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Global Service Providers Guide 2024.

Fourteenth edition

The guide to global chemicals management and control services

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Foreword

Welcome to the 14th edition of the Enhesa Product Intelligence 2024 Global Service Providers Guide.

For more than 16 years, Chemical Watch News & Insight has been reporting on the global chemicals regulatory landscape, keeping product safety and regulatory professionals abreast of developments and helping them to understand the impact on their business.

The annual Global Service Providers Guide offers a chance to examine and spotlight both regulatory and non-regulatory factors influencing the work of our global community of chemicals management, product safety and regulatory professionals. Through insights gleaned from the responses to our annual survey, we aim to illuminate the emerging trends that are crucial for businesses navigating the global chemicals regulatory landscape.

The detailed commentary on and analysis of regulatory market drivers, careers and salaries, and the industry outlook for the year ahead, starts on page 9. Alternatively, for a summary of these trends go to the introduction on page 5.

In this year's guide we have four special reports: why it is critical to engage with your suppliers to achieve supply chain transparency; how digital product passports have the potential to deliver safer products; how PFAS regulations are developing across the globe; and the key chemicals management developments taking place at an international level this year.

As illustrated in the guide, this year's survey findings reinforce the strength of the service providers' marketplace – supporting product safety and regulatory activities across key industry sectors.

The Global Service Providers Guide remains testament to the diversity and strength of this shared marketplace – with some 60 company profiles in this year's publication – we hope that it helps your business select and connect with the right provider for your needs.

As always, if you have any questions, comments or feedback, please do not hesitate to get in touch.

Sarah Thompson
Publishing manager

Contents

Enhesa Product Intelligence – formerly Chemical Watch – empowers product safety and compliance professionals to achieve market access and reduce the risks of non-compliance by giving you a view of the regulatory and business environment, today and tomorrow. We do this through a powerful suite of intelligence, including regulatory data, news, analysis, events & training, expert support and more. 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, Kingsland House, 39 Abbey Foregate, Shrewsbury, SY2 6BL, UK

Tel: +44 (0)1743 818 101

email: product.support@enhesa.com
website enhesa.com/product-intelligence

Business unit manager – Enhesa Product Intelligence
Stuart Foxon
stuart.foxon@enhesa.com

SVP commercial – Enhesa Product Intelligence & Sustainable Chemistry
Richard Butterworth
richard.butterworth@enhesa.com

Head of editorial
Kate Lowe
kate.lowe@enhesa.com

Global head of sales
Louise Osborne
louise.osborne@enhesa.com

GTM lead for Product Intelligence
Ryan McErlean
ryan.mcerlean@enhesa.com

Chief analyst
Nhat Nguyen
nhat.nguyen@enhesa.com

Publishing manager
Sarah Thompson
sarah.thompson@enhesa.com

Data and process innovation manager
Francesca Cotton
francesca.cotton@enhesa.com

Writers

Elaine Burridge, Emma Davies, Jillian Stacy, Nidia Calvo, Kimberley de Miguel, Leigh Stringer, Kate Lowe

Sub editors

Claudia Ward, Martina Chamberlain, Paul Lindsell

Design
Katie Benge
katie.benge@enhesa.com

Sales
Marc Gonzalez
marc.gonzalez@enhesa.com

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Key trends in chemicals management and control

The 14th Chemicals Management and Control Survey finds the EU's REACH and CLP regulations maintaining their lead as key drivers of market activity, while information services are the top requirement of professionals seeking support with their chemicals management work.

Between November 2023 and January 2024, professionals from the global chemicals management community took part in the annual Chemicals Management and Control Survey, which aims to uncover the key regulatory and non-regulatory factors driving activity in the market. The survey also seeks to identify trends in service provision as well as any changes in employment.

Some 565 professionals took part in the survey. Of those, 37% work in the chemicals and life sciences sector, 11% in general manufacturing and 10% in the consumer products (home and personal care) sector. Additionally, 8% work in the electrical and electronics, engineering, automotive and aerospace sectors, while another 11% are employed by service providers, including consultants, laboratories and law firms.

Regulatory affairs professionals continue to make up the largest group of respondents (27%). A further 16% are product stewards, followed by compliance managers (15%), consultants (10%), toxicologists or other scientists (7%) and EHS managers (6%).

Market drivers

This year's survey respondents made it clear that the EU's REACH regulation continues to dominate day-to-day work. However, for the first time in several years, the number citing "any aspect of REACH" as a key driver of activity fell – from 93% in last year's survey to 82% – perhaps reflecting the ever-growing body of regulation around the globe taking the attention of product stewards.

At the end of last year, the European Commission said it remains committed to a revision of REACH, now delayed to the next parliamentary term. Responding to a letter from NGO CHEM Trust, officials from DG GROW and DG Environment said that with just months left until the June European elections, the Commission's work programme would focus on a limited set of new initiatives. The REACH revision is "a very important initiative" that needs sufficient time to be prepared and discussed, said the 1 December letter signed by Aurel Ciobanu-Dordea from DG Environment and Kristin Schreiber from DG GROW, responding on behalf of president Ursula von der Leyen. "Therefore, the Commission came to the conclusion that such an initiative should not be presented at the end of a Commission mandate."

Meanwhile, the EU's regulation for the classification, labelling and packaging (CLP) of substances and mixtures continues to be cited as a leading driver of regulatory activity by the second highest number of respondents (63%). In late April, the European Parliament approved its provisional agreement with EU countries on the Commission's long-awaited proposal to revise the CLP regulation, one of the final steps before the amended legislation becomes law. The final text supports the Commission's 2022 proposal amending the 2008 legislation and backs the executive's compromise provisions that clarify rules on labelling substances and the required information for online selling.

Outside of Europe, "any aspect of US regulation" was cited by 58% of respondents as a leading driver of regulatory activity – up a little from 56% in 2023 – with TSCA new substance notifications and California's Proposition 65 flagged as key drivers of activity by 36% and 33% of respondents, respectively.

Among non-regulatory drivers in this year's survey, customer and supply chain demands continue to be cited by the largest number of respondents (63%) as a key driver of activity, followed by consumer concerns (51%) and sustainability initiatives (46%).

Service requirements

So how are the changes we are seeing in the relative importance of these regulatory and non-regulatory drivers being reflected in the kinds of services professional customers require? The responses to this year's survey show that just under half (48%) expect their use of external services to grow over the next 12 months, while 62% expect to increase their use of external services over the next five years.

Delving more deeply into specific areas of need, information services were cited by 76% of respondents as an area in which they would need more help to support their chemicals management work over the next 12 months – up from 72% last year. A further 63% anticipate greater use of training services and 62% anticipate greater use of IT and software services over the next 12 months. Meanwhile, more than half of respondents (52%) anticipate their company's need for advisory and consultancy services will grow over the next 12 months.

Turning to employment within the chemicals management sector, 32% of respondents expect the number of chemicals management and control staff employed in their organisation to increase over the next 12 months – down a little from 38% last year. Respondents were less bullish about job prospects globally this year, with 44% saying they are good – down from 56% in 2023.

Our detailed commentary on the findings of this year's survey starts on page 9.

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What are the key factors driving chemicals management and control activity in 2024?

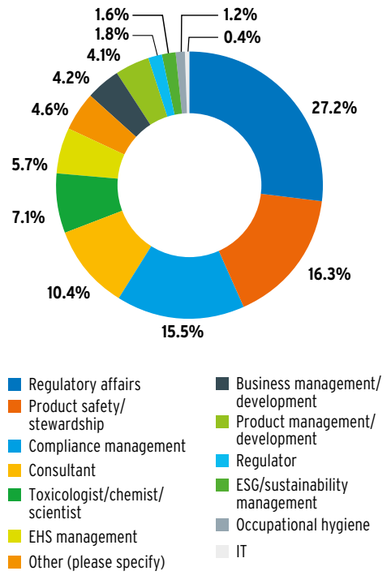
The EU's REACH and CLP continue to be key priorities for chemicals management activity, while regulatory activity in the US remains the second most important driver of work. Elaine Burridge reports on the 14th edition of Enhesa's Chemicals Management and Control Survey.

It will likely come as no surprise that Europe's REACH regulation – with its many parts – yet again tops the list of chemicals management activities. That said, the number of safety and regulatory compliance professionals citing REACH as a key regulatory driver in this year's Chemicals Management and Control Survey has dropped by 11 percentage points to 82%.

One factor behind the fall is a significant drop in the number of respondents citing REACH evaluation related activities (39% to 25%) as being a key driver of work. Other areas cited less frequently than in last year's survey include dossier updates (down from 39% to 34%). Meanwhile registration and SVHC obligations were ranked by respondents as the two most important drivers of REACH related work and were cited by 47% and 44% respectively.

This year's respondents also reference the EU's chemicals strategy for sustainability (CSS) as another key regulatory driver, accounting for 45% of responses this time, a drop of six percentage points from 2023.

What is your primary job function?



An important objective under the CSS is a revision of the CLP regulation, with 63% of respondents reporting this as a major driver of their regulatory work. The European Council of Ministers and Parliament reached provisional agreement last December on the Commission's final CLP proposal, which brings in several changes to the regulation, as well as clarifying labelling rules and information required for selling products online.

And it is not just CLP which is undergoing a revision. The long-awaited REACH revision has been delayed several times after originally being set for adoption by the end of 2022. The Commission left the proposed revision out of its 2024 work programme, but the revision could occur later this year once the new Commission is in place after the European parliamentary elections in June. The outcome of these elections will also determine how the EU moves forwards with the CSS.

US targets TSCA

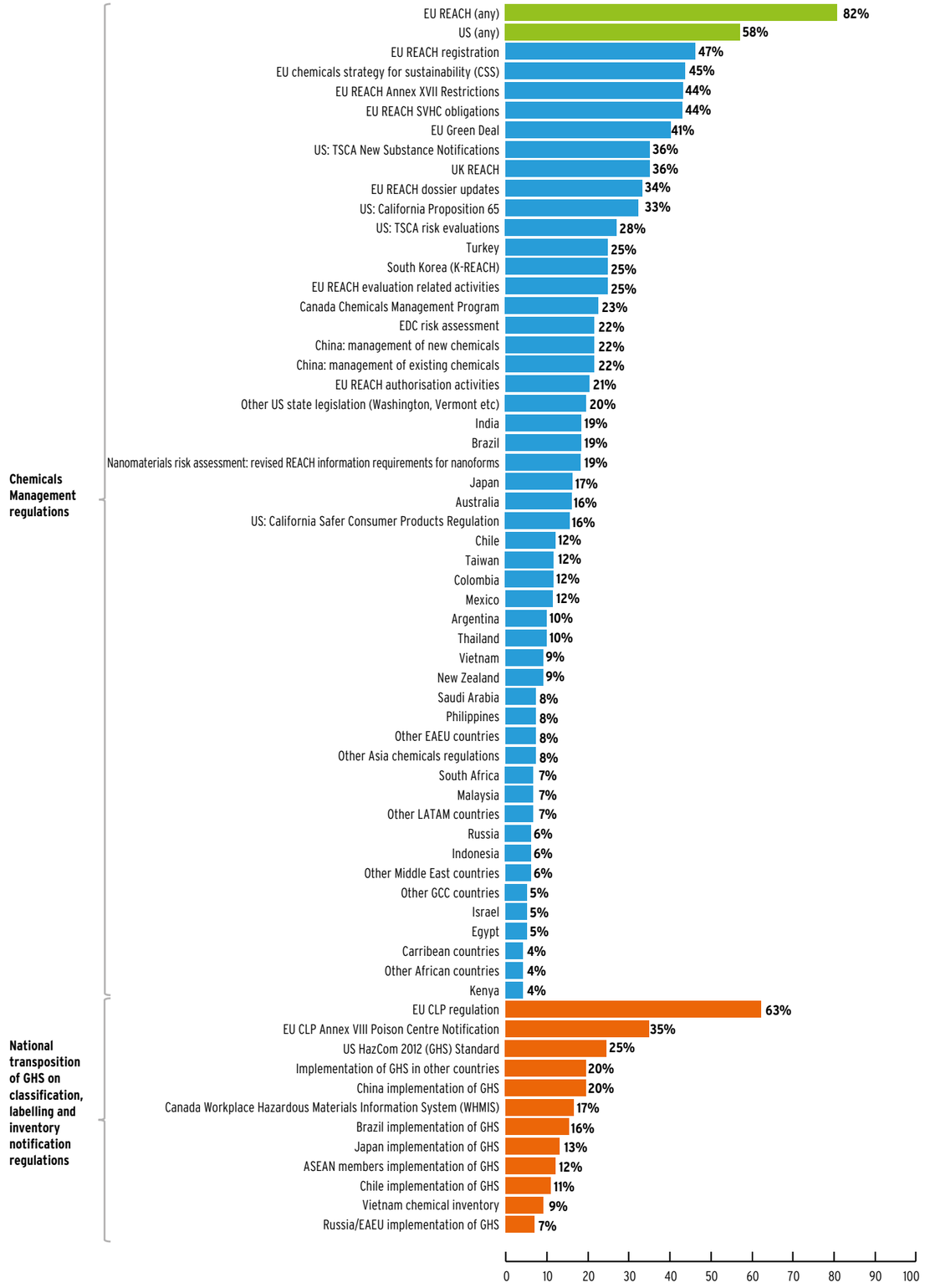
Outside of Europe US regulation is the second most important driver for survey respondents' workloads with 58% (up from 56% in 2023) citing US regulation (any) as a key driver of chemicals management related activity.

Much of the US EPA's focus in 2024 will be on finalising – after years of delays and missed deadlines – TSCA's risk management rules for the first ten high-priority chemicals. However, the agency is facing intense debate about its assessment methods, as well as a rising number of lawsuits, over key interpretations of the law

The EPA will also be seeking to fill information gaps to support its chemical evaluations, especially for per- and polyfluoroalkyl substances (PFAS). Last year, the agency unveiled its TSCA reporting rules for PFAS, which requires companies to provide information on the use of more than 1,460 compounds going back as far as 2011. In addition, the four-yearly chemical data reporting rule (CDR) makes a return this year, with the submission period open from 1 June to 31 September and covering activities from 2020-2023.

California's Proposition 65 law is cited by 33% of respondents as a key driver of work. A greater focus on PFAS – especially perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) – is anticipated this year under Prop 65. California is also proposing to phase out PFAS in fabrics and personal care items, starting 1 January 2025.

Leading regulatory drivers for survey participants (section one)



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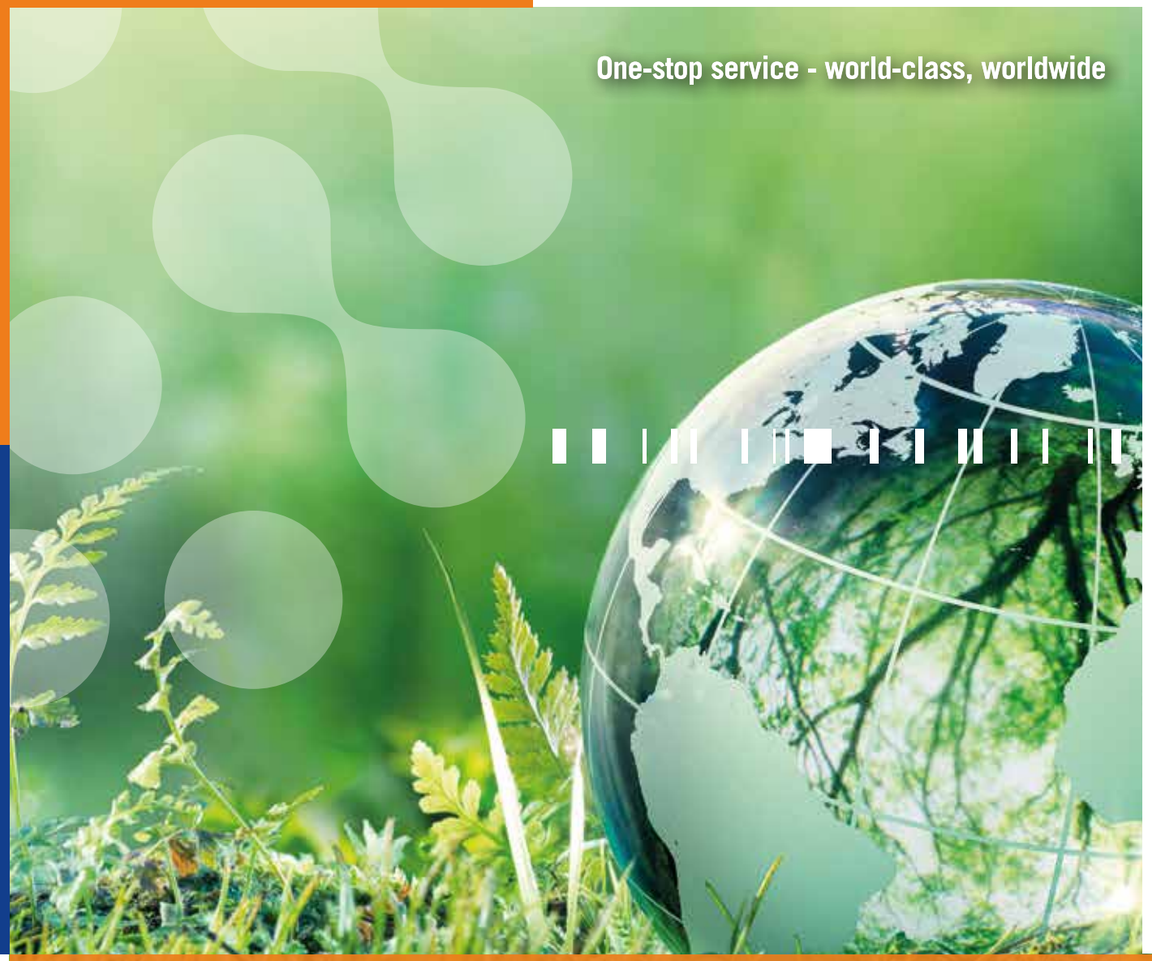

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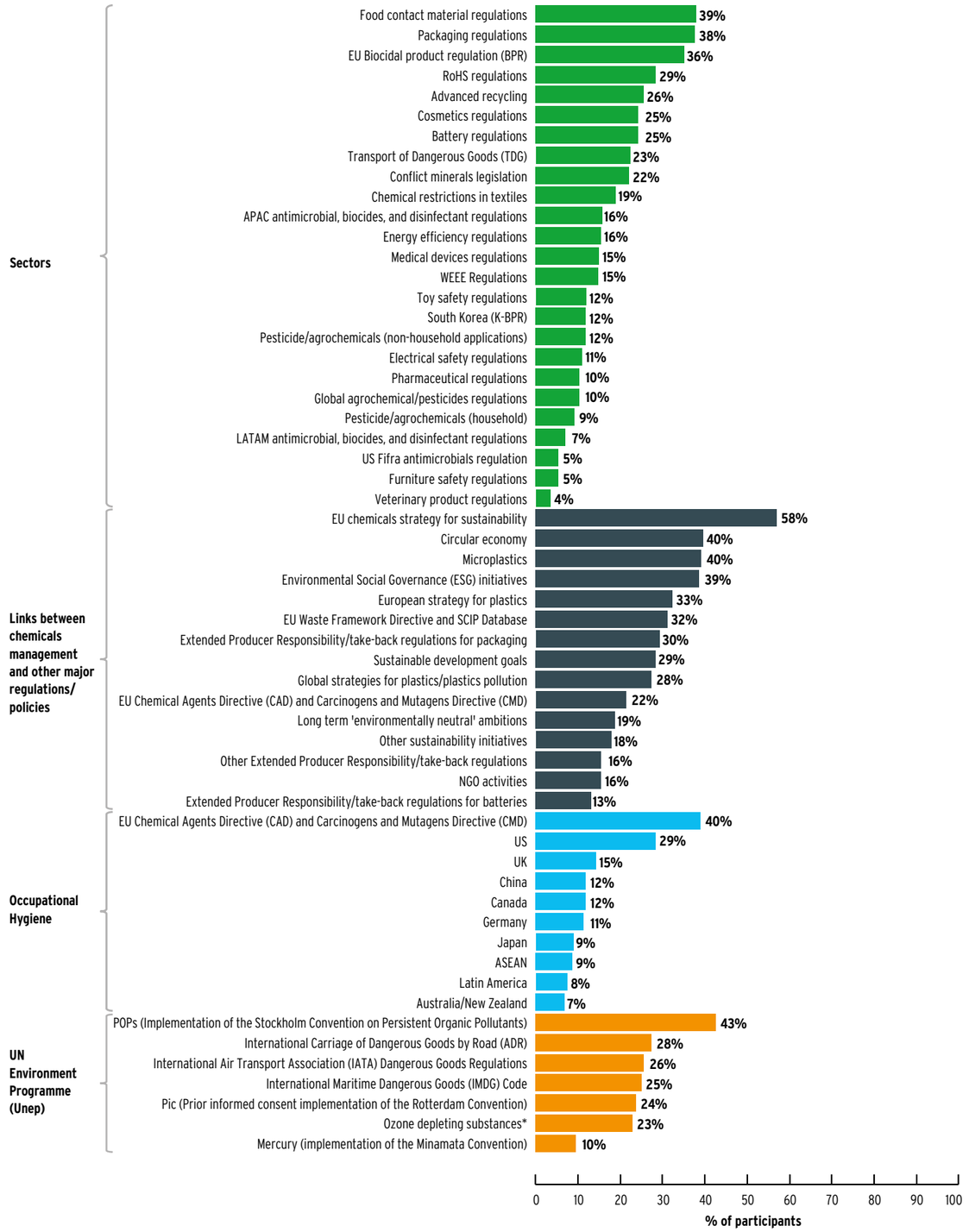
Leading regulatory drivers for survey participants (section two)



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Leading non-regulatory drivers

Meanwhile TSCA new substance notifications have seen an increase in the number of respondents citing them as a key driver of work this year – up from 29% to 36%

Turkey (KKDIK), South Korea (K-REACH), China, India and Japan also account for a significant portion of survey responses. Both KKDIK and K-REACH are cited as key drivers by 25% of poll participants, with 22% referencing China, 19% India and 17% Japan. The results for China and Japan were both three percentage points higher than last year's findings.

In December 2023, Turkey's environment ministry extended the registration deadlines under the KKDIK law – by up to seven years to between 2026 and 2030, depending on tonnage band and hazard properties. The move was in response to intense pressure from industry which had struggled to meet the end-2023 single registration deadline.

In South Korea, the National Assembly on 9 January passed amendments to two overarching chemical laws, namely K-REACH and the Chemical Control Act (CCA).

Under K-REACH, the annual volume at which new substances will have to be registered has been raised from 0.1 tonne to one tonne or above. The amendment also reorganises the management of toxic substances, which will be split between three categories depending on their hazard properties.

The National Assembly also introduced several changes to the CCA, including replacing the designation system for permitted, restricted and prohibited substances, as well as changing its process for non-hazardous substances to reporting only. In addition, it moved regulations on transporting chemical substances from the CCA to the Wastes Control Act.

China too has persisted in its efforts to strengthen chemicals legislation, especially in the areas of cosmetics under the Cosmetics Supervision and Administration Regulation (CSAR), electronics under ROHS 2 and hydroflurocarbons (HFCs) as it aligns with requirements under the Kigali Amendment to the UN's Montreal Protocol on Substances that Deplete the Ozone Layer.

The country is also progressing an action plan for toxic chemicals, including persistent organic pollutants (POPs) and endocrine disruptors. Under the plan, China's Ministry of Ecology and Environment (MEE) will develop an overarching chemicals framework, which is to be known as the Environmental Risk Management of Toxic and Hazardous Substances and will sit above MEE Order 12.

Progress is also anticipated within the coming year on China's plans to introduce QR codes that link to chemical information on labels, as well as transitioning to the eighth revised edition of the Globally Harmonized System (GHS) of classification and labelling of chemicals.

By contrast, progress in India on the development of an overarching chemicals law continues to be delayed. Any moves forward on this look unlikely until after the country's elections in mid-2024. Nonetheless, India did establish last October a chemicals inventory platform, which is expected to save costs for businesses that manually gather data, as well as support research and planning.

The ChemIndia portal is expected to expand significantly in 2024, providing a comprehensive list of organic and inorganic substances, alkali chemicals, dyes and pigments, pesticides and insecticides (within the chemical category), synthetic fibres, polymers, synthetic rubber (elastomers), synthetic detergent intermediates, olefins, aromatics, and other petrochemicals. It will offer analysis of hazard classifications, exposure routes and environmental impacts aligned with GHS.

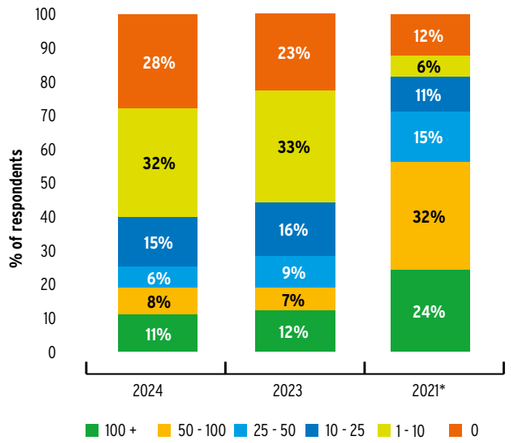
Meanwhile, the Bureau of Indian Standards has continued to issue quality control orders, making national standards compulsory for a growing number of chemicals, with more expected in 2024.

