic Regulation 1223/2009. We rely on more than 20 years of experience in product safety in the chemical and cosmetic industry.

SERVICES PROVIDED

- identify your obligations
- prepare late preregistrations
- prepare Echa inquiries
- prepare dossiers in Iuclid 6
- prepare all kinds of notifications
- represent your interests in Siefs and consortia
- monitor toxicological studies
- advise on classification and labelling and prepare C&L notifications
- prepare product notifications according to Art 45 CLP in several EU countries
- conduct safety assessments of raw materials and products and prepare cosmetic product safety reports according to EC 1223/2009

CLIENTS

DR MACH Chemical Compliance and Competence focuses on the European chemical and cosmetic industry: manufacturers, importers, distributors and downstream users of chemicals as well as manufacturers and importers of cosmetic products. The clients are both SMEs and large companies.

ecomatters

CONTACTS	
Website	www.ecomatters.nl
E-mail	info@ecomatters.nl
Head office	Museumlaan 2, 3581 HK Utrecht, The Netherlands
Tel	+31 (0)6 26 92 77 24
Contact	Johanne van Maurik
Ownership	Private company
Locations	The Netherlands: Utrecht; Spain: Barcelona
Founded	2009

OVERVIEW

Expert answers to your regulatory questions. That is what we stand for. Our team of regulatory consultants and toxicologists has extensive experience in the fields of REACH, EU-GHS, BPR and the cosmetics Regulation. We are committed to providing highly flexible support, customised to fit your needs.

SERVICES PROVIDED

We offer strategic and technical support in the areas of:

- REACH: (pre-)registrations, (Iuclid) dossiers, hazard and exposure assessment, Qsar analysis, read across, test plan preparation, study monitoring and Sief management;
- safety data sheets (SDSs): cost-effective SDSs in all European languages;
- EU-GHS / CLP: hazard classification, product labelling in all European languages and assistance with product (re)formulation;
- biocidal products: authorisation application, (Iuclid) dossiers, test plan preparation, study monitoring and R4BP 3 support;
- cosmetic products: product safety assessment, assistance in compiling product information files and product notification; and
- workshops and training: introductory and extensive trainings centred around REACH, CLP and SDS authoring.

CLIENTS

Among our clients are chemical companies, manufacturers of cosmetics, biocides and cleaning products, companies that provide water and environmental services and retailers. We work both with large multinational companies and SMEs.

enviresearch

CONTACTS	
Website	www.enviresearch.com
E-mail	info@enviresearch.com
Head office	34 Grainger Park Road, Newcastle upon Tyne, NE4 8RY, UK
Tel	+ 44 (0) 191 243 0687
Contact	James Garratt
Ownership	Private
Founded	2001

OVERVIEW

Enviresearch provide regulatory and environmental risk assessment services across a range of chemical sectors, including, plant protection products, biocides, REACH, human and veterinary medicines. While we are experts in regulatory services, from complete dossiers to managing efficacy trials, we specialise in environmental fate and ecotoxicology, from lower-tier modelling to landscape risk assessments and the evaluations of potential endocrine disrupting chemicals.

SERVICES PROVIDED

Regulatory advice and support: dossier preparation (dRR format and Iuclid) and submission, technical equivalence, study monitoring and coordination, representation in Sief/consortiums, only representation for non-EU companies, preparation of chemical safety reports (CSR) and SDS, and labelling according to GHS/CLP.
Environmental fate: higher-tier approaches for refined assessments, eg, spatial assessments and probabilistic modelling, modelling for core assessments and national authorisations, kinetic evaluations, analysis of field and semi-field data, relevance and reliability reviews of scientific literature.
Ecotoxicity and environmental risk assessments: higher-tier approaches eg, bespoke testing strategies such as pulsed exposure, ecological and TK/TD modelling, standard assessments for all groups of organisms, relevance and reliability reviews, assessment of potential endocrine disruptors, environmental assessments for veterinary and human medicines.
Efficacy: design and commission of trial programmes, preparation of BADs, comparative assessments.

CLIENTS

European and worldwide SMEs and large organisations from across the chemical industry.

eSpheres CLOUD HSE

CONTACTS	
Website	www.espheres.com
E-mail	charlotte.crauwels@espheres.com
Head office	Pères Blancs Street 4, 1040 Etterbeek, Brussels, Belgium
Tel/ Fax	+ 32 (0)2 740 43 36/ + 32 (0)2 740 43 87
Contact	Charlotte Crauwels
Ownership	Private
Locations	Belgium, France, Finland, Germany, The Netherlands
Founded	November 2011

OVERVIEW

eSpheres, HSE Information management consultants, founded in 2011 as a Solvay spin-out. eSpheres is a global leader in delivering cloud health, safety, environment (HSE) software solutions to organisations worldwide. Our in-depth IT solutions and HSE support services help industrial companies in improving their management of safety, industrial hygiene and occupational health processes.

SERVICES PROVIDED

SAP EHS Consulting: eSpheres experts are readily available to help companies with complex SAP EHS issues. eSpheres supports SAP EHS projects and strengthens corporate EHS and IT departments by efficiently providing them with adequate resources to lead and implement SAP EHS into any organisation. SAP Netweaver and SAP Fiori architecture and implementation. **Consultancy services expertise:** project management, implementation and maintenance for product safety and safety datasheet management; incident and accident, occupational health management; safety datasheet distribution; global label management; dangerous goods, conflict minerals and chemical management. **eSpheres Compliant Chemicals** software for chemicals management and (vendor) SDS management; substances and product inventory management, regulatory compliance checks for SVHC's and other regulations; incident/accident management; multilingual safety working instruction cards, risk management for workplaces.

CLIENTS

Team members have been working for a large number of industries and segments, like (petro)chemicals, pharmaceuticals, mining and minerals, steel and alloys, pulp and paper, but also at downstream users like polymers and polymer transformation, electronic, semiconductor, cosmetic, automotive industry.

EUPHOR Your Global Compliance Platform

CONTACTS	
Website	www.euphoreach.com
E-mail	info@euphoreach.com
Head office	2279 NJ-33, Suite 501, Hamilton, NJ 08690, US
Tel	+1 609 631 0054 ext 504
Contact	Ankur Saxena
Ownership	developed by xTensegrity
Locations	USA, Switzerland, India
Founded	1997

OVERVIEW

EUPHOR is the only software solution dedicated to the management of global chemical compliance. Co-developed with product stewardship experts, EUPHOR is designed to empower compliance teams and help them collaborate, manage and track their global compliance projects using a central and intuitive platform.

SERVICES PROVIDED

EUPHOR is an automation and collaboration platform which helps users ensure global compliance with peace of mind and confidently secure business continuity in regulated markets:

- management of a substance compliance lifecycle, pre and post registration;
- instant tracking with real-time dashboards and custom queries;
- single and central view of all compliance programmes;
- improved collaboration and accountability among internal and external teams;
- comprehensive audit trails;
- reusability of data across regulatory projects.

CLIENTS

Elementis, BASF, Merck, EMD, Bard, Celgene, LabCorp … EUPHOR helps a wide range of clients, from chemical manufacturing companies to consulting firms and consortia.
"EUPHOR has been an essential management and collaboration solution, helping us proactively manage our global registration projects."
"By automating administrative and reporting tasks, we are able to save time, focus on higher-level activities and be confident nothing gets missed."
"EUPHOR is like an app, very easy to set-up and requires no training to use the platform."

Eurideas LANGUAGE EXPERTS

CONTACTS	
Website	www.eurideastranslation.com
E-mail	translation@eurideastranslation.com
Head office	523 Avenue Louise, 1050 Brussels, Belgium
Tel	+32 (0)2 669 7701 / +32 (0)2 808 4406 / +36 1 505 8840
Fax	+32 (0)2 627 5655
Contact	Kristina Bitvai
Ownership	Private company
Locations	Belgium, Hungary
Founded	2007

OVERVIEW

Eurideas Language Experts provides professional translation and interpretation services. We specialise in chemical, technical, medical translations, as well as in other fields such as EU legislation, law, environment, health and many more. Our native speaker chemical translators are experts of the REACH regulation and other related EU, international and local legislations. We have great experience in translating SDSs and other regulatory documents. We have developed our own unique methodology through years of translating REACH documents, and are therefore able to offer 60% discount for the repetitions.

SERVICES PROVIDED

We provide translation, certified translation, proofreading, editing services in all EU languages, in many Asian, African and Latin American languages. The translations are always done by a native speaker translator and proofread by a second native speaker translator. We also carry out a thorough quality check on the ready translation.

CLIENTS

We have worked on REACH, BPR and other chemical related projects for Cefic, REACHCentrum, ISOPA, EuPC, Glencore International Imports, Rio Tinto, Wintershall, Molymet, the International Molybdenum Association, the International Lead Association, the Nickel Institute, Syngenta, DonauChem, Euromines, Chemtopia, Tokyo Chemical Industry, and many more.

GROW SMART SOLUTIONS

CONTACTS	
Website	www.produsebiocide.ro
E-mail	office@produsebiocide.ro
Head office	37 Salva St, 1st District, Bucharest, Romania
Tel	+40 752 303 453/ +4 031 105 37 98
Fax	+4 031 105 38 00
Contact	Simona ILIE
Ownership	Private company
Locations	Romania, Central and Eastern Europe. Other locations: Bulgaria, Hungary, Czech Republic, Slovakia, Poland, Italy, Moldavia
Founded	2011

OVERVIEW

Grow SMART Solutions is a European multi-services firm and the first company in Romania offering specific services dedicated to biocides. It brings together professional and partners with years of practical experience, truly dedicated to the client's needs. We offer a unique mix of regulatory affairs and commercial marketing insights, so that our clients do not have to worry about the labyrinth of bureaucracy. Our results, productivity, fast timing and international network make us a reliable service provider to be considered as first choice when outsourcing regulatory affairs.

SERVICES PROVIDED

- Biocides registration: national registration of biocides from all product types; authorisation and mutual recognition; dossier preparation; and R4BP, BPR, REACH, CLP, SDS and label compliance.
- Consultancy: compliance with the EU Regulation and Directives for placing chemicals on the Romanian/European market; support for biocides, medical devices, detergents, cosmetics, pest control, antifouling, preservatives, dangerous goods, etc; development of registration strategies and post registration support; and communication liaison with the competent authorities.
- Business representation: developing personalised support in building entry-strategy on the Romanian market; representation, sales support, distribution building and product marketing; and we facilitate the products' path from the factory to Romanian and other European markets, both FMCG and B2B.

CLIENTS

Our clients are primarily large and medium-size international and/or global businesses focused on chemicals' production. They have branches and operations in Romania, or they are seeking representation for their operation in Romanian and Central and Eastern Europe.

I+K

CONTACTS	
Website	www.i-k.ch, www.compliance-footprint.com
E-mail	weggimann@i-k.ch, hdiener@i-k.ch
Head office	Hadlaubstrasse 154, CH-8006, Zurich, Switzerland
Tel/ Fax	+41 44 364 22 33/ +41 44 363 22 36
Contact	Dr Walter Eggimann, Dr Heinz Diener
Ownership	Four board members
Locations	Switzerland
Founded	1993

OVERVIEW

I+K AG, in partnership with Compliance-Footprint AG provides:
BEST IN COMPLIANCE SOLUTIONS with a focus on SDS, label, working instructions, biocide registrations, HS tariff code management.
DEVELOPS and provides corresponding SOFTWARE, combining core competency in REGULATORY management with modern cloud/mobile IT.
SERVICES provided is the result of professional expertise in both CHEMISTRY and IT.
OPERATIONAL experience spans from large size global corporations down to middle/ small size companies.
I+K AG combines with corresponding partners, fit to purpose, to synergy and innovation.

SERVICES PROVIDED

- Safin.net and Trade.net, as web-based software, to manage SDS, label, HS code.
- Solutions to achieve regulatory compliance with positive market impact, at low operational cost, driven by modern data processing capabilities:
  - i) expert system functionality to facilitate GHS/CLP, transport and HS classification, including control in substance import/export restrictions.
  - ii) assistance to compose, to translate and to deliver SDSs.
  - iii) to allow for XML based SDS transfer.
  - iv) to deliver customised labels, including communication via integrated QR code.
  - v) enabling data interface to connect to enterprise systems, or to facilitate biocide registration in accordance with the Swiss biocide VBP directives.
- Compliance certification, in partnership with compliance footprint AG.

CLIENTS

Operational experience with international companies, covering some 35 languages on SDS, label, working instruction. Numerous smaller size companies to delivery on demand.

INFOTOX

CONTACTS	
Website	www.infotox.pt
E-mail	info@infotox.pt
Head office	INFOTOX, Lda, Rua de Moscavide 4.28.02B-7B, Parque das Nações, 1990-160, Lisbon, Portugal
Tel	+ 351 218 063 659
Contact	Elsa Casimiro
Ownership	Private company
Locations	Portugal, UK and India
Founded	2004

OVERVIEW

Originally, founded in 2004, INFOTOX is a specialist consulting company providing toxicology, human health and environmental risk assessment and advisory services to the private and public sector.

SERVICES PROVIDED

Our regulatory services include expert support for biocidal products Regulation (BPR) and cosmetic products Regulation, REACH, CLP/GHS, in terms of:

- dossier data gap analysis;
- luclid dossier preparation for BPR and REACH;
- electronic submissions and updates (CPNP, R4BP and REACH-IT);
- toxicological reviews and expert support (including Qsar);
- design of testing programmes (efficacy tests and (eco)toxicity);
- safety data sheets production, review, and translation;
- reviewing and updating marketing/efficacy claims and product label;
- guidance on setting up a post-market surveillance programme;
- BPR specific services: transitional period biocidal product registrations in Portugal; product assessment report (PAR); consortia for biocidal products; Article 95 listing of active substances;
- REACH specific services: only representative services; production of chemical safety reports (CSR);
- Cosmetic products specific services: responsible person services; Pif review and compilation; cosmetic product safety reports (CPSR);

We also provide a wide range of environmental health services including health impact studies for EIA, soil clean-up and climate change projects.

CLIENTS

Our clients include regulators, professional organisations, multinational companies and SMEs.

REACH SUPPORT NETWORK JongeriusConsult

CONTACTS	
Website	www.jongeriusconsult.com www.reachsupportnetwork.eu
E-mail	info@jongeriusconsult.com
Head office	Begijnenhof 26, 6584 CW Molenhoek, the Netherlands
Tel	+31 615962071
Contact	Onno Jongerius
Ownership	Private company
Locations	Netherlands
Founded	2009

OVERVIEW

Jongerius Consult BV contributes to an efficient and effective implementation of EU chemicals legislation (REACH and CLP) by companies leading to safe use of chemical products in the supply chain and at the workplace.

- Check www.jongeriusconsult.com/vision-mission.

The Reach Support Network provides (SME) companies online access to ready-to-use and practical REACH and CLP compliance solutions for fair prices

- Join our REACH Bootcamp to learn REACH for your business case in one day!
- Become member for free to remain informed and to obtain a small welcome gift.

SERVICES PROVIDED

Are you a chemical manufacturer, importer, formulator, distributor and/or user of chemical products in the EU and are you looking for strategic/practical support to efficiently comply with the EU chemicals legislation (REACH and CLP)?

- Check our website for practical support and project references
- Contact me to discuss your specific business case in a 30 minutes free call: info@jongeriusconsult.com.

CLIENTS

Our clients are companies and sectors that want to deal efficiently with REACH and related legislation up to safe use of chemicals and in alignment with their business needs. We are proud of our partners, satisfied customers and the many satisfied participants who attended our REACH compliance training programme. We'll continue to focus on providing added value and making REACH and CLP work for industry.

Kerona Scientific Ltd.

CONTACTS	
Website	www.kerona.ie
E-mail	info@kerona.ie
Head office	30 Thomas Hand Street, Skerries, K34 RX24, Co Dublin, Ireland
Tel	0035318495284
Contact	Dr Irene McGrath
Ownership	Private company
Locations	Ireland and Spain
Founded	September 2014

OVERVIEW

Formed in 2014, Kerona Scientific is an award winning regulatory consultancy based in Skerries, Co Dublin, Ireland with an office in Madrid, Spain. With experience amassed over 26 years and spanning all areas from biocides (Regulation EU (No) 528/2012) to plant protection products (Regulation (EC) No 1107/2009) we are positioned to assist you with all aspects of your European Regulatory needs.

SERVICES PROVIDED

We provide strategic regulatory advice to clients on the project management of new product introduction (NPI) programmes, from concept through to marketing and the optimization of existing portfolios.
As a key European biocidal consultancy, we provide services from dossier preparation to risk assessments for Annex I inclusion and national Member State applications.
We specialise in providing regulatory services to the plant protection sector which includes but is not limited to data matching evaluations, technical equivalence, study commissioning, preparation of full zonal dossiers and national addenda, AIR management and submissions. We manage projects for approval of fertilisers, plant biostimulants and agronomic additives at European and Member State level.
We also provide REACH services and assistance with classification and labelling.

CLIENTS

We are proud to work with all of our clients and delighted that four of the top ten worldwide agrochemical companies have chosen to work with us. Our client list includes leading names in the proprietary and generic plant protection, biocides, fertilisers, plant biostimulants and biopesticide industries.

LAUS

CONTACTS	
Website	www.laus.de
E-mail	info@laus.de
Head office	Auf der Schafweide 20, 67489 Kirrweiler, Germany
Tel/ Fax	+49 6321 96299 0/ +49 6321 96299 29
Contact	Ms Dr Swenja Dröge, Mr Martin Schaaf
Ownership	Dr Dietmar Kuhn, Managing Director
Locations	Germany, France, US
Founded	1991

OVERVIEW

LAUS is a young, dynamic company of more than 50 committed specialists, but 'young' doesn't mean that we are inexperienced. We are GLP certified since 1999 and have performed ecotox [OECD 201, 202, 203] and biodegradation studies [OECD 301] for 20 years. Your satisfaction is a matter of intense personal and professional pride to all of our team. Because we are a small team, you will have direct access to all of us: from the MD through to the people delivering the work in our labs. Our strength is prompt decisions making in order to move the project to a successful conclusion. The implementation of new test strategies as LuSens, DPRA and/ or adaptation of guidelines: OECD 209 (according to new guideline) demonstrate our innovative approach to our work.

SERVICES PROVIDED

LAUS comes first for... physico-chemical properties / *in vitro* toxicology / mutagenicity and genotoxicity / biodegradability / analytical services / ecotoxiology...
Better LAUS than never

CLIENTS

LAUS provides testing for various purposes:

- chemicals according to REACH, CLP and GHS;
- biocides and biocidal products according to BPD;
- agrochemicals and biopesticides according to BPR;
- medical devices for human and veterinarian use and cosmetic products; and
- food additives and food supplements

LINMARK CONSULTING

CONTACTS	
Website	www.linmarkconsulting.com
E-mail	martin.richards@linmarkconsulting.com
Head office	Bernoullistrasse 20, CH-4056 Basel, Switzerland
Tel	+41 79 500 9719
Contact	Dr Martin G Richards
Ownership	Private company
Locations	Switzerland, UK
Founded	2007

OVERVIEW

Linmark Consulting is a consulting and service company engaged in regulatory affairs, toxicology, interim management services, advocacy and communications for the chemical and life sciences industries. Linmark Consulting is headquartered in Basel, Switzerland. Its UK subsidiary, Linmark Consulting Europe Ltd, offers only representative (OR) services under REACH, for importers into Europe.