In Japan, food contact materials, workers and safety data sheets (SDSs) are key areas of focus. The Ministry of Health, Labour and Welfare (MHLW) is currently revising its positive list system that covers all raw materials allowed for food contact, such as packag-

ing, containers and utensils. The update is expected to be completed and enter into force from 1 June 2025.

The ministry is also strengthening controls on workplace exposure, with new measures due to take effect in 2024. In addition, during 2023 the MHLW expanded the list of chemicals for which companies must maintain SDSs and labels that comply with the UN'S GHS. There are various dates for enforcement between 2024 and 2027

If known, how many of the chemicals you manage within your company contribute to UN sustainable development goals?



*not asked in 2022

Non-regulatory drivers

Geopolitical and economic turmoil are once again impacting business conditions in the chemical industry. And while the shipping crisis and port closures of a couple of years ago have since eased, another crisis emerged in November last year with Houthi attacks on vessels in the Red Sea. This has consequently forced ships to divert around the Cape of Good Hope, lengthening journey times and driving up freight costs yet again for transporting chemicals and their raw materials.

Such factors will have helped to ensure that customer and supply chain demands remain the top non-regulatory driver of chemicals management activity in this year's survey, cited by 63% of respondents, which is down by four percentage points from last year's poll. And there is no change this year for second slot, taken once again by consumer concerns regarding products/ services – cited by 51% of respondents as a key driver of work.

There are, however, some notable shifts in responses in this latest survey. Respondents rate governmental policies/spending much lower this time around – indeed it falls to sixth place with just 28% of respondents citing them as a key driver of work – down from third place and 36% in 2023.

Economic performance drops too, now sitting in fifth position from fourth last year, and from second place in 2022. This is perhaps a reflection of the currently depressed economic environment as the cost-of-living crisis constrains consumer spending with higher energy and input costs also squeezing manufacturers' margins. Businesses are presently much more focused on containing costs as they seek to optimise operations and efficiency.

Perhaps surprisingly, NGO pressure slips again this year, to eighth place from fifth in 2023. But this could be a consequence of the fact that sustainability initiatives now rank as the third-highest non-regulatory driver, cited by 46% of survey participants.

Undoubtedly, the EU's Green Deal and push towards a circular economy, along with decarbonisation goals, have forced action on environmental sustainability higher up the corporate agenda. Industry is very focused on meeting mandated targets, such as for net zero and plastics recycling.

Who answered this year's survey

This year, 565 people took part in the Chemicals Management and Control Survey. More than half – 53% – are located in Europe, 23% are in North America and 17% in Asia, with the remainder split between Latin America (4%) and the Middle East and Africa (3%).

Breaking down respondents by industry, the vast majority (37%) work in chemicals, life sciences and similar.

Of the rest, 11% work either in service providers, other manufacturing or other; 6% are in consumer products, personal care and cosmetics; 5% in electrical and electronics; 4% in engineering, automotive, aerospace and similar; and 3% in healthcare, pharmaceutical and medical devices. Respondents from government and agencies account for 3% of input, and trade associations and professional bodies 2%.

Job functions are primarily in regulatory affairs (27.2%), product safety and stewardship (16.3%), or compliance management (15.5%).

Most survey respondents – 34% – come from businesses with more than 5,000 staff (enterprises), followed by 29% employed by companies with 250-5,000 staff (large companies). Businesses with less than 10 employees accounted for 7% of survey respondents.

Nearly a third of respondents say they manage between 100 and 1,000 chemicals within their companies, followed by 23% managing volumes of between 1,000 and 10,000.

Of these chemicals, between one and ten are chemicals of concern, according to most respondents (28%). In addition, between one and ten of these chemicals contribute to UN sustainable development goals (SDGs), which lists substances such as endocrine disruptors and PFAS as "issues of concern".

What is the outlook for chemicals regulatory and management services in 2024?

While REACH continues to lead demand for chemical compliance services, cost constraints mean some businesses are focusing on needs instead of wants when weighing options for support – and others are looking to build up their local markets. Elaine Burridge reports.

The chemical industry had a difficult year in 2023, and early 2024 is looking no different. Business operations are being dominated by a cost-of-living crisis that is leaving consumers with less cash to spend, persistently high inflation and energy costs, plus ongoing geopolitical tensions.

Demand globally has slowed for chemicals that go into a variety of products, including those for personal care, household use, construction and cars.

And for some service providers, that weaker demand has translated into their customers focusing on 'needs' rather than 'wants' in terms of complying with regulations: "Nowadays, due to the challenging circumstances, we see the tendency that clients differentiate thoroughly between services they really need now and other services that maybe can be postponed," says Michael Cleuvers, executive director, products and markets at knoell Germany.

Nevertheless, he says demand for the company's compliance services was fairly stable in 2023, with a strong need for REACH dossier updates, as well as master data management, safety data sheet (SDS) preparation and updates, and various global product stewardship services.

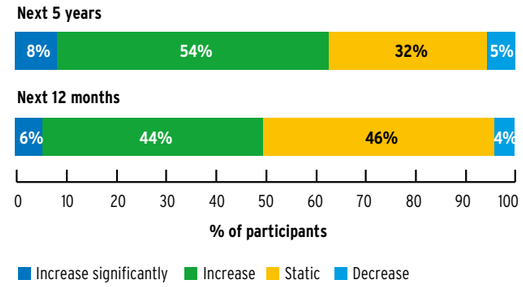
Most service providers report steady business, although it does appear to depend on the type of services sought. For instance, Antonio Conto, managing director of Chemsafe Consulting, reports an increase in SDS preparation and translation enquiries worldwide last year.

And Jana Zuffellato, sales and marketing manager at KFT Chemieservice in Germany, says demand rose because of ongoing regulatory changes, but adds: "At the same time, we notice that many existing customers are reluctant to invest in new products or expansion, which also directly leads to fewer orders for us.

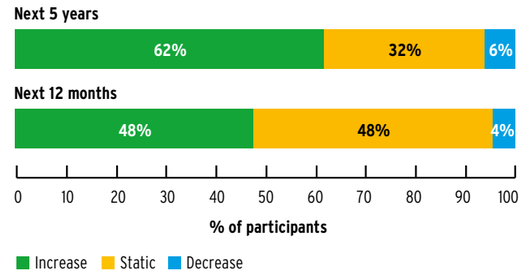
"Because of geopolitical events, many customers have reduced exports to some countries, resulting in a drop in demand for services in the chemical compliance sector."

Her view is echoed by Matthew Kane, CEO at consultancy LKC Switzerland. He says: "The demand for our regulatory and technical services to the industrial chemical sector in Europe for 2023 declined compared to 2022. The cause we understand is likely to be the sluggish recovery from the significant impact of previous year results following the pandemic and geopolitical issues in Eastern Europe.

Anticipated changes in need for inhouse staff



Anticipated changes in need for external services



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He adds that supply constraints along with a rapidly changing and more restrictive European regulatory environment are creating further uncertainties for market investors, noting too that Europe's higher labour costs and regulatory expense compared with other markets such as China is "unhelpful".

Local sourcing

Aside from the usual compliance services, top of the list for LKC's clients were services for forward planning with regard to self-sufficiency and local supply sourcing, which highlights an ongoing trend of deglobalisation.

Many of CIRS's EU-based clients have changed their strategy in the past two to three years and are concentrating more on their local market, says Bryan Zhou, its deputy general manager and senior regulatory consultant.

According to Zhou, requests for complying with EU REACH, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and poison centre notifications increased considerably last year, while other work was mainly related to Turkey's KKDIK, K-REACH, China REACH and UK REACH.

KKDIK also provided an uptick in demand at ReachLaw Finland (at its Istanbul office) for registration and only representative (OR) services, which was initially prompted by the end of 2023 deadline that was eventually postponed, says Ingrid Sekki, chief marketing and business development officer.

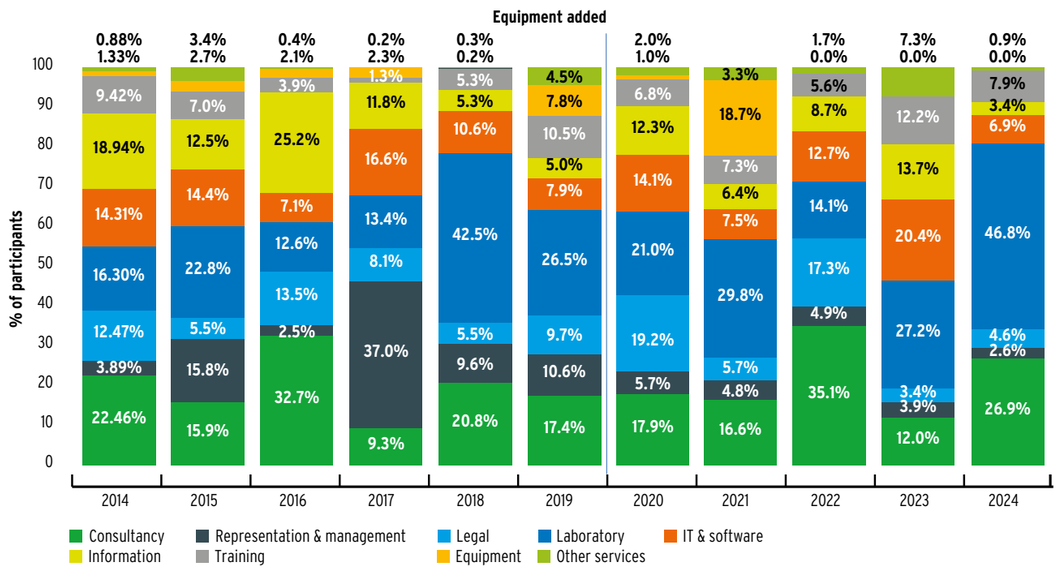
> *From a US TSCA perspective, clients worldwide were generally seeking assistance last year with persistent, bio-accumulative and toxic (PBT) substances and PFAS*

In late 2023, the Turkish environment ministry delayed the single-registration deadline by three years, to 31 December 2026, for substances above 1,000 tonnes, with an extra two years to (31 December 2028) for substances between 100 and 1,000 tonnes. For those between one and 100 tonnes, the deadline was delayed to the end of December 2030.

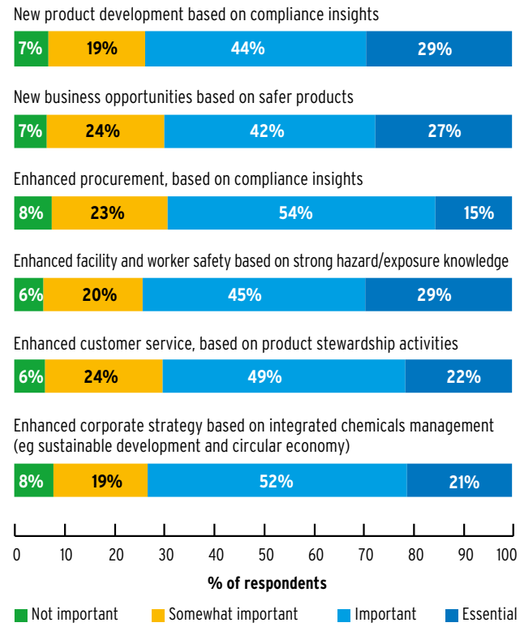
The 2026 deadline also applies to substances classified as aquatic acute 1 and aquatic chronic 1 of above 100 tonnes per year and carcinogenic, mutagenic and toxic for reproduction (CMR) substances (categories 1A and 1B) at above 1 tonne per year.

Simultaneously, there was a growing interest in K-REACH registration services, driven by the pending deadline of 31 December 2024 for phase-in substances, Sekki adds.

Changes in proportion of spend on external chemicals management and control services



How important are the following opportunities to your organisation?



The Finnish consultancy also saw heightened demand for services related to per- and polyfluoroalkyl substances (PFAS), Ecodesign for Sustainable Products Regulation (ESPR) and other initiatives under the EU's Green Deal.

From a US TSCA perspective, clients worldwide were generally seeking assistance last year with persistent, bio-accumulative and toxic (PBT) substances and PFAS, says Rose Passarella, director of the Assuris Chemical Group.

Looking ahead to 2024, Europe and South Korea will be the two dominant regions in terms of demand for services, according to service providers. In Europe, they say help with REACH and OR, the Classification, Labelling and Packaging (CLP) regulation, and PCN will be the primary areas of demand.

High demand is also anticipated for K-REACH registration services to meet the upcoming deadline, as well as the next K-BPR deadline in 2025.

Sekki is also predicting "sustained support" for Turkey KKDIK registration, with an emphasis on lead registration, OR and SDS-related work.

Service providers active in the US market anticipate greater demand for assistance with Chemical Data Reporting (CDR). Dr Cleuvers says the CDR rule requires companies to report every four years to the EPA on the manufacture, processing and use of chemicals manufactured or imported that are listed on the TSCA Chemical Substance Inventory if volumes are above an applicable threshold.

The EPA has set the deadline for the 2024 reporting cycle (covering the period 2020-23), with the submission period running from 1 June to 30 September.

Dr Passarella adds that changes in substantiating confidential business Information may also raise questions, bringing more requests for help.

On 1 June 2023 the US EPA issued a final rule to update CBI requirements under TSCA in a move it said would increase transparency, modernise reporting and review procedures for CBI, and align with the 2016 amendments to the Act.

Looking at industry sectors, the key areas of focus for customers are many and varied, including chemicals, food and nutraceuticals, energy, cosmetics, biocides, energy, metals and mining, pharmaceuticals and electronics, plus anything that relates to green chemistry and sustainable/bio-based products.

Digitisation

Unsurprisingly – and unchanged from recent years – digitisation remains a major trend in the industry as an increasing number of systems become automated and the adoption of artificial intelligence (AI) grows.

In April 2023, new rules for the harmonised classification and labelling of new hazard classes entered into force. There are periods of transition, with the first deadline – applicable to new substances on the market – taking effect on 1 May 2025, with other deadlines in place for 2026 to 2028.

In Europe, the Green Deal and a shift to a circular economy are dominating corporate agendas, even if many companies have slowed their initiatives as they rein in spending and adopt a tight focus on controlling costs.

Certainly, the evolving regulatory landscape around Green Deal initiatives will likely see companies needing external expertise and support on regulatory and policy developments. Consequently, some service providers have set up or are developing new services around topics such as the energy transition, decarbonisation, biodiversity and sustainability, as they report growing demand.

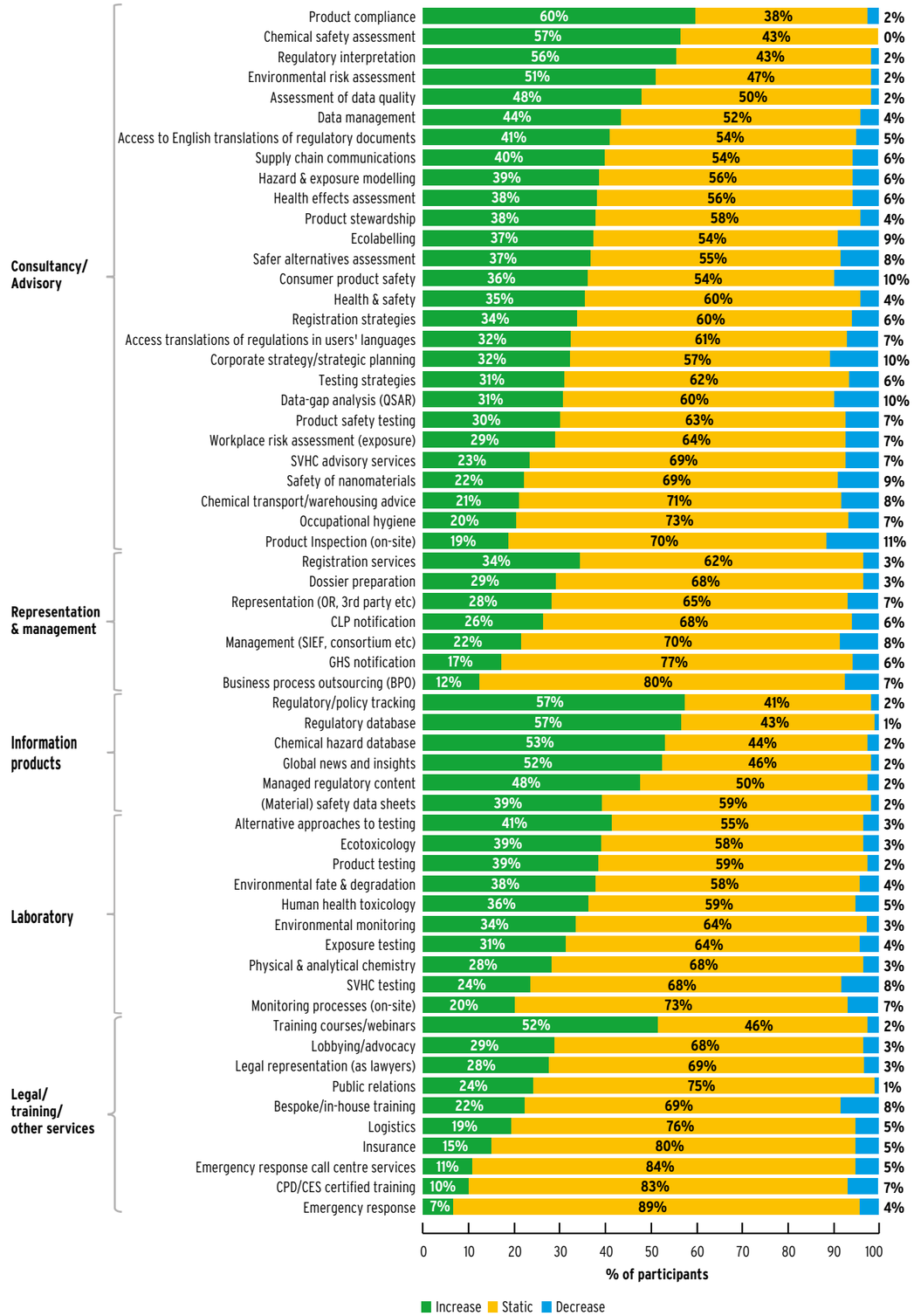
> *As the chemical sector continues to push towards more sustainable products with a notable focus on materials innovation, there will be an increasing necessity for emerging technologies such as AI that will help in collecting data and predicting toxicity, as well as optimising processes.*

SERVICES

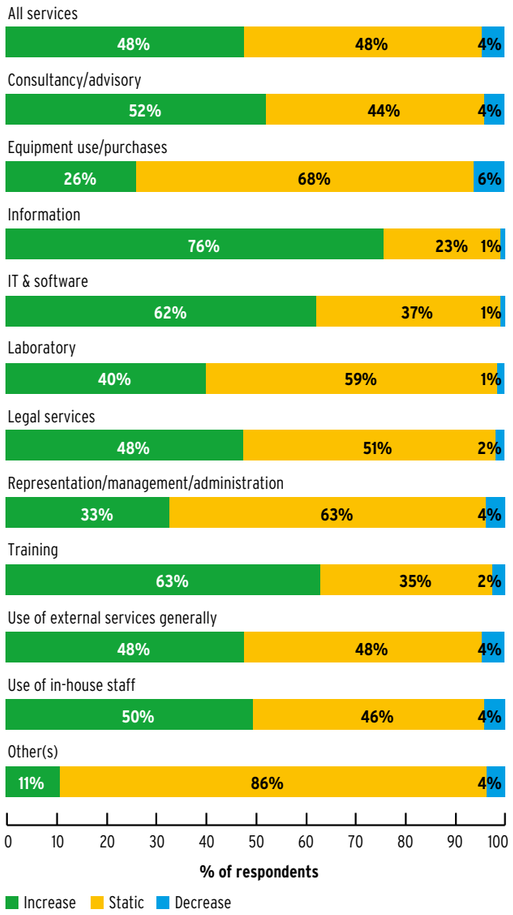
- REACH and chemical safety
- Biocides
- Agrochemicals
- Cosmetics
- Medical Devices
- Food and Nutraceuticals
- Food Contact Material
- Pharma
  - Safety
  - Regulatory Affairs
  - Pre-clinical development
- "In silico" evaluations
- Ecolabel
- Legal Affairs
- Consortia / Task Forces

CHEMSAFE S.r.l. | Registered office: Via Ribes, 5 - 10010 Colleretto Giacosa (TO) - Italy | Tel: +39 0125 538888
Operational seat: Via Lugnacco, 4 - 10010 Parella (TO) - Italy | Tel: +39 0125 669035 | Fax: +39 0125 538475
Email: chemsafe@chemsafe-consulting.com | www.chemsafe-consulting.com

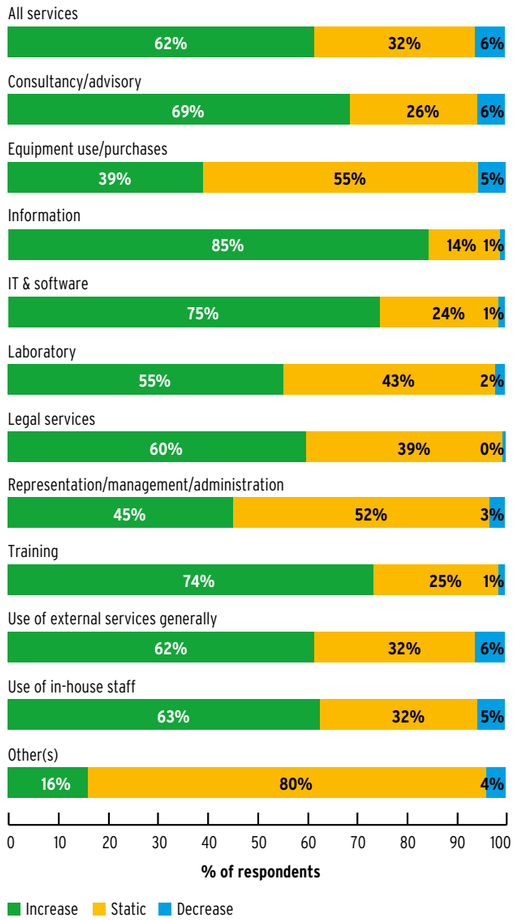
Anticipated change of services required over the next five years



Anticipated changes in need for external services by sector to support chemicals management work over the next 12 months



Anticipated changes in need for external services by sector to support chemicals management work over the next 5 years



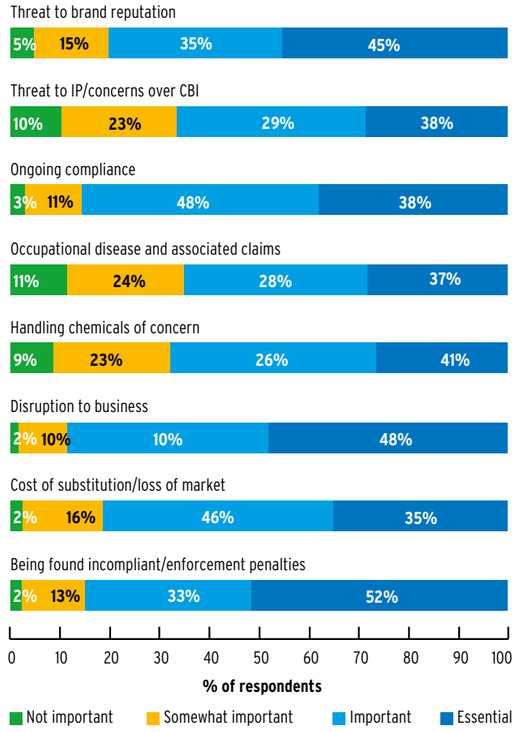
Sekki says as the chemical sector continues to push towards more sustainable products with a notable focus on materials innovation, there will be an increasing necessity for emerging technologies such as AI that will help in collecting data and predicting toxicity, as well as optimising processes.

Dieter Drohmann, CEO of the Chemservice Group, expects that environmental, social and governance (ESG) will play a more significant role for the big companies. And Maaike Bilau, senior product stewardship consultant and portfolio manager for product stewardship and sustainability at Arcadis Belgium, says customers will need more communication on product sustainability.

Due to increasingly complex international requirements, Zuffellato sees more and more customers outsourcing some or all of their systems' data maintenance to specialised service providers. She notes rising demand in 2024 for updating SDS, as well as help with changes to the CLP regulation.

In Europe, the Green Deal and a shift to a circular economy are dominating corporate agendas, even if many companies have slowed their initiatives as they rein in spending and adopt a tight focus on controlling costs.

How important to your organisation is it to assess business risks associated with chemicals management in the following areas?



Bilau says keeping up with both regulatory and scientific changes will remain a challenge for service providers, both now and in the longer term, noting that compliance is the main and urgent focus and "proactive stewardship is for the happy few".

Regulations, in particular REACH in the EU, are becoming very demanding, says Chemsafe's Conto. "As a consequence, competent authorities are becoming very demanding. So we all need to be more effective in dossier preparation, and to some extent more scientific. Regulatory toxicology is becoming a key factor," he says.

In silico tools

Dr Cleuvers notes that the trend to avoid animal testing continues, hence service providers need "comprehensive expertise and experience" in areas such as in silico tools and QSARS, among others.

He sees customers shifting away from "normal" service provider activities towards strategic consulting, not only to ensure compliance, but also to enable market entry and marketability of chemical products.

New regulations and/or amendments to existing regulations create even more complexity. "Adding new hazard classes for instance requires that you are continuously not only up to date, but actually earlier and better informed about potential impacts for your clients," Cleuvers says. "There is growing demand for a kind of watchdog service where we monitor and evaluate any regulatory changes that might have a specific impact on an individual client's product portfolio."