SERVICES PROVIDED

Particular skills in generating new business and protecting client businesses through regulatory knowledge and practice, stakeholder analysis, problem-solving, global network and communications with diverse stakeholders including value chain, government authorities and NGOs. Offerings based on over 30 years' senior operational experience in regulatory affairs management, consultancy and product development functions in multinational chemical, agricultural biotechnology and biopharma companies in UK, USA and Switzerland. Commissioning mammalian and ecotoxicology studies. REACH OR and third party representation. Key strengths in consortium management, REACH, global chemical regulation, reputation management, provision of interim managers and advocacy.

CLIENTS

Client confidentiality is guaranteed. Recent contracts include management of six REACH consortia, where 2010 and 2013 registration deadlines were successfully met. Consortia support continues for REACH registration, authorisation and other objectives. Linmark Consulting has successfully managed global and EU chemical advocacy programmes for industrial chemical and biocide clients. Global and smaller companies in chemicals, agriculture and life sciences represented in EU and Switzerland.

LKC Switzerland Ltd
Registration and Development

CONTACTS	
Website	www.LKC-ltd.com
E-mail	LKC@lkc-ltd.com
Head office	Postfach 167, Hauptstrasse, Fuellinsdorf, Switzerland
Tel/ Fax	+41 61 906 8500 / +41 61 906 8509
Contact	Dr David Kane
Ownership	Private company
Locations	Switzerland, UK
Founded	2001

OVERVIEW
LKC provides European registration and development services to the international chemical and biochemical industry. The LKC team is multi-disciplined, offering both technical and regulatory experience, project management proficiency and strategy planning expertise. Specialty chemical manufacturing clients benefit from our range of regulatory services to achieve the successful registration of products for crop protection, biocides, veterinary medicines and industrial chemicals.

SERVICES PROVIDED
Regulatory: data gap analysis, data evaluation, design, contract and management of data requirements including higher tier studies, chemistry, analytical methodology, mammalian toxicology, ecotoxicology, environmental fate and efficacy studies, PEC-reports and GLP multi-site residue studies. Conducting risk assessments and modelling for dietary, human and environmental exposures.
Dossiers: for active substance submissions for Annex I inclusion, product dossiers for national registrations, provisional and union authorisations and mutual recognition. CADDY.XML dossiers, luclid dossiers, re-registrations, renewals, label extensions, setting EU import tolerances/MRL's, REACH, CLP and JMAFF (METI) dossiers.
Technical support: pre and post submission discussion with authorities, negotiation communications, data package compensation for data-sharing and product registration maintenance and defence.

CLIENTS
LKC's clients are specialty chemical and biochemical manufacturers who benefit from technical support in market sectors that include crop protection, biocides, animal health and general chemicals.

mediator.as

CONTACTS	
Website	www.mediator.as
E-mail	info@mediator.as
Head office	mediator A/S, Centervej 2 E, DK-6000 Kolding
Tel	+45 75 54 08 24
Contact	Jens Haugaard
Ownership	Jens Haugaard
Locations	Denmark
Founded	2011

OVERVIEW
mediator A/S is a consultant company where all consultants are specialised in working with chemicals impact on human beings and the environment. We take pride in knowing the businesses of our customers and the challenges they face and work alongside authorities to deliver practice-oriented solutions for our customers.

SERVICES PROVIDED
We give expert counselling about formation of rules and handling of chemicals and their impact on their surroundings. Our services range from the production and update of safety data sheets to assistance on specific chemical substances and products. Furthermore, we offer regulatory advice concerning product launches abroad: we give advice on chemicals, cosmetics, biocides, electrical items etc. In terms of geography, we cover the EU, EAA (EU + Iceland, Lichtenstein and Norway) and Latin America. We know the industry and we provide regulatory lists for a large number of customers every month to keep them up to date on their area.

CLIENTS
We assist more than 500 active customers from both within Denmark, but also from all over Europe and abroad. We advice both the entrepreneur in the upstart of business and serve as specialists for large scale companies.

OCI

CONTACTS	
Website	www.oci.net.cn
E-mail	david.chang@oci.net.cn
Head office	Room 2006, Moma Towers, Chaoyang North Street No.199, Chaoyang District, Beijing (100026), China
Tel	+86-10-68091928 extn 8008
Fax	+86-10-68091928 extn 8018
Contact	David Chang, Cissy Zhou, Wendy Sun
Ownership	Licensed company
Locations	China Beijing, Shanghai, Guangzhou
Founded	2006-06

OVERVIEW
OCI (北京正智远东化工) is one of the earliest and leading legal regulatory services providers in China, with more than 3,000 successful registration approvals in chemicals, food relevant, cosmetics and new ingredients, fertilisers; especially in aspects of FCMs, NCI, and hazardous chemicals registration.
OCI **IS** a consulting agent and compliance service provider, it **IS NOT** a conference organiser or media publisher.

SERVICES PROVIDED
- Regulatory strategic assessment in China and the Far East
- Compliance check / support and consulting assistance
- Data gap analysis / update / SDS-GHS authoring,
- Regulatory affairs news service presentation
- Client site and emergent RA backup
- Authorities' liaison support here or there

CLIENTS
DSM, Ashland, KANEKA, Meiwa, Degussa, etc.

Peter Fisk Associates

CONTACTS	
Website	www.ecotoxchem.co.uk
E-mail	peter.fisk@pfagroup.eu
Head office	Saxon House, John Roberts Business Park, Pean Hill, Whitstable, Kent, CT5 3BJ, UK
Tel	+44 (0)1227 470901 and +44 (0)1227 765117
Contact	Dr Peter Fisk
Ownership	Limited company
Locations	UK
Founded	Originally founded in 1995. Founded as a limited company in 2006

OVERVIEW
Peter Fisk Associates offers specialist services to industry and regulatory organisations in the fields of environmental chemistry, toxicology and risk assessment. We bring expertise and high-level experience to chemical consultancy, tailored to our clients' needs. We collaborate closely with our clients to harness their insights into their own products.

SERVICES PROVIDED
PFA provides a wide range of commercial and technical services associated with chemical safety and regulation, based on over 20 years' experience. Our services include: chemistry, toxicology, ecotoxicology, quantitative structure-activity relationships, exposure assessment and modelling, risk management options, consortium management, supply chain analysis and authorisation support. We apply this range of expertise to support industrial and regulatory clients, within and beyond REACH: in all aspects of REACH and CLP requirements (dossier development and chemical safety assessment for more than 150 substances in Phases 1 and 2); socio-economic analysis, biocidal products Regulation, cosmetics, plant protection products, food safety and other areas of chemical regulation and voluntary assessment. We can collaborate with reliable expert partners to provide complementary services. We have successfully provided secretariat services, including REACH consortium management and Sief communications. We also offer training in our areas of expertise, including custom-built courses tailored to our clients' individual needs.

CLIENTS
A wide variety of industrial clients including chemical manufacturers' consortia from several sectors, downstream users of chemicals and regulatory authorities.

PFA – Brussels

CONTACTS	
Website	www.pfa-brussels.eu
E-mail	peter.fisk@pfagroup.eu
Head office	Rue Abbé Cuypers 3, 1040 Etterbeek, Brussels, Belgium
Tel	[+32] 02 741 2444
Contact	Dr Peter Fisk
Ownership	SPRL
Locations	Belgium
Founded	2016

OVERVIEW

PFA-Brussels is a scientific consultancy that provides technical and policy support on the chemicals. We work with chemical manufacturers and importers, downstream users and related manufacturing industries, as well as regulatory authorities and government organisations. We offer scientific/technical support and advice on: the regulatory process for prioritisation and authorisation of substances of concern, the regulatory and political landscape within which scientific information on chemical risks is interpreted, the robustness of regulatory challenges, and compliance with REACH, and EU legislation on biocides and cosmetics.

SERVICES PROVIDED

As a wholly owned subsidiary of Peter Fisk Associates Limited, PFA-Brussels SPRL works in collaboration with PFA Ltd on REACH and other regulatory work but focuses on:

- strategic needs within REACH risk management; authorisation, restriction, RMO and evaluation. As experts on chemical hazard, risk and control measures we can provide a comprehensive service to identify potential substances of high concern and deliver successful authorisation applications;
- chemicals policy – development of policy and strategy on substances; product stewardship, advantages and drawbacks of proposals. Our in-depth knowledge of the industry means we can offer clients a solid analysis and understanding of the regulatory framework within which chemicals and products are made and marketed;
- appeals / awareness. If you are facing legislation challenges, we have the experience and scientific expertise to work with you and your legal representatives to optimise a successful outcome; and
- strategy for regulatory compliance. We can provide you with a full service to meet the requirements of chemical regulations, including REACH, EU cosmetics and biocides

Prefusion

CONTACTS	
Website	www.prefusion.co.uk
E-mail	geoff.legrys@prefusion.co.uk
Head office	32 Scampton Close, Bicester, OX26 4FF, UK
Tel	+44 (0)1869 354154
Contact	Professor Geoff Le Grys
Ownership	Limited Liability Partnership
Locations	UK, China
Founded	2010

OVERVIEW

Prefusion provides chemical regulation and strategy consulting services. We are skilled at helping prepare compliance documents, their submission and advocacy for companies to the EU market, and supporting international companies to comply with Chinese regulations. We have extensive experience working with a number of industry sectors and government policy makers in EU and China. Our outstanding capability lies in sustainability and market strategy, supply chain and chemicals management.

SERVICES PROVIDED

We specialise in chemical regulation for market entry into the EU and China. These include, in the EU: REACH, CLP, BPR, PPP, medicinal products regulation, endocrine disrupting chemicals, cosmetic products regulation, novel foods, health / nutritional claims, RoHS and eco-labels; in China, new chemical registration (China REACH); hazardous chemical registration; disinfectants regulation, food safety and health related regulations. We also provide regulatory foresight and policy interpretation. Our featured services include: 1) intelligent testing strategies – helping design environmental and health testing strategies that save money and meet regulatory requirements; 2) hazard and risk assessments in the environment and workplace – PBT, CMR, exposure assessments and chemical safety reports; 3) representation and advocacy – representing clients to REACH and other consortia; and 4) substances of very high concern (SVHCs) advocacy and supply chain management.

CLIENTS

Industry, NGO and government clients in a wide range of sectors, such as industrial chemicals; energy; agrochemicals; pharmaceuticals; medical devices; veterinary medicines; personal care products; pesticides; biocides / disinfectants; water and sewage treatment; food and ingredients; electronic chemicals; construction materials and consumer products.

REACH Orphan Substances Consortium ROSC

CONTACTS	
Website	www.ROSconsortium.eu
E-mail	karine@ROSconsortium.eu
Head office	Peggersstraat 25, 2340 Antwerp (Beerse), Belgium
Tel/Fax	+32 3 297 60 92/ +32 3 297 60 92
Contact	Karine Van de Velde
Ownership	Private
Locations	Belgium
Founded	21/05/2015

OVERVIEW

The REACH Orphan Substances Consortium (ROSC) delivers an all-included REACH package (including authorisations). We provide potential registrants the **unique** opportunity to register your 'orphan'substance (metal, organic and inorganic) under one **overarching horizontal consortium** thereby minimising cost and effort. Orphan substances have no or limited data and no existing organisation working on them. **ROSC makes REACH manageable, also for small SMEs and for multinationals that don't want to become the lead registrant for the small tonnage substances they still need to register.**

SERVICES PROVIDED

Registrations: choose from our strategic, technical and administrative services: consortium formation/management, Sief communication, data and test gap analysis, exposure scenarios, risk assessment, preparation of REACH dossier: chemical safety report / luclid, review and / or preparation of safety data sheets, letter of access management, (temporary) REACH help in general, classification and labeling (CLP). **Authorisations:** services include socio-economic analysis (SEA), analysis of alternatives (AoA), risk management options analysis (RMOA) and cross industry consortium formation – horizontal approach starting from the use of the substance.

CLIENTS

ROSC has a variety of clients from multinationals to small SMEs: we welcome you all.

REACH Ready

CONTACTS	
Website	www.reachready.co.uk
E-mail	enquiries@reachready.co.uk
Head office	Kings Buildings, Smith Square, London SW1P 3JJ
Tel	+44 (0) 20 7901 1444
Contact	Rachel Nabudde
Ownership	REACHReady is a wholly owned subsidiary of the Chemical Industries Association
Founded	2006

OVERVIEW

REACHReady offers a confidential, comprehensive and cost-effective "one-stop shop" service, right through from keeping you informed of all the latest developments, to fulfilling your specific registration and authorisation needs. We aim to save you time, trouble and money.
We have established a track record as the place to go for help with chemical regulatory compliance and have thousands of subscribers located all over the world, in every industry sector, working for companies from SMEs to multinationals.
Our strong reputation and extensive experience of the chemical and downstream industries makes us the best choice for REACH, CLP and BPR services. Our extensive understanding and knowledge of legislation stems from the in-depth involvement of our parent organisation, the Chemical Industries Association, in its development at every stage.

SERVICES PROVIDED

- Helpdesk
- Consultancy
- Training
- Matchmaker

CLIENTS

- Chemical manufacturers
- Formulators
- Downstream users of chemicals
- Article manufacturers
- Retailers
- Service providers

REACHwise

CONTACTS	
Website	www.reachwise.eu
E-mail	info@reachwise.eu
Head office	22, St Albans Avenue, London W4 5JP, UK
Tel	+44 (0)20 87470873
Contact	Peter Douben
Ownership	Private company
Locations	UK, Netherlands, Germany
Founded	2007

OVERVIEW

With extensive knowledge of REACH, CLP and BPR, REACHWise provides tailor-made services overseen by Peter Douben, formerly Director REACH, Cefic, and head of environmental protection, Unilever. Our focus on these areas means our efforts are targeted. We change complex situations into manageable elements, and provide cost-effective solutions, using IT tools where possible, efficiently.

SERVICES PROVIDED

Impact of REACH, CLP and BPR: finding comprehensive solutions for companies on the best way to approach the REACH, CLP and BPR "problem" and to remain compliant: stay on the market and grow!
Sief support: we provide the whole spectrum of Sief and consortium management.
REACH registration: for individual and groups of companies, our REACH support covers data evaluation and sharing, preparation of the technical dossier, use and exposure requirements, chemical safety assessment and exposure scenarios.
Safety data sheets: we prepare and update SDSs (body and annexed ESs) including translations.
Exposure scenarios: for individual substances as well as mixtures we ensure they are comprehensive and communicable: you discharge your obligations; your customers find them easy to understand.
Downstream uses: using specialist models we ensure that your conditions are compliant even when they deviate from the registrant's information.
Biocides: actives or products, we take care of them: from start to finish.

CLIENTS

Our clients receive an efficient service. Satisfied customers come from the ceramics industry, fertilisers and related industries, fragrance sector, health care sector, home and personal care, lubricants manufacturers and suppliers, metals sector, minerals sector, pigments and colorants sector, speciality chemicals industry.

SCAS Europe

CONTACTS	
Website	www.scas-eu.be/
E-mail	scaseurope07@scas-eu.be
Head office	SCAS Europe (Sumika Chemical Analysis Service), Leonardo da Vincilaan 19 (MC Square Offices) B-1831 Diegem, Belgium
Tel	+32 (0) 2 719 0475
Fax	+32 (0) 2 719 0480
Contact	Dr Rick Stanton
Ownership	Sumika Chemical Analysis Service, Tokyo, Japan
Locations	For parent company: Japan, China, Singapore, Taiwan, South Korea
Founded	Parent company 1972; SCAS Europe 2007

OVERVIEW

Since 2007 SCAS Europe (SCASE) has grown to be one of the largest REACH OR service providers in the EU. SCASE also represents our Japanese parent company, Sumika Chemical Analysis Service (SCAS), which is a significant provider of chemical regulatory services in Asia. SCAS provides global notification and multi-regional registration capabilities from our offices in Japan. Countries serviced include Japan, China, Korea, Taiwan, Philippines, Australia, New Zealand and Turkey as well as the US and Canada. Our parent company SCAS is a major analytical service provider with laboratories in Japan, China, Korea and Singapore. Founded in 1972, SCAS has consistently been satisfying requirements of its customers by providing the best analytical solutions in many industrial sectors.

SERVICES PROVIDED

EU REACH registration and OR for Asia clients; Asia chemical regulation support for Asia and Western clients.

CLIENTS

From many sectors, including both manufacturers and downstream users, for example in the following industries: chemical, petrochemical, electronics, pharmaceutical, automotive, paint, ink, rubber, fibre and others.

scivera

CONTACTS	
Website	www.scivera.com
E-mail	rapidscreen@scivera.com
Head office	Scivera LLC, 300 Preston Avenue, Charlottesville, VA 22902, US
Tel	+1 434 974 1301
Contact	rapidscreen@scivera.com
Ownership	Private
Locations	US
Founded	2008

OVERVIEW

Scivera is fundamentally changing the way brands and suppliers worldwide screen and select chemicals. Through affordable cloud-based software that translates basic data into informed decision-making, Scivera goes beyond list screening to provide deep insight into underlying human and environmental health characteristics.

SERVICES PROVIDED

Scivera is committed to simplifying chemicals management to enable companies of any size and sector to protect their brand, their budget, and their customers. SciveraLENS is redefining the market through its Rapid Screen solution, delivering current dynamic list screening and instant chemical hazard assessment. Scivera's Enterprise solution enables teams to collect, assess, and manage product, material, and process chemical data throughout a brand's supply chain. SciveraLENS Enterprise includes the capability to put chemicals into context of use at any/all stages of the product lifecycle, adding chemical exposure compliance support across all major global markets. The system includes a secure supplier platform to protect proprietary ingredient information for all involved parties, while enabling targeted transparency so that globally-recognised brands can trust that finished products meet necessary standards – enhancing and enabling efficiencies in conventional product testing strategies. Scivera empowers companies throughout the supply chain to take control and drive sales.

CLIENTS

SciveraLENS serves household-recognised brands – and their suppliers – across all key product categories where articles and formulations require chemical safety assessment for toxicological hazard and risk, including automotive, electronics, footwear/apparel, household goods, office furniture, toys, textiles, and specialty chemicals.

SENZA GEN

CONTACTS	
Website	www.senzagen.com
E-mail	CEO: amh@senzagen.com Sales: peter.sandberg@senzagen.com
Head office	SenzaGen AB, Medicon Village, Scheelev. 2, 223 81 Lund, Sweden
Tel	+46 46 2756200 office / +46 708 204481 sales
Contact	Dr Anki Malmborg-Hager
Ownership	Private ownership
Locations	Sweden, US
Founded	2010

OVERVIEW

SenzaGen markets, sells and performs the *in vitro* GARD sensitisation test for skin sensitisation and potency classification according to the CLP standard. A novel test for respiratory sensitisation is also under development.The genomic technology based GARD test is developed by technical engineers and immunological researchers at Lund University, Sweden, has been further adapted to industry and commercialised by SenzaGen. As a quality-orientated and innovative international player, SenzaGen supports its clients with stringent quality assessments recommended by Echa and accepted by OECD for validation.

SERVICES PROVIDED

High accuracy *in vitro* sensitisation testing of chemicals. For safety assessment and REACH registrations. Relevant for cosmetics, household and personal care ingredients, pharmaceuticals, agrochemicals and medical devices.

- skin sensitisation (OECD TGP 4.106)
- potency classification for CLP
- respiratory sensitisation

Our scientists and immunological experts can provide customised advice to help your development projects or your tricky ingredient as well as your straightforward testing as part of your sensitisation testing.

CLIENTS

Our clients range from small size companies to global corporations. Manufacturers, pharmaceutical companies, cosmetic and personal care ingredient producers, food industry as well as research institutes.

Siam

CONTACTS	
Website	Website: www.siam-it.com Product website: www.siam-it.com
E-mail	export@siam-it.com
Head office	Ortega y Gasset 17 bajo, 26007 Logroño, Spain
Tel	+44 2 037 697 400
Ownership	Private company
Locations	Europe
Founded	2007

OVERVIEW

Siam is a company that developed the software Chemeter for the generation of SDS, labels and transport documents according to European legislation.
Our vision and commitment is to making sure that all chemical companies have legislative compliance with regards to REACH, CLP, GHS, etc.

SERVICES PROVIDED

Siam offers complete customer support with data accuracy, quality and integral services. Our main services include reference and integrated regulatory data, SDS authoring systems, SDS distribution and management, transport documentation and support.

CLIENTS

From the beginning Siam has been oriented towards having an international network. Today we have a well-established international presence through our sales network in many countries like: France, Italy, Portugal, Finland, Poland, Greece, Romania, Sweden, Turkey, US, etc. Our clients are European and non-European companies manufacturing and distributing all kinds of chemical products in many sectors, such as: cleaning, paints and coatings, paints, rubber, detergents, adhesives and sealants, flavours and fragrances etc.

toxfocus

CONTACTS	
Website	www.toxfocus.com
E-mail	barbara.vogt@toxfocus.com
Head office	2 Glenridge Road, Little Rock, AR 72227, US
Tel/ Fax	+1 501 351 4389
Contact	Barbara Vogt, PhD, DABT
Ownership	Private company
Locations	US
Founded	2008

OVERVIEW

Tox Focus LLC provides the toxicologic and scientific content for REACH, cosmetics Regulation, and other regulatory programmes, drawing upon 20 years experience in corporate and clinical toxicology. The consultancy authors luclid 6 dossiers for REACH, CLP notifications and harmonisation, weight-of-evidence positions and REACH evaluation responses to Echa/member states. Tox Focus LLC is a qualified risk assessor for the EU cosmetics Regulation and for the US Department of Commerce.

SERVICES PROVIDED

REACH: quality toxicology assessments and strategic planning for compliance with data requirements, including data gap filling, adaptations to data requirements, identification of analogues and categories, computer modelling and support (QMRF, QPRF), laboratory test monitoring, robust study authoring, construction of luclid 6 files with completeness reports, chemical safety reports, risk assessments, classification, labelling and packaging (CLP), and evaluation support/dossier defence. **EU cosmetics Regulation:** product risk assessment certificates and cosmetic product safety reports (CPSR) as part of the product information file (PIF).

CLIENTS

Cytec Industries Inc, The Redstone Group, Unilever, Mayer Brown International LLP, Lucite International, Ineos Europe Ltd, The Cyanide Council, Evonik-DeGussa GmbH, Abercrombie and Fitch, Air Products and Chemicals Inc, Vertellus Specialties Inc, Arch Chemicals Inc, Gerber Scientific International, AW Chesterton Company, Calumet Specialty Products Partners LP, Gulf Bayport Chemicals LP, The Nail Consultants, Ltd, US Department of Commerce.

toXcel INTERNATIONAL LTD

CONTACTS	
Website	www.toxcel.com
E-mail	Christine.McAlinden@toxcel.co.uk / info@toxcel.com
Head office	PO Box 93, Ledbury, HR8 9JE, UK
Tel	+44(0)1531 638999 (UK) / +1 703 754 0248 (US)
Contacts	Christine McAlinden (UK) / Alan Katz (US)
Ownership	Limited company
Locations	UK, US
Founded	1999

OVERVIEW

toXcel's European and North American offices work closely together to provide a coordinated regulatory resource for seamless development and execution of strategies, designed for cost-effective regulatory approvals, leading to domestic, regional, and global export market expansion.

SERVICES PROVIDED

toXcel provides a full range of services to support obtaining marketing approvals by governmental agencies, with emphasis on regulatory strategy development and all aspects of preparing applications and dossiers. toXcel advises companies about compliance with REACH, CLP, the biocidal products Regulation, the cosmetics Regulation, the plant protection products Regulation, and other EU registration requirements. We can provide you with a full REACH registration service (including only representative function), or we can support your in-house activities as required. Our experts provide Fifra, TSCA, and FDA services to our global clientele in our US office. toXcel has global experience in the performance of exposure and risk assessments, environmental assessment, safety and toxicological evaluations, nanoparticles, and the design and management of GLP analytical chemistry, residue, efficacy, environmental fate, mammalian toxicity, metabolism/pharmacokinetics (ADME), and ecotoxicity studies.

CLIENTS

Our leading consultants focus their collective professional talents on assisting chemical manufacturers, formulators, pharmaceutical companies, personal care/consumer product manufacturers and suppliers, trade associations, law firms, and the food industry.

τοξικόν Toxicon

professional expertise for your compliance

CONTACTS	
Website	www.toxicon.it
E-mail	info@toxicon.it
Head office	Via Robolini 1, 27100 Pavia, Italy
Tel / Fax	+39 0382 1938015 / +39 0382 1938026
Contact	Raffaella Butera, MD
Ownership	Private company
Locations	Italy
Founded	2010

OVERVIEW

Toxicon provides a wide range of expert advice services in regulatory fields and in the areas of toxicology, pharmacology and occupational medicine for companies and institutions. Our know-how is based on a solid academic background in risk assessment. Our team consists of specialists in different areas: physicians, pharmacologists, biologists, chemists, biotechnologists, food technologists, economists and lawyers. We believe that complex problems can be solved with success and quality only through teamwork.

SERVICES PROVIDED

Overall services: guidance on regulatory interpretation, compliance support, auditing.
REACH: data sharing, Sief and consortium management. Data gap analysis and testing strategy development, including the use of Qsar models. Dossier preparation (inquiry, lead and member registrants) including CSA/CSR. PPORD notification. SDS and e-SDS. Compliance check with exposure scenario (ES), scaling, CSR-DU development. ES development for mixtures. Applications for authorisation including SEA.
CLP/GHS: hazard assessment, classification and labelling, notification to Echa C&L inventory and to member states bodies for emergency health response on mixtures.
BPR Regulation: data sharing agreements, dossier development for active substances approval and biocidal products authorisation at national and UE level.
Cosmetic products: safety assessment, product information file, notification.
Medicines: CTD, genotoxic impurities assessment, PDE assessment, environmental risk assessment, provisional OELs for APIs and other chemicals.
Occupational medicine: risk assessment and management (CAD, CMD).
Other: training for companies, universities and institutions.

CLIENTS

Toxicon assists large companies and SMEs. Moreover, Toxicon works in partnership with institutions, industries and associations for R&D and compliance projects.

CONTACTS	
Website	www.vrs-regulatory.net
E-mail	jobs@vrs-regulatory.net
Head office	Vantage House, 26a Northenden Road, Sale, M33 3BR, UK
Tel	+44 (0)161 976 2825
Fax	+44 (0)161 976 2561
Contact	John Sherratt
Ownership	Limited company
Locations	UK
Founded	2006

OVERVIEW

VRS Regulatory is the specialist regulatory affairs and risk assessment recruitment division of scientific recruiter VRS. We focus on recruitment in regulatory affairs, registrations, REACH, CLP, SDS authoring, product safety, compliance, risk assessment, regulatory toxicology, regulatory ecotoxicology and environmental fate in the chemicals, agrochemicals and biocides sectors. We recruit for jobs at all levels from experienced regulatory professional to someone just starting their career in the regulatory / risk assessment field. We focus on the UK and often have opportunities based in continental Europe or even further afield.

SERVICES PROVIDED

- Recruitment consultancy for regulatory affairs and risk assessment positions.
- Contingency and search and selection
- Advice on salaries, skills availability, recruitment methods
- Careers advice to regulatory affairs job hunters

CLIENTS

We work with many UK based companies – SMEs and multinationals – manufacturers, distributors, retailers, consultancies, CROs and government bodies.
We focus on organisations involved in chemicals, agrochemicals and biocides.

CONTACTS	
Website	None
E-mail	Williameawilson78@gmail.com
Head office	94 Queens Road, Clifton, Bristol BS8 1NF
Tel	+44(0)7885-551-405
Contact	William Wilson
Ownership	Private company
Locations	UK
Founded	2016

OVERVIEW

Wyeside Consulting Ltd supplies the legal services as a UK barrister and consultancy services of William Wilson. His background experience includes 25 years of specialist environmental and energy law in government and private practice; 9 years in the UK Government Legal Service and 15 years with a leading UK law firm's environmental and energy law practice, which he helped to build up. He was also founder and director for 6.5 years of his own environmental policy consultancy, which advised governments and companies on REACH and chemicals regulation.
William Wilson spent two and a half years closely involved with REACH negotiations at the EU with the metals, mining and aerospace industries, and he continues to advise on REACH and chemicals regulation issues across a range of industries, including the impacts of Brexit on chemicals regulation.

SERVICES PROVIDED

William Wilson is a skilled UK environmental lawyer and barrister, with direct experience of EU negotiations and legislation as well as all aspects of UK legislation, regulation of chemicals and policy and environmental issues.

CLIENTS

William Wilson has advised governments, public bodies, trade associations and multinationals on REACH and chemicals regulation.

CONTACTS	
Website	www.wrcplc.co.uk
E-mail	ncet@wrcplc.co.uk
Head office	Frankland Road, Swindon, UK
Tel/ Fax	01793 86 5000/ 01793 86 5001
Contact	Sarah Bull
Ownership	Private company
Locations	UK
Founded	1927

OVERVIEW

WRc's team within the National Centre for Environmental Toxicology (NCET) consists of experienced mammalian and environmental toxicologists, risk assessment analysts, chemists, Qsar and exposure scenario modellers and REACH legislation experts. WRc/ NCET has extensive experience of dealing with national and European regulators (including Echa) and industrial clients and consortia.

SERVICES PROVIDED

- Hazard identification and classification
- Human health and environmental risk assessment
- Chemical legislation (REACH, BPR, CLP, cosmetics, WRAS, ecolabel)
- Data gap analysis
- Substance grouping, Qsar and read across for data gap filling and test replacements
- Study monitoring for toxicological and ecotoxicological testing
- Compilation and evaluation of physico-chemical, environmental, fate, toxicological and ecotoxicological data packages
- Exposure modelling and derivation of exposure scenarios
- Reviews of epidemiological data and health monitoring studies
- Preparation of technical dossiers in luclid 6, chemicals safety reports (CSRs) and safety data sheets (SDSs)
- Emergency response
- Training

CLIENTS

A wide variety of clients ranging from single industrial chemical manufacturers to multinational consortia.

CONTACTS	
Website	www.wspgroup.com
E-mail	alan.ritchie@wspgroup.com
Head office	70 Chancery Lane, London, UK
Tel/ Fax	+44 20 3116 6072
Contact	Alan Ritchie/ Dr Stephen Bounds
Ownership	Private company
Locations	UK, Europe, worldwide
Founded	8 April 1987

OVERVIEW

WSP provides a wide range of environmental, health and safety, product stewardship and regulatory consultancy services. Our global REACH Group includes chemical industry professionals experienced in all aspects of chemical regulation and includes registration specialists, toxicologists and ecotoxicologists experienced in dealing with REACH and other chemical regulatory projects for a wide range and size of clients. We are a leading global design and engineering firm with over 30,000 staff around the world.

SERVICES PROVIDED

We offer a complete range of services to deal with all our client's REACH, biocidal products Regulation requirements including: identifying a client's REACH and biocidal registration obligations and developing the registration strategy; Sief and consortium management; all aspects of substance registration dossier preparation and submission; joint registration submission; socio-economic analysis; authorisation of a substance (WSP was the technical advisor on the first ever application for authorisation to clear Echa; classification, labelling and packaging (CLP) management and compliance; only representative (OR) and third party representative services; safety data sheet (SDS) preparation and management; REACH compliance checks. We also now provide a full service for supporting the new EU cosmetics Regulation including cosmetic product safety assessments, notifications to the cosmetics products notification portal and artwork reviews.

CLIENTS

WSP assists a large group of companies to fulfil their REACH obligations ranging from SMEs through to large multinational corporations. Our clients include manufacturers, importers and downstream users. We act as only representative for approximately 15 companies and provide support over and above the basic service as required. We specialise in helping companies respond to their business challenges and effectively manage compliance.

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

Sector-Specific Homepages

NEW

Chemical Watch is proud to introduce a selection of sector-specific homepages - 'lenses' through which you can view our latest news stories and features specifically about, and relevant to, your sector. This latest innovation saves your team time in picking out the stories that affect your organisation and you personally, in your role.

AEROSPACE, AUTOMOTIVE & ENGINEERING

BUILT ENVIRONMENT

CHILDREN'S PRODUCTS

CLEANING PRODUCTS

ELECTRICAL & ELECTRONICS

FOOD CONTACT MATERIALS

PERSONAL CARE PRODUCTS

RETAIL

TEXTILES

View the full range of sector homepages at www.chemicalwatch.com/sectors

	Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
	1cc GmbH	**221**	Germany	United States	25-50	2-5	●	◗	◗			◗	◗		
	24-7 Response		UK		50-100	10-25	●					◗	◗		
▶	**3E Company**	**72**	USA	Denmark, Canada, Japan	100-500	100-500	◗				◗	●			
	3S-SafelyServingScience	**221**	Greece		2-5	2-5	●	◗					◗		
	A.S.C.	**221**	France	Poland	25-50	25-50	◗	◗		◗		◗	◗		
	Accenture		Belgium		5,000 plus		◗	◗			◗	◗	◗		
▶	**Acta**	**74**	USA	UK, China	25-50	25-50	◗	◗	◗		◗	◗	◗		
	Actio Software Corporation		USA		25-50	2-5					●				
	Active Steward		UK	Belgium	25-50	25-50					●				
	Advinus Therapeutics Limited		India		100-500	50-100				●					
	Aegis Regulatory Inc		Canada		2-5	2-5	●								
	AG-HERA		UK		2-5	2-5	●								
	AGREXIS AG		Switzerland		5-10	5-10	●								
	Alan Best		UK		1	1	●	◗		◗					
	Alberi EcoTech		USA		1	1	◗						◗		◗
	Alchemy Compliance Ltd.		UK		1	1	●								
	Alemare Solutions		UK		2-5	1	◗	◗				◗	◗		)
	ALSTER Consulting > Chemical Compliance		Germany		1	1	◗	◗				◗	◗		◗
	Altox a/s	**221**	Denmark		2-5	2-5	◗	)				◗	◗		)
	AMEC Environment and Infrastructure		UK	Germany, Netherlands, USA	2,000-5,000	25-50	◗	◗		◗		◗	◗		◗
	Anderson Materials Evaluation, Inc.		USA		2-5	2-5	)			●					
	Annex3 Consulting		The Netherlands		1	1	●								
	Annray Test Co., Ltd.		China		25-50	10-25	◗			●		◗			
	Antea Group		USA	Europe, Colombia, Africa	5,000 plus	100-500	●	◗			◗	◗	◗		◗
	Anthesis-Caleb	**222**	UK	Germany, North America, Sweden, Phillipines	100-500	10-25	●	◗			◗				◗
▶	**APC**	**76**	UK	France, Poland, Czech Rep, Australia, Brazil	25-50	25-50	●								
▶	**Apeiron-Team NV**	**78**	Belgium		10-25	10-25	●	◗				◗	◗		◗
▶	**Arcadis**	**80**	The Netherlands	Belgium, Switzerland, North America	5,000 plus	50-100	◗	◗		◗	◗	◗	◗		)
	Arcerion GmbH	**222**	Germany		10-25	5-10	◗	◗	)	)	)	◗	)		
▶	**ARCHE Consulting**	**82**	Belgium		25-50	25-50	●	◗			◗		◗		
	Argentum Environment		Sweden	UK	100-500	25-50	◗	◗			◗	◗	◗		
	Arrow Regulatory Ltd	**222**	UK		2-5	2-5	◗	◗				)	)		
	AsiaInspection		Hong Kong	China, USA	1,000-2,000	50-100				●					
	Assent Compliance		Canada	USA, Germany, UK, Taiwan, India, Kenya	100-500	10-25	◗	◗			◗	◗			
	ATOUT REACH		France		2-5	2-5	◗	◗					◗		
	Austen Business Solutions Ltd		UK		2-5	1	◗	◗							
	Auxilife Scientific Services Pvt Ltd		India		5-10	5-10	●	◗				◗	◗		
	AW-ChemAdvice		The Netherlands		1	1	●								
	Ayansan Chemical Consultancy Ltd. Co.	**222**	Turkey	Hungary	5-10	5-10	◗	◗	◗	◗		◗	◗		
	Baytouch Ltd		UK	USA	5-10	5-10	◗				●				
	Beijing BoardingCard Chemical Consulting Co., Ltd.		China		10-25	10-25	◗	◗		◗		◗			
	Beveridge & Diamond, PC		USA		50-100	10-25			●						
▶	**bibra toxicology advice & consulting**	**84**	UK		10-25	10-25	●	◗			)	)	)		
	BIG vzw	**223**	Belgium		25-50	25-50	◗	◗	◗		◗	◗	◗		
	BioQuanta		France	Japan, Thailand, USA	25-50	10-25				●					
	BIOVIA, Dassault Systemes		USA		25-50	25-50					◗	◗			
	Bird & Bird LLP		Belgium		500-1000	2-5			●						
▶	**Blue Frog Scientific Limited**	**86**	UK		10-25	10-25	●	◗			◗				
▶	**bluesign technologies ag**	**88**	Switzerland	Germany, HK, representatives globally	50-100	5-10	●	◗				◗	◗		
	Boeije Consulting	**223**	Belgium		1	1	◗	◗							
	Bond Dickinson		UK		1,000-2,000	50-100			●						
	Bootman Chemical Safety	**223**	UK		2-5	2-5	◗	◗			◗	◗	◗		
	Borenius & Kemppinen, Attorneys at law Ltd		Finland		100-500	5-10			●						
	Bristol Environmental		USA		100-500	100-500									●
	Buckman		USA		2,000-5,000		◗	◗	◗	◗	◗	◗	◗		
	Bureau Veritas		France		5,000 plus	100-500	◗	◗		◗	◗	◗	◗		
	Bureau Veritas HSE Denmark A/S		Denmark		5,000 plus	50-100	◗				◗		◗		
	Burges Salmon		UK		500-1000	5-10			●						
	Butterworth Laboratories Ltd		UK		50-100	50-100				●					
▶	**C.S.B. GmbH**	**90**	Germany		10-25	10-25	◗	◗				◗			
	Cambridge Environmental Assessments		UK		5-10	5-10	◗	◗					◗		
	Cardno ChemRisk		USA		50-100	50-100	●								
	Cardno ENTRIX		USA	South America, Canada	1,000-2,000	25-50	●								