Consolidation among service providers is another key challenge, and one that has been mentioned several times in past years. Some of the founders of consultancies in the early years of EU REACH are nearing retirement and will be looking to sell, says Drohmann. "I see challenges for smaller consultancies of less than ten employees since the issues are getting more complex and clients want a one-stop-shop service provider," he says.

Zhou says customers would like to have a long-term partnership with their service provider, communicating across different markets and requests, such as SDSs, labels and other regulatory documents, as well as regular monitoring on pending/future legislation.

The upheaval in supply chains from Covid-19 and more recently the Russia-Ukraine conflict has also spurred many manufacturers to review their own production and procurement, seeking to become more localised.

"I feel our clients will likely be most interested this year in trying to be less reliant on importing raw materials and energy, with more focus on sourcing in Europe," says Kane, noting that the European Commission has prioritised the need to be more self-sufficient in sectors such as agriculture, including crop protection, fertilisers and seeds.

This could lead to non-EU chemical manufacturers seeking to establish or acquire European manufacturing sites with sectors such as food production, energy generation and electronics driving future demand for services, he says.

He adds that geopolitical tensions in Eastern Europe and the Middle East and Asia are driving a requirement for action in Europe and the US to stabilise markets through research and innovation.

The world of chemical compliance is constantly shifting in response to legislative, economic and geopolitical events, and keeping pace with developments is not easy. But this is creating demand for service providers able to monitor and predict regulatory changes for their clients. Whether customers have the funds to invest in this valuable expertise is another question.

> *There is growing demand for a kind of watchdog service where we monitor and evaluate any regulatory changes that might have a specific impact on an individual client's product portfolio.*

What are the prospects for professionals working in chemicals management and control in 2024?

This year's Enhesa Chemicals Management and Control Survey finds an increasingly static jobs market, reflecting continued challenging economic conditions. Nevertheless, plenty of good opportunities can still be found, says Chemical Watch News & Insight's Emma Davies.

Nearly two-thirds (63%) of respondents have told this year's Chemical Management and Control Survey that the number of chemicals management and control professionals employed by their organisation is likely to remain static over the next 12 months. The finding continues a trend from last year when 57% said they expected numbers to remain static – up from 48% in 2022 – and reflects continuing challenging economic conditions around the globe.

Nearly a third (33%) expect staffing levels to increase over the year – down from 38% last year – while just 4% expect them to fall.

The SPG survey received 565 responses in total, with 53% based in Europe, 23% in North America and 17% in Asia Pacific. The remaining 7% were from Latin America, Africa and the Middle East. The largest proportion of respondents work in regulatory affairs, followed by product safety and compliance management.

Around 57% of workers report being satisfied with their work – a finding which has remained largely consistent throughout the history of the survey.

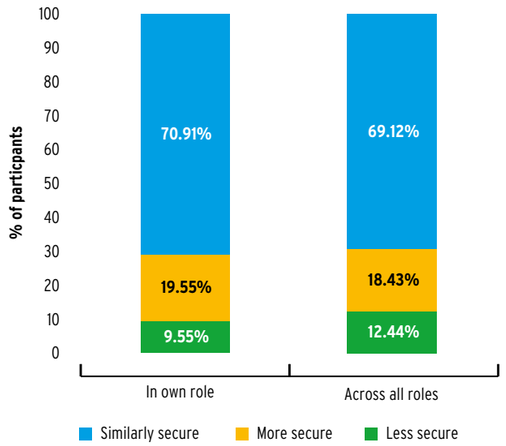
In-house need

Of the respondents, 55% estimate that more than four fifths of their organisation's work in chemicals management and control is currently performed by the in-house team. As such, more than half of respondents predict an increasing need for in-house chemicals management staff over the next five years, with 8% foreseeing a "significant" increase.

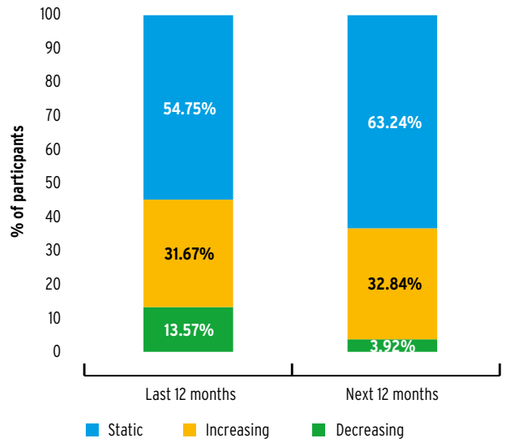
However, more than 12% of professionals surveyed said they feel less secure in their current role, compared with the same time last year. This figure has doubled since the 2023 survey, although around 70% describe job security as stable. Dieter Drohmann, managing director of Chemservice, has witnessed staff in industry regulatory affairs retire or be made redundant without being replaced. "This gap is likely to be filled with consultant hours," he says.

Meanwhile, some service providers are boosting IT provision so customers can be more self-reliant. For example, CIRS – the Chemical Inspection & Regulation Service – is developing free online inventory search and global compliance tools.

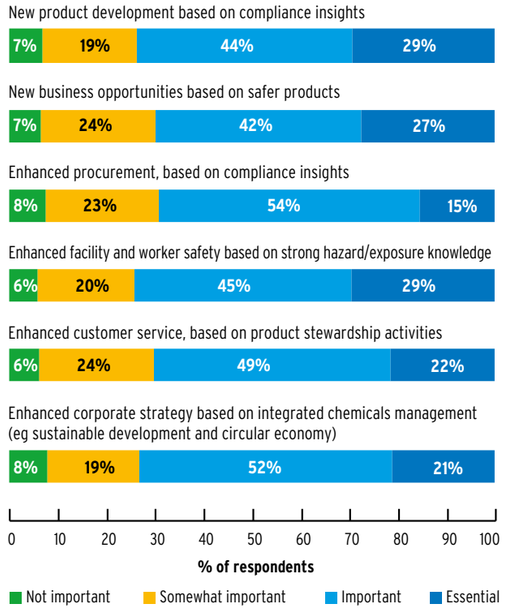
Job security felt by respondents in their own roles and across all roles within organisations



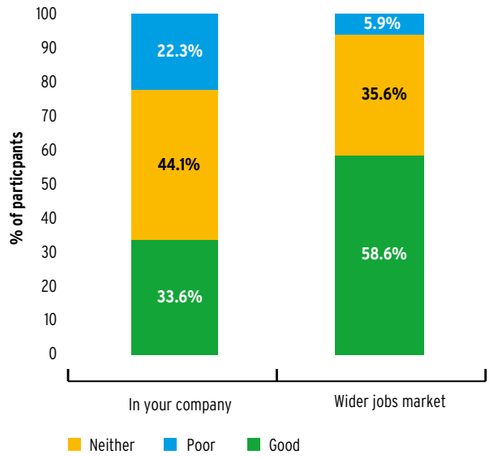
Within your employer, what is the trend in terms of number of chemicals management and control professional staff?



How important are the following opportunities to your organisation



Opportunities to progress in a chosen career within respondent's organisation and the wider jobs market



Although IT tools may reduce numbers employed in some areas, three quarters of respondents predict the need for staff working on IT and software will increase over the next five years.

One respondent commented that "regulatory resourcing" is a "next big issue" for their organisation. This includes ensuring enough funding to meet the challenges of an ever-changing global regulatory landscape, including appropriate tools and processes to stay ahead, they said.

Prospects for progression and pay

A slightly higher number of respondents this year feel career progression opportunities with their current employers are "poor" (22%, up from 19%), although 33.6% describe opportunities as "good". People have a more positive view of opportunities beyond their current companies, with 58.6% considering there are "good opportunities" to progress in the wider jobs market.

Meanwhile this year's survey identified a significant increase in average salaries compared with last year for respondents working in product safety and stewardship – up from €74.6k to €84.5k. Average salaries have also increased for those working as compliance managers, consultants, toxicologists, regulators and EHS managers. Bucking the trend are those working as regulatory affairs managers who have seen a fall in average salary this year from €77k to €69k.

Looking at salary movements from a geographical perspective, those working in North America and Asia have seen the most significant increases in average pay. By contrast, Europe and Latin America both saw falls in reported average salaries. Balancing both local and global issues and regulations as a complex global enterprise is growing increasingly difficult. Such regulatory variation in and between regions poses a real challenge for companies operating across the world and often requires local expertise.

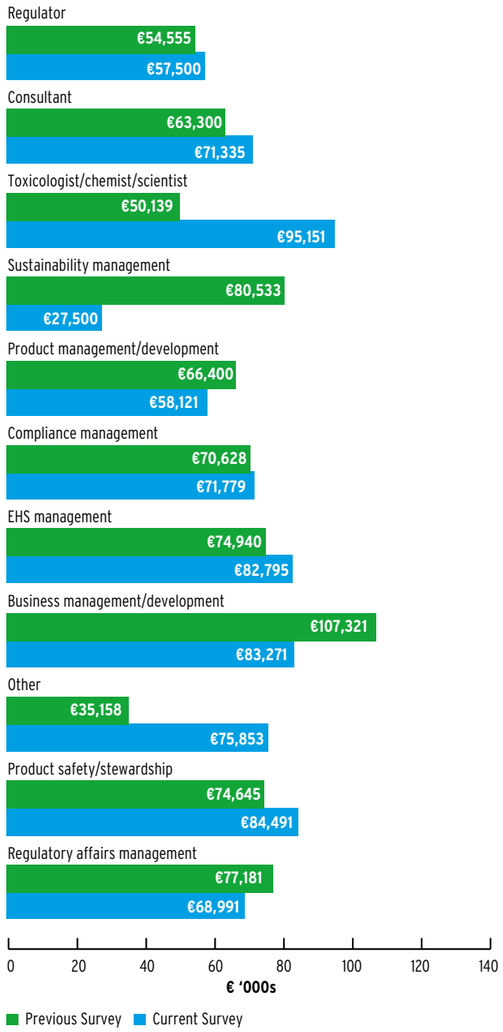
For example, CIRS is based in China but is rapidly expanding in other parts of Asia and the US. "We'd like to have some experts in the local regions," said Bryan Zhou, deputy general manager, Europe.

In general, issues are becoming more global, said Dieter Drohmann, managing director of Chemservice. He gave the example of companies needing to keep up with the proposed EU PFAS restriction, together with PFAS action elsewhere, such as in US states Minnesota and Maine. "Clients need more and more global coverage," he said.

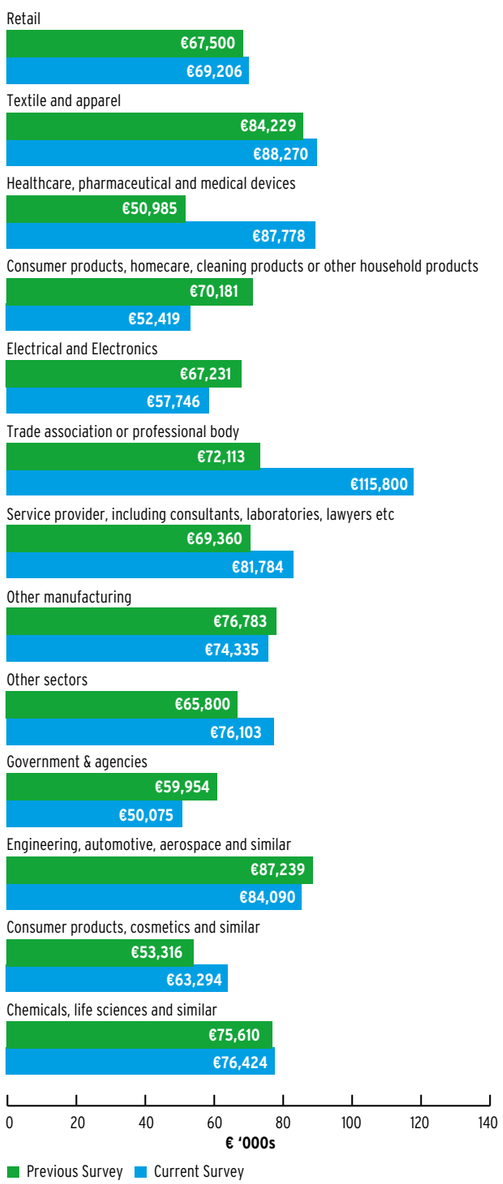
Several other survey respondents also described the proposed EU PFAS restriction as the next "big issue" that their organisation needs to manage in relation to chemicals management and control.

In general, the list of regulatory drivers is long. It includes EU REACH, as well as several national regulations such as South Korea's K-REACH. Also on the list are risk assessments for endocrine-disrupting chemicals and nanomaterials.

Average salary by job title



Average salary by industry sector



More than 50% of respondents said that their organisation was only partly or sometimes able to respond to the compliance drivers in an "agile way", although 42% were satisfied with the response. One survey respondent also described the challenge of dealing with "divergence" between UK REACH, EU REACH and Turkey's KKDIK.

Training boost

The need for subject-specific and specialist regional knowledge makes in-job training indispensable. Around half of professionals are clear that training needs in their fields are growing, for both courses and webinars. Yet every survey since 2019 has shown that up to 50% of people think their training needs are not being identified and met, despite consistent increases.

The latest survey results show that 40% of respondents believe their employer does not provide a large enough budget to cover these training needs for them and their teams. The survey revealed that "expertise of key staff" and in-depth knowledge of country-specific regulations are the most important factors when selecting a new supplier. Paying for additional training is therefore likely to pay off, with happy in-house teams and more business for external suppliers.

How to engage with your suppliers to protect your business

In this special report, first published in April this year, Business Manager for Enhesa Sustainable Chemistry Jillian Stacy, explains why it's critical to engage with your suppliers to achieve supply chain transparency for chemical management.

By now, everyone has heard the term supply chain. Empty shelves in stores during the pandemic highlighted the complexity of global supply chains and how one kink in the chain can have a massive domino effect. Getting goods through the supply chain is one thing, getting information through may be even harder. Responses to requests to suppliers are often like those of the childhood game telephone where the initial request gets changed with each pass to another person in the chain, so the end response has nothing to do with what was originally asked.

Why the push for supply chain transparency?

Regulatory compliance

Over the past few years, we have seen several regulatory drivers pushing companies to increase their supply chain transparency generally, but also specifically when it comes to the chemicals used in their products and processes:

- digital product passports – while specific requirements under the European Green Deal are still unknown, it is likely they will include a listing of master data, such as product, manufacturer, composition, chemicals of concern, toxicity and sourcing information;
- PFAS reporting requirements – globally, we are seeing an increase in rules and regulations requiring companies to report on the presence of PFAS in their products, detailing the amount as well as the purpose of the PFAS. Companies can often carry out finished product testing which will show them there is PFAS in the finished product, but they won't know where it is coming from and how to go about replacing it; and
- corporate Sustainability Due Diligence Directive – although not yet approved, the directive would require companies to identify, prevent, stop or mitigate impacts on human rights and the environment throughout their value chains.

Sustainability initiatives

While most companies are still focused on climate change, we are seeing an increasing number branching out into other sustainability initiatives around product circularity, increasing reusability and

recyclability, preventing biodiversity loss etc that will involve gathering chemical data from suppliers and getting them on board with initiatives.

Consumer demand

We are seeing an increase in consumer demand to understand what is going into the products they use. From food to cosmetics, children's toys to clothes, people want to understand potential risks and choose safer products. A quick search in your phone's app store will yield several results for apps whereby consumers can scan products in stores and review ingredients and associated safety information, as well as compare products. In the digital age, consumer product information is widely available, so it is important to identify any issues and make the necessary changes in your products before consumers raise a flag.

Challenges to engaging with suppliers

As we work with companies across sectors, we see that they all struggle to engage with their multi-tiered supply chains. Common themes relate to the fact that when it comes to chemicals management, most companies have very lean teams, and struggle to communicate effectively with their suppliers. Communication within a single company is a challenge; consider the even greater challenge of communicating with hundreds of suppliers who speak different languages and many of whom you may not even realise supply something in your product. Engaging the supply chain is difficult and tedious work and requires much upfront planning and buy-in.

Generally, companies run into the following issues:

- data – don't know what specific information to obtain from suppliers;
- analysis – don't know what to do with that information once it is obtained and who needs to be involved in the review process;
- staff – don't have dedicated staff to engage with the supply chain and chase suppliers;
- buy-in – don't have buy-in across departments such as sourcing, purchasing and compliance;
- cost – don't want to increase costs or add additional requirements for suppliers;
- tools – don't have single system/solution across the organisation; and
- relationships – don't know who their suppliers are or how to access them

Add to these the many reasons suppliers are reluctant to cooperate. Suppliers are constantly receiving information requests from their suppliers, which, while often asking for similar data, are in different formats, units, systems etc. They don't understand how their data is going to be used and by whom. A supplier's ingredient information is their most valuable possession, so they need to be sure it will be protected. All of these requests also translate into added costs for the supplier.

Where we see success

While engaging with the supply chain is difficult, many companies are seeing success and there is much variation in their approach. Some companies, such as **Under Armour** and Nike, focus on new product innovation. Lisa Clerici, senior manager global restricted substances compliance at Under Armour, says its supply chain engagement strategy is part of its broader sustainability goals. "We realise that in order to do business – especially in places like Europe – we really have to be sustainable. The consumers are asking for it, and NGOs are asking for it. And then of course there are regulations, like the PFAS regulations coming through, which is just a small little section of things, but there's such a push for it, and it's just going to keep going and going."

Like Under Armour, **Nike** understands the importance of and ensuring that problematic chemicals are not included in the product in the first place. Renee Hackenmiller-Paradis , former lead, Chemistry Center of Excellence, Global Sustainability at Nike, says: "One of our goals related to all of our chemistry assessments is that our chemical suppliers give us preferred chemicals... Understanding all chemicals used in a new process is really important because we don't want to start using something that may not be regulated right now but is just as bad as what it is replacing."

Other companies approach their supply chain engagement differently. Some look at their top existing products to identify opportunities to substitute safer alternatives. Still others look across their suppliers to identify those that affect the most products.

Although the approach and the reason behind engagement may be different, there are commonalities among the successful programmes. These companies have buy-in around supplier engagement initiatives at the highest levels of the company and several teams supporting. The teams are committed and willing to put in the effort to effectively communicate with suppliers and give them the support they need. There is clear guidance on what information is needed, how it will be collected, who will have access, how supplier information will be protected, and how the information will be used. They start small then scale up once they determine effective communication and processes.

Best practices for engaging suppliers

We suggest a five-step process to ensure success when engaging your supply chain:

1. define your why;
2. find your foothold;
3. create clarity;
4. implement your process; and
5. empower your suppliers.

Define your why

In order to have a successful programme, you need to first decide your goals and what success looks like. Why are you engaging with your suppliers in the first place? Is it to meet sustainability goals? Protect your workers, consumers and the environment? Maintain competitive advantage? Your why will set the foundation of your programme and provide context for why you are reaching out to suppliers in the first place.

Find your foothold

Many clients ask: "Where do I begin?" That's a tough question but let your why inform that decision. Are you looking towards the future with new materials like Nike and Under Armour? Are you trying to get an understanding of potential hazards in your current products to identify risks? Are you trying to identify opportunities to phase out chemicals of concern and replace them with safer alternatives? The answer to these questions will help you determine which suppliers to engage with.

Create clarity

Clarity is of key importance, as misunderstanding within the supply chain is one of the key reasons for not getting necessary sourcing information. Consider:

- What level of disclosure do you require? Ingredients? Impurities?
- What are you doing with the information? How are you using it?
- Who will have access to the information submitted by suppliers?
- How will the suppliers be affected; are your expectations reasonable?
- What is your timeline?
- What are the rewards/punishment for responding/failing to respond?

The clearer you are with your requests to suppliers, the more likely they are to respond.

Implement your process

Once you have your why, your foothold (where to start), and your clarity (the why and hows for your suppliers), you can move into implementation. Over time, what we've seen is that it's critical to have these steps in place and solidified for implementation to be a success and there are different ways to implement.

You can take a top-down approach like **Beautycounter®** which came up with its own restricted substances list or "never" list, using verified CHAs to create a list that goes beyond any current regulatory list. Lindsay Dahl, senior vice president of the mission team at Beautycounter, says: "There seems to be no indication that governments are slowing down in continuing to advance chemicals policies. So if current formulations are not on existing authoritative lists that's great, but it does not mean a brand is safe, and it would take a full-time person to constantly be assessing what's coming next. And for us, it would be better to invest in thinking about what would come next in scientific literature rather than always having to play catch-up after it's too late."

Another option is a prior review and approval approach such as Nike uses where suppliers need to provide full disclosure of their chemical products (this can be redacted) and this information needs to be assessed using Nike's framework, which includes list screening and chemical hazard assessments. Nike then works with its supplier to better understand any flagged chemicals before they can be approved for next steps in the innovation process.

Another approach to supply chain transparency is through certification requirements. Depending on your sector or products, certification programmes exist that aim to address chemical transparency and chemical hazard assessments. For example, in the textiles world, EIM and Screened Chemistry are two such programmes.

Empower your suppliers

Regardless of which one of these approaches works best for your scenario, make sure you are empowering your suppliers:

- consider engaging suppliers in developing an innovative process that works for everyone;
- help suppliers understand the why – to help protect their workers, products and business;
- build clear requests for information;
- set expectations for an adequate response;
- provide further clarification as needed; and
- enable access to tools to help them proactively meet expectations.

Key takeaways

Working towards supply chain transparency is becoming more and more critical as regulations continue to develop and consumers demand access to ingredient information. While engaging with suppliers can be a daunting task, you don't need to tackle your entire supply chain at once. Once you develop a plan and process, you can segment your suppliers and start with a small proof of concept that follows the best practices described above. With clear communication and collaboration, both internally and externally, you can get the chemical information you need to mitigate existing risks and prevent chemicals of concern from being used in the future.

What can we expect from digital product passports?

In this special report, first published in December 2023, managing analyst, EMEA, Kimberley de Miguel shows how digital product passports have the potential to deliver safer products and help companies demonstrate sustainable chemicals management.

Over the past few years there has been a significant surge in regulatory measures worldwide focusing on product traceability, chain of custody and data sharing requirements. This proliferation is notable in the EU, where an array of regulations are being introduced or proposed, which include reference to a digital product passport (DPP). This increase stems from the EU's digital transition plans that are designed to harmonise, and standardise, data access in alignment with the Green Deal.

The DPP is a linchpin of this transition, and aims to transform how products are traced, their lifecycles are assessed, and their environmental impacts are evaluated. The EU's approach involves a number of sectors that are under mounting pressure to adopt more sustainable business practices. These include textiles, construction, electronic waste, plastics, chemicals and automotive industries. Defining the precise data requirements for different product categories remains a work in progress. Achieving a DPP necessitates the cooperation of the entire supply chain to establish vital information that can mitigate product wastage.

Who will digital passports benefit?

The introduction of digital passports will bring transparency to intricate supply chains for brands and manufacturers. Implementing them has the potential to prompt a re-evaluation of business practices and partnerships, offering environmental insights, expediting sustainability goals and allowing premium pricing for responsibly produced goods. In addition, they have the potential to bring the following benefits to value chain stakeholders:

- material suppliers will be acknowledged for transparent processes that prioritise environmental safety and worker welfare;
- repair professionals will have access to comprehensive repair histories of products, aiding in the identification and resolution of new issues;
- recyclers will possess detailed information about component and material compositions, allowing for optimised take-back programmes and improved material recovery;
- governments and public authorities will gain a new set of standards and an easily accessible method to confirm compliance; and
- consumers and end users will be able to make well-informed purchasing decisions and foster sustainable behaviours, such as embracing repair and recycling.

What are the ecodesign requirements?

The EU Ecodesign for Sustainable Products Regulation (ESPR) proposal which builds on the existing Ecodesign Directive 2009/125/EC encompasses performance and information requirements, both of which are integral to the DPP.

Performance requirements refer to the functional aspects, and overall efficiency, of a product during its lifecycle. They are typically related to energy use, resource efficiency, environmental impact and circularity. Performance requirements aim to regulate how well a product operates, consumes energy and uses resources, as well as its impact on the environment. Compliance with these requirements ensures that a product meets specific standards regarding its performance and sustainability throughout its lifecycle.

Information requirements are focused on the data, details and transparency surrounding a product's composition, environmental impact, and other crucial information. Information requirements are essential for the DPP, ensuring that comprehensive details about a product's contents, environmental performance, energy usage, recyclability and other relevant factors are available and accessible. This information is critical for consumers, recyclers, policymakers and other stakeholders to make informed decisions and facilitate better product lifecycle management.

The DPP is specifically concerned with the information requirements within the broader framework of the ESPR. It functions as a means to provide detailed information about a product's compliance with the Ecodesign information requirements. This includes disclosing data about the product's energy use, water consumption, environmental footprint, recycled content, traceability in the supply chain and other essential aspects. The DPP ensures that this information is easily accessible and available to stakeholders, contributing to greater transparency and informed decision-making throughout the product's lifecycle.

Which product categories will need a DPP?

Batteries will be the first product segment required to comply with the DPP by 2026. Apparel and consumer electronics will follow soon after.

The European Commission highlights electrical and electronic equipment (EEE) as a fast-growing source of waste, posing environmental and health risks. Circular solutions are pivotal for resource recovery, reducing waste and decreasing dependence on expensive imports of rare-earth elements.