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20%) <5%

	Focus of activities																	Regulatory expertise															
Organisation	Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	Further information
1cc GmbH	■				□			■		□				□			■	■	■	■	□	■	□			■		□					www.1cc-consulting.com
24-7 Response																	□	□	■	■		□	□										www.24-7response.org
3E Company	■	□	■	□	□	■		□	□	■	■	□	■	□	■	□	■	■	■	■	■	□	□		■	■	□	□			□	■	www.3ecompany.com
3S-SafelyServingScience	■	□	■	□	■	■							■			□	□	■	■	■		■	■	□									www.3s-chem.gr
A.S.C.	■	■	□	□	■	■	□						□	□	□		■	■	■	■		■	■	□	□			□					www.ambrosiconsulting.com
Accenture	■	■	■	■	□	■	□										■	■	■	■	■	□	□	■									www.accenture.com
Acta	■	■	□	■	■	■	□	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	□	□	■	■	■	■	www.actagroup.com
Actio Software Corporation	■	■	■	■	■	■	■										■	■	■	■	■	■	■	■									www.Actio.net
Active Steward	■	□		□	□	□							□		□		■	■	■	■	□	□	□	□	□	■					□		www.activesteward.com
Advinus Therapeutics Limited	■	■	■	■		□	□										■							■									www.advinus.com
Aegis Regulatory Inc	■				□	□											□	□	■	■	□		□										www.aegisreg.com
AG-HERA	■	■	■		□	□	■										■	□	■	■	□	□	□	□									www.ag-hera.com
AGREXIS AG		■			■														□	□		■		■									www.agrexis.com
Alan Best	■																■	□	□	□	□	□											www.alanbestsustainability.com
Alberi EcoTech	□	□	■	■	□	□	□										■	□	□	■	■												www.alberieco.com
Alchemy Compliance Ltd.	■																■		■														www.alchemycompliance.com
Alemare Solutions	■	■			□	□											■		■	■		□	□										www.alemare.co.uk
ALSTER Consulting > Chemical Compliance	■				□	□											■		□	□		□	□										www.alster-consulting.eu
Altox a/s	■			□	■	■		□	□	■	□	□	■	□	□	■	■	□	■	□		■	■		□	□	■	□				□	www.altox.dk
AMEC Environment and Infrastructure	■	□	□	□	□	□											■	□	□	□	■	□		□									www.amec.com/reach.htm
Anderson Materials Evaluation, Inc.	■	□	□	□	□	□	□	■	□	■	■	□	■	□	■	□								□	□		□	■					www.andersonmaterials.com
Annex3 Consulting	□	□	□	□	■						□		□		□		□	□	□			■			□								www.annex3.eu
Annray Test Co., Ltd.	■			■		□											■	□															www.annraytest.com
Antea Group	■	■	■	□	□	□											□	□	□	□	■			□									www.anteagroup.com
Anthesis-Caleb	■	□			□	□		■	□	■	■	■	□		□		■	■	■	■	■	□	□		□	■			□	□	□	■	www.anthesisgroup.com
APC	■	■			■		□										■	□	■	■		■		■									www.apc.eu.com
Apeiron-Team NV	■		□		■	□		□	□	□			□	□		□	■	□	■	■	□	■	□		□	□	□			□			www.apeiron-team.eu
Arcadis	■	■	■	■	■	■	□	■	□	■	□	□	□	■	□	□	■	■	■	■	■	■	■	■	□	■		□	□	□	□	■	www.arcadis.com
Arcerion GmbH	■	■	□		■	□	□	□	□	□		□	■			■	■	■	■	■	■	■		□	□	■	□	□	■	□			www.arcerion.com
ARCHE Consulting	■	■	■		■	■	□			□		□	■	■	□		■	□	■	■	□	■	□	■		□		□					www.arche-consulting.be
Argentum Environment	□	□	□		□	□											■	□	■	■	□	□	□	□									www.argentumenvironment.se
Arrow Regulatory Ltd	■	□	□	□	■	□	□						□	□	□	□	■	■	■	■	□	■	□	□	□			□	□		□	□	www.arrowregulatory.com
AsiaInspection	□	□				□		■	■			■	□		■	□	■						□		■	■	■						www.asiainspection.com
Assent Compliance	□	□	□	□	□	□											■	■	□	□	□	□	□	□									www.assentcompliance.com
ATOUT REACH	■					□											■	■	■				□										www.atoutreach.fr
Austen Business Solutions Ltd	■																■		□														www.austenbusinesssolutions.co.uk
Auxilife Scientific Services Pvt Ltd	□	■	□		■	□							□	□	□		□	□	■	■	□	■	□	■	■	□		□					www.auxilife.com
AW-ChemAdvice	■				□												■		□														
Ayansan Chemical Consultancy Ltd. Co.	■	□	□		■	■	□	■	■				■	□	□	□	□	■	■	■	□	■	■	□	□	■	■	□					www.ayansan.com
Baytouch Ltd	■	□	□	□	□	□	□										■	□	□	□	□	□	□	□									www.baytouch.com
Beijing BoardingCard Chemical Consulting Co., Ltd.	■	□	□	□	□	□												■		■													www.bjboardingcard.com
Beveridge & Diamond, PC	■	■	■	■	■	□											■	■	■	■	■	□	□	■									www.bdlaw.com
bibra toxicology advice & consulting	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	□	www.bibra-information.co.uk
BIG vzw	■	□	□		■	□			□	□	□	□	□				■	■	■	□		■	□	□									www.big.be
BioQuanta	■	□	■	■		■																											www.bioquanta.net
BIOVIA, Dassault Systemes	■	■	■	■	■	■	■										■	■	■	■	■	■	■	■									www.accelrys.com
Bird & Bird LLP	■	■	■	■	■	■	■										■	□	■	■	□	■	■	■									www.twobirds.com
Blue Frog Scientific Limited	■	■	■		□	□	■								□		■	□	■	□		□	□	■	□								www.bluefrogscientific.com
bluesign technologies ag												■				■	□	□	□	□													www.bluesign.com
Boeije Consulting	■	□			□	□							■				■	□	■	□	□	□	□	□									www.boeijeconsulting.com
Bond Dickinson	■	■	■	■	■	□	□	□	□	□	■	□	□	□	□	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	www.bonddickinson.com
Bootman Chemical Safety	■	□			□								□			□	■	□	■	■	□	□		□					□	□	□		www.bootmanchem.com
Borenius & Kemppinen, Attorneys at law Ltd	■	■	■	■	■	■	□										■	□	■	□	□	■	■	□									www.borenius.com
Bristol Environmental	□				□															■	□												www.bristolenvironmental.com
Buckman	■	□		□	■												□	■	□	□	■	■	□	□									www.buckman.com
Bureau Veritas	■	□	□	□	■	□	□										■	■	■	■	□	■	□	□									www.bureauveritas.com
Bureau Veritas HSE Denmark A/S	■	□	□		□	□											■	□	■	■		□	□	□									www.bvhse.dk
Burges Salmon																	■	■	■	■	■	■	■	■									www.burges-salmon.com
Butterworth Laboratories Ltd	■	□	■	■	□	■	■	□		□	□	□	□	■	□																		www.butterworth-labs.co.uk
C.S.B. GmbH	■				■	□					■		■		□		■		■	■	□	■			□								www.csb-online.de
Cambridge Environmental Assessments	■	■	□	□	■	□	■										■		■	□		■	□	■									www.cea-res.co.uk
Cardno ChemRisk	■	■	■	□	□	□											■	□	□	□	■	□	□	□									www.cardnochemrisk.com
Cardno ENTRIX	■	■	□		■												■	■	■	■	■	■		■									www.cardnoentrix.com

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service □ Service that is occasionally provided □ Service provided by partners and third parties

	Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
	CE.way: Cosmetics Regulatory and Testing Solutions		Slovenia		2-5	2-5	●			◗					
	Cefas		UK		500-1000	25-50	◗			●					
▶	**CEHTRA**	**92**	France	Belgium, Canada, India, UK	50-100	50-100	●	◗	☽		☽	◗	◗		
	Centro Reach		Italy		5-10	2-5	◗	◗	◗			◗	◗		
	CFCS		Germany	Italy	5-10	5-10	●	◗				◗	◗		◗
▶	**CGI**	**94**	Canada	United States, France	5,000 plus	100-500	◗	◗			◗		◗		
▶	**Charles River**	**96**	USA	UK, Netherland, France	5,000 plus	50-100	◗			●					
	Chem-Academy	**223**	Switzerland	Gernany	10-25	5-10							●		
	ChemADVISOR, Inc.		USA	Belgium, Singapore	50-100	50-100	◗	◗			◗	◗	◗		
	ChemAdvocacy S.A.		Luxembourg		5-10	5-10	●								
▶	**Chementors Ltd**	**98**	Finland	China	5-10	5-10	◗	◗	◗	◗	◗		◗		
	Chemest Ltd.		Finland		2-5	2-5	◗	◗	◗	◗		◗	◗		
	Chemex Environmental International Ltd		UK		10-25	10-25	◗			●			◗		
	ChemHaz Solutions		Ireland		1	1	●						◗		
	Chemical Consultant		USA		1	1	●	◗				◗	◗		
	Chemical Regulatory Affairs – Israel		Israel		1	1	◗					◗			
	ChemPharmaServe Ltd		UK		2-5	2-5	◗								◗
	Chemphex		Finland		1	1	●					◗			
	ChemRegs (UK) Ltd		UK		2-5	2-5	●						◗		
▶	**ChemSafe**	**100**	Italy	Qatar	10-25	10-25	◗	◗	◗	◗	◗	◗	◗		
▶	**Chemservice**	**102**	Germany, Luxembourg	South Korea, France	50-100	50-100	◗	◗			◗	◗	◗		◗
	Chemservice EHNS GmbH		Germany		2-5	1	●						◗		
	ChemService Srl Controlli e Ricerche		Italy	Agent in China	25-50	25-50	◗			●			◗		
	Chemtopia Co., Ltd.		South Korea	EU, USA, Canada, China, Thailand, Japan, Vienam, Malaysia	50-100	25-50	◗	◗	◗	◗	◗		◗	◗	◗
	chemtrac®	**224**	UK	Italy, USA, Japan, China	25-50	25-50	◗				◗	◗	◗		
▶	**CHEMTREC**	**104**	USA		25-50	25-50	◗				◗	●			◗
	Chemwatch		Australia	China, India, Indonesia, Israel, Italy, Japan, Japan, Korea, Malaysia, Mongolia, New Zealand, Philippines, Poland, Qatar, Saudi Arabia, Singapore, South Africa, Thailand, The Netherlands, Turkey, UK, USA	100-500	50-100	◗				●	◗	◗		
	CHESSOL B.V.		The Netherlands	Belgium, France, Italy	5-10	2-5	●				◗				
▶	**China National Chemical Information Center**	**106**	China		100-500	25-50	◗			◗	◗	◗			☽
▶	**ChIR – Chemical Innovation and Regulation**	**108**	Portugal	Spain, Italy, UK	5,000 plus	50-100							●		
	Chris Braun Consultancy		The Netherlands		1	1	●						◗		
	Chymeia ApS	**224**	Denmark		10-25	10-25	◗				●		◗		
▶	**CIRS**	**110**	China	Ireland	100-500	50-100	◗	◗		◗	◗	◗	◗		
▶	**CIS Center**	**112**	Russia		50-100	25-50	◗	◗		◗	◗	◗	◗		
▶	**CiToxLAB**	**114**	France	Hungary	1,000-2,000	100-500	◗			●					◗
	CJV Consulting Ltd		UK		1	1	●	◗	◗			◗	◗		
	Clariant		Italy		5,000 plus	100-500	◗		◗	◗			◗		
	Compliance & Risks		Ireland	US, UK, Belgium	50-100	5-10	◗		◗		◗				
	Compliance Footprint AG		Switzerland	global offices	5-10	5-10	◗				◗				◗
	Compliance Services International		USA	UK	10-25	10-25	●	◗		◗		◗	◗		
	compliance2business		Italy		1	1	◗	◗	◗			◗	◗		
	Consortia Management GmbH		Germany		5-10	5-10	◗	●							
	CONUSBAT Regulatory Services		Germany		Globally	5-10	●	◗							
	Cosanta		The Netherlands	Germany, Belgium, Finland, UK, Ireland, Austria, Sweden, Poland, Spain, France, Portugal, Italy	10-25	5-10	◗			☽	◗	◗	◗		
	Cosmetic Design Laboratories		UK		2-5	1	◗			●					
▶	**CRAD**	**116**	Turkey	Representatives in EU, UK, USA, Japan, Korea	10-25	10-25	◗	◗			◗	◗	◗		
	Crowell & Moring		USA		25-50	5-10	◗	◗	◗						
	CS Regulatory Ltd	**224**	UK	Republic of Ireland	5-10	5-10	●	◗				◗	◗		
	CTT		China		100-500	100-500	◗			●		◗	◗		
	Currenta GmbH & Co. OHG		Germany		100-500	25-50	◗	◗	◗	◗			☽		☽
▶	**Cyprotex**	**118**	UK	USA	100-500	25-50				●					
	Danger and Safety srl		Italy		5-10	5-10	●	◗				◗	◗		
	DanGoods Training & Consultancy		UK		1	1	◗					◗	◗		
	Danish Technological Institute		Denmark		25-50	5-10	◗			●		◗			
	Datalab		USA		2-5	1									●
	David Ryberg		Norway		10-25	2-5	◗		◗			◗			
	Defense Logistics Agency		USA		1,000-2,000	10-25		◗			◗	◗			◗

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20% ☽ <5%

Organisation	Focus of activities: Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	Regulatory expertise: REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	Further information
CE.way: Cosmetics Regulatory and Testing Solutions						■																	■										www.ceway.eu
Cefas	■	◘	◘		◘	◘	■			◘	◘		◘	◘	■	◘	◘	◘			■	◘		◘	■								www.cefas.co.uk
CEHTRA	■	■	■	■	■	■	■	■	◘	■	■	◘	■	◘	■	■	■	■	■	■	■	■	■	■	■	◘	◘	◘	◘	◘	◘	◘	www.cehtra.com
Centro Reach	■	□	■	◘	■	◘	□										■	□	■	□	□	■	◘	□									www.centroreach.it
CFCS	■	◘			■	■	◘										■	◘	■	■	■	■	■	◘									www.cfcs-consult.com
CGI	■	◘	■	◘	□	◘	◘	◘	◘	◘	◘	◘	■	■	◘	◘	■	■	■	■	■	■	◘	◘	◘	◘	◘	■			■	■	www.cgi.com/environment
Charles River	■	■	■	■	■	■	■		◘				■	■	■	□	■	■	■	■	■	■	■	◘	◘	◘	◘	◘	◘	◘	◘		www.criver.com
Chem-Academy																																	www.chem-academy.com
ChemADVISOR, Inc.	■	◘	■	◘	■	■	◘	◘	■	■	■	■	■	◘	◘	■	■	■	■	■	■	■	■	◘	◘	◘	◘	◘	◘	◘	◘	■	www.chemadvisor.com
ChemAdvocacy S.A.	■	◘			■	◘			◘				◘	◘	■		■	■	■	■	◘	■	■	◘	■	◘	◘	◘					www.chemadvocacy.com
Chementors Ltd	■	◘			■	■					◘	◘	◘	◘	◘	◘	■	◘	■	◘		■	■	◘	◘	◘		◘					www.chementors.fi
Chemest Ltd.	■	◘	□	◘	■	◘	□										■	□	■	■		◘	◘	□									www.chemest.fi
Chemex Environmental International Ltd																																	www.chemex.co.uk
ChemHaz Solutions	◘		◘														◘		◘	◘		◘											www.chemhazsolutions.com
Chemical Consultant	■	◘	◘	◘	◘	◘	◘	◘		■	◘	◘	◘	◘	◘		◘	◘	◘	◘	◘	◘		◘	◘			◘					www.chem-consult.com
Chemical Regulatory Affairs – Israel	■	■			◘	◘	◘										◘		■	■													
ChemPharmaServe Ltd	◘	◘	■	■													□																www.chempharmaserve.com
Chemphex	■	□															■	□	□	□													www.chemphex.com
ChemRegs (UK) Ltd																	■	■	■	■		■	◘										www.chemregs.co.uk
ChemSafe	■	■	■	◘	■	■	◘	◘	◘			◘	■	◘	■	■	■	■	■	■	■	■	◘	■	◘	◘	◘	◘					www.chemsafe-consulting.com
Chemservice	■	■	□	◘	■	■	□		◘		◘	◘	◘	◘	■	◘	■	■	■	■	■	■	◘	■	■	◘	◘	◘	◘	◘	◘	□	www.chemservice-group.com
Chemservice EHNS GmbH																◘				◘							◘						www.chemservice-ehns.com
ChemService Srl Controlli e Ricerche	■	■			■	◘	◘										■	◘	■		■	◘	■	■									www.chemservice.it
Chemtopia Co., Ltd.	■				■			◘		◘			◘	■		□	■	■	■	■	◘	■	□		□	◘	◘						www.chemtopia.net
chemtrac®	■	◘	◘		■	■		■	■	■		■	■	◘	◘	■	■	■	■	■	■	■	■	◘	◘	◘	◘	◘	◘	◘	■	■	www.chemtracglobal.com
CHEMTREC	■	■	◘			◘		◘		◘	◘		■																				www.chemtrec.com
Chemwatch																■	■	■	■	■	■	■	■	■	■	◘	◘	◘	◘	◘	■	■	www.chemwatch.net
CHESSOL B.V.						■							◘				■	◘	■	■	◘	■	■										www.chessol.nl
China National Chemical Information Center	■	■			■	■									■			■		■				■	■								www.chemhse.com/english
ChIR – Chemical Innovation and Regulation	■	◘	■	◘	◘												■		■	■	◘	◘	◘	◘		◘				◘	◘		www.emmcchir.org
Chris Braun Consultancy	■																■	■	■	■													
Chymeia ApS	■	■	■	■	■	■	◘				◘	◘	◘	■	■	◘	■	■	■	■		◘	◘			■					■		www.chymeia.com
CIRS	■	◘			◘	■		■	■			■	■	◘	■	□	■	■	■	■	□	◘	□	◘	◘	■	■	◘				■	www.cirs-reach.com
CIS Center	■	◘											◘			◘	◘		■	■						◘							www.ciscenter.ru
CiToxLAB	■	■	■	■	■	■	■						◘	■	◘		□	□	□		□		□										www.citoxlab.com
CJV Consulting Ltd	■	◘			■	◘											■	◘	■	■	◘	■	◘										cjvconsultingltd.wix.com/cjvconsultingltd
Clariant																	■	■	■	■	■	■	■										www.clariant.com
Compliance & Risks			◘	◘	■	■		■	■	■		■	◘	■	■	■	■	◘	◘	■	■	◘	◘		■	■	■	■			■	■	www.complianceandrisks.com
Compliance Footprint AG	■	■															■	□	■	■													www.compliance-footprint.com
Compliance Services International	■	■	◘	◘	■	■	◘							◘	■		■	■	■	■	◘	■	■	■	◘		◘			◘			www.complianceservices.com
compliance2business	■	□	□	□	◘	◘	□										■	◘	■	◘	□	■	■	□									www.compliance2business.eu
Consortia Management GmbH	■				■												■				■												www.consortia-management.com
CONUSBAT Regulatory Services		■		■		◘	■																◘										www.conusbat.com
Cosanta	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	◘	□	■	■	□				◘			■	■	■			www.stoffenmanager.nl; www.cosanta.nl
Cosmetic Design Laboratories	◘	□	◘	□	□	■	□										□	□	□	□	□	□	◘	□									www.cosmeticdesignlaboratories.co.uk
CRAD	■	■	◘	◘	■	◘	◘										■		■	■	□	■	□	□									www.crad.com.tr
Crowell & Moring	■	■	■	■	■			■		■	■	■					■	■	■	■	■	■		■				■					www.crowell.com
CS Regulatory Ltd	■				◘			□				◘	◘		□		■	■	■	■	■	■			□	□				◘	◘		www.csregulatory.com
CTT	■	◘	◘	■	◘	■	□										■	■	■	■	■	■	■	◘									www.cttlab.com
Currenta GmbH & Co. OHG	■	■	■		◘	◘	◘										■	◘	■	◘	◘	◘	◘	■									www.analytik.currenta.de
Cyprotex	■	■	■	■	■	■	◘		◘			◘	■	◘		◘	■	■	■	■	■	■	■	■		◘	◘		◘	◘			www.cyprotex.com
Danger and Safety srl	■				■	■											■	■	■	■	◘	■	■										www.dangerandsafety.it
DanGoods Training & Consultancy	■	◘			◘	◘											◘	◘	■	■		◘	◘										www.dangoods.co.uk
Danish Technological Institute	◘		◘	■				◘		■	◘	◘		◘			◘		◘		■	◘				◘							www.dti.dk
Datalab	■																																www.datalabsj.com
David Ryberg																	◘		◘														
Defense Logistics Agency																	■		■	■	■												www.dla.mil