While the ESPR excludes the food sector, the proposed legislative framework for sustainable food systems aims to transition to sustainable food systems, strengthen policy coherence and reduce food waste. Similarly, the Packaging and Packaging Waste Directive focuses on achieving reusable or recyclable packaging across the EU market by 2030. Member countries must establish producer responsibility schemes by 2024 and aim for high collection rates, particularly for PET bottles. The European Commission aims to enhance the directive by focusing on design improvements, high-quality recycling and stronger enforcement. Leveraging digital tools like a digital packaging platform can aid waste management and sustainability goals among professionals.

These regulations collectively underscore the EU's concerted effort to standardise, and digitise, data related to product lifecycles, traceability and environmental impact, across various sectors and fostering a more sustainable and transparent market ecosystem.

With regards to other products, an announcement is expected in 2024, subject to the finalisation of the ESPR. It is difficult to predict when and which products will be affected by new and revised regulations, yet we can conclude that the following areas are of upmost importance:

- product-specific requirements — the EU battery regulation focuses exclusively on batteries, introducing a battery passport with specific data requirements targeting materials, recycling and carbon footprint, unique to battery products;
- reporting and compliance — the corporate sustainability reporting directive introduces detailed company-wide reporting, intending to align with EU sustainability standards and potentially digitise reported information for regulatory compliance;
- product information accessibility — the construction products regulation intersects with the DPP's objectives by seeking enhanced digital product information accessible to various stakeholders involved in the construction industry; and
- environmental focus —the sustainable and circular textiles regulation and the ESPR prioritise environmental sustainability by emphasising product durability, repairability, recyclability and energy efficiency.

Missing: specific information requirements

Companies currently lack definitive access to the specific information requirements for DPPs. There are challenges particularly for smaller entities dealing with complex value chains. Overcoming the hurdles will require concerted efforts, leveraging technological solutions and fostering collaboration throughout the supply chain. The balancing act between disclosing information and protecting confidential business data remains a critical challenge.

As regulations advocating DPPs evolve, companies will find themselves in a transformative phase regarding compliance. Some larger corporations might have initiated the process by actively engaging in stakeholder consultations or aligning with industry groups involved in the policymaking process. However, numerous small and medium-sized enterprises (SMEs) might lack clarity or comprehensive guidance on the specific data elements needed to comply with these evolving regulations.

What challenges are facing companies?

- Data availability and standardisation: the foremost challenge for companies is the lack of standardised information templates or clear guidelines regarding the data required for DPPs. Accessing, compiling and standardising data across complex supply chains poses significant hurdles, especially for SMEs with limited resources and disparate data management systems.
- Interoperability and technical adaptability: ensuring interoperability between existing enterprise resource planning (ERP) systems and new digital passport requirements remains a significant obstacle. Integrating diverse data formats, legacy systems and technologies into a unified digital passport system might necessitate substantial technological investments and adaptations, affecting operational efficiency.
- Resource constraints and compliance costs: SMEs might encounter resource limitations, both in terms of financial capabilities and expertise. Acquiring the necessary
- technological infrastructure, data management tools, and expertise to meet compliance standards could pose financial burdens, especially for smaller entities.

Which new regulations require a DPP?

Regulation	Compliance date	Key aspects
Ecodesign for sustainable products regulation (ESPR)	Draft proposal published in March 2022, with initial adoption expected in 2024	Aims to make consumer products more durable, reusable, repairable, recyclable and energy efficient. The updated initiative will likely identify additional product categories requiring DPPs, aligning with the Circular Economy Action Plan
EU battery regulation	Ongoing prototype development with an implementation target set for 2024	Introduces a battery passport, setting forth stringent data requirements for batteries. This includes specifications on material sourcing, carbon footprint, percentages of recycled materials used, battery durability and guidelines for repurposing and recycling
EU toys safety legislation	Revision of legislation ongoing	Focuses on enhancing the safety standards for toys available on the market. It ensures stringent safety measures, material specifications and compliance standards for toys, especially those intended for children. The specifics regarding the incorporation of digital product passport requirements for toys are under review
EU sustainable and circular textiles regulation	Ongoing prototype development with an implementation goal set for 2024	Focuses on enhancing textile durability, repairability and recyclability. The regulation mandates a digital product passport for textiles based on mandatory circularity and other key environmental aspects
Revised regulation on detergents	Currently under consideration and subject to the approval of the European Parliament and Council	Simplifies market rules, introduces voluntary digital labelling for prepackaged and refill products and sets safety requirements for detergents with micro-organisms. It promotes sustainability by regulating refilled detergents similarly to prepackaged ones and mandates a product passport for enforcement
EU construction products regulation	The regulation was signed in 2022, and the implementation date is yet to be determined	Intends to enforce greener and safer construction products, highlighting the need for improved digital product information accessible to citizens and businesses. The regulation's requirements correlate with those of the digital product passport, suggesting a potential overlap in implementation strategies
Corporate sustainability reporting directive	Adoption by Parliament and Council of Ministers in 2022, implementation in 2024	Requires detailed company-wide reporting in accordance with EU sustainability reporting standards. It may involve digitally 'tagging' reported information to be machine-readable and incorporated into the envisioned European single access point under the capital markets union action plan

How can companies overcome these challenges?

- Collaborative industry efforts: collaboration across industry sectors, consortia or trade associations could provide a platform for sharing best practices, developing standardised templates and collectively addressing challenges. Joint initiatives can streamline data gathering and ensure uniformity in compliance strategies.
- Government support and guidance**:** government bodies or regulatory authorities can play a crucial role in supporting companies by providing clearer guidelines, facilitating training programmes and offering financial incentives or grants for compliance efforts, particularly for SMEs.
- Adoption of digital solutions**:** investing in specialised software solutions or traceability platforms designed for digital product passports could assist companies in organising, standardising and managing the required data. Using modern technology can streamline data collection, enhance transparency and improve compliance readiness.
- Capacity building and education: offering educational programmes, workshops or training sessions to SMEs can build capacity and awareness regarding compliance requirements. Such initiatives can empower smaller businesses to navigate the complexities of data collection and management for DPPs.

While larger corporations may have started navigating the landscape of digital product passports, numerous challenges persist for SMEs in terms of access to information, technical adaptation and resource limitations. Collaborative efforts, government support, technological adoption and educational initiatives can collectively aid companies in overcoming these challenges, fostering a more inclusive and prepared business ecosystem for compliance with evolving regulations.

Key takeaways

Gaining transparency within the value chain is crucial for eliminating toxic chemicals. The DPP has potential to drive market shifts toward safer products, aiding companies in demonstrating sustainable chemicals management. Challenges persist, especially for smaller businesses navigating complex value chains and data requirements. However, the benefits may outweigh these obstacles in the long run, considering potential litigation or costs associated with chemical impacts.

The emergence of DPPs signals a significant paradigm shift towards sustainability and transparency, offering both challenges and opportunities for businesses in the EU market. This evolving regulatory landscape requires businesses to adapt, ensuring compliance while strategically leveraging these changes to foster innovation and sustainable practices.

How are PFAS regulations developing across the globe?

In this Chemical Watch News & Insight article, first published in January 2024, Chemical Watch Americas managing analyst Nidia Calvo outlines the path to regulation for per- and polyfluoroalkyl substances in key jurisdictions, including the latest developments.

Why are PFAS causing concern?

PFAS are a large group of man-made organic chemicals known for their exceptional resistance to heat, water and oil. Since the 1940s, these characteristics have led to their use in many industrial applications and consumer products such as carpeting, waterproof clothing, upholstery, food paper wrappings, personal care products, firefighting foams and metal plating.

The physico-chemical characteristics that made these chemicals so popular are the reason for current concerns regarding their use and effects in the environment and human health.

PFAS are persistent, which means they do not easily break down in the environment. Combined with their widespread use, this means many are found in the blood of humans. Because PFAS also bioaccumulate, the concentration builds up over time in the blood and organs. During the 1960s and 1970s, scientists detected the presence of PFAS in the blood of exposed workers. Further studies in the 1990s reported the detection in the blood of the general population. In 1999, the US Centers for Disease Control and Prevention (CDC) measured at least 12 different PFAS in human blood serum, indicating exposure to these chemicals in the US population.

In the late 1990s and early 2000s, the hazards, and ubiquitous occurrence, of two PFAS in particular – perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) – began to be reported. Since then, research and risk management measures have expanded from these two PFAS to a wider range of compounds

How are PFAS defined?

In 2021, the OECD published a general definition of PFAS, based on molecular structure, which serves as a reference for understanding the scale and diversity of chemicals in the group.

The OECD defines PFAS as "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), ie, with a few noted exceptions, any chemical with at least a perfluorinated methyl group (-CF3) or a perfluorinated methylene group (-CF2-) is a PFAS".

In the EU, PFAS are defined as: "Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it)." Although the definition is aligned with the OECD definition, it is broader than that of the US – and consequently, up to 10,000 substances fall under the scope of the EU PFAS restriction.

General classification of per- and plyfluoroalkyl substances (PFASs) based on the commonly agreed terminology for omenclature of PFAs (Buck et al. 2011); this figure is reproduced from OECD (2013) and updated with new information available (in particular, regarding per- and polyfluoroalkly ether-based substances).

Per- and polyfluoroalkyl substances (PFASs)

- **PFASs**
  - **non-polymers**
    - **perfluoroalkyl acids (PFAAs)** C_nF_{2n+1}-R
      - **perfluoroalkyl carboxylic acids (PFCAs)**, C_nF_{2n+1}-COOH
      - **perfluoroalkane sulfonic acids (PFSAs)**, C_nF_{2n+1}-SO_3H
      - **perfluoroalkyl phosphonic acids (PFPAs)**, C_nF_{2n+1}-PO_3H_2
      - **perfluoroalkyl phosphinic acids (PFPiAs)**, $(C_nF_{2n+1})(C_mF_{2m+1})$-$PO_2H$
    - **perfluoroalkane sulfonyl fluoride (PASF)** $C_nF_{2n+1}SO_2F$ → **PASF-based substances** $C_nF_{2n+1}SO_2$-R, R = NH, $NHCH_2CH_2OH$, etc.
    - **perfluoroalkyl iodides (PFAIs)** $C_nF_{2n+1}I$ → **Fluorotelomer iodides (FTIs)** $C_nF_{2n+1}CH_2CH_2I$ → **Fluorotelomer-based substances** $C_nF_{2n+1}CH_2CH_2$-R, R = NH, $NHCH_2CH_2OH$, etc.
    - **per- and polyfluoroalkyl ether-based substances**
      - **per- and polyfluoroether carboxylic acids (PFECAs)** e.g., $C_2F_5OC_2F_4OCF_2COOH$
      - **per- and polyfluoroether sulfonic acids (PFESAs)** e.g., $C_6F_{13}OCF_2CF_2SO_3H$
  - **polymers**
    - **fluoropolymers (FPs)** — polytetrafluoroethylene (PTFE), polyvinylidene fluoride (PVDF), fluorinated ethylene propylene (FEP), perfluoroalkoxyl polymer (PFA), polyvinyl fluoride (PVF), etc.
    - **side-chain fluorinated polymers** — fluorinated (meth)acrylate polymers* / fluorinated urethane polymers* / fluorinated oxetane polymers
    - **perfluoropolyethers (PFPEs)** — e.g., $HOCH_2O$-$[C_mF_{2m}O]_n$-CH_2OH

* These polymers are based on monomers derived from PASFs or fluorotelomer-based raw materials.

In this figure, reproduced from the OECD, we can see a general classification of PFAS based on the original definition from 2011 updated with some new considerations. This shows how the scope of PFAS evolves as scientific studies identify compounds with similarities in their structural behaviour.

The path to regulation

Driven by concerns about the adverse impacts of PFAS on the environment and humans, risk reduction actions have been implemented to cut environmental and human exposure to PFAS. For instance, major global manufacturers in OECD countries have voluntarily discontinued production of certain long-chain PFAS.

In 2015, the OECD conducted a project to map the activities of different countries seeking to develop PFAS risk reduction approaches. The project has provided a reference point for many of the regulations now being considered to monitor, report or restrict these substances in the supply chain.

As a first step in this regulatory framework, the production and use of several long-chain PFAS and their precursors have been restricted under national, regional or international regulations.

Europe

In October 2020, the European Commission published the chemicals strategy for sustainability (CSS), which includes;

- phasing out the use of PFAS in the EU unless their use is essential; and
- initiatives to reduce emissions from PFAS using all feasible available legislative and non-legislative tools.

However, the EU had already been concerned with PFAS – and restricted related substances:

- the Stockholm Convention listed PFOS in 2009 and PFOA in 2019; and
- REACH adopted restriction 689 on PFOA, effective 2020; restriction 73 on C6 silanetriols in spray products, effective 2021; and restriction 6811 on C9-C14, effective 2023. Three more restrictions are currently pending.

In January 2022, ECHA introduced a restriction proposal for PFAS used in firefighting foams. ECHA's scientific committees supported the proposal in their opinions which were finalised in June 2023. The European Commission together with EU member states will decide on the restriction in due course.

In January 2023, ECHA published a universal restriction proposal on PFAS. The proposal was prepared by authorities in Denmark, Germany, the Netherlands, Norway and Sweden and aims to restrict the manufacture, placing on the market and use of PFAS as such, and as constituents in other substances, mixtures, and articles above a certain concentration. (PFAS used in firefighting foams is excluded).

Perfluorinated carboxylic acids (C9-14 PFCA), their salts and precursors were restricted in the EU/EEA from February 2023 following a decision by the European Commission on a proposal by the German and Swedish authorities. Germany has proposed a further restriction for undecafluorohexanoic acid (PFHxA), its salts and related substances. This proposal was evaluated by ECHA's scientific committees in December 2021. The European Commission together with the EU countries will decide on the restriction in due course.

US

In April 2021, the US EPA created the EPA Council on PFAS and has since been extremely active in publishing related documentation, proposed regulations or amending existing ones to address PFAS.

In June 2021, the EPA proposed a rule to require all manufacturers (including importers) of PFAS in any year since 2011 to provide it with a wide range of data, including on how they are using certain PFAS. Once finalised, this rule would be the first targeted effort under the Toxic Substances Control Act (TSCA) to collect information on the manufacture of PFAS and would provide the EPA with the most comprehensive dataset of PFAS manufactured in the US. As originally proposed, this rule would compel companies to submit information on any PFAS manufactured, imported or imported in an article since 2011 with no exemptions for small businesses, impurities or byproducts.

In October 2021, the EPA released its PFAS Strategic Roadmap that highlights concrete actions the agency will take across a range of environmental media and EPA programme offices to protect people and the environment from PFAS contamination.

The fifth Unregulated Contaminant Monitoring Rule (UCMR 5) was published on 27 December 2021. UCMR 5 requires sample collection for 29 PFAS between 2023 and 2025 using analytical methods developed by the EPA and consensus organisations. This action provides the EPA and other interested parties with scientifically valid data on the national occurrence of these contaminants in drinking water.

In January 2023, the EPA proposed the Inactive PFAS SNUR, a rule that would prevent anyone from starting or resuming, without a complete EPA review and risk determination, the manufacture, processing or use of an estimated 300 PFAS that have not been made or used for many years, known as "inactive PFAS".

Effective from November 2023, all entities that manufacture or import PFAS or PFAS-containing articles in any year since 1 January 2011 must report the information to the EPA on PFAS relating to their use, production volumes, disposal, exposure and hazards (40 CFR Part 705).

At the state level, the US is one of the most active countries on PFAS.

The legislation tracker tool developed by Enhesa Product identified 133 bills this year that have mentioned PFAS as chemicals to be regulated. Ten of these 133 bills turned into a signed law in different states, including Indiana, Indianapolis, Maine, Maryland and New York.

Top mentioned chemicals in US state legislation	No of legislations
PFAS	133
Mercury	33
Polystyrene	32
Lead	21
Formaldehyde	19
Phenol	19
Phthalates	16
Cadmium	12
Toluene	12
Triclosan	12

The use of PFAS in pesticides, textiles, food contact materials or general use are some of the topics these states address with their regulations.

Future

PFAS regulations will continue to increase in number and variety. Whether the proposals for restriction of PFAS are feasible will depend on the degree of alignment of the definitions of PFAS. The impact of regulations will potentially vary from a few thousand substances to more than 10,000 and impact different companies in many different ways because of the differing interpretations.

The most vital aspect of PFAS discussion will be the communication between authorities, industries and users. The substances are hazardous enough to make all stakeholders worry about the next steps, but the extensive uses and dependencies created over the years bring a compelling need to work together to find alternatives or ways to regulate the use of and exposure to these substances.

What does 2024 hold in store for the UN?

In this special report, first published in January 2024 as part of the Chemical Watch News and Insight Global Outlook series, managing editor for Europe Leigh Stringer outlines the key chemicals management developments taking place at an international level this year.

Key developments

A key focus for February's sixth session of the biennial UN Environment Assembly will be progress towards the sound management of chemicals and waste, including implementation of the Global Framework on Chemicals

In April, the fourth round of negotiations will take place regarding a global plastics treaty that could see caps on plastic production, and bans on certain chemicals of concern introduced

September will see further consideration of proposals to add medium-chain chlorinated paraffins (MCCPs) and long-chain perfluorocarboxylic acids (LC-PFCAs) to the list of chemicals to be eliminated under the Stockholm Convention on persistent organic pollutants (POPs)

International environmental policy will continue to drive action this year with efforts focusing on the UN's identified triple planetary crisis of climate change, biodiversity loss and pollution, including the impacts of chemicals.

Here we outline what is planned as another crucial year addressing environmental and human health issues globally gets underway.

UN Environment Assembly

The international agenda kicks off this year with the sixth session of the UN Environment Assembly (UNEA-6) – the world's highest decision-making body on the environment.

The meeting will take place from 26 February to 1 March and will aim to help shape global environmental policy, including efforts to address pollution and chemicals of concern.

Under the pillar of pollution, chemicals production and management has become a more prominent global issue. Rising higher up the environmental agenda, chemicals are now being assessed in most countries and are being considered across environmental and health-related legislation.

UNEA-6 will raise global awareness of the multilateral action being taken to address the triple planetary crisis, including the frameworks and conventions established to tackle the environmental and human health impacts chemicals.

Held every two years, the meeting will help guide environmental efforts around the world, making it important for all stakeholders, including companies large and small, to take note of the outcomes of the meetings.

Global chemicals framework

UNEA-6 will consider progress towards the sound management of chemicals and waste, including implementation of the Global Framework on Chemicals, which was adopted in September last year.

The framework sets out a vision, objectives and funding system that aims to "free the world of harm from chemicals".

Following adoption, 2024 will see UNEP and other stakeholders begin promoting the framework's objectives and implementing actions to achieve its goals. These include, by 2030:

- governments to adopt and have started implementing and enforcing legal frameworks [to manage chemicals]; and
- companies to implement measures identified to prevent or, where this is not feasible, minimise adverse effects from chemicals throughout their lifecycle.

Although voluntary, like its predecessor the Strategic Approach to International Chemicals Management (SAICM), the new framework is considered more ambitious because of its specific objectives and timelines.

Companies and other stakeholders should become familiar with these global goals as they will set the direction for regional and national chemicals policy, as well as how industry should operate and manage chemicals.

Global plastics treaty

The global treaty to address plastics pollution aims to create a legally binding instrument that addresses the full lifecycle of plastic, including its production, design and disposal.

Talks that took place in November last year in Nairobi marked the halfway point in the negotiations. The aim is to finalise the treaty in 2025.

UNEP says the "rapidly increasing levels of plastic pollution represent a serious global environmental issue that negatively impacts the environmental, social, economic and health dimensions of sustainable development".

The severity of the issue means the treaty will likely see strong measures agreed and many stakeholders are calling it one the most important environmental agreements since the 2015 Paris climate agreement.

The treaty will have significant implications for plastics producers and plastic additives manufacturers, as well as all sectors along the supply chain that use plastics. Aspects currently being debated include caps on plastic production and global bans on certain chemicals of concern often used in the materials.

The fourth round of negotiations will take place from 23 to 29 April in Canada. Some stakeholders are hoping for more progress after NGOs blamed a group of "oil producing" countries for slowing the process down in the previous three rounds of talks.

Science policy panel

In 2022, UN member states agreed to establish an intergovernmental science-policy panel on chemicals, waste and pollution. The panel is expected to perform a similar role for chemicals to that of the Intergovernmental Panel on Climate Change (IPCC) and the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES).

The third meeting of the Open Ended Working Group (OEWG) will be held on 17-21 June in Switzerland.

In November last year, 34 scientists from around the world said industry experts with potential conflicts of interest (COI) should be limited to observer status of the panel and not participate directly in discussions.

The extent to which industry will be involved in the panel has been a key topic of discussion since the idea was first discussed and will likely continue into OEWG3 and beyond.

Stockholm Convention

This year will see further consideration to add medium-chain chlorinated paraffins (MCCPs) and long-chain perfluorocarboxylic acids (LC-PFCAs) to the list of chemicals to be eliminated under the Stockholm Convention on persistent organic pollutants (POPs).

Both groups of substances were recommended for inclusion at the last meeting of the convention's POPs Review Committee (POPRC) in October last year.

The POPRC said the most efficient control measure would be to include these substances in Annex A of the convention. If approved, such a listing would require signatory nations to take measures to ban the chemicals' production, use, import and export, subject to potential exemptions.

However, experts acknowledged that more work is needed on a number of outstanding issues, including specifying the proposed exemptions, ahead of a final vote at the Conference of the Parties (COP) of the Stockholm Convention in 2025.

This means there will be an opportunity at the next POPRC meeting between 23 to 27 September 2024 to introduce addendums to the suggested bans.

Key dates

- Sixth session of the UN Environment Assembly (UNEA-6) – 26 February to 1 March, Nairobi
- Fourth round of negotiations for a plastics treaty – 23 to 29 April, Ottawa, Canada
- Open Ended Working Group (OEWG) for the global science policy panel – 17-21 June, Switzerland
- Stockholm Convention POPRC meeting – 23 to 27 September, Rome

Key dates for cosmetics regulation in 2024 and beyond

2024

1 May

China: Full safety assessment reports required for cosmetic notifications or registrations

1 July

Taiwan: Special use cosmetics to be regulated as ordinary cosmetics

21 November

Philippines: Chemical restrictions for cosmetics based on the 36th Asean Cosmetic Committe meeting take effect

December

US federal: Cosmetics product labels must give details for responsible parties in case of an adverse event

2025

1 January

California: State ban of listed PFASs in cosmetics takes effect

1 January

Maryland: State to prohibit cosmetic products that contain certain ingredients as defined in the bill

Key dates for food contact materials regulation in 2024 and beyond

2024

1 January

Colorado, Maryland, Minnesota and Rhode Island: State restrictions on intentionally added PFASs in food contact materials come into effect

1 January

New Jersey: Any glass container, plastic beverage bottles or rigid plastic containers sold or offered for sale must contain at least 35%, 15% and 10% post-consumer recycled content respectively

Year end

EU: The Working Group concludes on preferred policy options for legislative FCM revision

2025

1 June

Japan: Enforcement of the Ministry of Health, Labour and Welfare's positive list of food contact substances expected to start

1 July

Colorado: A producer may not sell or distribute any product that uses covered materials unless the producer is participating in the state-appointed Producer Responsibility Organization (PRO)

31 December

Sweden: National food agency commences control operations of companies placing food contact materials on the market

31 December

Germany: Transition deadline for Annex 14 added to the consumer goods ordinance, specifying monomers, colourants, solvents, photointiators or other additives permitted in printing inks for printed food contact materials

Year end

EU: DG Sante expected to start work towards formal legislative FCM revision

Key dates for PFAS regulation in 2024 and beyond

2024

1 January

Colorado, Connecticut, Maryland, Minnesota and Rhode Island: State restrictions on intentionally added PFAS in food contact materials come into effect

1 March

Maine and Minnesota: End of consultation for industry to submit 'currently unavoidable use' (CUUS) of PFAS

11 March

EU: Revised EU f-gas regulation, which will provide for a complete phase-out of hydrofluorocarbon (HFC) consumption by 2025, enters into force

1 May

Washington: Restrictions on PFAS in food packaging take effect

1 October

US: Deadline for the Department of Defense to transition away from using PFAS-containing aqueous film forming foam (AFFF) to extinguish liquid fuel fires, under the 2020 NDAA

3 June

UK: Deadline for submissions to Health and Safety Executive's call for evidence in firefighting foams

2025

1 January

Oregon: Restrictions on PFAS in food packaging take effect

1 January

Maine: Deadline for manufacturers to provide information on PFAS-containing items sold in the state

31 December

Hawaii: Restrictions on PFAS in food packaging take effect

12 November

US: EPA launch of submission period for reporting under the TSCA section 8(a)(7) PFAS reporting rule, which asks manufacturers to detail their use of over 1,460 compounds, backdated to 2011

1 January

California and New York: First-ever prohibitions on PFAS-containing apparel take effect

1 January

Washington: Ban on PFAS-containing carpets, rugs, and aftermarket treatment takes effect

1 January

California, Colorado and Washington: Pioneering bans on PFAS-containing cosmetics take effect

1 January

Colorado: Multi-product PFAS prohibition enters into force, including the nation's first ban on compounds in fracking fluid

1 January

Illinois: Ban on class B firefighting foam containing intentionally added PFAS begins, requiring manufacturers to register with state EPA

1 January

Minnesota: Restrictions of 11 PFAS-containing goods take effect. Includes menstrual articles, dental floss, cleaners, and cookware

2026

May

US: Date by which most companies are due to submit information on their historical use of PFAS, under TSCA reporting rules, section 8(a)(7)

31 December

New Zealand: Ban on import or manufacture of cosmetics products containing PFAS comes into force

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

Contacts	
Website	actagroup.com
E-mail	lbergeson@actagroup.com
Head office	2200 Pennsylvania Avenue, NW, Suite 100W, Washington, DC 20037, USA
Tel	+1 202 266 5020
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	Washington DC, Manchester England, Brussels Belgium
Founded	2000

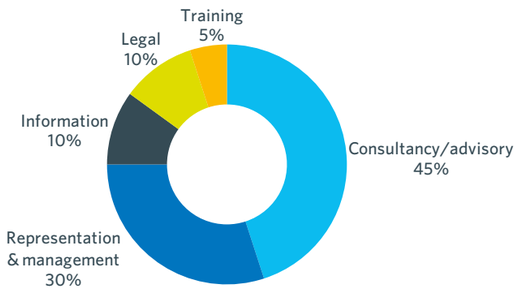
Overview

The Acta Group (Acta®) is a leading international consulting firm focusing on chemical product approval, compliance support, business strategy development and implementation, and regulatory defence, providing a full-range of support for the processes of developing, commercialising, and sustaining industrial and specialty chemicals, biocides, cosmetics, metals, food contact chemicals, products of biotechnology, and nanotechnology. Acta professionals are scientists, lawyers, and business and regulatory consultants. This combination and our wealth of experience in and out of laboratories, global chemical companies, and government agencies make Acta an exceptional resource for companies in the chemical space. Acta maintains offices in the US, the UK, and Europe, and offers expertise with regulatory programmes and chemical product approvals in North America, Europe, UK, the Eurasian Economic Union (EAEU), South and Central America, Asia, the Middle East, and the Pacific Rim.