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service ◘ Service that is occasionally provided □ Service provided by partners and third parties

	Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
▶	**DEKRA**	**120**	UK	80+ globally	5,000 plus	100-500	◗	◗		◗			◗	◗	
	DEKRA Assurance Services GmbH		Germany		25-50	5-10	●	◗					◗		
	DEKRA Consulting GmbH		Germany	France, Hungary, Turkey, UK	100-500	50-100	●	◗					◗		◗
	Dell Tech Laboratories Ltd.		Canada		5-10	2-5	◗			◗		◗			
	Delphic HSE Solutions Limited		UK	Hong Kong	10-25	10-25	◗	◗		◗		◗	◗		
	Dentons		USA	Belgium	100-500	10-25	◗	◗	◗				◗		◗
▶	**DHI**	**122**	Denmark	30 offices worldwide	1,000-2,000	50-100	◗	◗		◗	◗		◗		
	DIPHEX Ltd		UK		5-10	2-5	◗						◗		●
	Distefano Law Office		Belgium		2-5	2-5	◗		●						
▶	**DORUK SISTEM**	**124**	Turkey		25-50	10-25	◗	◗		◗	◗	◗	◗		
	DR MACH Chemical Compliance & Competence	**224**	Germany		1	1	●	◗					◗		
	Dr Prerna Shinde		India		1	1	●			◗			◗		◗
	Dr. Andrea Volpato		Italy		1	1	●								
▶	**Dr. Knoell Consult GmbH**	**126**	Germany		100-500	100-500	●	◗		◗	◗	◗	◗		
	Dr. Philipp Langenbach GmbH		Germany		1	1	●	◗							
▶	**EAG Laboratories**	**128**	USA	China, France, Germany, Japan, Singapore, Taiwan	1,000-2,000	100-500	◗			●					
	Eagle Environmental		South Africa		2-5	1	◗								●
▶	**EBRC Consulting**	**130**	Germany		50-100	25-50	●	◗			◗		◗		
	ECD Compliance		Canada		2-5	2-5	◗	◗		◗		◗	◗		◗
	ECETOC		Belgium		5-10	5-10									●
	Ecolab		USA		5,000 plus	50-100	○								●
	Ecomatters BV	**225**	The Netherlands	Spain	5-10	2-5	●				◗		◗		
	EcoMole Ltd.		UK	Czech Republic	5-10	5-10	◗	◗			◗	◗	◗		
	ECOMUNDO		France	Canada	25-50	25-50	◗				◗		◗		
▶	**EcoOnline**	**132**	Norway	Sweden, Finland, Denmark, Switzerland	50-100	5-10	◗				●	◗	◗		
	Ecotox Services International		Australia		5-10	5-10				●					
	ECT Oekotoxikologie GmbH		Germany		25-50	25-50	◗	○		◗		○	○		◗
	Edif ERA		UK		100-500	5-10	●								
	Edupalli Ramakrishna		India		500-1000	100-500				◗			●		
	eftec		UK	Belgium	10-25	10-25	●						◗		
	EggCentris		Belgium		5-10	5-10	◗			●					
	EHS Strategies, Inc		USA		1	1	●						◗		
	EHSCareers.com, Inc		USA		5-10	2-5									●
	elc group		UK	Czech Republic, India, Romania	50-100	10-25	◗	◗		◗	○	◗	○		
	Elemica		USA	Europe, Asia	100-500	100-500					●				
	Emveo		Belgium		1	1	◗	◗	◗				◗		
	Enthone BV		The Netherlands		2,000-5,000	10-25									
	Envigo		USA	Offices in 14 countries worldwide	2,000-5,000	500-1,000	◗			●					
	Enviresearch	**225**	UK		10-25	10-25	●	◗		◗	◗				
	Environmental Assessments		Germany	Sweden	2-5	2-5	◗	◗				◗	◗		
	Environmental Science Limited		UK		2-5	2-5	◗				◗		◗		
	EnviroPlanning AB		Sweden		5-10	2-5	●								
	EquiTox		France		2-5	2-5	●	◗				○	◗		
▶	**ERM**	**134**	UK	Worldwide offices	5,000 plus	100-500	●	◗			◗		◗		
	ES4chem		The Netherlands		1	1	◗	◗			◗				
	eSpheres	**225**	Belgium	Finland, Germany, France, Netherlands	25-50	25-50	◗				◗	◗			
	ETC		Slovakia		10-25	5-10	●	◗				◗	◗		
	EUPHOR	**225**	USA		50-100	10-25	◗				●				
	Eupoc		Germany		1	1	◗	◗	◗			◗	◗		
	Eurideas Language Experts	**226**	Belgium	Hungary	10-25	10-25	●								
	Euro Safety and Health		UK		2-5	2-5	●					◗	◗		
▶	**Eurofins**	**136**	Belgium	Germany, UK, Switzerland, Denmark, Asia, US	5,000 plus	100-500	◗			●					
	Eurofins Air Toxics		USA	Denmark, Germany, France, China	5,000 plus	2,000-5,000	◗			●					
	Eurofins Product Testing A/S		Denmark	Europe, China, USA	5,000 plus	100-500	◗			●					
	Euromines		Belgium		5-10	2-5									
	Eversheds LLP		UK	Europe, Middle East, Asia	2,000-5,000	25-50			●						
	Exitss		Belgium		10-25	2-5	◗	◗	◗		◗	◗	◗		◗
▶	**Exponent International Limited**	**138**	UK	USA, Switzerland, China	500-1,000	50-100	●	◗				◗	◗		
	f_OXYDE GmbH		Austria		5-10	2-5	●	◗							◗
	Fanwood Chemical, Inc		USA	Germany	2-5	2-5	●								
	Fera Science Ltd		UK		100-500	100-500	◗	○		●	◗		○		
▶	**Fieldfisher LLP**	**140**	UK	Belgium, France, Germany, Italy	100-500	10-25	◗	◗	●		◗		◗		

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20% ○ <5%

	Focus of activities																Regulatory expertise															
Organisation	Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	Further information
DEKRA	■	■	■	◘	◘	◘	◘	◘		◘	◘	◘	◘	◘	◘	◘	■	■	■	■	■	◘	◘	◘	◘	◘	◘	◘	◘	◘	◘	◘	www.chilworth.co.uk
DEKRA Assurance Services GmbH	■	◘	□	□	□	◘	□										■	◘	■	■	◘	□	□	□									www.dekra.de/reach
DEKRA Consulting GmbH	■	◘	◘			◘											■	◘	■	■	□	□	◘	□									www.dekra.de/en/reach
Dell Tech Laboratories Ltd.	■	■	◘	◘	■	■	◘											□	◘	■	□		□	◘									www.delltech.com
Delphic HSE Solutions Limited	■	◘	◘		■	■											■	■	■	■	◘	■	■	◘									www.delphichse.com
Dentons	■	◘	■	■	■	■	◘										■	■	■	■	■	■	■										www.dentons.com
DHI	■	◘	■	◘	■	■	■	◘	◘				◘	■	■	■	■	■	■	■	◘	■	■	◘	■	◘	◘	■	◘	◘	■	■	www.tox.dhigroup.com
DIPHEX Ltd	■	■	■	■		■																											www.diphex.com
Distefano Law Office	■	■	■	◘	■	◘		◘	◘	□	■	◘		■	■	□	■	◘	■	◘		■	■	◘	■	◘	◘	■	□	□	□	□	www.distefanolawoffice.com
DORUK SISTEM	■	■	◘	◘	■	■	■										■	■	■	■	■	■	■	■									www.doruksistem.com.tr
DR MACH Chemical Compliance & Competence	■					■											■		■				■										www.mach-chemguide.com
Dr Prerna Shinde	■	◘	■														□			■	◘												
Dr. Andrea Volpato	■	◘			◘			◘		◘		◘		◘			■	■	■	■	□	◘		◘		◘		◘					www.andreavolpato.it
Dr. Knoell Consult GmbH	■	■	■		■	■	■	◘	■	■	◘	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	◘	◘	◘	■	www.knoell.com
Dr. Philipp Langenbach GmbH	◘		■	◘		◘											■	◘	■	◘			◘										www.dr-langenbach.de
EAG Laboratories	■	■	■	■	■	■	■	■	◘	■	◘	◘	■	■	■	◘	◘	□	□	□	◘	◘	◘	■		◘		◘					www.eag.com
Eagle Environmental																																	www.eagleenv.co.za
EBRC Consulting	■	■	◘		■	◘			◘				◘	■		■	■	■	■	■		■	◘	■			◘		◘					www.ebrc.de
ECD Compliance																	■			◘													www.ecdcompliance.com
ECETOC	■	■	■	■	■	■	◘																										www.ecetoc.org
Ecolab	■				◘												■	■	■	■	■	■	■										www.ecolab.com
Ecomatters BV	■	◘			■	■							■				■		■			■	■	◘									www.ecomatters.nl
EcoMole Ltd.	■	□	□	■	□	□			◘		◘	◘	◘		◘	□	■	□	■	□	□	◘	◘	□	◘	□	□						www.ecomole.com/reach-clp-consulting.html
ECOMUNDO	■				■	■		■		■		◘	◘			■	■	■	■	■	■	■	■			■							www.ecomundo.eu/en
EcoOnline	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	www.ecoonline.com
Ecotox Services International	■	■	■	■	■	◘	◘																										www.ecotox.com.au
ECT Oekotoxikologie GmbH	■	■	■		◘	◘	■										■	□	◘	◘		◘	◘	◘									www.ect.de
Edif ERA								■		◘				◘			■		◘		◘	◘				■	◘	◘						www.edifgroup.com
Edupalli Ramakrishna	□	□	□	□	□		□										□	□	□	□	□	□		□									www.bhu.ac.in
eftec	□	□	□	□	□	□	□										■	□	□	□	□	□	□	□									www.eftec.co.uk
EggCentris	■	■	■	■	■	■	■										□		□	□	□	□	□	□									www.EggCentris.com
EHS Strategies, Inc	■	◘		◘													◘			■													www.ehsstrategies.com
EHSCareers.com, Inc																																	www.ehscareers.com
elc group	■	◘	■	□	◘	■	◘										■	■	■	■	□	◘	■	◘									www.elc-group.com
Elemica	■	■			■	■											□	□	□	□	□	□	□	□									www.elemica.com
Emveo	■	■			■												■		◘	◘		■		■									www.emveo.be
Enthone BV	■																■	■	■	■	■												enthone.com
Envigo	■	■	■	■	■	■	◘	■									■	■	■	■	■	■	■	◘	■								www.envigo.com
Enviresearch	■	■	■		■		■						◘				■	◘	■	◘	◘	■		■		◘							www.enviresearch.com
Environmental Assessments	■	◘	□	□	◘	◘											■	■	■	■	■	◘	◘	◘									www.enas-online.com
Environmental Science Limited	■	◘	■		◘												■	□	■	■	□	◘											www.esldatasheets.com
EnviroPlanning AB	■		□		■	■											■		■				■										
EquiTox	■				■	■											■	□	■	■		■	■										www.equitox.eu
ERM	■	■	■	◘	■	■	◘	■	◘	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	◘	◘	■	■	■	■	■	www.erm.com
ES4chem	■	◘			◘												■																
eSpheres	■	◘	■	◘	■	■		◘		◘							■	■	■	■	■	■	■	◘		◘							www.espheres.com
ETC	■				■	◘											■	□	■	■		■	◘										www.ekotox.sk
EUPHOR	■	■	◘	◘	◘	◘	■	◘	◘	◘	◘	◘	◘	■	■	◘	◘	■	◘	◘	◘	◘	■	■	◘	◘	◘	◘	◘	◘	◘	◘	www.euphoreach.com
Eupoc	■																■	◘	◘	◘													www.eupoc.com
Eurideas Language Experts	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	www.eurideastranslation.com
Euro Safety and Health	■		◘		◘	◘				■	◘					■	■	◘	■	■		◘									■	■	www.eurosh.com
Eurofins	■	■	■	■	■	■	◘	■	■			■	■	■	■		■	□	■	■	□	■	■	■	■	■	■	■	■	■			www.eurofins.com
Eurofins Air Toxics	◘	■	■	◘	■	■											■	■	■	■	■	■	■	■									www.airtoxics.com
Eurofins Product Testing A/S	■	■	■	■	■	■											■	■	■	■		■	■	■									www.eurofins.com/galten
Euromines	■																■	◘	■	◘	□												www.euromines.org
Eversheds LLP	■	■	■	■	■	■	■										■	■	■	■	□	■	■	■									www.eversheds.com
Exitss	◘																■	◘	■	■		◘											www.exitss.eu
Exponent International Limited	■	■	◘	■	■	■	◘	■	■	■	■	◘	◘	◘	■	■	■	■	■	■	■		■	■	◘	◘	◘			◘	■		www.exponent.com
f_OXYDE GmbH	◘				■																■												www.foxyde.com
Fanwood Chemical, Inc	■																■																www.fanwoodchemical.com
Fera Science Ltd	■	■			■		■				◘		◘		■		■	◘	◘			■		◘	■						■		www.fera.co.uk
Fieldfisher LLP	■	■	◘	◘	■	◘	◘							■	◘		■	■	■	■	□	■	■	◘	■	◘	■						www.fieldfisher.com

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service ◘ Service that is occasionally provided □ Service provided by partners and third parties

Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
Flashpoint srl		Italy		10-25	5-10	●						◗		
FoBiG	**142**	Germany		10-25	10-25	●	)				)	)		)
Food and Environment Research Agency (Fera)		UK		5-10	5-10	●						◗		
Foresite Systems		USA		25-50	5-10	◗				●				
Fraunhofer ITEM		Germany		100-500	25-50	◗	◗		◗			◗		◗
GAB Consulting GmbH	**144**	Germany	Italy, Cyprus, Slovenia, Spain, Poland	50-100	50-100	●	◗				)	)		
Gain Claude		France		1	1	●								
GBK GmbH Global Regulatory Compliance		Germany		25-50	10-25	●	◗	◗		◗	◗	◗		
Gentrochema BV		The Netherlands		2-5	1	◗	◗	◗	◗					
GHD		USA	Australia, Canada, Chile, New Zealand, UK	5,000 plus	100-500	●								
GHS Training & Consulting		Canada		1	1	◗						●		
GHS-expert Ltd		Hungary		1	1	●				◗		◗		
Gillies Associates Limited		UK		2-5	2-5	●					◗	◗		
GlobalMSDS		UK		5-10	5-10	◗				◗	◗			
GLTaC, Inc.		USA		10-25		◗		◗		◗	◗	◗		
Golder Associates		Italy	Offices in over 20 countries	5,000 plus	50-100	●	◗							
Gradient	**146**	USA		100-500	50-100	●								
GreenSoft Technology, Inc		USA	Taiwan, Japan, China, Spain	50-100	50-100					◗	◗			
Greenwich Chemical Consulting		USA		1	1	●								
Grow Smart Solutions	**226**	Romania	-	2-5	2-5	◗	●	)	)	)	◗	)		
H2 Compliance		Ireland	USA	10-25	10-25	◗	◗			◗		◗		◗
Haley & Aldrich, Inc.		USA		500-1000	10-25	●						◗	◗	
Hangzhou RUIO Technology Co. Ltd		China		50-100	50-100	◗	●		◗	◗		◗		◗
HAZMAT Ltd		Israel	UK	25-50	10-25	●	◗				◗	◗		
HDTS Chemicals Inc.		Canada		2-5	2-5	◗	◗			◗		◗		
herbert smith llp		UK		2,000-5,000	2-5			●						
HFL Consulting Ltd		UK		25-50	2-5	●						◗		
Hohenstein Group	**148**	Germany	Bangladesh, China, Hong Kong, India, Turkey, USA	500-1,000	100-500	◗			●	)	◗	◗		◗
Hunton & Williams		Belgium	USA	5,000 plus	1,000-2,000			●						
I+K AG, Compliance-Footprint AG	**226**	Switzerland		2-5	2-5	◗	◗			◗		◗		◗
IBACON GmbH		Germany		100-500	100-500				●					
ICB Pharma	**150**	Poland		50-100	25-50	◗			◗					●
ICF International		USA	Belgium, Brazil, China, Russia, India	2,000-5,000	50-100	●								
IDRG (International Development of Regulatory Globalization)		Germany		2-5	2-5	◗						◗		
IFF China		China		5,000 plus	50-100	◗				◗	◗	◗		◗
IGCON		The Netherlands		1	1	●	◗				◗	◗		
INERIS	**152**	France		500-1,000	500-1,000	◗	◗		◗		◗	◗	◗	)
INFOTOX	**226**	Portugal	UK & India	2-5	2-5	●	◗					◗		
INSCX exchange		UK	USA, Turkey	5-10	2-5	◗	◗				◗			
International Cosmetics & Chemical Services Ltd	**154**	USA	UK	5-10	5-10	●	◗					◗		
Intertek	**156**	UK	110+ Countries	5,000 plus	1,000-2,000	◗			◗	)	)	)		◗
IOM		UK	Singapore	100-500	10-25	●	◗	◗	◗	◗				
IPO O/Pszczyna		Poland		50-100	50-100				●					
iPoint-systems gmbh		Germany	Austria, France, Benelux, Sweden, UK, USA, Japan, China, South Korea	100-500	25-50	◗				●		◗		
Jaehak Jung		South Korea	China, Vietnam	50-100	2-5	◗	◗	◗	◗	◗	◗	◗		◗
Japag Regulatory Consultancy		India		2-5	2-5	●								
Japan Chemical Safety Institute		Japan		1	1	◗	◗	◗		◗	●	◗		
Jean Warshaw, Esq.		USA		2-5	2-5			●						
Jones Day		Belgium	North America, Europe, Japan	5,000 plus	50-100			●						
Jongerius Consult BV	**227**	The Netherlands		1	1	◗	◗	◗		◗		◗		
JRF Global		India	USA, UK	100-500	100-500	◗			●					
JSC International Limited	**158**	UK		25-50	25-50	●	◗					◗		◗
K J Bray & Associates		UK		1	1	◗	◗							
K&L Gates LLP		Belgium		1,000-2,000	25-50			●						
KAELTIA Compliance Services	**160**	Spain		5-10	5-10	●	◗			◗	◗	◗		
Kathrin Lanz		Germany		10-25	10-25			◗		◗	●			◗
Keller and Heckman LLP		USA		100-500	50-100	●								
Kerona Scientific Ltd	**227**	Ireland	Spain	5-10	5-10	●						◗		
KFT Chemieservice GmbH	**162**	Germany		10-25	10-25	◗	◗	)	)	)	◗	◗		◗
Konica Minolta Business Expert, Inc		Japan		2,000-5,000	10-25	◗	◗	●						
KREATiS		France		2-5	2-5				◗	◗				

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20%) <5%

Organisation	Focus of activities: Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	Regulatory expertise: REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	Further information
Flashpoint srl	■	◘	■	◘	◘	■	◘										■	■	■	■		◘	◘										www.flashpointsrl.com
FoBiG	■	◘	◘		■	◘			◘		◘	◘	◘	■	◘	◘	■	◘	■	■		■	◘	◘	◘	◘	◘	◘	■	■	◘	www.fobig.de
Food and Environment Research Agency (Fera)	■	■	□		■	□	■										□	□	□	□	□	□	□	□								www.fera.defra.gov.uk
Foresite Systems	◘		■	■													■	■	■		■		■									www.foresitesystems.com
Fraunhofer ITEM	■	◘	■	■	■	◘	■										■	◘	■	■		■	◘	◘									www.item.fraunhofer.de
GAB Consulting GmbH	■	■	◘		■	◘	■						◘		◘		■	■	■	■	■	■	◘	■	◘								www.gabconsulting.de
Gain Claude	■	◘															■		■														
GBK GmbH Global Regulatory Compliance	■	■	■	■	□	◘	□	■	◘	■	■	◘	■	◘	◘	◘	■	■	■	■	◘	◘	◘	□	□	◘	□	◘	◘	□	□	◘	www.gbk-ingelheim.de/en
Gentrochema BV																																www.gentrochema.nl
GHD											◘								■	◘			◘						■	◘	■	www.ghd.com
GHS Training & Consulting	■																		■													www.ghstc.com
GHS-expert Ltd	■				■	□											■		■	■	■											www.REACHexpert.eu
Gillies Associates Limited	■	◘	◘	◘				◘		◘	◘		◘	◘		■	■		◘							◘		◘	◘		■		www.gilliesassociates.co.uk
GlobalMSDS	■	■	■	◘	■	◘											■	◘	■	■												www.globalmsds.co.uk
GLTaC, Inc.	■	■	■	■	■	■											■	□	■	■	□	□	■	□								www.gltac.com
Golder Associates	■	□	□		□	□											■	■	■	■	◘	□	□	□								www.golder.com
Gradient	■	◘	◘	◘	■	■		■				◘	■	■	■	■	◘	■		■	■											gradientcorp.com
GreenSoft Technology, Inc	■	◘	■	◘		■											■	■	■	■	■		◘									www.greensofttech.com
Greenwich Chemical Consulting	■		□														◘	■	■	■	■											www.grcci.com
Grow Smart Solutions	◘	◘	◘		■	■	◘		◘				■	■	◘	□	◘	□	■	■		■	■	■	◘		◘	■					www.produsebiocide.ro
H2 Compliance	■		■	◘	◘	◘		◘		◘			◘	◘	◘	□	■	■	■	■	◘	◘	□			■		◘					www.h2compliance.com
Haley & Aldrich, Inc.																																www.haleyaldrich.com
Hangzhou RUIO Technology Co. Ltd	■	◘			◘	◘											■	◘	■	◘	◘	◘	◘									www.reach24h.com
HAZMAT Ltd	■	■	◘	◘	◘	◘											■	◘	■	■	◘	◘	◘	◘								www.hazmat.co.il
HDTS Chemicals Inc.	■	■	■	■	◘	◘	◘											■	◘	■	◘											www.hdtschemicals.com
herbert smith llp	■	■	■	■	◘	■	◘										■	■	■	■	◘	◘	◘	■								www.herbertsmithfreehills.com
HFL Consulting Ltd	■	■	■	■	◘	◘	◘										◘		■	◘												hflconsulting.uk
Hohenstein Group	◘		◘	◘		◘		■				■	◘				■	■				■	◘			■						www.hohenstein.com
Hunton & Williams	□																■								■							www.hunton.com
I+K AG, Compliance-Footprint AG	■	◘			◘										◘		■	◘	■	◘	◘	◘	◘		◘							www.i-k.ch, www.complinace-footprint.com
IBACON GmbH	■	■	◘		■		■																									www.ibacon.com
ICB Pharma		■			■	■	■						■	■																		www.icbpharma.com
ICF International	■	◘			◘												■		■	■	■											www.icfi.com
IDRG (International Development of Regulatory Globalization)		■			◘																	◘		■								www.idrgplantprotection.eu
IFF China	■					◘													■	■	◘											
IGCON	■	◘	◘		■	◘											■	□	■	■	◘	■	◘									www.igcon.nl
INERIS	■				◘	◘				■	◘		◘		◘	◘	■	◘	■	◘		◘		◘									www.ineris.fr
INFOTOX	■				■	■							■	◘			■	◘	■	■		■	■					◘					www.infotox.pt
INSCX exchange	■	◘															■			■												www.inscx.com
International Cosmetics & Chemical Services Ltd	◘		◘	◘		■	◘	◘	■			■	■	◘	◘	◘	■	■	■	◘	◘		■		◘	◘	◘	◘			◘		www.Intlcosmetics.com
Intertek	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	www.intertek.com
IOM	■	■	■	■	■	■	■										■	■														www.iom-world.org
IPO O/Pszczyna	■	■	■	■	■		■										■	◘	◘	◘	◘	■		■								www.ipo-pszczyna.pl
iPoint-systems gmbh	■	◘	■	◘	■	■	◘	■	■	■	◘	■	◘	■	◘	◘	■	□	■	■	■	■	□	◘	■	■	■	□	□	◘	□		www.ipoint-systems.com
Jaehak Jung	◘				◘												■	■	□	□			◘									www.kotiti.re.kr
Japag Regulatory Consultancy																	□	□	■	■	□	□	◘	◘								
Japan Chemical Safety Institute	■																■	■	■	■	■											
Jean Warshaw, Esq.	■	■																			■											
Jones Day	■	■	■	■	■	◘	◘										■	◘	■	■	■	■	◘	◘								www.jonesday.com
Jongerius Consult BV	■	◘	◘		◘	◘							◘			◘	■	◘	■	◘		◘	◘									www.jongeriusconsult.com
JRF Global	■	■	■	■	■		■										◘	◘	◘	◘		■		■								www.jrfonline.com
JSC International Limited	■	■	◘		■	◘	◘						■	◘			■	□	■	■	□	■	◘	■				◘				www.jsci.co.uk
K J Bray & Associates	■				◘												■	◘	■	◘		◘										
K&L Gates LLP																	■		◘	◘		◘	◘	◘								www.klgates.com
KAELTIA Compliance Services	■	■	■	◘	■	■	■		■				■	■	■		■	■	■	■	■	■	■	■	■	■	■			■	■	www.kaeltia.com
Kathrin Lanz	■	◘	■	◘	■	■	◘										■	□	■	■		■	■									www.qualisys.eu
Keller and Heckman LLP																																www.khlaw.com
Kerona Scientific Ltd	◘	■			■												■	■	■			■		■								www.kerona.ie
KFT Chemieservice GmbH	■	◘			■	■		◘	◘	◘		◘	■	■	◘	◘	■	■	■	■	□	■	■		◘	◘	◘	◘			◘	■	www.kft.de
Konica Minolta Business Expert, Inc	■				□												◘	■	◘	■	◘											www.konicaminolta.com
KREATiS	■	□	□	□	□	□	□										■	□	□	□		□	□	□								www.kreatis.eu

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service ◘ Service that is occasionally provided □ Service provided by partners and third parties

Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
Kumi Consulting Ltd		UK		5-10	2-5	●								
KV Consulting Services BVBA		Belgium		1	1	◗	◗							
LAUS	**227**	Germany	France, USA and UK	50-100	25-50	◗	◗		●					
LG CNS		South Korea	Asia, South America, Europe, USA, Middle East	5,000 plus	50-100	◗	◗	○	○	◗	◗	○		○
LGC		UK		1,000-2,000	50-100				●					◗
Linmark Consulting	**227**	Switzerland	UK	2-5	2-5	●	◗					◗		
Linnunmaa Oy		Finland		10-25	5-10	◗	◗	◗						
▶ **Lisam Systems**	**164**	Belgium	USA, Canada, UK, France, Germany, Romania, India, Turkey, Brazil	100-500	100-500	◗	○			●	◗	◗		
LKC Switzerland Ltd	**228**	Switzerland	UK	5-10	5-10	●	◗		◗		◗			
Loufakis Chemicals SA		Greece	Bulgaria, Servia, Macedonia	25-50	2-5	◗	◗		◗					●
LSR Associates		UK	USA, Japan	1,000-2,000	25-50	◗	◗				◗	◗		
Manatt, Phelps & Phillips, LLP		USA		100-500	25-50			●						
MB Research Laboratories		USA		25-50	2-5				●					
mediator A/S	**228**	Denmark		5-10	5-10	●	◗			◗		◗	◗	
Mercer		USA	Asia-Pacific, EMEA, Americas	100-500	2-5						●			
Mérieux Nutrisciences		USA	Italy, Brazil, France, China	2,000-5,000	1,000-2,000	◗	◗		●		◗			
Miami Chemical		USA		10-25	5-10	◗	●							
Micromeritics Analytical Services		USA		10-25	1				●					
Modern Testing Services (Global)		Hong Kong	US, UK, Germany, China	1,000-2,000	100-500	◗			●					
MSDS Europe		Hungary	France, Germany, Poland, Italy, Spain	10-25	10-25	◗	◗	◗	○	◗	◗	◗		
National Chemical Emergency Centre (NCEC)		UK		25-50	25-50	◗					◗	◗		◗
National Physical Laboratory (NPL)		UK		500-1000	100-500	◗			●			◗	◗	
Neuralog, LP		USA	Canada	25-50	10-25					●				
NimkarTek Technical Services Pvt. Ltd		India	Sri Lanka, Bangladesh	10-25	10-25	◗						●		◗
Noerr LLP		Germany		1,000-2,000	10-25			●						
NovaTox		Canada	Ireland, UK	2-5	2-5	●								
Oriental Chemical Information Co., Ltd	**228**	China	Japan, Taiwan, France, Philippines, Korea, Germany, Thailand	10-25	5-10	◗	◗		◗	◗	◗	◗		◗
Pace Regulatory Services		USA		2,000-5,000	100-500	●								
Paul Illing Consultancy Services Ltd		UK		1	1	●	◗							
PeerAspect		USA	France	10-25	5-10					●				
Penman Consulting		Belgium	UK, The Netherlands	5-10	5-10	◗	◗			◗	◗	◗		
Pera Technology		UK		100-500	10-25	●								
Peter Fisk Associates	**228**	UK	Belgium	10-25	10-25	●	◗			◗	◗	◗		
PFA-Brussels	**229**	Belgium	UK	2-5	2-5	●								
plEt Consulting BVBA		Belgium		1	1	●						◗		
Pinnacle Associates		UK		2-5	2-5	◗				◗				
Pirjo Heikkilä		Finland		1	1	●								
Polgar ACRO		Hungary	Belarus, Kazakhstan, Moldova, Russia, Ukraine	10-25	5-10	●					◗			
Pöyry Finland Oy		Finland		2,000-5,000	10-25	●					◗	◗		
Prefusion LLP	**229**	UK	China	5-10	5-10	◗	◗			◗	◗	◗		
Proactima AS		Norway		100-500	10-25	●						◗		
ProductIP		The Netherlands	China, Hong Kong, Germany, UK	25-50	25-50	◗		◗			●	◗		
Prosacon GmbH		Germany		5-10	5-10	◗	◗	◗		○	◗	◗		○
PwC		The Netherlands	Global presence	2,000-5,000	25-50	◗	◗							◗
▶ **Ramboll Environ**	**166**	UK	130 in 28 countries	2,000-5,000	50-100	●	◗			◗				
Randis ChemWise (Shanghai) Co., Ltd.		China	Taiwan	10-25	5-10	●	◗	◗	◗		◗	◗		
REACH Advice GmbH		Germany		1	1	◗	◗	◗				◗		
▶ **REACh ChemAdvice GmbH**	**168**	Germany	Portugal, Sweden, USA, India, China, South Korea	5-10	5-10	●	◗			○	◗	◗		○
REACh ChemConsult GmbH		Germany	UK	5-10	5-10	●	◗			◗		◗		
Reach Chemical BV		The Netherlands		1	1	●	◗							
REACH Delivery		UK	USA, Japan	25-50	25-50	◗			●			◗		
▶ **REACH Global Services S.A.**	**170**	Belgium	Turkey	10-25	10-25	◗	●		○		○	◗		○
▶ **REACH mastery**	**172**	Italy		10-25	5-10	●	◗	○			○	◗		○
REACH Monitor		Spain		10-25	2-5	●	◗					◗		
Reach Only Representative Ltd		UK	Agents: Asia, Middle East	5-10	2-5	◗	◗	◗	◗	◗	◗	◗		
REACH Orphan Substances Consortium bvba ROSC	**229**	Belgium		2-5	2-5	◗	◗	○			○			
Reach Registration Services		UK		10-25	2-5	◗	◗	◗	◗	◗	◗	◗		○
REACH24H Consulting Group		China	Ireland, USA	100-500	50-100	●	◗		◗	◗	◗	◗		
▶ **ReachCentrum SA**	**174**	Belgium	EU, Taiwan, Vietnam, S.Korea, China, USA	10-25	10-25	◗	●	◗		◗		◗		
REACHECK Solutions GmbH		Germany		5-10	2-5	◗		◗			◗	◗		◗
▶ **REACHLaw**	**176**	Finland	Belgium, India, Turkey	25-50	25-50	◗	◗	◗	◗	◗	◗	◗		