Vital statistics

	2022/23
No of offices	3
No of countries represented	>25
Staff: group	35+
Staff: chemical service provision	35+

Service area breakdown



Global offices

US: 2200 Pennsylvania Avenue NW, Suite 100W, Washington, D.C. 20037
Tel: 202-266-5020
UK: 26 Cross Street, Manchester, M2 7AQ, UK, Tel: +44 (0) 330 223 0610
EU: Place du Luxembourg 2, 1050 Brussels, Belgium, Tel +32 2 588 48 85

Acta has affiliates in Shanghai and Guangzhou, China; Seoul, South Korea; Istanbul, Turkey; and Eurasia.

Services provided

General consulting services

We counsel global business entities, trade associations and industry associations. Our fundamental goals are to solve our clients' existing problems and minimise future difficulties to assist them in achieving their regulatory and business goals. We take a multidisciplinary approach in assisting our clients. Attention must be paid to various regulatory and scientific nuances and the interplay of all branches of government and interest groups.

Our extensive national, regional and international expertise on chemicals policy and regulatory matters, combined with our global partnerships, positions us perfectly to strategically manage the worldwide needs of our clients and industry with expert judgement, creativity and efficiency.

Acta's general consulting services cover virtually all jurisdictions and types of chemicals. We offer unparalleled technical, regulatory, scientific and legal support under a wide range of global chemical programmes, including the US Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (Fifra), EU REACH Regulation, UK REACH Regulation, Biocidal Products Regulation (BPR), South Korean REACH (K-REACH), Turkey REACH (KKDIK) and Eurasia REACH.

Our general consulting services cover a wide array of activities to support our clients, including regulatory interpretation, strategic support and persuasive advocacy for wide-ranging issues.

Global product registration and agent services (representative services)

Acta offers a range of 'hands-on' practical compliance services, with Acta (alone or in concert with trusted global partners) serving as an agent or representative under the relevant regulatory framework. These services include chemical product notification, registration and technical defence under global chemical programmes, including UK REACH, EU REACH, EU BPR, the UN Globally Harmonized System (GHS) of classification and labelling of chemicals, TSCA, FIFRA, K-REACH, KKDIK, China REACH and Eurasia REACH. Acta is a global market leader in providing expert, seamless only representative (OR) services under EU REACH, UK REACH and similar global programmes. Acta remains heavily engaged in managing post-2018 EU REACH compliance (eg dossier evaluation, new registrations) and providing OR services under K-REACH and KKDIK. Acta's 'boots on the ground' in Manchester, UK, are valuable assets to our clients.

We are optimally positioned to provide expert representative services under new chemical laws in the UK including UK REACH. Our clients benefit from our strategic planning, presence in various locations, and assurances of uninterrupted compliance in the UK, Europe and beyond. Acta's expert knowledge of KKDIK, the Turkish Classification, Labelling, and Packaging (CLP) Regulation, and the Turkish Safety Data Sheet (SDS) Regulation, coupled with our strong ties to a trusted business partner and OR in Turkey, allows Acta to assist the global chemicals industry in managing compliance under the important KKDIK registration deadlines. Similarly, Acta clients seeking South Korean regulatory support benefit from our in-depth knowledge and ability to provide superior representative services.

Acta focuses 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, EEA, UK, Switzerland, Turkey, EAEU, Australia and New Zealand, Malaysia, China, Japan, South Korea, Taiwan, Philippines, Singapore and Indonesia.

Data compensation and competition support services

Acta is engaged extensively in worldwide data compensation matters under a wide range of chemical regulatory frameworks, including EU REACH and Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Acta's regulatory and legal personnel have an in-depth understanding of applicable rules and guidelines, and support clients in managing data sharing, maintaining compliance, and optimising data compensation.

Our activities include developing letter of access costs, managing cost negotiations and supporting clients in resolving disputes.

Many clients are evaluating and pursuing competition-related issues. Acta is well-positioned to assist companies in understanding applicable rules and achieving fair and favourable outcomes. We are actively involved in attempts to resolve competition-related disputes under EU REACH. While amicable resolution is typically beneficial, it is not always possible. Acta provides strategic and practical support for competition- and data-related mediation, arbitration, and litigation.

We are the industry experts in managing challenging and contentious data compensation- and competition-related matters and are heavily engaged in these practice areas.

Technical document preparation activities – hazard, exposure and risk assessment

We undertake the appropriate analysis, document preparation, and coordination to support registration and post-registration activities under global chemical regulatory regimes (ie chemical substance dossier preparation, exposure assessments, hazard assessments, specific effect assessments).

GHS, CLP services

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

Regulatory training

The TSCA Tutor® and Fifra Tutor® training platforms provide live in-person training at a company's site, live webinar training, and on-demand online training modules – all designed to offer expert, efficient, and essential TSCA and Fifra training. Companies can mix and match training modules and training approaches to provide the most suitable combination for their work needs. Visit our TSCA Tutor (**TSCAtutor.com**), and Fifra Tutor (**Fifra tutor.com**) web pages for more information.

Partners

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

Clients

Acta'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

Case study 1

Chemical registration and regulatory support

Acta assists clients across a wide range of industry sectors with pre-registrations, new and existing substance notifications, and registrations in South Korea, China and Taiwan. Expert resources develop registration and notification strategies for businesses seeking to launch new products or to expand into new regions. Acta support services include robust study summary review and preparation, guidance on testing for data requirements, and OR, third party representative or agent appointment. Acta advocates, on behalf of its clients, with regulatory bodies against unnecessary, and often costly, animal testing. Acta closely monitors the region for changes and is equipped to support clients with complex regulatory challenges in a dynamic and ever-changing regulatory environment.

Case study 2

Lead registrant support

Acta serves as lead registrant under EU REACH for an important substance globally, as OR on behalf of a non-EU manufacturer. The joint registration for the substance has multiple co-registrants and numerous issues, including a lead registrant dispute, challenging data compensation matters, confidential business information issues, lead member collaboration and substance evaluation. Acta continues to successfully manage the registration for the substance, engaging in various important activities, including strategic planning, advocacy, legal review and negotiation, engagement of external service providers, cost reconciliation, downstream user support and coordination for substance evaluation. Acta's clients benefit from our efforts and are able to sell their products uninterruptedly across Europe.

Staff selection

Lynn L Bergeson – President

Ms Bergeson assists companies, a wide range of trade groups and ad hoc consortia on chemical-specific legislative, scientific 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, Director of Toxicology

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

Karin F Baron, MSPH – Director of Hazard Communication and International Registration Strategy

Ms Baron has significant experience leading hazard communication, industrial hygiene, and environmental health and safety (EHS) programmes for multinational 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 certified by the Dangerous Goods Advisory Council.

Richard E Engler, PhD – Director of Chemistry

Prior to joining Acta Dr Engler worked as a senior staff scientist at the US Environmental Protection Agency. Dr Engler's expansive understanding of the specific challenges and opportunities TSCA presents for new chemistries and processes is a powerful asset for clients during regulatory review. Dr Engler assists clients in performing toxicological reviews, performing environmental fate modeling, and preparing scientific and test data for regulatory submission.

Emma Louise Jackson – Manager, REACH

Ms Jackson has more than a decade of experience in testing and 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.

Karen L Lorusso – Regulatory Consultant

Ms Lorusso is a highly experienced product safety professional assisting clients with global hazard communication and regulatory compliance projects including classification and labeling of substances and mixtures, and preparing and submitting dossiers to support REACH, UK REACH, K-REACH and other chemical regulatory programmes.

Carolyn Wray – Regulatory Assistant

Ms Wray ensures contracts, data sharing agreements, and other regulatory documents are accurate and submitted timely to clients and government entities.

Contacts	
Website	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, Hiram Moerman, Tine Vandenbrouck
Ownership	Private company
Locations	Mortsel (Antwerp), Belgium
Founded	2009

Overview

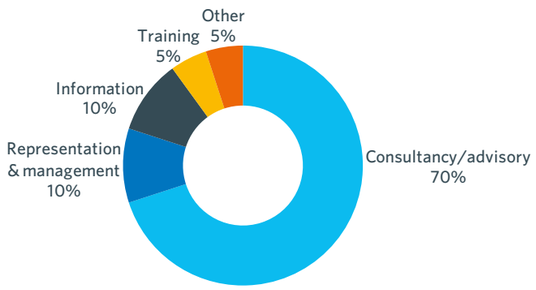
Our mission is to guide our clients to sustainable, future-proof use of chemicals and business operations. Regulatory compliance is our point of departure. From there we go the extra mile to drive long-term improvement for human health and the environment, with added value for society. We do this by means of incremental improvements or, even better, by a step change.

We are a highly motivated, multidisciplinary group of experts: (eco) toxicologists, chemists and engineers with industrial experience. As a team, together with a limited number of subcontractors with niche knowledge, we turn your project into a success. We provide specific expertise, while being able to act flexibly and maintain our client focus.

Vital statistics

	2022/23
No of offices	1
No of countries represented	1
Staff: group	>15
Staff: chemical service provision	>15

Service area breakdown



Services provided

We assist our clients with the following: REACH, CLP, Biocides regulations, UK chemicals legislation, EU and national nano legislations, food contact, RoHS, waste legislation, sustainability goals amongst other developments in circular economy. 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 assist clients in the development of chemicals management systems and product stewardship programmes.

Sustainability

- Product portfolio sustainability assessment
- Safe and sustainable by design
- Sustainable recycling
- Alternatives assessment
- Set-up of circular business models

REACH and CLP

Set-up REACH import/export strategy.

REACH registration dossiers from A to Z: substance identification, hazard assessment, study monitoring, exposure and risk assessment, evaluation of PBT and endocrine disrupting (ED) properties, integration of nano data.

Substance portfolio management: fully outsourced management of REACH registrations including updates and tracking of regulatory position of registered chemicals.

REACH authorisation dossiers: strategy development, chemical safety assessment, analysis of alternatives, socio-economic analysis, supply chain communication.

Other REACH topics: support during evaluation, support during Board of Appeal (BoA) cases, RMOA generation for individual companies or associations, DU-CSR generation, Annex XV dossier generation, representation of clients in consortia, position papers, set up of monitoring programmes (occupational hygiene), communication with authorities.

Biocides

Transitional regulation and BPR-related services: authorisation strategy development, transitional notifications/registrations, BPR biocidal products dossier generation including biocidal product family concept integration, data gap analysis, study monitoring, risk assessment, PAR generation, follow-up with authorities, technical equivalence dossier preparation, Article 95 listing, renewal dossiers (BP and AS).

UK chemicals legislation

Brexit-related chemical legislation: strategy definition, UK REACH, GB CLP GB BPR, only representative services.

Due diligence

- Audit programmes: compliance, system, supply chain, project, due diligence and SCC audit
- Merger and acquisition support
- Prepare and support during enforcement inspections

Out-of-the-box solutions

Expect the unexpected!

Clients

Our references are based 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 and retail. Apeiron-Team provides support to regulators and authorities in the development of the regulatory framework for chemicals.

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 process of authorisation, 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*

Corporate developments and achievements

2009	Apeiron-Team NV was founded
2010	Gradual development of all REACH-related aspects from registration to authorisation. Resulting in >100 registration dossiers and the first authorisation applications
2013	Addition of biocides-related services to our portfolio
2014	Development of a standard approach for application for authorisation used in several chromates, TCE and other application dossiers Submission of various Union authorisations under the BPR Successful conclusion of a BoA case on additional persistence testing Development of an inhouse RMOA methodology. Successful submission of >150 registration dossiers for the 2018 deadline
2018	Development of regulatory support for circular economy based business models
2019	Ten years of Apeiron-Team Managing outsourced REACH registrations for more than 400 substances. Development of more than five authorisation dossiers
2022 onwards	Focus on supporting companies to achieve their sustainability goals and develop future-proof businesses. On the one hand by supporting companies to set-up circular business flows, on the other hand through identification of SVHCs and alternative assessments

Accreditations

European registered toxicologists (ERT). Environmental advisor (Milieu Coordinator).

Partners

Burgess Regulatory Services Ltd, The Economics Interface, eftec, Jongerius Consult, Vander Straeten Consulting Services, VIB fabriek.

Case study 1

REACH authorisation application – from strategic support to dossier generation

Apeiron has developed a standardised approach to developing authorisation applications. This approach covers single and multiple sites cases and has been used in several successful applications. The approach is structured and strongly project driven allowing a cost and time-efficient development of applications. The expectations towards the applicants are clear and agreed in function of resource availability of the applicant.

In collaboration with the applicant, the strategy for the application is developed at the start of the project. Guidance is provided to the applicant on the required data including exposure/emission monitoring and socio–economic data. Alternatives are scrutinised and development plans are thoroughly justified on timing and relevance.

The application dossiers are subject to a specific QC in order to assure a consistent, complete and transparent application file allowing correct opinion and decision making by the authorities. In all cases, this has resulted in a granted authorisation period equal to the requested period.

Case study 2

Overcoming regulatory hurdles in the circular economy

Several companies have approached us on overcoming the regulatory hurdles to implementing circular economy-based business models. While safeguarding the principles of safe chemicals management, strategies are developed with the clients to comply with the chemical regulations in a cost-effective manner. Business models in circular economy are often not considered in the legislation.

Apeiron-Team supports its customers in discussions with the authorities to find solutions. Apeiron-Team has advised successfully on cases in the recycling of industrial goods and consumer goods.

Case study 3

Board of appeal case on PBT

Apeiron-Team, on behalf of its client and together with its legal partner Steptoe & Johnson, challenged the request for additional P testing in the context of substance evaluation, before the ECHA Board of Appeal (BoA). The case was defended and won on the basis of lack of proportionality. This was the first PBT case won by the appellant and the first in which the BoA decided in favour of the appellant in a case of scientific uncertainty.

Explorative science with unclear interpretation as requested by the member state was avoided in favour of scientifically proven testing methods. The case showed that a close collaboration of technical-scientific and legal support results in a strong defence of substances.

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 was within product type 4. The composed biocidal product family, and its meta-SPCs, was evaluated in detail together with the client to ensure that the different criteria of a BPF were fulfilled.

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 and new information was integrated into IUCLID and a draft risk assessment covering the complete BPF was generated. Apeiron actively defended the dossier with the authorities and during working group meetings at ECHA. As such, a positive final commission decision for one of the first submitted Union dossiers was received.

Staff selection

Elke Van Asbroeck – (Bio-) Chemical Engineer

Polymer science; regulatory business strategy; sustainable chemicals management; circular economy and due diligence.

Hiram Moerman – Chemical Engineer

Previously in polymer industry; REACH authorisation; alternative assessment; risk management option analysis; sustainable chemicals management and circular economy.

Tine Vandenbrouck (ERT) – Ecotoxicologist and Risk Assessor (PhD)

Biocidal product strategies and registrations; REACH registration and authorisation; exposure estimation and modelling; UK chemicals legislation; specialised in mixture effects.

ARCADIS

Contacts	
Website	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:** maaike.bilau@arcadis.com +32 492 73 0489 **North America:** andy.newcombe@arcadis.com +1 302 584 5999
Directors	Alan Brookes (CEO)
Ownership	Public company
Locations	350+
Founded	1888

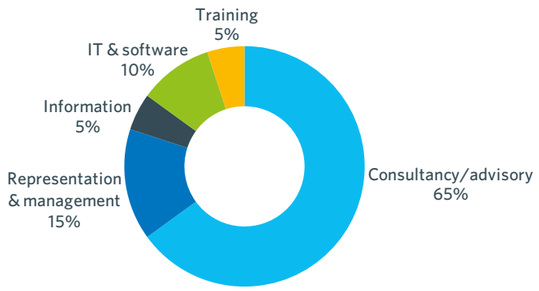
Overview

Arcadis works in partnership with its 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 lifecycle, its deep market sector insights, and its ability to integrate health, safety and sustainability into the design and delivery of solutions across the globe.

Vital statistics 2022/23

Turnover: group	€4bn
Turnover: chemical service provision	€10m
No of offices	350+
No of countries represented	70+
Staff: group	36,500+
Staff: chemical service provision	75+

Service area breakdown



Global offices

Key offices for Product Stewardship and Sustainability support:

- **Belgium** (Brussels, Antwerp, Ghent)
- **US** (Tallahassee, Novi, Cincinnati)
- **UK** (Cambridge)

Services provided

We help companies identify and manage their business risks, enabling them to market their products in a safe, responsible, sustainable, and globally compliant manner covering the whole product lifecycle. Our practice focuses on the following services:

Product Stewardship organisation and auditing

Product compliance strategy development and implementation, auditing, due diligence, and post-merger integration assistance.

Worldwide regulatory monitoring

Continuous regulatory tracking of changes for emerging and existing chemical (eg REACH, GHS, BPR), product (eg PPWR, WEEE, RoHS, MDR, batteries, waste), and sustainability (eg EU Green Deal, SSbD, Chemical Strategy for Sustainability, EPD, PEF) regulations, evaluating the potential risks and opportunities this might create for your business.

Data management for product compliance

Evaluation of off-the-shelf data providers and data management solutions and the implementation of software solutions supporting product stewardship, product compliance, sustainability, environmental, health and safety (EHS) compliance and operational risk management.

Scientific and regulatory compliance support

Chemical/nano risk assessment and dossier preparation for registration and authorisation under EU REACH and REACH-like regulations; country-specific chemical licensing/permitting; classification, labelling, and packaging for GHS and national variants; hazard communication, biocides authorisation, plant protection product authorisation (US FIFRA, (EC) 1107/2009), EU medical device Regulations, RoHS, and California Proposition 65 assistance.

Consortium management and only representative

General and financial consortium management, third party communication and representation (SIEF, MS CA, ECHA), role as trustee, EU or UK only representative, as well as technical consultant for dossier preparation.

Agrochemical fate and exposure

Conduct of environmental and consumer safety field studies, aquatic and terrestrial modelling, risk assessment, spatial data analysis, environmental stewardship, and regulatory support for plant protection products.

Corporate developments and achievements

1888	Parent company, Heidemij, formed in the Netherlands
2002	Establishment of a product stewardship Centre of Excellence (CoE) in North America
2006	Arcadis Belgium becomes a product stewardship CoE
2008	Arcadis acquires LFR Levine-Fricke in the US, a leader in the conduct of environmental safety field studies, to support the registration of plant protection products
2017	Arcadis acquires E2 ManageTech, the preeminent enterprise technology solutions firm providing IT and business services for the EHS information market in the US
2022	Arcadis acquires DPS Group creating a leading global position in consultancy, engineering and construction management for the life sciences and semiconductor manufacturing market Arcadis acquires IBI Group creating the opportunity to leverage the global footprint and client base of both firms while adding significant scale in North America and a strong position in Canada Arcadis acquires Giftge Consult GmbH, strengthening its position in energy transition in Germany

Case study 1

Applications for authorisation under REACH

Arcadis has assisted several companies in the pharmaceutical sector to compile applications for authorisation under both EU and UK REACH. Support included scoping of uses, comprehensive data gathering within the companies and in-house preparation of the analysis of alternatives, socioeconomic analysis and the chemical safety report. Arcadis provided support in the identification of exemptions and overall strategy development.

Case study 2

Product Environmental Footprint (PEF) strategy

Arcadis has supported the development of a science-based, robust methodology to perform product carbon footprint and lifecycle environmental assessments. Product carbon footprinting was performed on products to improve/further develop a harmonised methodology. Arcadis can also provide technical expertise to ensure that sustainability strategy targets can be reflected in product environmental footprint assessments.

Case study 3

California Proposition 65 consulting and compliance support

Arcadis has assisted multiple clients in evaluating the compliance of their products with California's Proposition 65 (Prop 65) requirements. Support included reviewing their portfolio of products, identifying product categories based on composition and toxicological considerations, developing analytics test plans for the products, coordinating analytical testing, developing exposure estimates, and comparing exposure estimates to Safe Harbor Levels (SHLs). Arcadis also develops provisional SHLs for substances that have not been assigned a SHL by regulatory authorities and tracks Prop 65 trends, such as those related to bisphenol A, phthalates, lead, and per- and polyalkyl substances (eg PEOA, PFOS).

Case study 4

Product stewardship organisational redesign and supporting tool selection

Arcadis has supported global companies with (re)defining a strategy and approach for a future-proof and proactive product stewardship organisation with efficient processes and reliable tools to enable market access. We have prepared detailed business plans, reviewed existing processes, identified potential weaknesses, and supported the selection of software solutions. Arcadis provided support for implementation of the strategy including change management, process development, and training.

Case study 5

Collection of public monitoring data on plant protection products to support re-authorisation, environmental stewardship, and regulatory surveillance

To support the re-registration of plant protection products (PPP) and as part of regulatory surveillance and environmental stewardship activities in the Europe, North America, and South America, Arcadis routinely searches for and compiles publicly available environmental monitoring data (eg groundwater, surface water, air, sediment, and drinking water) on PPPs.

These tasks are performed by searching online databases and contacting regulatory agencies, authorities, and third-party organisations. Web scraping applications were developed to expedite data access and download from regulatory agency websites. To date, Arcadis has compiled environmental monitoring data on some 230 different active substances and metabolites collected from monitoring programmes conducted in more than 30 countries. More than 13 million analytical results have been identified through project work conducted to date. Automated data transformation and import to a common data structure facilitates data compilation. Compiled data has been visualised and contextualised for our clients using customised dashboards.

Case study 6

Feasibility study of industrial symbiosis opportunities

The International Copper Alliance (ICA) aimed to identify and quantify possible opportunities for industrial symbiosis for its members. Arcadis has analysed the valorisation of two by-products linked to the copper sector: iron silicate, and end-of-life EV batteries. This was done using lifecycle assessment (LCA), which analysed the environmental feasibility, and a cost-benefit analysis (CBA), which evaluated the economic aspects. A market analysis was also carried out to understand the opportunity. Further information can be found here:
copperalliance.org/resource_topic/industrial-symbiosis/

Staff selection

Norm Forsberg, PhD – Principal Toxicologist

Norm has more than ten years' experience as a toxicologist and risk assessor. He has designed and performed toxicology-based projects for a wide range of industrial clients and provided technical review for projects in which the critical evaluation of toxicological data is key. He routinely applies toxicological and risk assessment principles to support clients facing challenges related to compliance with California's Proposition 65, EU REACH and TSCA.

Maaike Bilau, PhD – Senior Product Stewardship Consultant

Maaike has more than 15 years' experience in human health risk assessment of hazardous chemicals. She supports multinational companies with the development and implementation of product compliance strategies. She partners with clients and guides them when strategic decisions need to be taken and business impact is large.

Andy Newcombe – Principal Environmental Scientist

Andy has more than 30 years' techno-regulatory experience with multinational agrochemical and life science companies. He has extensive expertise in assessing and evaluating the environmental safety of agrochemicals and biopesticides. Andy has also represented agrochemical industry clients on environments fate issues associated with their products and has considerable experience in providing clients with litigation support services.

Chrystelle Verhoest – Senior Product Sustainability Consultant

After about 15 years in the energy sector, Chrystelle has joined Arcadis aiming to put her experience at the services of various industries. Chrystelle has a technical expertise background in bioenergy and biorefinery technologies, carbon capture use and storage (CCUS), circular economy, and carbon offsetting. She has operational experience in the implementation of supply chain due diligence and environmental and social governance.

Christina Clements – Principal Environmental Scientist

Christina has more than 25 years' experience in EH&S as a regulatory compliance consultant and product stewardship professional with a proven track record of implementing product safety development strategies. She has a working knowledge of applicable regulatory guidelines across multiple industry sectors and jurisdictions in the areas of OSHA safety and health initiatives, GHS and EU CLR TSCA, FIFRA and import/export of chemicals and consumer products.