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20% ○ <5%

	Focus of activities																					Regulatory expertise																			
Organisation	Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	Further information
Kumi Consulting Ltd								◘	◘	◘																														kumi.consulting
KV Consulting Services BVBA	■	◘						■	■	■	■	■	■		◘		■	◘	■	■	■	◘			◘	■	■														www.kvconsultings.com
LAUS	■	■	■		■	■	■						■	■	■		□	□	□	□	□	□	□	□	□	□	□	□													www.laus.de
LG CNS																	□	□	□	□	□	□	□	□																	www.lgcns.com
LGC	■	■	■	■	■	■	■										■		■				■	■																	www.lgc.co.uk
Linmark Consulting	■	■	■	□	■	■	□	□	□	□	◘	■	■	□	□	□	■	■	■	■	□	■	■	◘	□	□	□	□													www.linmarkconsulting.com
Linnunmaa Oy	■	■	◘	◘	◘	◘	□										■	■	■	■	◘	◘	■	◘																	www.linnunmaa.fi
Lisam Systems	■	◘	◘		■	■	◘	◘		◘	◘		■			■	■	◘	■	■	■	■	■	◘		■					◘	■									www.lisam.com
LKC Switzerland Ltd	■	■	◘	◘	■	◘	■					◘	■	□	◘	◘	■	■	■	■	◘	■	◘	■	◘			□			◘										www.LKC-ltd.com
Loufakis Chemicals SA	■	□			□	□											■		■	■		□	□	□																	www.loufakis.gr
LSR Associates	■	■	■	■	◘	◘	■										■	■	■	■	■	◘	◘	■																	www.lsr-associates.com
Manatt, Phelps & Phillips, LLP	■	■	■	■	■	■			■				■		■		◘			■					◘	■																www.Manatt.com
MB Research Laboratories	■	■	■	□		■	◘		◘			◘	■	■	■		■		■	■	◘			■	■				■												www.mbresearch.com
mediator A/S	■	■			■	■	■					◘	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■				■									www.mediator.as
Mercer	■																◘																									www.mercer.com
Mérieux Nutrisciences	■	■	■	◘	■	■	■										■	□	□	□	□	□	■	■																	www.merieuxnutrisciences.com
Miami Chemical	■																																								www.miamichemical.com
Micromeritics Analytical Services	■	◘	■	◘		◘											■																									www.particletesting.com
Modern Testing Services (Global)	■	□	□	◘	◘	■	□										■	■	■	■	■	◘	■	□																	www.mts-global.com
MSDS Europe	■	◘	◘	◘	■	□											■	◘	■	■	□	■	□	◘																	www.msds-europe.com
National Chemical Emergency Centre (NCEC)	■	■	■	◘	■	■	◘	■	◘	■	◘	◘	◘	◘	◘	◘	■	■	■	■	◘	□	□	□	□	□	□					■	◘								www.the-ncec.com
National Physical Laboratory (NPL)	■	■	■	■	◘	■	◘	■	◘	■	◘	◘	◘	■	◘	◘												◘													www.npl.co.uk
Neuralog, LP																	◘			■	◘																					www.neuralog.com
NimkarTek Technical Services Pvt. Ltd																	◘	◘	◘	◘	◘	□																				www.nimkartek.com
Noerr LLP	■	□	■	◘	■	■	◘										■	□	◘	□	□	■	■	□																	www.noerr.com
NovaTox	◘	◘	■	◘	◘	■	■										◘	□	□	□	□	◘	◘	◘																	www.novatox.ca
Oriental Chemical Information Co., Ltd	■	◘	◘	◘	◘	■	◘						◘		■	◘	□	■	□	■	□	□	□	◘	■																	www.oci.net.cn
Pace Regulatory Services	■	■	◘	◘	◘	◘	◘	◘	◘	■	■	◘	■	◘	◘	■	■	■	■	■	■	◘	◘	■	◘	◘	◘	◘													www.pacelabs.com/regulatory
Paul Illing Consultancy Services Ltd	■	◘			◘	◘											■		■	■	◘																					
PeerAspect	■	◘	◘		◘			◘	◘	◘		◘	◘	◘	◘	◘	■	■	■	■	■	■	◘	◘	■	■	◘	◘	◘	■			■	■								www.peeraspect.com
Penman Consulting	■					◘											■	■	■	■	■		◘																			www.penmanconsulting.com
Pera Technology	■																◘																									www.peratechnology.com
Peter Fisk Associates	■				◘	◘											■	■	■	■	□	◘	◘	□		◘																www.ecotoxchem.co.uk
PFA-Brussels	■				◘	◘											■	■	■	■		◘	◘	□		◘																www.pfa-brussels.eu
pIEt Consulting BVBA		◘			■	□											□		□		■	□	□																			www.pietconsulting.eu
Pinnacle Associates	■				◘		□										■	◘	■	■	◘	◘																				www.pinnacleassoc.com
Pirjo Heikkilä	■																■																									
Polgar ACRO	◘	■		◘	■	◘											□	□	□			□		■																	www.polgar-acro.eu
Pöyry Finland Oy	■	◘		■	□												■	◘	◘	◘		□																				www.poyry.com
Prefusion LLP	■	■	■	◘	■	■	■	◘	◘		◘		◘	■	■	■	■	◘	■	◘	□	■	■	■	■	◘	◘	◘			◘	■									www.prefusion.co.uk
Proactima AS	■	◘			◘	◘											■	◘	◘	◘		◘																				www.proactima.no/en
ProductIP					■	■											■		■	■		■	■																			www.productip.com
Prosacon GmbH	■	◘			■	◘		◘	◘	◘	◘	◘	◘	■	◘	◘	■	◘	■	■		■	◘	◘	◘	◘	◘	◘													www.prosacon.eu
PwC	■																■																									www.pwc.nl/nl/reach
Ramboll Environ	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■								www.ramboll-environ.com
Randis ChemWise (Shanghai) Co., Ltd.	■	□			◘	■											□	■	■	■	□	◘	□	□																	www.randis.cn, www.randischem.com
REACH Advice GmbH	■	□															■	■	■																							www.reach-advice.com
REACh ChemAdvice GmbH	■				■	□							■			□	■	■	■	■		■																				www.reach-chemadvice.com
REACh ChemConsult GmbH	■	◘	◘		■	◘	◘		◘			◘	◘		◘		■	■	■	■	◘	■	◘	◘	◘	◘	◘	◘													www.reach-chemconsult.com
Reach Chemical BV	■																■		■	■		◘		◘																			www.reacheu.nl
REACH Delivery																	■	■	□	■	■		■																			www.reachdelivery.com
REACH Global Services S.A.	■	◘			◘	■			◘	◘	◘	■	■		◘		■	■	◘	◘		◘	■		◘		◘														www.reach-gs.eu
REACH mastery		■	■		■	■							■	□	□	□	■	◘	■	◘	□	■	■	■	□	□															www.reachmastery.com
REACH Monitor	■	■	■	◘	■	■	■										■	■	■	■	◘	■	■	■																	www.reachmonitor.org
Reach Only Representative Ltd	■	□	□	□	□	□	□										■	◘	■	■	◘	□	□	□																	www.rorltd.com
REACH Orphan Substances Consortium bvba ROSC	■	■	◘	□	□	□	□	■	◘	■	■	■	■	□	□	□	■	□	■	□	□	□	□	□	□	◘	◘	□													www.ROSconsortium.eu
Reach Registration Services	■	□	□	□	□	□	□										■	◘	■	■	◘	□	□	□																	www.reach-rs.com
REACH24H Consulting Group	■	■			■	■	◘										■	■	■	■	◘	■	■	■																	www.reach24h.com/en-us
ReachCentrum SA	■	□	◘	◘	■			□	□	□	□	□	□	□	□	□	■	■	■	■	◘	■		◘		◘	◘	◘			◘	□									www.reachcentrum.eu
REACHECK Solutions GmbH	■				◘	◘		■	■	◘			◘		◘		■	■	■	■		◘	◘		◘	■	■															www.reacheck.eu
REACHLaw	■	■	◘		◘	◘		■	◘	■	◘	◘	◘		◘		■	■	■	■	■	■	◘	◘	◘																www.reachlaw.fi

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service ◘ Service that is occasionally provided □ Service provided by partners and third parties

Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
REACHLINKED		China		5-10	5-10	◗	◗				◗			
REACHReady	**229**	UK		5-10	2-5	◗	◗	◗	◗	◗	◗	◗		
ReachSpektrum, s.r.o.		Czech Republic		2-5	2-5	●					◗	◗		
REACHWise	**230**	UK	The Netherlands, Germany	2-5	2-5	●	◗					◗		
Redebel Regulatory Affairs S.C.R.L.	**178**	Belgium		50-100	50-100	●				◗		◗		
Redeker Sellner Dahs Rechtsanwälte		Germany	Belgium	100-500	5-10	◗		●						
ReFaC	**180**	UK		2-5	2-5	●	◗					◗		◗
RegScan Inc.		USA								◗	◗			
Regulatory Services International Ltd	**182**	China	UK, USA	10-25	10-25	◗	◗		◗	◗	○	○		
Regulatus		UK		1	1	●								
Ricerca Biosciences, LLC		USA		500-1,000	500-1,000	◗	◗		●					
RimaOne		Germany		25-50	25-50					●				
Risk & Policy Analysts Ltd (RPA)	**184**	UK	Belgium UK	25-50	10-25	●						◗		
Risk Control Services Ltd		UK		1	1	●								
Riskchem		South Africa		2-5	1	◗	◗					●		
Rivendell International		Ireland	USA, Spain and Japan	10-25	10-25	◗	◗	◗				◗		
RoHS Ready LLC		USA	Canada	1	1	●								
Roisin McEneany		Ireland		1	1	◗					◗	◗		
Rovaltain Research Company	**186**	France		25-50	10-25	◗			●			◗		◗
Royal HaskoningDHV	**188**	The Netherlands	100 offices worldwide	5,000 plus	50-100	◗	◗	◗	○	◗	◗	◗		
RTC, Research Toxicology Centre S.p.A.	**190**	Italy		100-500	50-100	◗			●					
SAFENANO		UK	Singapore	100-500	25-50	●			◗			◗		
Safety Data Services		UK		1	1	●						◗		
Safeware Quasar Ltd		UK	USA, Ireland, Greece, Japan, Turkey, The Netherlands	50-100	10-25	◗				●		◗		
SAP AG		Germany		5,000 plus		◗				◗				
SAP Japan Co, Ltd		Japan		1,000-2,000	5-10					●				
SATRA Technology		UK	China	100-500	5-10	◗			●			◗		
SCAS Europe	**230**	Japan	China, Singapore, South Korea, Taiwan	1,000-2,000	25-50	●								
SCC	**192**	Germany	Japan	100-500	25-50	●	◗	○		○	○	○		○
Science & Environnement		Switzerland	France	5-10	5-10	●	◗			◗	◗	◗		
Scivera	**230**	USA		10-25	10-25	◗				●		◗		◗
Selcia Ltd.		UK		50-100	50-100	◗			●					
SenzaGen	**230**	Sweden	Sweden, US	10-25	5-10	◗			●			◗		
ServiREACH, S.A.		Spain		10-25	10-25	◗			◗	◗		◗		
SGS		Switzerland	China, France, Germany, Hong Kong, UK, USA	5,000 plus	2,000-5,000	◗			◗			◗		◗
ShawCor		Canada		2,000-5,000	2-5		●							
SHES Chemical Consulting Co., Ltd		South Korea		10-25	10-25	●	◗			◗		◗		
Shridhar Rajappanavar		India		2,000-5,000	50-100					◗		◗		◗
Siam S.L.	**231**	Spain	France, Italy, Greece, Portugal, Poland, Romania, Finland, Ireland, UK, EL	10-25	10-25	◗			◗	●	◗	◗		
SIEF-IT		Poland		5-10	5-10	◗	◗			◗				◗
SiteHawk		USA		25-50	25-50					◗	◗			
Sitmae Reach Services BV		The Netherlands		2-5	2-5	◗	◗							◗
Smithers Viscient	**194**	USA	UK	100-500					●					
Spetsinterproject Oy		Finland	Russia, Ukraine	5-10	5-10	◗	●		◗		◗			
Sphera Solutions	**196**	USA	Worldwide	100-500	100-500	◗				◗	◗	◗		
Spinnaker Coating, LLC		USA		2-5	2-5	○	●	◗	○	◗	○	○		
Spring Trading Company, LLC		USA		5-10	2-5	●	◗		◗		◗			
Star Wang		China		500-1000	50-100								●	
Stefanie Merenyi		Germany		1	1	●		◗				◗		
Steptoe & Johnson LLP		USA	Belgium, UK, China	100-500	25-50	◗	◗	●						
Stewardship Solutions Ltd		UK		5-10	5-10	●								
Subvise		Germany		2-5	2-5					●				
Surface Science Western		Canada		10-25	10-25	◗			●			◗		
Sustainability Consult		Belgium		5-10	1	●								
Sustainability Support Services (Europe) AB	**198**	Sweden	India, South Korea	25-50	25-50	◗	◗	◗	◗	◗		◗	○	
SustChem Engineering Ltd		Greece		5-10	5-10	●	◗		◗			◗		
Syska Voskian Consulting		USA	Denmark	2-5	2-5	●						◗		
TB-Klade		Austria		1	1	●								
Ted Simon LLC		USA		1	1	●								
TEI Analytical, Inc		USA		5-10	5-10	◗			●					
Telematic srl		Italy		10-25	5-10	◗				●		◗		
Tenviro		Sweden	The Netherlands	1	1	◗	◗	◗			◗	◗		

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20% ○ <5%

	Focus of activities																	Regulatory expertise														
Organisation	Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	Further information
REACHLINKED	■	□															■		■	■													www.reachlinked.com
REACHReady	■	□	□	□	■	□	□										■		■	■	□	■	□										www.reachready.co.uk
ReachSpektrum, s.r.o.	■				■	□											■	□	■	□		■	□	□									www.reachspektrum.eu
REACHWise	■	□	□	□	■	■	□					■	■	□		□	■	□	■	■	□	■	■	□			□						www.reachwise.eu
Redebel Regulatory Affairs S.C.R.L.	■	■			■	□		□					■	□	■		■	■	■	■		■	■	■									www.redebel.com
Redeker Sellner Dahs Rechtsanwälte	■	□	□	□	■	■	□										■		■	■		■	■	□									www.redeker.de
ReFaC	■				■												■	■	■	■		■											www.refac.eu
RegScan Inc.																																	www.regscan.com
Regulatory Services International Ltd	■														□		■	■	■	□	■				□								www.rsireg.com
Regulatus	■	□	□		■	□	□										□		■	■		■	□	□									
Ricerca Biosciences, LLC	■	■	■	■	■	□	■										■	□	□	□	■	□	□	■									www.ricerca.com
RimaOne	■	■	□	■	■	□	□										■	□	■	■	□	□	□	□									www.rimaone.com
Risk & Policy Analysts Ltd (RPA)	■	□	□	□	■	■		□	□	■	□	■	■	■	□	□	■		■	□		■	■		□	■	■	■	■		□	□	www.rpaltd.co.uk
Risk Control Services Ltd	■				□	□											■	■	■	■	□	□	□										www.linkedin.com/in/rossfielding
Riskchem	■	□	□														□	□	□	■													www.riskchem.co.za
Rivendell International	■	■	■	□	■	■	□										■	■	■	■	■	■	■	■									www.rivendell.ie
RoHS Ready LLC								■		□				□			■									■								www.rohsready.org
Roisin McEneany	■	□	■			□											■		■														
Rovaltain Research Company	■	■	■	■	■	□	□					□	■	□	□	□	□	□	□	□	□	□	□	□		□		□	□	□			rovaltainresearch.com
Royal HaskoningDHV	■	□	■	□	■	■	■	■	□	□	■	■	■	■	■	■	■	□	■	■	□	□	□	□	■	□		■					www.royalhaskoningdhv.com
RTC, Research Toxicology Centre S.p.A.	■	■	■	■	■	□	□	□	□			■	■	■	□	□	■	■	■	■	□	□	■	■	■	■	□	■					www.rtc.it
SAFENANO	■	□	□		□	□											■	□	■	□	□	□	□	□									www.safenano.org
Safety Data Services	■																		■														
Safeware Quasar Ltd	■	■	■	□	■	■	□										■	□	■	■	■	□	□	□									www.safeware.co.uk
SAP AG	■	■	■		■	■											■	■	■	■	■	■	■	■									www.sap.com
SAP Japan Co, Ltd	■					□											■	■	■	■	■		□										www.sap.com
SATRA Technology																	■		□			□											www.satra.co.uk
SCAS Europe	■				□	□									□		■	■	■	■	□	□	□		□	□							www.scas-eu.be
SCC	■	■	□	■	■	■		□	□	□		□	■	■	■	■	■	■	■	■	□	■	■	■	□	□	□	■	□	□	□	□	www.scc-gmbh.de
Science & Environnement	■	□			■	■											■	■	■	■		■	■										www.sci-env.ch
Scivera	□	□	□		□	□	□	■	■	□	□	■	□	□	□	■	■	■	■	■	□	□	■		■	□	■	□	□	□	□	□	www.scivera.com
Selcia Ltd.	■	■	■	■	■	■	■						□	□	□		■			■	■	■	■										www.selcia.com
SenzaGen	■	□	□	□	□	■			□			□	□	□	□	■																	www.senzagen.com
ServiREACH, S.A.	■	■	■	□	■	■	□										■	■	■	■	□	■	■	■									servireach.com
SGS	■				■	■			■				■				■	■	■	■	■	■	■										www.sgs.com/reach
ShawCor	■																□		■	■													www.shawcor.com
SHES Chemical Consulting Co., Ltd	■	□	□	□	□	□											■	■	■	■	■	□	□	□									
Shridhar Rajappanavar																																	www.cae.com
Siam S.L.	■	■	□	□	■	■	□					■	■	■			■	■	■	■	□	□	□	□									www.siam-it.com
SIEF-IT																																	www.sief-it.com
SiteHawk	■	■	■	■	■												□	■	■	■	■												www.sitehawk.com
Sitmae Reach Services BV	■	■			□	□											■	□	■	■	□	□	□	□									www.sitmaereachservices.com
Smithers Viscient	■	■	■	□	■	■	■						□	□	□	■	■	■	■	■	■	■	■	■									www.smithersviscient.com
Spetsinterproject Oy	■	■	□		□								□				■	□	■	■	□	■	□	■	□	□							www.spetsinterproject.com
Sphera Solutions	■	■	■		■	■							■	■		■	■		■	■	■	■	■			■			■	■	■	■	www.spherasolutions.com
Spinnaker Coating, LLC	■		■														□	□			□												www.spinps.com
Spring Trading Company, LLC	□	■	□	□	■	□	□										□	□	□	□	■	□	□	■									Springtradingcompany.com
Star Wang	■							■									■	■	■	■	■					□						■	
Stefanie Merenyi																																	www.merenyi.net
Steptoe & Johnson LLP	■	■	■	■	■	■	■	■	■			■	■	■	■		■	■	■		■	■	■	■	■	□	□	□					www.steptoe.com
Stewardship Solutions Ltd	■	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	■	□	■	□	□	□	□	□	□	□	□	□					www.stewardshipsolutions.co.uk
Subvise																	■		□														www.subvise.com
Surface Science Western	□		□																														www.surfacesciencewestern.com
Sustainability Consult				■																													sustainabilityconsult.com
Sustainability Support Services (Europe) AB	■	■	□	■	□	■		□	■	□		■	□		□		■	■	■	■	□	□	□	□	□	□	■						www.ssseurope.org
SustChem Engineering Ltd	■	□			■	□											■	□	■	□	□	■	□	□									www.sustchem.gr
Syska Voskian Consulting	■	□				□											■		■	■	□												www.sysvoskconsulting.com
TB-Klade					■												□		□		■												www.tb-klade.at
Ted Simon LLC	■	■	□	□	■	□	□										□	□	□	□	■	□	□	□									www.tedsimon-toxicology.com
TEI Analytical, Inc	■	□	□		□	□											□		□		□												www.teianalytical.com
Telematic srl	■	■	■	□	■	■	□										□	□	■	■	□	□	□	□									www.epyplus.com
Tenviro	■	□	□	□	□	□											■	□	■	■	□	□	□	□									www.tenviro.eu

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service □ Service that is occasionally provided □ Service provided by partners and third parties