Nele Deleebeeck, PhD – Senior Environmental Risk Assessor

Nele has more than 15 years' experience in metal risk assessment. She coordinates technical work related to environmental risk assessment of organic and inorganic compounds in view of the REACH regulation. She has been coordinating scientific work for the Rare Earth Consortium and the Mixed Oxides and Zirconium Oxides Consortium for almost 15 years. Nele is a European Registered Toxicologist (ERT) and has the Certificate of the International Board of Environmental Risk Assessors.

arcerion
REACH | CLP | Seveso | Biocides

Contacts	
Website	**arcerion.com**
E-mail	**info@arcerion.com**
Head office	Arcerion GmbH, Gabrielenstr. 15 80636 Munchen, Germany
Tel	+49 89 38899797/+49 89 38899798 Fax
Contact	Anne Feldhaus
Directors	Dr Michael Piber, Executive Director, Dr Florian Wrage, Managing Director
Ownership	Private limited company
Locations	Germany
Founded	2007

Overview

Arcerion is an experienced full service and consulting provider aimed at assisting companies to comply 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 supports our clients in their regulatory duties, to enable them to maintain secure market access for their products.

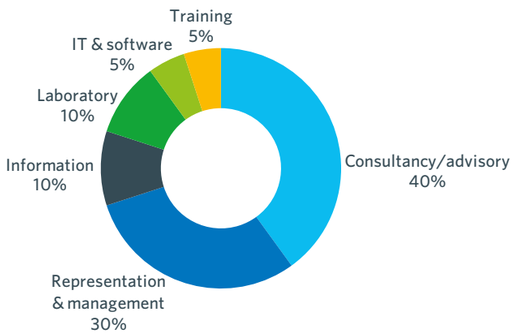
Our objective is to facilitate the most efficient and cost-effective implementation of the requirements of all applicable control legislation. All of our consultants have a solid background in the chemical industry, management consulting and academia – combining strong commercial experience and technical 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.

Vital statistics 2022/23

No of offices	3
No of countries represented	Global
Staff: group	18
Staff: chemical service provision	11

Service area breakdown



Global offices

Germany (Munchen and Hamburg)

Services provided

Consultancy/advisory

- Regulatory support and interpretation (REACH, CLP, Biocides, Seveso)
- Product compliance assessment and implementation (including certificates of compliance)
- Environmental risk and health effects assessments
- Hazard and exposure modelling
- SVHC advisory/REACH authorisation
- Data management/data-gap analysis
- Reducing of animal testing/QSAR read-across
- Brexit implications on suppliers of chemicals
- Chemical transport/warehousing advice

Representation and management

- REACH registration services (including inquiries, notifications)
- SIEF representation, completion of data requirements
- Dossier preparation and submission (IUCLID files)
- CLP implementation (including authoring of eMSDS, CSA/CSR)
- Only representative of non-EU manufacturer (REACH article 8)
- Third party representation (REACH article 4)
- Supply chain management and communication
- Consortium and letter of access (LoA) management
- SIEF representation and management
- 24/7 emergency phone services
- Management of downstream user obligations (REACH articles 31-38)
- Preparation of applications pursuant Seveso-III directive
- EU Poison Centre Notifications (PCN) (CLP article 45)

Information/IT solutions

- (Material) safety data sheets/product labels
- Supply chain management
- Exposure scenario/chemical safety assessment management
- Consortia/registration management
- Regulatory information management
- Chemical inventory management

Corporate developments and achievements

2007	Arcerion GmbH founded in Munich, Germany
2008	REACH registration and only representative department created
2011	Opening of laboratory facility for the assessment of pyhs-chem properties in Kassel, Germany
2013	Successful preparation of more than 100 REACH registration dossiers
2015	Launch of IT-system and database for the automated creation of CLP-compliant MSDS for preparations
2019	Preparation and submission of more than 300 REACH registration dossiers
2021	Launch of emergency information service for hazardous substances

Accreditations

Certified Expert pursuant to 5 BImschV (German Seveso Directive), ChemVerbotsV (dangerous substance directive), and KrW-/AbfG and TgV (dangerous waste directive). Member of DGSV (German technical and scientific experts association). Member of the EU EEG qualified expert group for chemistry.

Partners

We work with a number of different partners (including laboratories for process safety toxicological and environmental fate) to extend the services offered to our clients.

Clients

Arcerion serves more than 150 clients in Europe, North America, Africa, Australia and Asia, across multiple industry sectors including industrial, petrochemicals, food, mining, pharmaceutical, specialty chemicals, electronics and consumer products.

Testimonials

We do not disclose our clients publicly. Specific references can be provided to potential clients upon request.

Case study 1

REACH compliant supply chain for a consumer goods manufacturer

Client situation: A China-based manufacturer of consumer goods (including detergents and cleaning agents) exports products to the EU market, which are made of numerous raw materials. While some of the raw materials are sourced from the EU, others are manufactured outside of Europe, including some substances that are exempted from the obligation to be REACH registered (pursuant Annex IV/V). The Chinese manufacturer wishes to comply with REACH for exported goods to his European customers, without disclosing the identity of all raw materials to his European customers.

Arcerion solution: We assess the status of all raw materials/substances used for products exported to Europe. We assure and verify that all volumes of the substances are either registered by an only representative, or sourced in the EU and already registered before re-import to Europe within the same supply chain, or exempted from the obligation to be registered. By recording and documenting the necessary information for all raw materials, Arcerion is able to ensure overall REACH compliance for the Client's products.

Result: The client receives consistent and unified certificates of REACH compliance (including tonnage certificates) by Arcerion. The client is able to proof compliance to his European customers, while keeping certain data confidential.

Case study 2

CLP compliant labelling and hazard communication of specialty chemicals preparations

Client situation: A German specialty chemicals producer is challenged by the obligation to classify all of his products according to the CLP regulation. While the producer manages to classify and label pure substances pursuant to EC/1272/2008 with his existing IT solutions, the classification and labelling of custom-made mixtures according to CLP causes difficulties since the 2015 deadline. The classification of newly produced preparations has to be performed manually.

Arcerion solution: We develop and implement a custom specific IT solution aimed to generate product labels and MSDSs for all relevant preparations of the client's product portfolio. The CLP compliant classification is based on an up-to-date EH&S chemicals database.

Result: The client is able to generate CLP-compliant product labels for custom-made mixtures within a fully automated workflow. The delivery of hazard communication by REACH/CLP-compliant MSDSs is integrated in the production process. Changes in chemical legislation are taken into account at the time of the generation of labels and SDSs by utilising Arcerion's chemical database.

Staff selection

Dr Michael Piber – Director

Michael holds a degree in organic chemistry and was a faculty member of the LMU University, Munich, lecturing in organic chemistry. He has more than 15 years' experience consulting in different industries. Before joining Arcerion, Michael led the REACH and CLP implementation of a leading European chemical industry company. He leads the Munich office of Arcerion and focuses on the European and North American regions. His areas of expertise include chemicals and Seveso regulatory support, as well as corporate strategy for the chemical industry. Michael is the legally responsible person as REACH only representative for Arcerion's non-European manufacturer or formulator of products that are exported to the European market.

In recent years he has been heavily involved in assisting North American companies to prepare for and comply with REACH and CLP.

Dr Florian Wrage – Director

Florian holds a degree in environmental technology. His area of expertise includes chemical control legislation and global regulatory management. During his graduate studies, he researched the fate of fluorinated chemicals in the environment. Florian leads the Arcerion Hamburg office, focusing on the Asian region. Florian is in charge of the REACH department, where he is responsible for the complete spectrum of services for (co-)registrants, including the creation and successful submission of IUCLID dossiers, compiling chemical safety reports (CSR), and providing overall supply chain communications.

In recent years Florian has been involved in assisting Asian companies to prepare for and comply with REACH and CLP. He is an expert safety data sheet and exposure scenario author. Before joining Arcerion, Florian was the competent person with regard to the Seveso regulation of a German power plant operator.

Hakim Shaheen – Principal Consultant

Hakim is a toxicologist with more than 20 years' experience in the assessment of health risks of industrial chemicals, agrochemicals and biocides. His area of expertise includes chemicals regulation, regulatory toxicology, hazard assessment and communication. He provides toxicology expertise to Arcerion's clients in the industrial and specialty chemicals sector. Hakim is an expert in developing strategies to avoid animal testing by applying read-across or QSAR. Over the course of his career, Hakim has managed the preparation of more than 200 chemical registrations in the EU, Korea and the US. Hakim is responsible for the support of Arcerion's clients with regard to biocide regulations.

Lin Cheng – Project Manager

Lin holds a degree in business administration. She has several years of experience in consortia management. Her responsibilities include management of lead registrant projects, SIEF organisations and letter of access management. Lin has advised companies from Europe, Asia and North America on REACH compliance issues since 2013.

Contacts	
Website	arche-consulting.be
E-mail	info@arche-consulting.be
Head office	Liefkensstraat 35d, 9032 Gent-Wondelgem, Belgium, Tiensevest 132, 3000 Leuven, Belgium
Tel	+32 9 216 70 38
Contact	Marnix Vangheluwe
Directors	Frederik Verdonck, Koen Oorts
Ownership	Private company
Locations	Gent and Leuven, Belgium
Founded	2009

Overview

ARCHE Consulting provides several essential services, including the development of registration dossiers for biocidal products, plant protection products and fertilisers. We also specialise in preparing REACH-related risk assessments and full dossiers for inorganic substances such as metals, alloys, slags, etc. As such, the ARCHE Consulting experts have contributed to many guidance documents (for example for ECHA).

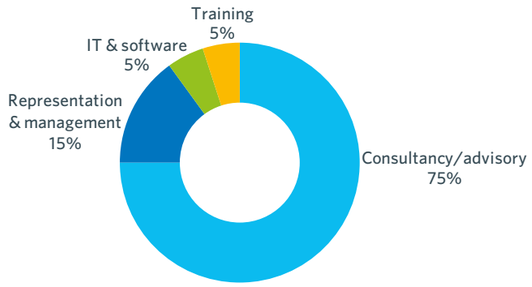
Additionally, ARCHE Consulting offers services such as classifying substances and mixtures according to the GHS/CLP, evaluating (site specific) environmental quality standards and conducting environmental risk assessments of medicinal products for human use. ARCHE Consulting is also a certified material health assessor and can assist companies in certifying their products in line with the Cradle Certified Products Programme CM (Cradle-to-Cradle) or EU Ecolabel certification.

ARCHE Consulting creates added value for its clients by linking research activities to daily risk assessment practises under various EU legislation.

Vital statistics 2022/23

No of offices	2
No of countries represented	1
Staff: group	39
Staff: chemical service provision	32

Service area breakdown



Services provided

REACH and chemical strategy for sustainability (CSS)

Under REACH, companies are responsible for assessing the risks associated with the chemicals they produce or import. Compliance with REACH is essential for EU chemical product sellers as non-compliance risks penalties and loss of market access. ARCHE Consulting offers high-quality risk assessment services to help industry meet the Regulation's rigorous demands.

Our area of expertise covers new REACH registrations and updates of existing registrations, authorisation and restriction among other services. We develop chemical safety reports and exposure scenarios to demonstrate adequate control or acceptable risks. Our team is highly proficient in the CLP Regulation. ARCHE Consulting is actively involved in writing guidance on REACH-related topics and developing new tools to facilitate implementation.

Biocides

ARCHE Consulting offers a one-stop shop for the registration of your biocides and 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 agrochemicals. Services include:

- effect and exposure assessment for active substances and products;
- data gap identification and designing higher-tier studies;
- exposure modelling (FOCUS, Euses, Consexpo, EASE);
- higher-tier exposure scenario development;
- CLP;
- dossier preparation, submission and follow-up;
- client representation in meetings with regulatory authorities;
- product stewardship; and
- training IUCLID for biocides.

Crop protection

The plant protection products (PPP) Regulation covers criteria and procedures for the approval of active substance and product authorisation. ARCHE Consulting provides support in preparing and submitting active substance and product dossiers for EU-wide, zonal and national registrations.We offer tailored solutions for every part of the process:

- data gap analysis;
- pre-submission support;
- ED assessments according to EFSA/ECHA;
- dossier preparation; and
- follow-up until approval.

Fertilisers and biostimulants

The fertilising products Regulation (FPR) covers a wide range of products. Compliance with the FPR is necessary for producers and importers seeking access to the EU market. Additionally, substances in fertilising products must be registered under REACH. At ARCHE Consulting, we provide expertise in every step of the process:

- identifying specific requirements;
- preparing technical documentation:
- coordinating with a notified body;
- complying with EU member state fertiliser legislation for products not complying with, or not included, in the FPR.
- meeting country-specific requirements (eg labelling) and pre-market procedures (eg notification, registration); and
- development of tailored environmental risk assessment schemes for fertilisers.

Cradle to Cradle certification®

As a certified material assessor, ARCHE Consulting assesses healthy and sustainable products under the Cradle-to-Cradle certified CM Products programme. The Cradle-to-Cradle product standard addresses five quality categories relating to human and environmental health:

- material health;
- material reutilisation;
- renewable energy and carbon management;
- water stewardship; and
- social fairness.

The ultimate goal of the Cradle-to-Cradle Certified CM Products programme is to encourage continuous improvement, innovation and formulation of products that benefit humans and the environment.

EU Ecolabel

The EU Ecolabel helps manufacturers and service providers gain recognition for their high environmental standards. To ensure compliance with the rigorous standards, products that have been certified are subject to documentation review and inspections. ARCHE Consulting supports you with your application for EU Ecolabel certification.

Corporate developments and achievements

2009	Foundation of ARCHE (staff: five people)
2010-2012	Expansion of the team to 16 people, with offices in Ghent and Leuven
2013-2022	Expansion to a team of more than 30 people, and further development of the services on biocides, plant protection products, fertilisers and cosmetics

Accreditations

- IBERA Diplomates
- European Registered Toxicologists
- Certified Environmental Risk Assessor
- Certified Material Health Assessor (Cradle-to-Cradle)

Partners

Deloitte. PietConsulting. ECTX-Consulting. ROSC. Toxicological Consulting (Dr Daniel Bernard). REACHlaw. Vander Straeten Consulting Services. ERMC (Dr Mike Holland). EBRC Consulting. RPA (Risk & Policy Analysists ltd). Fieldfisher. Fertiliser Consultants Network (FCN). Amelior. SETAC Europe.

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;
- organic compounds – chlorinated flame retardants, organic acids;
- plasticisers, amines, plant protection products;
- complex materials – Cu slags, Ti slags;
- other inorganic substances – Ca, B, NaOH, KOH, sulphur dioxide-related substances (SO2, sulphites, thiosulphates, dithionites), lime, nitric acid, phosphoric acid; and
- several biocide consortia such as sodium chloride (active chlorine generated from NaCl by electrolysis) consortium, permethrin and *in situ* peracetic acid consortium.

Testimonials

"We have worked with ARCHE Consulting on several environmental safety projects and would like to emphasise the great quality of their work. We have been very impressed with their delivery and ARCHE Consulting has shown themselves to be a very capable and effective partner. We would recommend working with ARCHE Consulting without hesitation." *Amelie Ott, Environmental Science Manager, Cosmetics Europe*

"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 PT 19. 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 Consulting, 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, HSE Executive, International Molybdenum Association (IMOA)*

More testimonials can be found at arche-consulting.be

Case study 1

Biocidal product family

ARCHE Consulting has successfully submitted more than 100 applications under the BPR, ranging from technical equivalence applications, over Union authorisations, BPR family applications, simplified authorisations to Article 95 applications and active substance renewals.

Case study 2

REACH registration dossiers

ARCHE Consulting has supported more than 450 REACH dossiers for individual companies and consortia. We cover organic and inorganic, mono- and multi- constituent substances as well as UVCBs. In addition, we have experience with different applications for authorisation (AfA) and have provided expert opinions on restriction dossiers proposed by various EU member states.

Case study 3

Cradle-to-Cradle certification

ARCHE Consulting has played a crucial role in generating more than 200 Cradle-to-Cradle Certified® certificates for companies. Our expertise in chemical risk assessment was instrumental in certifying the world's first C2C Certified® Gold packaging. ARCHE Consulting provided valuable guidance on phasing out non-optimised chemicals and materials, ensuring that the certification process met the highest standards.

Staff selection

Patrick Van Sprang – Director

Patrick graduated as Master of Science in engineering (environmental technology) from Ghent University (1988). At that university (1994-2000) he was responsible for the aquatic ecotoxicology research group. He was co-founder of EURAS, a consultancy company specialising in environmental risk assessment. Patrick 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 – Director

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

Frederik Verdonck – Managing Director

Frederik obtained his PhD degree in bioengineering on probabilistic risk assessment at Ghent University. At ARCHE Consulting, his main area of expertise comprises the implementation and application of statistical and modelling approaches in exposure, effects, and risk/safety assessment. He is currently 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 Vanden Bosch – Regulatory Affairs Manager

An graduated in 2004 as Master in bioengineering (gene technology) from the Catholic University of Leuven. She obtained her PhD in medical sciences in 2009. From 2010 until 2013, she worked as a registration specialist in industry, responsible for the development and registration of plant protection products. In 2014, she started working as a consultant for ARCHE Consulting. At that time, she also obtained her certification as European Registered Toxicologist (ERT). Her expertise is focused on plant protection products and biocides. Within these fields, she mainly deals with environmental exposure and ecotoxicological risk assessments, as well as general regulatory matters.

ARROW REGULATORY

Contacts	
Website	arrowregulatory.com
E-mail	info@arrowregulatory.com
Head office	6th Floor East West Building , 2 Tollhouse Hill, Nottingham, NG1 5FS, UK
Tel	+44 1159352243
Contact	Dr Sara Kirkham/Dr Carlo Poncipe
Directors	Dr Sara Kirkham Dr Carlo Poncipe Elicia Hodgson Dr Joanna Ganatsiou (Austria)
Ownership	Limited company
Locations	UK, Ireland, Austria
Founded	May 2016 (UK), Oct 2017 (IE), Mar 2020 (AT)

Overview

Arrow Regulatory possesses in-depth expertise in chemical legislation, with a particular emphasis on the EU Biocidal Products Regulation, REACH, CLP, and the corresponding regulations in Great Britain. The company boasts substantial experience in formulating regulatory strategies, devising test programmes, and delivering customised advice. Additionally, Arrow Regulatory excels in preparing dossiers and conducting risk assessments.

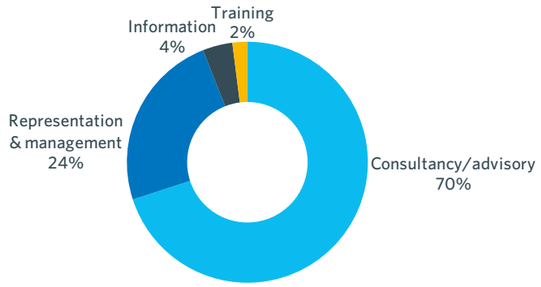
Having collaborated with both international consortia and global partners, Arrow Regulatory has successfully obtained registrations for chemicals and biocides on a worldwide scale. The collective expertise of the Arrow Regulatory team is evidenced by their involvement in over 65 REACH lead dossiers, biocide active substance inclusion dossiers, more than 128 active substance/PT combinations, and close to 110 single product or product family authorisations.

Arrow Regulatory is committed to providing an integrated and personalised service, with its experts enhancing value by applying their comprehensive understanding of individual pieces of legislation to address each company-specific inquiry. Our overarching goal is to deliver a high level of service to all clients, regardless of their size.

Vital statistics 2022/23

No of offices	3
No of countries represented	3
Staff: group	10
Staff: chemical service provision	10

Service area breakdown



Global offices

United Kingdom (Nottingham). **Ireland** (Dublin). **Austria** (Innsbruck).

Services provided

Biocides

Arrow Regulatory's wide experience in supporting active substances and biocidal products under the EU and GB Biocidal Product Regulations and globally, is your guarantee of a quality service.

Chemicals (REACH and CLP)

With offices in the UK, Republic of Ireland and Austria, Arrow Regulatory is well placed to assist with all aspects of EU/GB REACH.

Arrow Regulatory provides a comprehensive service to help you achieve compliance with the Classification, Labelling and Packaging (CLP) Regulations for the EU and GB.

Consortium management (REACH and Biocides)

At Arrow Regulatory, we have a long history of consortium management not only under the BPR for both active substance approval and product authorisation, but also in REACH.

EU and GB only representative

With offices in the UK, Republic of Ireland and Austria, Arrow Regulatory is well placed to assist with all aspects of EU/GB REACH and CLP.

Corporate developments and achievements

2016	Formation of Arrow Regulatory Limited in Nottingham, UK
2016-2024	Team expands to ten consultants
2017	Formation of Arrow Regulatory (Ireland) Limited in Dublin, Ireland
2020	Formation of Arrow Regulatory GmbH in Innsbruck, Austria

Clients

Manufacturers, importers or downstream users of industrial chemicals, biocides, veterinary drugs, plant protection products or cosmetic ingredients.

Staff selection

Sara Kirkham, PhD

Sara is a Director of Arrow Regulatory and has more than 20 years' regulatory experience in biocides registration.

She has been involved in the preparation of more than 30 active substance dossiers for Union approval and biocidal product submissions through the BPD/BPR process and under national schemes.

In addition to the preparation of dossiers and risk assessments, Sara has experience of consortium management, and worked on regulatory strategies for biocides, designing testing programmes and providing tailored regulatory advice.

She has been involved on behalf of industry with the development of new guidance under the BPR on disinfection by-products, *in situ* generation systems and PT 11 and PT 12 efficacy.

Carlo Poncipe, PhD

Carlo is a Director of Arrow Regulatory and has more than 20 years of regulatory experience in both biocides and industrial chemical registration.

Since 2008, he has focused on all aspects of the EU REACH Regulation, providing technical and administrative support to consortia, preparing lead registration dossiers in IUCLID and chemical safety reports using Chesar in combination with Tier II modelling when necessary. He also acts as TPR and is experienced in the only representative role.

In addition to EU REACH, he is now supporting GB-based companies to meet their obligations under UK REACH and manages the UK only representative service for non-GB companies.

Joanna Ganatsiou, PhD

Joanna is a Director of Arrow Regulatory GmbH and has more than 15 years' regulatory experience in biocides registration.

Professional consulting on technical and regulatory matters for biocides within the EU. Involved in the preparation of active substance dossiers under the BPD and biocidal product authorisations under the BPR and submissions of application under national schemes.

Experienced in providing regulatory strategies for biocides, including data gap analysis, intelligent testing strategies, devising product families, providing tailored regulatory advice and consortium management.

Juncal Caubilla-Barron, PhD

Professional consulting on technical, regulatory and efficacy matters for biocides within the EU and GB. Involved in the preparation of active substance dossiers and biocidal product authorisations under the BPR.

With more than 13 years' experience as a consultant providing efficacy advice and support on the efficacy tests required for the different BPR product types, her previous experience in industry was acquired while working in different microbiological roles for a global biocide manufacturer.

Skilled in delivering regulatory strategies for biocides, including data gap analysis, intelligent testing strategies, devising product families and providing tailored regulatory advice. Building strong relationships with clients and liaising with the relevant regulatory authorities, attendance at pre-submission meetings and providing post-submission support.

Hannah Leach

Professional consulting on technical and regulatory matters for biocides within the EU and GB.

With more than 17 years' experience in the preparation of active substance dossiers and risk assessment, including *in situ* actives and biocidal product authorisations under the BPD and BPR. Experienced in providing regulatory strategies for biocides, including data gap analysis, intelligent testing strategies, devising product families and providing tailored regulatory advice.

Joanna Sackey

Professional consulting on technical and regulatory matters for biocides within the EU and GB.

Joanna has more than 17 years' experience in the preparation of active substance dossiers and biocidal product authorisation under the BPD and BPR. Working on consortium management, devising regulatory strategies for product families, including data gap analysis, intelligent testing strategies, and providing tailored regulatory advice, she builds strong relationships with clients, liaising with the relevant regulatory authorities, as well as attending pre-submission meetings and providing post-submission support.

Nick Jarvis

Nick Jarvis is an experienced consultant specialising in technical and regulatory aspects related to biocides, agrochemicals, and REACH within the European Union and Great Britain. With more than 17 years' experience, Nick excels in preparing active substance dossiers and obtaining biocidal product authorisation under the BPD and BPR, covering a wide range of product types.

Furthermore, Nick actively engages in project management and dossier development for agrochemical Annex III dossiers, demonstrating proficiency in REACH Annex X dossiers. His expertise extends to devising regulatory strategies for product families, conducting data gap analyses, implementing intelligent testing strategies, and offering tailored regulatory advice.

Nick has a proven track record of building robust relationships with clients, effectively liaising with regulatory authorities, participating in pre-submission meetings, and providing valuable post-submission support.

Ciarán McGlynn, PhD

Ciarán earned his PhD in Chemistry from the University of Dublin, Trinity College in 2018. His doctoral research encompassed investigating the reactivity of graphene with common oxidants and biomimetic catalysts, as well as synthesising graphene/MoS2 hetero-structures for use in hydrogen evolution electrocatalysis. He joined Arrow Regulatory (Ireland) Limited as a Regulatory Affairs Consultant in June 2019, specialising in CLP and Biocide Product Registrations.

Alexander Raith, PhD

After completing his PhD in metal-organic chemistry at Technical University Munich, Alex began his regulatory career at a major European pool water treatment company. By the end of 2018, he had assumed leadership of the regulatory department. With 9 years of experience in European chemicals legislation, particularly the Biocide Products Regulation, Alex has expertise in preparing and submitting biocide product dossiers. He has also provided support for active substances in the Review Programme and led various task forces. Additionally, he has actively participated in national biocide product registrations, CLP, ECHA poison centre notifications, and Dangerous Goods regulations. Alex's strengths lie in strategic product family development and a detailed understanding of BPR and related regulations. He joined Arrow Regulatory in April 2021.

ARTEMISA

Contacts	
Website	artemisa.si
E-mail	registrations@artemisa.si
Head office	Artemisa d.o.o., Cvetlicna ulica 20, 2270 Ormoz, Slovenia
Tel	+386 8 181 00 20
Contact	Ms Bojana Zgonec
Directors	Ms Bojana Zgonec
Ownership	Private company
Locations	Slovenia, Slovakia, Poland, Hungary, Croatia, Romania
Founded	2018

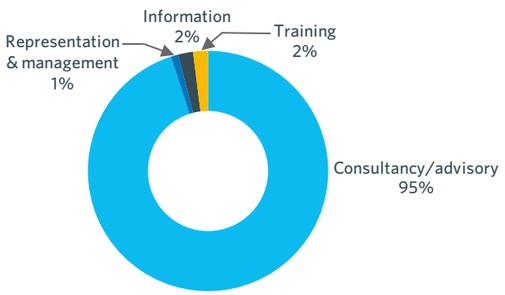
Overview

Supporting the chemical industry to comply with regulatory requirements in place in the EU, as well as at the national level of individual countries in the eastern and central EU (CEE) and beyond.

Vital statistics

	2022/23
No of offices	5
No of countries represented	27
Staff: group	19
Staff: chemical service provision	13

Service area breakdown



Services provided

Plant protection services in eastern EU, Ukraine, Georgia, CIS countries (Belarus, Kazakhstan) and the Balkans including Turkey

We offer the following services:

- preparation of national submission dossiers for zonal, MR, renewal and other procedures – preparation of documentation in local languages adjusted to national requirements including label and SDS preparation;
- submission of dossiers;
- post submission work/product stewardship (communication with national enforcement bodies on an as-needed basis, compliance with annual reporting duties, national electronic registers, etc);
- facilitation of communication with local authorities in local language;
- strategic advice given, taking national specific rules into consideration; and
- project management in cases of multiple submissions into multiple countries.

Areas of expertise

- Plant protection products
- Adjuvants
- Biopesticides

Regulatory services for registration of fertilisers, biostimulants and supplementary soil substances in the eastern EU, Ukraine, Georgia, CIS countries (Belarus, Kazakhstan) and the Balkans including Turkey

We offer the following services:

- preparation and submission of national submission dossiers – preparation of documentation in local languages adjusted to national requirements including label and SDS preparation;
- services according to the Fertilizer Products Regulation (FPR) to achieve CE-marking: definition of the fertiliser product category, preparation of technical dossiers, co-ordination of proceedings with notified bodies
- post submission work/product stewardship (communication with national enforcement bodies on an as-need basis, compliance with annual reporting duties, national electronic registers, etc);
- facilitation of communication with local authorities in local languages;
- strategic advice given, taking national specific rules into consideration; and
- project management in cases of multiple submissions into multiple countries.

Biocide products regulatory services the eastern EU, Ukraine, Georgia, CIS countries (Belarus, Kazakhstan) and the Balkans including Turkey

We offer the following services:

- preparation and submission of applications following EU transitional measures or BPR rules in local language and according to national requirements;
- SPC (summaries of product characteristics) translation services into multiple languages;
- R4BP3 submissions and project management;
- post submission work/product stewardship;
- facilitation of communication with local authorities in local language;
- strategic advice taking national specific rules into consideration; and project management in cases of multiple submissions into multiple countries.

Poison centre notifications

We offer the following services:

- consultancy based on the most current information available;
- compliance with national requirements where applicable;
- facilitation of communication in the relevant national language; and
- preparation and submission of a poison centre notification (PCN) dossier via the ECHA portal.

SDS services

We offer the following services:

- SDS adaptation to specific national requirements and in the national language of a specific country;
- SDS updating, reformatting or editing to accommodate changes in legislation (REACH, CLP, ADR), classification changes of the product, product composition, company specific information; and
- SDS extension to extended safety data sheets (eSDS) to comply with your substance chemical safety report (CSR).

Translation and proofreading support

We offer the following services:

- translations of technical texts in the following expert areas – agriculture, chemistry, regulatory, security in the workplace, business, environmental and healthcare; and
- proofreading of general and technical texts, labels, MSDSs, SPC and PAR documents.

Strategic advice

We offer the following services:

- preliminary assessment of your portfolio or individual products taking the EU status of your substance as well as data protection rules into consideration; and
- advice on the data requirements in place in the different countries of the regions we cover, with all the nuanced differences and local specifics that need to be taken into consideration for the successful registration of your products.

Corporate developments and achievements

2018	Company established Branch offices established in Poland and Slovakia
2020	Services extended to CIS countries and Turkey
2021	Branch office in Croatia
2023	Office in Romania

Partners

Artemisa has developed a broad network of partners at national level in all the countries where regulatory support is offered. Additionally, we can rely on translators familiar with expert terminology in all the countries we cover.

Clients

Our clients are typically bigger multinationals as well as small generic companies, that are based in western EU countries. Artemisa helps them place their products on the market in eastern EU countries and countries outside the Union, by preparing all the necessary documentation according to national rules and in compliance with the specific national legislation and data requirements.

Artemisa also takes care of the compliance of already registered products in the post-registration phase.

Case study 1

PPP registration following Art. 43 in a very short timeframe

Our client had a very short timeline to prepare and submit an Article 43 PPP application in a very challenging eastern EU country. Thanks to our reliable local partners and good contacts with the authority, Artemisa's team was able to deliver the submission on time.

Our ability to act quickly and flexibly is contributing to the success in achieving complete registrations in different eastern EU geographies.

In this way, we contributed to the success in obtaining authorisations in a timely manner. In addition, we prepared national versions of product labels and SDSs, ensuring high compliance of all elements of the approved SPC and content of the authorisation decision.

Case study 2

Data package preparation for multiple EU countries

With our experience and a large network of local partners, we were able to minimise the extent of data and documentation (including local testing) for the client. With that, we have confirmed our know-how and ability to optimise data packages for multiple markets and regions wherever possible.

Additionally, we have the ability to handle the entire registration process on behalf of a client, especially in cases where multiple countries and short timelines are involved.

Case study 3

Translation of SPCs in multiple languages in a very short timeframe

Under the BPR, our client had a very short timeline to prepare and submit high quality national versions of a summary of product characteristics (SPC) in eight EU languages (Slovenian, Slovak, Czech, Bulgarian, Romanian, Polish, Hungarian, Croatian). Thanks to our staff being fluent in Eastern European languages, and having a thorough regulatory knowledge, all national SPC versions were prepared by the required deadline.

Staff selection

Bojana Zgonec – Managing Director and Founder

Over the past 20 years, Bojana has gained extensive experience in regulatory affairs and business development in Eastern Europe. Prior to founding Artemisa in 2018, she worked for TSGE, an international consulting company, as managing director (2009-18). Before moving into a regulatory consultancy role in 2006, she gained experience as a registration manager, working for Bayer CropScience and Pinus TKI d.d.

Bojana has worked with both multinational and local, generic companies, as well as cooperating with a partner/legal during a period of self-employment.

As managing director of Artemisa, she has created a successful network of offices in Slovenia, Poland, Slovakia and Hungary with a dedicated team of experts. She is fluent in Slovenian, English, French, German, Croatian and Serbian, and has a basic understanding of Russian.

Liana Skok – Principal Expert

Liana started her career in 1995 as a PPP registration manager with Ciba. She continued her career with Novartis and Syngenta as the person responsible for registration work in the ex-Yugoslavian countries (Slovenia, Croatia, Bosnia, Macedonia, Kosovo, Serbia) and Albania.

Prior to joining Artemisa in 2018, she worked for TSGE, an international regulatory consultancy company as senior regulatory manager (2012-18). Since June 2018, Liana has been with Artemisa in the position of principal regulatory expert. With extensive experience in regulatory affairs, she provides advice to clients on the national registration requirements under national, Eastern European and Balkan region legislation, and liaises with the regulatory authorities.

She also prepares submissions (zonal and national) for Eastern European and Balkan countries. Liana is fluent in Slovenian, English, German, Croatian and Serbian, and has a basic understanding of Macedonian.

Viktor Prachar – Principal Expert

Viktor joined the Slovak Centre for Chemical Substances and Preparations in 2001, where he was head of the Biocides Unit at the national competent authority for biocides. For ten years, Viktor was national representative at the EU CA meetings and the Standing Committee for Biocidal Products for Slovakia. He is an associate professor at the Slovak University of Technology.

In 2014, he moved into regulatory consultancy and joined TSGE. Viktor has been with Artemisa since June 2018, in the position of principal regulatory expert for BP and PPP Slovakia and the Czech Republic.

Viktor's extensive experience covering the areas of science, work in regulatory bodies and consultancy within the private sector is ideal for properly understanding the needs of clients, thorough interpreting the requirements of the authorities, and a facilitation of discussions between the private sector and national/EU bodies. Viktor is fluent in Slovak, English, German and Czech.

Contacts	
Website	**biogenius.de**
E-mail	**info@biogenius.de**
Head office	Technologie Park, Campus 1, Friedrich-Ebert-Straße 75, 51429 Bergisch Gladbach, Germany
Tel	+49 2204 83077 0, +49 2204 83077 11 (fax)
Contact	Alexander Brux
Directors	Mike Bublitz, Alexander Brux
Ownership	Private company
Locations	Germany
Founded	2004

Overview

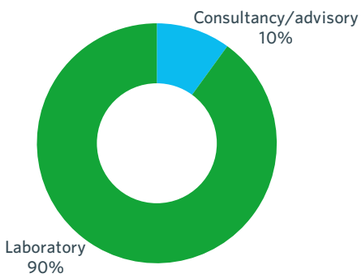
Since 2005, BioGenius has been supporting its customers with an in depth competence in providing services and data packages for the international registration of biocides, plant protection products and several other product segments. With our team and state-of-the-art facility comprising analytical and efficacy testing laboratories in Germany, BioGenius is a strong partner of the global chemical industry. For us, competence means recognising your needs as a customer and being aware of our own limits of performance.

The competence of our employees is characterised above all by their motivation to identify themselves with your goals and to use their knowledge and skills to achieve them. At least, we define competence as the creative combination of information and expertise in order to provide you as our customer with the best possible benefit to achieve your goals.

Vital statistics 2022/23

No of offices	1
No of countries represented	1
Staff: group	28
Staff: chemical service provision	19

Service area breakdown



Services provided

Analytical services and physico-chemical data for the BPR and PPP regulations

The GLP laboratories of BioGenius are capable of providing tailor-made analytical solutions for a variety of biocidal (PT 1 to PT 22) and plant protection products. With our extensive GLP-facilities, BioGenius also provides flexible solutions for a broad range of physico-chemical test parameters:

- analytical method development;
- method validation (SANCO);
- five-batch analysis for technical equivalence (eg Art. 95);
- accelerated storage stability studies;
- ambient storage stability studies;
- application tests for solid, liquid and spray products;
- safety data packages;
- active ingredient residues; and
- analysis of impurities and byproducts.

Efficacy data for insecticides and repellents (PT18 and PT19)

BioGenius is one of the leading European efficacy testing institutes for biocidal, insecticide and repellent applications. With our broad range of efficacy testing protocols against crawling and flying insects, BioGenius fulfils all requirements of national and international product authorisation according to the BPR as well as other international requirements:

- field tests;
- laboratory tests; and
- simulated use test (semi-field).

Data packages for different other approaches, such as:

- dose response tests for actives;
- screening tests for claim support; and
- testing for product development.

All required insect pest species are bred at BioGenius.

Technical consulting

There are many guidelines and regulations that need to be followed during registration processes, especially for biocides. However, these documents and the aforementioned methods cannot be applied to each product and each application. Therefore, a practical and technical evaluation is always required, and is mandatory for the required technical data packages of efficacy, shelf life and physico-chemical data. In addition, tests may need to be adjusted for products that are not covered by the method descriptions. We as BioGenius define this kind of support as “technical consulting”.

Accreditations

The analytical department of BioGenius is GLP certified.

Partners

Our extensive network of partners consists of consultants, laboratories and authorities. This network enables us to fully support you in the implementation of your projects, because where we cannot help, we have a reliable partner at hand.

Clients

With more than 700 customers worldwide, we at BioGenius GmbH have an extensive spectrum of experience. Our range of activities extends from biocides to plant protection actives and products.

BioGenius
2004 - 2024

YOUR COMPETENT TEST INSTITUTE

Analytics Efficacy Insects Development

“We define competence as the creative combination of information and expertise in order to provide you as our customer with the best possible benefit to achieve your goals.”

Mike Bublitz – Managing Director

www.biogenius.de

BioGenius GmbH | 51429 Bergisch Gladbach, Germany

CHEMDOX®
...because safety matters.

Contacts	
Website	chemdox.com
E-mail	office@chemdox.com
Head office	Salztorgasse 1/2A, 1010 Vienna, Austria
Tel	**Europe:** +43 1 5321489 0, **Americas:** +1 888 8369462
Contact	Anton Zrzavy
Directors	Anton Zrzavy
Ownership	UCS – unique computing solutions gmbh
Locations	Austria, United States
Founded	2011

Overview

The CHEMDOX® company provides an outstanding software solution for the chemical industry:

- Classify chemicals according to numerous regulations
- Generate high-quality safety-related documents in the most efficient way
- Assure regulatory compliance

What do our clients like about us?

The CHEMDOX® software has been developed by experts for experts. It's efficient, open, flexible and supports compliance. It's easy to use, easy to integrate and easy to automate. All this, based on state-of-the-art technology and an outstanding customer support.

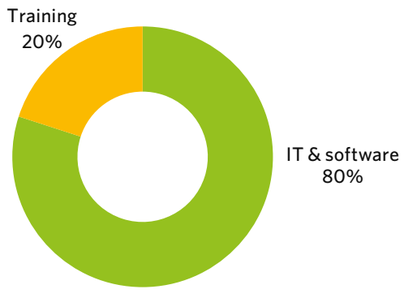
Good software adapts to the needs of its users. This is what we believe in. This is what we work on every day.

The CHEMDOX® company is a subsidiary of UCS – unique computing solutions gmbh – developing high-quality software since 1999.

Vital statistics 2022/23

No of offices	2
No of countries represented	Europe, Americas
Staff: group	>50
Staff: chemical service provision	>20

Service area breakdown



Global offices

Austria (head office), United States.

Services provided

Where does CHEMDOX® help?

The CHEMDOX® software supports experts in all tasks regarding hazardous materials management.

SDS authoring software

Generate SDSs efficiently and 'translate' your SDSs into more than 50 countries, taking into account official languages, national legal terminology, as well as national regulations. You can automate your SDS creation process by using templates and rules, maintaining all the flexibility required when authoring your documents.

Through frequent interaction with all CHEMDOX® users, a wide variety of applications and use cases have been developed, and we are constantly adding new ones. Even special use cases, such as private labelling, are handled efficiently.

Classification calculators

Improve regulatory compliance when classifying chemicals according to different regulation types such as GHS, transport and national regulation. CHEMDOX® regulatory calculators provide automatically computed classification suggestions.

Poison Centre Notifications

Create Poison Centre Notifications super efficiently with CHEMDOX®. Your entire product portfolio including product data is already available on your installation and can therefore be converted into a notification with just a few clicks.

Regulatory coverage

Meet global regulatory requirements on a best practice level, staying up-to-date for all major markets in Europe, the Asia-Pacific region, and the Americas.

Chemical management software

With the CHEMDOX® software, including its legal content and substance database, managing your chemicals is easy and efficient. Track your substances to stay up to date and compliant. With these tools, the generation of your hazard communication documents and regulatory reports is a matter of a few simple steps.

Hazard labelling software

Create multilingual hazard labels with our flexible label editor or integrate CHEMDOX® with your existing solution.

SDS distribution

Distribute SDSs automatically with no manual effort.

System integration and data exchange

The CHEMDOX® software provides easy and state-of-the-art integration with other IT systems via its comprehensive API. Furthermore, the electronic exchange of data improves productivity and quality.

Technical data

- All the benefits of a web-application with the perfect usability of a desktop application
- State-of-the-art technology makes CHEMDOX® future-proof
- Freedom of choice regarding hardware, operating system, and installation scenario

Training, support and professional services

Updates and support

At least quarterly, CHEMDOX® updates ensure that the software is up-to-date and in accordance with regulatory changes.

Our team of experts provides continuous support via e-mail, on the phone, or on our service desk platform.

Training

To get the most out of CHEMDOX®, we offer introductory, individual, and open trainings for users, as well as technical trainings (eg development with the CHEMDOX® API, system integration, etc.) especially tailored to your needs.

Installation and implementation

Install CHEMDOX® easily on a server that is accessible for one or more users, or a specific workstation in your company. No matter which option you choose, installation is just as smooth and intuitive as using the CHEMDOX® software. If you still need help, we are here for you.

Hosting and SaaS

For your comfort, CHEMDOX® can also be installed on our servers and is accessible via an internet connection.

By adding the CHEMDOX® Hosting service to your rental plan, you easily get a SaaS solution.

Configuration and customisation options

- Installation, implementation, and configuration support for the CHEMDOX® software
- Connection of your ERP system to CHEMDOX®
- Data transfer or migration from other programmes
- Implementation of interfaces to other systems
- Development of special software modules
- Document template configuration

Corporate developments and achievements

1999	UCS – unique computing solutions gmbh
2011	CHEMDOX GmbH
2016	CHEMDOX Inc

Partners

- Several regional consulting and sales partners worldwide
- Several software partners (ERP, labelling, etc)

Clients

CHEMDOX® clients range from medium to multinational companies across all industries and the chemical supply chain:

- Authorities
- Substance producers
- Formulators
- Industrial users (eg automotive)
- Regulatory consultants
- Distributors, etc

Testimonials

We work very closely with our customers, appreciate their inputs, and strive for a durable, long-term partnership.

Find out for yourself

We would be happy to connect you with one of our customers.

Case study 1

A major player in the automotive industry has to implement a chemical management solution for compliance reasons.

- Manage and check SDSs and regulatory information provided by suppliers for plausibility
- Automatically track the regulatory status of substances in use (classification calculators)
- Comply with Global Automotive Declarable Substance List (GADSL)
- Integrate with SAP® for substance volume tracking and VOC reporting

Case study 2

A consulting firm has to replace the software solution for their main service: Safety data sheet (SDS) authoring.

- Migration of more than 25,000 products to CHEMDOX®
- Comprehensive regulatory and language support
- Respect customer's corporate identity when authoring SDSs
- Strong focus on accuracy and efficiency

Case study 3

A multinational company wants to avoid differences in product information or documentation due to multiple software installations in their subsidiaries.

- Centralisation of product and regulatory information, as well as documentation in CHEMDOX®
- Working remains decentralised taking into account official languages, national legal terminology, as well as national regulations and national GHS-implementations
- Web-application with the perfect usability of a desktop application, but without the need for a local client installation
- Multilingual user interface including regional specifics (eg date, time or number formats)
- Fine grained permission settings, versioning, change history, statutory retention
- Quality improvements and efficiency gains due to collaboration across the subsidiaries
- Interfacing with multiple IT systems
  - Keeping ERP system and CHEMDOX® in sync
  - Generating labels in a high throughput production environment with variable data like batch numbers, individual barcodes, etc
  - Distributing technical information and technical datasheets generated with CHEMDOX® to different systems

Staff selection

CHEMDOX® Team

The CHEMDOX® staff includes professional, qualified, and skilled experts from the areas of chemistry, law, and software engineering.

We are working as a team to constantly improve CHEMDOX® and our outstanding customer support.

CHEMDOX® Partners

Our certified partner network extends the CHEMDOX® team offering local presence and specific knowhow. Therefore, we engage in targeted, long-term partnerships with renowned suppliers of complementary products and services. For our customers, the regional availability of professional services and regulatory expertise, as well as the possibility to professionally integrate CHEMDOX® into the existing infrastructure is of great use.

ChemSafe®

Contacts	
Website	chemsafe-consulting.com
E-mail	chemsafe@chemsafe-consulting.com
Head office	Chemsafe Srl, Via Ribes, 5, 10010 Colleretto Giacosa (TO), Italy
Tel	+39 0125 538888, +39 0125 669035, +39 0125 538475 (fax)
Contact	Dr Antonio Conto, Managing Director
Directors	Dr Antonio Conto, European Registered Toxicologist (ERT), Managing Director
Ownership	Private company
Locations	Italy
Founded	6 August 2001

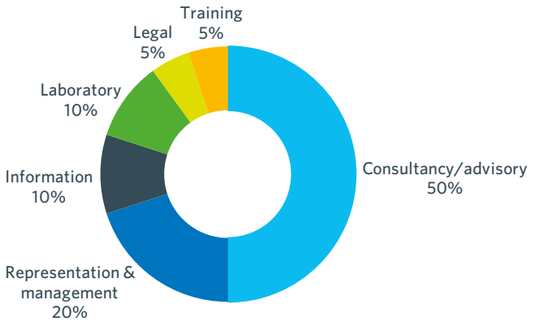
Overview

Chemsafe's vision is to offer regulatory and technical/scientific solutions and services in the field of chemical and pharma safety with a "key point" approach and customer care attitude.

Vital statistics

	2022/23
Turnover: group	€3.5m
Turnover: chemical service provision	€1.8m
No of offices	2
No of countries represented	1
Staff: group	37
Staff: chemical service provision	18

Service area breakdown



Global offices

Chemsafe Srl, Colleretto Giacosa (TO), Italy and Operative Office in Quagliuzzo (TO), Italy

Services provided

Worldwide regulatory affairs consulting

Chemsafe assists its clients with a range of regulatory affairs services worldwide that encompass legal and technical solutions to compliance with international and national chemical and medical control legislation. For almost 20 years Chemsafe has developed unique expertise in regulatory toxicology provided to customers from different fields from chemicals including biocides and agrochemicals, to pharma, medical devices and food/feed. The company is organised in five business units as follows:

Business Unit (BU) Chemical

Chemsafe provides its clients with strategic and technical support to comply with REACH and CLP/GHS as well as SDS and e-SDS preparation. Our technical support includes full dossier preparation (LR: lead registrant or JR: joint registrant), data gap analysis, review and analysis of physico-chemical, environmental fate. It also includes ecotoxicology and toxicological study monitoring, CSA/CSR preparation, human and environmental exposure scenarios, risk assessment and application of alternative strategies to testing such read-across approach and QSARS.

SIEF/consortia management as well as OR appointment for non-EU companies is offered. UK OR service and UK REACH registrations are offered in partnership with a UK company.

Biocides and agrochemicals services are managed by BU Chemical. Our specialised team can prepare and submit technical dossiers for authorisation of active substances and for registration of formulated products. We coordinate the regulatory strategy with the national and/or international authorities as well as the preparation of the technical equivalence data for active substances.

Coordination includes study monitoring for toxicology, eco-toxicology, efficacy studies (laboratory and field) as well as phys-chem and analytics. First product with two actives submitted in Italy by Chemsafe in 2011.

Cosmetics

- General regulatory consultancy and RP (responsible 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

BU Pharma

Safety

- OEL/OEB/ASL for occupational evaluation
- PDE from cross-contamination evaluation
- ERA (Environmental Risk Assessment of Medicinal Products)
- *in silico* with DEREK, SARAH, METEOR, ZENETH and other approaches
- Extractables and Leachables toxicological evaluation
- Quantification/qualification of impurities
- Evaluation of impurities of active substance and formulated product (pharma and medical devices)

GMP

- DMF preparation in CTD format (module 3, section 3.2.S) for the European registration, US and Canada
- International audits for active substances, intermediates
- Preliminary evaluation of all dossier documentation and DMF preparation

GLP activity

- From candidate profiling to preclinical development. Study monitor and CROs (contract research organisation) selection

BU Medical Devices

- Strategic/regulatory consultancy as per new EU Reg No 745/2017
- MD class identification
- Biological evaluation
- Human health risk assessment
- Technical dossier preparation
- Quality system application
- Liaison with regulatory bodies

BU Food/Feed

We advise our clients on legal and technical aspects. In particular:

- consultancy;
- novel foods;
- food contact materials (FCMs);
- nutraceuticals and functional foods;
- food additives, enzymes and flavouring;
- food supplements;
- GRAS (Generally Recognised As Safe) and NDI (New Dietary Ingredient) Notification for US; and
- study monitoring (toxicological, clinical).

Training on demand

Training onsite. Webinars and specific technical/regulatory courses are available on demand.

Corporate developments and achievements

2001	Started up in Italy as a one man company
2007	REACH and OR services offered
2009	Biocides and agrochemicals group creation
2010	Technical advisers for three international consortia. Staff increase to ten people
2011	Petrochemicals derivatives, waste, cosmetics and pharmaceuticals consortia management Staff increased to 12 people First biocides product dossier for two actives submitted and authorised
2012	Pharma business service created Staff increased to 14 people
2015	Operative offices moved to Parella (TO), Italy and organisation in business units (BU)
2017	New business development manager
2018	ISO 9001:2015 Certification acquired and renewed in 2021, BU medical devices created, 20 employees
2019	BU food/feed created Acquisition of ILC Srl, a company active in GMP activities for pharma companies worldwide
2020	New operative offices open in Quagliuzzo (TO), Italy New partnership with China, Brazil. 26 employees
2022	Creation of the BU training, staff up to 32, GLP-like archive established
2023	Staff increased to 37 persons, GLP-like archive offered

Accreditations

Chemsafe is a full member of ORO, the EU Only Representatives Organisation and the Industrial Union of Turin and Federchimica, Italy. Chemsafe acquired the Quality Management System (QMS) as for ISO 9001-2015 in 2018.