Organisation	Page	Headquarters	Other locations	Global staff	Chemical staff	Consultancy/advisory	Representation/management	Legal services	Laboratory services	IT & software solutions	Information services	Training	Equipment	Other(s)
Tetra Tech		USA	Germany, Canada, UK	5,000 plus	25-50	◗	◗			◗	◗	◗		
The Isosceles Group		USA		10-25	10-25	◗	◗			◗	●	◗		
The Martec Group		USA	Germany, China, Japan, Brazil, Chile	50-100	1	●								
The REACH Centre	**200**	UK	Italy, USA, Japan, China	25-50	25-50	◗	◗		◗	◗	◗	◗		
The Redstone Group		USA	The Netherlands	10-25	10-25	●								
The Sapphire Group		USA		5-10	5-10	●		◗		◗	◗			
the SDS factory | de ViB fabriek		The Netherlands	UK, Germany, Belgium	2-5	2-5	●				◗		◗		
The Windsor Consulting Group, Inc.		USA		5-10	2-5	◗	◗	◗			◗	◗		◗
TJS Technical Services Inc.		Canada		2-5	1	●								
TO21.Co.,Ltd.		South Korea		50-100	25-50	◗	◗	◗		◗	◗			
Tox Focus LLC	**231**	USA		2-5	2-5	●	◗		◗		○	○		
toXcel	**231**	UK	USA	10-25	10-25	◗	◗		◗		◗	○		○
Toxicon	**231**	Italy		5-10	5-10	◗	◗	◗	◗	○	◗	◗		○
Toxi-Coop Toxicological Research Centre Ltd.		Hungary	Switzerland, USA	50-100	25-50	◗			●					
Toxikon		USA	Belgium	100-500	5-10	◗			●					
ToxMinds	**202**	Belgium		10-25	10-25	●	◗				◗	◗		
ToxServices	**204**	USA	0.15	25-50	10-25	●				◗	◗	◗		
ToxSolve LLC		USA		1	1	●	◗							
ToxStrategies		USA		25-50	5-10	●	○				○	○		
TraceGains		USA		25-50	25-50				●					
Trade Wind B.V.	**206**	The Netherlands		5-10	2-5	◗		◗		◗	◗	◗		
Tradebe UK		UK	Spain, USA, France	1,000-2,000	500-1000	◗	●		◗					
TRASYS		Belgium	Europe	500-1000	50-100	◗	◗			◗		◗		
Triskelion B.V.	**208**	The Netherlands	Japan, USA, Canada (sales offices)	100-500	100-500	◗	◗		◗	◗	◗	◗	◗	
TSG		USA		100-500	50-100	●	◗				◗	◗		◗
TSGE Consulting		UK	Ireland, Spain, Germany, France, Slovenia, Poland	50-100	50-100	●	◗							
TUV Rheinland		USA	Germany, China, Japan, India, Taiwan, South Korea	5,000 plus	10-25	◗			◗	◗		◗		
TUV Rheinland Hong Kong Ltd		Hong Kong		5,000 plus	100-500	◗	◗		◗	◗	◗	◗		
TÜV Rheinland LGA Products GmbH		Germany	Europe, China, Japan, Thailand, Vietnam, India, North America, Brazil, Russia, Australia, South Africa,	5,000 plus	500-1000				◗	◗	◗	◗		◗
TUV Rheinland of North America		USA	Germany, China, Hong Kong, India	5,000 plus	1,000-2,000	◗	◗		◗		◗	◗		
TÜV SÜD Iberia S.A.U.	**212**	Spain	Taiwan	100-500	25-50	●		◗	◗			◗		
TÜV SÜD Industrie Service GmbH	**210**	Germany	Japan, Singapore, China, India	2,000-5,000	50-100	◗	◗		◗	◗	◗	◗		
TUV SUD Japan		Japan		100-500	2-5	◗	●		◗		○	○		
UL	**214**	USA	France, Belgium, UK, China, Germany, Japan	5,000 plus	100-500	◗				◗		◗		◗
UMCO GmbH	**216**	Germany		50-100	25-50	●	◗	◗			◗	◗		◗
Universit Bordeaux Segalen		France		500-1,000	100-500	◗	◗	◗	◗	◗	◗	◗		◗
Vanta Bioscience		India		25-50	10-25				●					
Verdant Law, PLLC	**218**	USA		5-10	5-10	◗	◗	●			◗	◗		◗
Vidaris, Inc.		USA		100-500	2-5	●						◗		
VITO NV team EHS Toxicology Services		Belgium		10-25	10-25	◗	◗	◗	●		◗			
Von Roll REACH GmbH		Germany		2-5	2-5	●	◗					◗		
VRS Regulatory	**232**	UK		5-10	2-5	●								
W.E. Train Consulting		USA		2-5	1	◗						●		◗
wca environment		UK	Scotland, Italy	10-25	10-25	●	◗							
Weeset Advisors		USA		1	1	●								
Wiley Rein LLP		USA		100-500	10-25	◗	◗	◗			◗	◗		
WILLIAM WILSON Wyeside Consulting Ltd	**232**	UK		1	1	●		◗						
Wilmer Tox Consulting		Switzerland		1	1	●						◗		
WRc plc	**232**	UK		100-500	10-25	◗	◗				◗	◗		
WSP UK Ltd	**232**	UK	Wordwide	5,000 plus	50-100	●	◗				◗	◗		
WTConsulting		Switzerland		5-10	5-10	●	◗				◗	◗		
YASH Technologies		USA	Europe, Asia, Australia	2,000-5,000	50-100	◗				●	◗	○		○
Zanos Limited		UK		2-5	1	◗	◗						●	

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◖ 40-60% ◗ 20-40% ◗ 5-20% ○ <5%

Organisation	Focus of activities																Regulatory expertise												Further information
	Industrial chemicals	Agrochemicals	Medical & pharmaceuticals	Biotechnology	Biocides	Personal care (inc. cosmetics)	Veterinary medicine	Electrical and electronics	Toys/children's products	Aerospace, automotive & engineering	Construction	Textiles & apparel	Cleaning products	Medical devices	Food (contact)	Occupational	REACH	Global chemical notifications	CLP	GHS-based regulations	New TSCA/LCSA	Biocidal products Regulation	EU cosmetics Regulation	Agrochemical registrations	Food contact	RoHS	Toy Safety Directive	Medical devices Regulation	CMD	CAD	COSHH	US HCS	
Tetra Tech	■	□	■	□	■	■											■	■	■	■	■	■	■	■								www.tetratech.com
The Isosceles Group	■	◘		◘	◘	◘		■		■	◘	◘	◘		◘	■	■	■	■	■	■	◘	◘		◘	■	◘				■	■	www.theisogroup.com
The Martec Group	■	■	■	■	■	■	◘	◘	◘	■	■	■	■	■	■		□				□	□	□	□			■					www.martecgroup.com
The REACH Centre	■	◘	◘		■	■		■	■	■		■	■	◘	◘	■	■	■	■	■	■	■	■	◘	◘	◘	◘	◘	◘	◘	■	■	www.thereachcentre.com
The Redstone Group	■	◘	■	□	◘	◘	◘	◘	□	□	◘	□	■	◘	◘	■	■	■	■	■	■	◘	◘	◘	◘	■	◘	◘	□	□	◘	■	redstonegrp.com
The Sapphire Group	■	■	◘	□	■	■											■	■	◘	◘	■	■	■	■								www.thesapphiregroup.com
the SDS factory | de ViB fabriek	■	■	■		◘	□							◘			■	□		■	■	◘	□	□	□	□						◘	www.theSDSfactory.com | www.deViBfabriek.nl
The Windsor Consulting Group, Inc.	■	■	◘	◘	◘	◘	◘										◘	◘	◘	■	■	◘	◘	◘								windsgroup.wix.com/windsconsultingroup
TJS Technical Services Inc.								■		◘				■														■				tjstechnical.com
TO21.Co.,Ltd.	■	◘			■			◘	◘	■	◘	◘	◘		◘		■	■	■	■	■	■	◘	◘	◘	◘	◘					www.to21.co.kr
Tox Focus LLC	■	◘		◘	◘	■		◘	◘	◘	◘	◘	■		◘	◘	■	■	■	■	■	◘	■	◘	◘	◘							toxfocus.com
toXcel	■	■	■	■	■	■	◘	◘		■		◘	■	◘	■	■	■	■	■	■	■	■	■	◘	■	■			■	■	◘	◘	www.toxcel.com
Toxicon	■	◘	■	◘	■	■	◘	◘	■	◘	◘	◘	■	■	■	■	■	■	■	◘	■	■	■	◘	■	◘	■	■	■	■			www.toxicon.it
Toxi-Coop Toxicological Research Centre Ltd.	■	■	■		■	◘	◘						◘	■	◘		■		◘	◘		■	◘	■	◘			■					www.toxicoop.com
Toxikon	■	◘	■	■	◘	◘	■										◘	□	□	□	□	□	◘	□									www.toxikon.be
ToxMinds	■	■	■	■	■	■							■	◘	■	■	■	□	■	■	□	■	■	■	◘								www.toxminds.com
ToxServices	■	□	■		■	■		■	■	◘	■	■	■	■	■	◘	□	■	■	■			■		■	◘	■	■	□	□	■	■	www.toxservices.com
ToxSolve LLC	■					◘							◘		◘	◘	■	◘	◘	◘	■			◘								◘	
ToxStrategies	■	■	■	■	■	■	◘	◘	■	■	◘	■	■	■	■	■	■	■	◘	■	◘	■	■	■	■	■	■	■	□	□	■	■	www.toxstrategies.com
TraceGains																																	www.tracegains.com
Trade Wind B.V.	■	■			◘	◘				◘			■		◘	◘	□		■	■	□	□	□										www.twnl.com
Tradebe UK	■	■	■	■	■	■	■																										www.tradebe.co.uk
TRASYS	■	◘	■		■	■	◘										■	◘	■	◘	◘	■	■	◘									www.trasys.be
Triskelion B.V.	■	■	■	□	■	■							◘		■	◘	■	◘	■	■	□	■	◘	■	■	◘			■	■	■		www.triskelion.nl
TSG	■	■	◘	■	■	■											■	■	■	■	■	■	■	■									www.tsgusa.com
TSGE Consulting	■	■			■	■											■		■	■		■	■	■									www.tsgeurope.com
TUV Rheinland	■		◘	◘	◘	■											■	■	■	■	□		■										www.tuv.com/us/green-solutions
TUV Rheinland Hong Kong Ltd	■	◘	■	◘	◘	■	■										■	■	■	■	■	◘	◘	◘									www.chn.tuv.com
TÜV Rheinland LGA Products GmbH	■			■	■	■											■	■	■	■	■	■	■										www.tuv.com
TUV Rheinland of North America	■				■	■		■	■	■		■		■	■	■	■		■	■	■	■	■		■	■	■	■					www.tuv.com/en/usa/home.jsp
TÜV SÜD Iberia S.A.U.	■	◘	■		■			□	□	□	■	□		□	□	■	■	■	■	■		■			□	□	□				◘		www.tuv-sud.es/process-safety
TÜV SÜD Industrie Service GmbH	■	◘	◘		■	◘		◘	◘	■	◘	■	■	◘	◘	■	■	◘	■	■		■		◘	■	◘	◘						www.tuev-sued.de/technical_installations/reach
TUV SUD Japan	■		◘			◘											■	◘	■	■													www.tuv-sud.jp
UL	■	■	■	■	■	■		■				■	■	■			■	■	■	■	■	■	■			■							ul-scs.com
UMCO GmbH	■	◘	◘		■	◘		◘	◘	◘			◘	◘	◘	◘	■	□	■	■	□	■	□	□	◘	◘		◘	◘	◘	□	□	www.umco.de
Universit Bordeaux Segalen	■	◘	◘	◘	■	◘	◘										■	◘	◘	◘	◘	◘	■	■									www.u-bordeaux2.fr
Vanta Bioscience	◘	◘	■	◘	◘	■	◘										◘		■		◘	◘	◘										www.vantabio.com
Verdant Law, PLLC	■	■	◘	◘	■	■		■	■	■	◘	◘	■	◘	■	■	■	□	□	■	■	□		□	■	◘			□	□	□	■	www.verdantlaw.com
Vidaris, Inc.	◘																◘			◘	◘												www.vidaris.com
VITO NV team EHS Toxicology Services	■	◘	■	◘	◘	■	■	□	◘	□	□	□	■	■	◘	■	■		■	■		■		◘	□	□	◘	□		◘	◘	ehs.vito.be/
Von Roll REACH GmbH	■																■	◘	■	◘	◘												www.vonroll.com
VRS Regulatory	■	■			■	◘	◘	◘	◘	◘	◘	◘	■		■		■	◘	■	■	◘	■	◘	■			◘	◘				◘		www.vrs-regulatory.net
W.E. Train Consulting	■	◘	■	■	■	◘	◘											■		◘														www.WEtrainConsulting.com
wca environment	■	◘	■	◘	◘	◘	■										■	■	■	■	◘	◘	◘	◘									www.wca-consulting.com
Weeset Advisors	◘		◘	◘													◘			◘													
Wiley Rein LLP	■	■	■	■	■	■	◘	■	■	◘	◘	◘	■	■	◘	■	◘		◘	■	■		■		◘		■						www.wileyrein.com
WILLIAM WILSON Wyeside Consulting Ltd	■				■			◘		■		◘		◘	◘		■		■		■	◘		◘	■		◘						
Wilmer Tox Consulting	■	◘	◘		■	◘											■	◘	■	◘		◘	◘	◘									www.reachwilmer.com
WRc plc		◘	◘		◘	◘							◘		◘	◘	■	◘	■	◘		◘	◘	◘	◘								www.wrcplc.co.uk
WSP UK Ltd	■	◘	◘		◘	■											■	◘	■	■	□	◘	■	□									www.wspgroup.com
WTConsulting	■	□	◘	□	□	■	□										■	■	■	■	■	□	■	□									www.wtconsulting.ch
YASH Technologies	■	■	◘		◘	◘											■	◘	■	■	■	◘	◘										www.yash.com
Zanos Limited	◘					◘											◘		◘														www.zanos.co.uk

Key: Icons above represents the extent to which the company provides the service as follows:
■ Core service ◘ Service that is occasionally provided □ Service provided by partners and third parties

10 years of informing businesses globally on product safety

Since our launch in 2007, Chemical Watch has been on a groundbreaking journey together with the global chemical regulatory and compliance community, helping businesses across the globe rise to the challenge of creating safer products for humans and the environment.

During our first ten years covering this critically important issue - engaging with businesses, regulators, downstream users, service providers, NGOs and academia - we have witnessed much progress, with massive investments by industry and regulators in pursuit of a common goal.

As a trusted, impartial observer, Chemical Watch and its sister products have helped our readers keep pace with the changing regulatory landscape and to understand other drivers that affect custom and competition for products in many sectors.

In the last decade we have seen our service grow significantly - we now offer four subscription services covering chemicals regulation globally, in Asia specifically, biocidal product regulation, and helping product safety professionals with the practical risk management challenges they face daily. We also host a well-respected annual series of conferences and live training events across the globe, complemented by premium quality online courses.

At this milestone, while acknowledging progress, we know there is still much more to explore. Our mission - to provide businesses with the information they need to manage the risks of chemicals in products - remains as relevant today as when we started. At the same time, our readership is diversifying into new sectors and new geographies as the message permeates supply chains that regulators and customers demand that businesses take responsibility for the safety of the chemicals they produce and use in their products.

Product trading patterns are likely to look quite different in ten years' time and our readership will diversify but our aim - to do whatever we can to help businesses ensure safer products - will remain constant.

ChemicalWatch

GLOBAL RISK & REGULATION NEWS

CW+ AsiaHub

CW+ BiocidesHub

CW+ ChemicalRiskManager

"Your one-stop-shop for global chemicals regulatory content"

Resources

Conferences

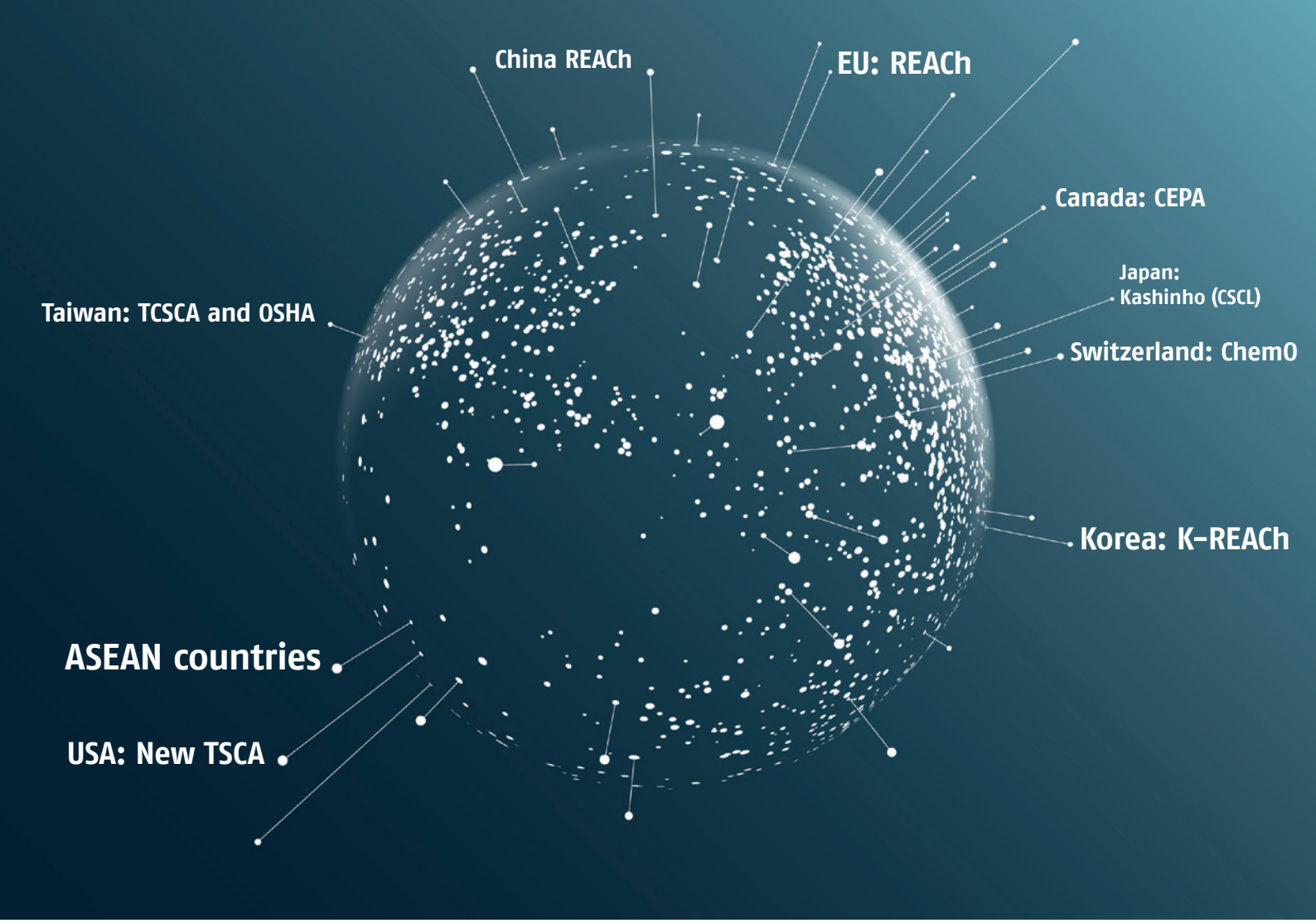
Reports

Training

News

Jobs

www.chemicalwatch.com/10-years



Solutions for Global Chemical Compliance

knoell
worldwide registration

The responsibilities for the safe management of your chemical products do not end at the border of the European Union. Many of your target markets may have their own legislations – different to EU-REACh, but not necessarily less challenging. Thus, a key factor for a successful global business is to ensure the compliance and marketability of your products. Knoell is not only one of the leading consultancies for all services required for EU-REACh.
We also established a global network of affiliates and partners offering solutions to cope with the quickly changing regulatory landscape.

Our services include, but are not limited to:

- Strategic advice how to comply with your global regulatory duties in the most efficient way
- Global check of chemical inventories and catalogues of hazardous substances
- Representative service in the EU, Switzerland, Taiwan, China and Korea
- Global testing and notification strategies
- Complete registration services for EU, Switzerland, China, Taiwan, Korea, Japan, ASEAN countries, USA, Canada, Australia and others
- Global Safety Data Sheets

We have been an independent service provider for the chemical and pharmaceutical industries since 1996, with currently over 550 employees at sites within the EU, Asia and the USA. For further information visit www.knoell.com or call us.

Dr. Knoell Consult GmbH
Dr. Michael Cleuvers
Managing Director
Industrial Chemicals & Biocides
Tel +49 214 20658-170
info@knoell.com

www.knoell.com