Partners

Chemsafe is 100% privately owned.

Clients

Our clients are manufacturers and importers in the following market sectors: chemicals, pharmaceuticals, agrochemicals, biocides, cosmetics, food, feed, medical devices, nanomaterials and petrochemicals worldwide.

Testimonials

Any companies requiring testimonials or references will be provided with them upon individual written request.

Case study 1

REACH testing programme

Working 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 2,000 REACH dossiers completed, including lead registrant and joint submission; including some for UVCB substances. Our team has also completed a significant number of CSRs and hundreds of SDS and e-SDS.

Staff selection

Dr Antonio Conto – Managing Director

Biology Degree, European Registered Toxicologist (ERT). Founder of Chemsafe, more than 33 years' experience as a toxicologist.

Dr Paolo Rossi – BDM Chemical Area

Biotechnologist. 15 years' experience in business development management activities at an international level.

Dr Iavello Alessandra – Head of BU Medical Devices

Medical biotechnologist, 11 years' experience.

Dr Francesca Fasano – Head of BU Chemical

Industrial chemist and chemist, 15 years' experience.

Dr Marco Rodda – Head of BU Pharma

Biologist, European registered toxicologist (ERT), 12 years' experience.

Dr Federica Carra – Head of Quality System

Chemical-pharmaceutical technology degree. Qualified person for pharma companies. Implementation of the ISO 9001-2015 in Chemsafe activities.

Dr Camilla Conto – Deputy Head of BU Food/Feed

Chemical-pharmaceutical technology degree. Masters in food legislation and safety (London). Four years' experience in this specific field.

Dr Emanuela Fino – CFO

More than 30 years' experience.

CHEMSERVICE

Contacts	
Website	chemservice-group.com
E-mail	contact@chemservice-group.com
Head office	**Chemservice GmbH** Herrnsheimer Hauptstr. 1 b, 67550 Worms, Germany **Chemservice SA** 13, Fausermillen, 6689 Mertert, Luxembourg **Chemservice Asia Co Ltd** Technical Innovation Building B-201,202,15, Jongga-ro, Jung-gu, 44412 Ulsan, Korea
Tel	+49 6241 95480 0 /+352 270776 1 /+82 52 223 6232
Contact	Karl-Heinz Reis (Germany), Dr Dominik Kirf (Luxembourg), Jae-Seong Choi (Korea)
Directors	Dr Dieter Drohmann, CEO Chemservice Group Karl-Heinz Reis, Director Global Regulatory Affairs Christopher Cohrs, Director Supply Chain Compliance Dr Dominik Kirf, Director Toxicology & Risk Assessment Thomas Schaefer, Director Data & System Services Doris Peters, Director Consortia Management Jae-Seong Choi, Director Korea Dr Jaime Sales, Managing Director Iberia Lara Dickens, Managing Director UK
Ownership	Privately owned group of companies
Locations	Germany, Luxembourg, Korea, Switzerland, Spain, UK, US, Turkey
Founded	2007

Overview

Chemservice is a leading global consultancy to the chemical industry and its value chain. As an independent service provider, we support our clients in regulatory affairs, national and international chemical regulations, toxicology, risk assessments and environmental sciences. We use our scientific, technical and strategic know-how to overcome regulatory barriers globally, giving our clients a competitive edge.

We are an interdisciplinary team of chemists, biologists, toxicologists and environmental scientists. Our expertise in consortium and LoA management, advocacy and socio-economic assessment enables us to provide comprehensive advice to our clients, even beyond the boundaries of chemical regulations. Our business philosophy? Commitment to finding the best solutions for your needs!

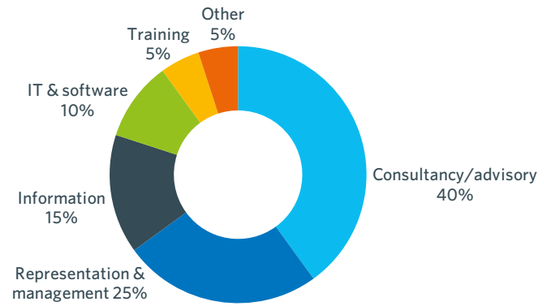
Vital statistics 2022/23

Turnover: group	€12m
Turnover: chemical service provision	€12m
No of offices	10
No of countries represented	8
Staff: group	ca.80
Staff: chemical service provision	ca.70

Global offices

Chemservice Luxemburg, Mertert, Luxembourg. **Chemservice Germany**, Worms, Germany. **Chemservice Asia**, Ulsan, South Korea. **Chemservice Schweiz**, Gersau, Switzerland. **Chemservice Iberia,** Castellon, Spain. **Chemservice UK**, Maidstone, United Kingdom. **Chemservice Americas,** Chicago (IL), United States. **Consortia Management,** Worms, Germany. **Consortia Asia**, Seoul, South Korea **ChemAdvocacy**, Mertert, Luxembourg. **ChemAdvocacy Turkey**, Istanbul, Turkey.

Service area breakdown



Services provided

Global regulatory affairs consulting

We provide a wide range of services to help you comply with national and international chemical control legislation to ensure product safety, producer liability and consumer and environmental protection to regulate the marketing of chemical substances. In addition to inventory notifications, we also carry out registrations of biocides and food contact materials. Through our offices and regional partners, we support our clients in complying with international chemical regulations such as REACH, K-REACH, UK REACH, KKDIK, Taiwan REACH, AICIS (Australia), PMPIN (Philippines), etc.

REACH and GHS/CLP

We provide strategic and technical support for REACH and GHS/CLP. The technical support includes, for example, registration cost evaluation and strategy leading to dossier preparation and registration, data gap analysis, testing strategy proposals, placing/monitoring of studies, compilation of chemical safety reports, exposure, hazard and risk assessments, PBT/vPvB evaluation, C&L notification, safety data sheet and label creation, as well as support on environmental health and safety (EH&S) issues.

In addition, we provide REACH authorisation and restriction services (including RMOA and SEA), advocacy and product stewardship consulting.

Consortia and letter of access management

For more than 14 years, Consortia Management GmbH has provided independent secretarial, fiduciary, and financial services (including trustee account management) in the field of national and international chemicals legislation and biocide regulations. We support consortia and lead registrants in an efficient and competent manner, implementing the data generation and cost sharing required by the regulations while guaranteeing a high level of confidentiality and compliance with competition law.

Our new online letter of access (LoA) portal (**reach-loa.com**) offers efficient letter of access management for all parties who need data access rights for certain substances to fulfil their registration obligations.

Via our legal entities Consortia Asia Co Ltd and ChemAdvocacy Turkey we offer consortia, LoA and data management services for K-REACH and KKDIK.

Combining expertise and competence: your partner for managing consortia.

Only representative and third-party representative

In accordance with REACH, non-EU manufacturers must have appointed an only representative (OR) within the EU to implement the substance registration process. We assume this role on your behalf, and thereby play a pivotal role in the successful marketing of your products in the EU.

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.

We also act as your third-party representative according to REACH Article 4.

Corporate developments and achievements

2007	Start-up in Luxembourg
2008	Opening of Chemservice office in Germany Development of 'REACH-Code-Model'
2009	Launch of Consortia Management GmbH in Germany
2010	Opening of Chemservice Asia office in Korea
2011	Launch of Chemservice EHNS GmbH in Germany, launch of JV ChemCehtra in France
2016	Chemservice acquired a two-digit share of CEHTRA
2017	Ten years of Chemservice
2018	Launch of Chemservice Schweiz GmbH in Switzerland Launch of Consortia Asia Co Ltd in Korea Acquisition and merger of REACH ChemAdvice GmbH into Chemservice GmbH
2019	Establishment of three new Chemservice entities: Chemservice Iberia, Spain; Chemservice UK, Great Britain; Chemservice Americas, US
2020	Extension of Chemservice offices in Germany and Luxembourg, merger of Chemservice EHNS GmbH into Chemservice GmbH
2021	'Chemservice OR-Trustee', the fully automated and web-based successor of the well-established REACH Code Model system, goes online for REACH, UK REACH and KKDIK Launch of ChemAdvocacy Turkey
2022	15 years of Chemservice Opening of new US office in Chicago
2023	Implementation of Service Unit structure

Accreditations

We are a founding member of ORO, the Only Representative Organization in Brussels. We adhere to the quality standards of ORO, which is led by Dr Dieter Drohmann as president.

Partners

With our global network of experienced partners, located in Argentina, Brazil, Canada, China, Colombia, India, Japan, Mexico and Taiwan, among others, we ensure that you receive the best chemical compliance support worldwide.

Clients

We are a global consultancy to the chemical industry and its value chain. Our clients range from multinational chemical companies to SMEs, formulators, traders, retailers and original equipment manufacturers (OEMs). We do not disclose our customers publicly, but provide reference names and testimonials upon request.

Case study 1

Advocacy work

Chemservice has become an important player in the field of advocacy. In addition to conducting more than 15 authorisations for different uses and participating in several restriction dossiers, Chemservice has recently performed more than ten RMOAs and socio-economic impact assessments for different substances. In addition, we have been involved in about 20 calls for evidence and public consultations related to REACH and the EU BPR.

Case study 2

Consortia and letter of access management

Our affiliate Consortia Management has made a name for itself as an independent service provider for consortia and letter of access (LoA) management as well as for data sharing for some 60 consortia and lead registrants under REACH, K-REACH and KKDIK. Services range from setting up new consortia including the creation of the respective consortium documentation and opening a trustee account on behalf of the consortium members, to taking over existing consortia, LoA management and calculations.

Our clients benefit from the centralised management of secretarial, fiduciary and financial services to keep processes as lean as possible while ensuring compliance with tax and competition law.

Case study 3

'Chemservice OR-Trustee' – a unique compliance solution for supply chains

The REACH Regulation does not distinguish between direct and indirect imports into the EU, which complicates trade outside the EU with subsequent imports into the EU. This is especially true when several companies are involved along a non-EU supply chain formulating substances into mixtures with confidential compositions.

In such multi-stage non-EU supply chains, manufacturers of substances usually do not know through which channels and in which products and quantities their substances are imported into the EU. The ingredients of their products and the names of their suppliers and customers are confidential business information (CBI) that is closely guarded by distributors or formulators. Therefore, neither non-EU manufacturers (represented only by agents) nor importers can meet their REACH obligations without disclosing CBI and risking loss of their business.

To solve this problem, Chemservice developed a software-based solution, the 'Chemservice OR-Trustee', which is available for REACH, UK REACH and KKDIK. Many leading companies in the chemical industry globally benefit from this unique compliance solution from Chemservice.

For further information, please see **chemservice-group.com/our-services/compliance-in-the-supply-chain/or-trustee.**

Case study 4

REACH, Korea REACH and UK REACH dossier work

The REACH Regulation entered into force in 2007 with the aim of updating and harmonising chemical legislation within the European Union. Since then, regulations modelled on REACH have been developed worldwide. For example, Korea REACH was introduced in South Korea in 2013 and the UK REACH Regulation was introduced in the UK in 2021 following its withdrawal from the EU.

Since the beginning of each regulation, one of Chemservice's core services has been the support of its clients in the preparation and submission of various types of dossiers. These range from about 1,800 REACH member dossiers and lead dossiers to 1,500 small volume substance registrations in South Korea and about 5,000 downstream user import notifications (DUINS) under UK REACH.

Our many years of international experience ensure that we can provide you with comprehensive advice on the special requirements of the country specific chemical regulations.

CHEMTREC®

Contacts	
Website	chemtrec.com
E-mail	chemtrec@chemtrec.com
Head office	US
Tel	1-800-262-8200
Founded	1971

Overview

With more than 50 years of experience, CHEMTREC's world-leading call centre operates on a 24-hour basis, seven days a week, providing emergency response information wherever hazardous materials are manufactured, stored, transported, or used. With the right procedures and protocols in place, and by doing what's right quickly and effectively, CHEMTREC helps protect people, minimise environmental impacts, and preserve the assets and reputations of its customers.

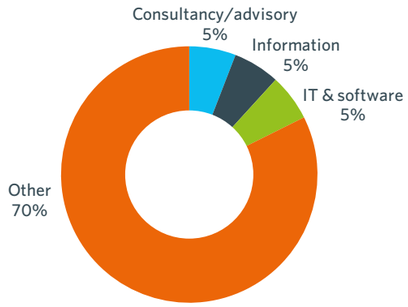
Operating globally, CHEMTREC has offices and partners in major regions and on-the-ground knowledge of local regulations, understanding of local nuances and appreciation of cultural sensitivities. CHEMTREC offers a suite of services including emergency response information, safety data sheet solutions, hazardous materials training, consulting solutions, incident reporting and lithium battery compliance.

CHEMTREC is proud to contribute to the practice of safe handling and transportation of hazardous materials throughout the supply chain.

Vital statistics

	2022/23
No of offices	2
Staff: group	78
Staff: chemical service provision	35

Service area breakdown



Services provided

Emergency response

- Emergency response phone number

Incident reporting

- 5800.1 regulatory reporting
- Incident report distribution

Consulting solutions

- Assessment and prevention
- Preparedness
- Response and recovery

Training

- Online hazmat training

Safety data sheet solutions

- Authoring
- Access
- Distribution

Battery compliance

- Emergency response phone number
- CRITERION® battery test summary service
- Online training

Corporate developments and achievements

1971	Created by the MCA (now The American Chemistry Council), CHEMTREC becomes fully operational
1980	The US Department of Transportation (DoT) formally recognises CHEMTREC as an approved source of information relating to chemical and hazmat incidents
2004	CHEMTREC launches medical information coverage as a service
2006	CHEMTREC hosts its first International Emergency Response Summit in Miami, Florida
2009	CHEMTREC develops an industry solution for the effective marking of lithium batteries in transportation
2010	CHEMTREC establishes the first global network of in-country telephone numbers
2014	CHEMTREC extends its services to include global shipments
2017	CHEMTREC launches safety data sheet solutions
2019	CHEMTREC establishes UK office and introduces online hazmat training
2020	CHEMTREC offers CRITERION lithium battery test summary management service, and partners with China's Nations Registration Centre for Chemicals (NRCC) to create a unified global response for chemical emergencies in China
2021	CHEMTREC launches Consulting Solutions and celebrates 50 years of serving the chemical industry and emergency responder community
2022	CHEMTREC introduces incident reporting and holds its 3rd international hazmat summit
2023	CHEMTREC develops an online HAZWOPER 8-hour refresher training course CHEMTREC launches Safety Data Sheet Authoring services

Testimonials

Testimonials about our Consulting Solutions services:

"Excellent and safe environment to discuss difficult and sensitive aspects of our role around decision making. Excellent and knowledgeable trainers."

"We have received nothing but positive comments from our line level personnel to our leadership team. Your energy was infectious and your presentation professional."

"I am certain that the site is better prepared and will apply the properties of your training to manage an emergency event! We highly recommend you and your efforts for other endeavours in the network!"

Case study 1

Lithium battery fire on cargo plane

A box of lithium-ion batteries for mobile phones was damaged while being unloaded from a cargo plane. The airport fire department knew how to fight lithium-ion battery fires, but called CHEMTREC and asked about hazard information related to the health effects of the combustion and decomposition products given the specific chemistry of the batteries. CHEMTREC identified that the manufacturer was a CHEMTREC customer. CHEMTREC's emergency services specialists (ESS) discussed the safety data sheet (SDS) from the battery manufacturer with the fire department. Then, the ESS called the manufacturer to help identify the exact battery models present in the shipment. Afterwards, CHEMTREC sent the manufacturer a written case report.

Case study 2

Medical advice for human exposure

A Spanish-speaking doctor called CHEMTREC from a major hospital in Mexico. Two construction workers had been accidentally exposed to a solvent through inhalation and skin contact. The manufacturer of the solvent was a CHEMTREC customer. After connecting to a Spanish interpreter, CHEMTREC identified the manufacturer and product name located on the safety data sheet.

CHEMTREC connected the caller and interpreter to our poison centre partner and provided them with the SDS. The poison centre partner provided the required medical advice related to treatment strategies. The manufacturer was notified by phone and received a written case report from CHEMTREC.

Case study 3

Rail transport gas release

A fire department called CHEMTREC about a leak of chlorine from the discharge valve of a tank railcar close to a residential area. The shipper was a CHEMTREC customer. Our emergency services specialists (ESS) provided information from the emergency response guide and product specific information from the manufacturer's safety data sheet to help the fire department conduct a risk assessment. The ESS connected the fire department with the manufacturer's product specialists.

It was decided that the CHLOREP mutual aid scheme should be invoked. Our ESS initiated the scheme, making sure that appropriate response support was deployed on the scene. CHEMTREC activated the shipper's crisis management teams using mass communications. Afterwards, the case report was sent to the shipper.

Case study 4

Less than a truckload (LTL) spill

A carrier called CHEMTREC reporting that a forklift had punctured a 55-gallon drum of flammable and toxic (class 3 and 6.1) product, causing a product release of 20 gallons in the trailer at the terminal. The shipper of the product was a CHEMTREC customer and the carrier was also registered with CHEMTREC. While the carrier was aware of the hazards of transporting such products, a CHEMTREC emergency services specialist (ESS) provided them with detailed product-specific information, including precautions, PPE, clean-up methods, and disposal information. The carrier did not want to handle the spill response, so the ESS provided them with the contact details of a Level 3 provider in the area who could respond to the spill.

Immediately after receiving the call, the ESS contacted the shipper's emergency contacts and notified them of the situation involving their product. A written case report was sent to both parties involved.

Case study 5

Spill at a furniture manufacturing plant

A furniture manufacturing plant called CHEMTREC and reported the rupture of a pipe that caused the release of several hundred litres of flammable adhesive in an enclosed area of the plant. The manufacturer of the adhesive was a CHEMTREC customer. Using the manufacturer's SDS and considering available resources, CHEMTREC proposed a plan to promote fire safety and clean up the spill. However, it was revealed that the staff at the plant did not have the spill response training and equipment required to handle the situation safely.

CHEMTREC recommended calling the fire department to make the situation safer and provided the contact details of a Level 3 provider in the area for proper spill cleanup. The adhesive manufacturer was notified by phone and received a written case report.

Staff selection

Andrew LaVanway – Chief Executive

Andrew H. LaVanway is responsible for the strategic direction and performance of the company as well as leading the senior management team. Before CHEMTREC, Andrew was employed at ICF, where he led a series of mission-driven businesses serving both public- and private-sector clients. Previously, Andrew led a boutique government, transportation, and healthcare public affairs firm in the DC metro area. He also worked as an associate staff member for the US House Appropriations Committee (Subcommittee on Defense), a legislative director for former US Rep. Jay Dickey, and a senior legislative assistant for former US Rep. Curt Weldon.

He has a BA in Economics from Gettysburg College, an MBA from Georgetown University, and a series of leadership certificates from Harvard Business School. Andrew is an active angel investor, former chairman of the Alexandria Public Health Advisory Commission, a certified firefighter, and an emergency medical services officer in Calvert County, Maryland.

Rich Davey – International Business Director

Rich Davey serves as the Director of International Business. With nearly 20 years of experience working with private and public sector organisations who have complex risk and compliance challenges, Rich is responsible for forming strategic partnerships with international accounts that interface into and out of the US. Having worked with many multi-national businesses, Rich uses his experience to develop international partner networks around the world. His international customers truly value Rich's efforts to minimise operational risks and help with compliance whilst protecting their bottom line.

Erica Fischer – Training, Outreach, and Partnerships Director

Erica joined CHEMTREC in 2019 overseeing crucial aspects such as training, public service initiatives including TRANSCAER, the HELP Award, and Community Outreach programmes, and fostering partnerships. Her role involves cultivating relationships with private and public sector entities such as government partners, chemical manufacturers, distributors, emergency responders, trade associations, and transportation carriers. Heading a dedicated team of curriculum developers and training specialists, Erica spearheads the creation of hazmat training programmes for CHEMTREC and manages the execution of projects under the TRANSCAER programme. Her expertise extends to all-hazard exercise design and evaluation, reflecting her commitment to excellence in emergency preparedness.

Erica has a Master of Arts in Homeland Security and Emergency Preparedness from Virginia Commonwealth University and has completed the Master Exercise Practitioner Program (MEPP) at the Emergency Management Institute. She is an EMT and HAZWOPER Instructor.

Contacts	
Website	**chemhse.com** **cncic.cn**
E-mail	**liangmy@cncic.cn**
Head office	No. 53 Xiaoguan St, Anding Menwai, Beijing, China
Tel	+86 10 64434938
Contact	Minyan Liang
Directors	Victor Lu, Richard Tong
Ownership	China state-owned company
Locations	Beijing, China
Founded	1959

Overview

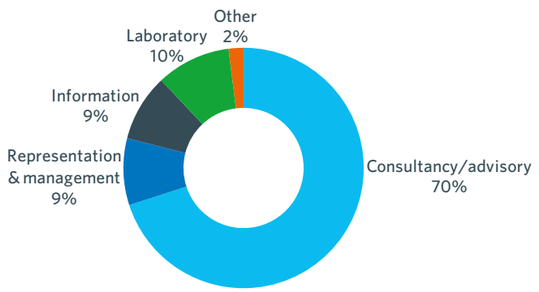
The China National Chemical Information Center Co, Ltd (CNCIC), formerly the Intelligence Institute of the Ministry of Chemical Industry, has become a leading consulting, research and information service institution for China's chemical industry since its founding in 1959.

CNCIC Consulting has a highly professional and experienced consulting team, combined with its scientific and rigorous methodology, global professional database resources and multi-field expert advisory group, providing authoritative, professional, objective and rigorous consulting services related to strategy, marketing, investment, product compliance, HSE consulting for both domestic enterprises and multinational companies worldwide.

Vital statistics 2022/23

No of offices	4
No of countries represented	Global
Staff: group	400
Staff: chemical service provision	200

Service area breakdown



Global offices

Beijing office (Headquarters): No. 53 Xiaoguan St, Anding Menwai, Beijing, China, Tel: +86 10 64434938. **regulation@hse.cncic.cn**

Services provided

Regulatory compliance consulting

Chemical Compliance department has been tracking relevant domestic and overseas regulations and policies regarding industrial chemicals, cosmetics, food-related products, agricultural and household products, among others.

With highly qualified experts, Chemical Compliance department is committed to providing professional, reliable and efficient technical consulting and compliance services to help clients control risks.

Services include:

- new chemical registration in China, South Korea and Japan;
- cosmetics and new ingredients registration and filing;
- biocides, pesticides registration;
- disinfectants registration;
- global GHS compliance;
- food contact materials registration and notification;
- fertiliser registration and filing;
- 24-hour emergency service agent;
- local only representative;
- testing services; and
- customised regulation services.

REACH-like services

- CNCIC can provide REACH-like registration services including:
- EU-REACH;
- UK-REACH;
- K-REACH;
- CSCL/ISHL services; and
- Taiwan TCSCA/OSHA.

HSE consulting

CNCIC provides onsite hidden danger investigation and identification, safety management consulting and auditing, safety management training, and safety information and intelligence services for chemical enterprises and institutions to help them establish/improve safety management systems and thus improve their safety performance.

Corporate developments and achievements

1959	Intelligence Institute of China Ministry of Chemical Industry (IICMC) established in Beijing, China. In the planned economy era of China, it was part of the Chinese government
1984	The Economical Information Center of the Ministry of Chemical Industry (EIC) was established
1992	IICMC and EIC was merged into China National Chemical Information Center (CNCIC), a China state-owned company
2017	China National Chemical Information Center was changed to China National Chemical Information Center Co, Ltd.
2020	Established Shanghai branch
2022	Established Suzhou branch

Accreditations

- ISO 9001 Quality Management System
- Information System Integration and Service Qualification
- CMMI Software Certification
- Information Security Service Qualification Certificate

Testimonials

CNCIC has been dedicated to new chemical registration for almost 20 years and has assisted numerous clients to obtain more than 300 regular registration certificates. Under the new regulation (MEE Order No. 12), CNCIC has achieved more than 20 regular registration certificates, accounting for almost 30% of the total approved ones.

CNCIC has successfully received filing approval for some 10 cosmetics new ingredients under the new regulation and assisted the client in avoiding animal testing during the cosmetic product filing.

As part of our market consulting service, we have extensive experience across various professional domains in the realm of customer service. Our involvement spans the entire industrial chain within the chemical industry.

Case study 1

IECSC listing

Using rich database resources, CNCIC has helped some of its clients list new chemicals into the IECSC without going through the registration or filing process. We submitted the evidence (references, published books etc) that could prove the importation and domestic manufacturing before 15 October 2003, which is a cost- and time-saving achievement for clients to enter into the Chinese market.

Case study 2

New chemical registration

Risk assessment reports and economic and social benefit analyses are a major concern for an applicant under the current regulation for new chemicals.

Combining the professional expertise of both the compliance department and market consulting department, several regular registrations for a chemical with special characteristics have been approved.

Case study 3

Pesticide registration

CNCIC has good government relations and a professional team to help you control your filing costs and reduce all kinds of uncertain risks. More than 500 pesticide registration certificates have been obtained, including 20 new pesticide registration certificates. A new pesticide herbicide product successfully obtained a pesticide registration certificate after communicating with ICAMA and laboratory experts.

Staff selection

Victor Lu – CNCIC Chemical Compliance General Manager and Vice Chairman of China Fine Chemical Raw Material &Intermediate Industry Association.

Mr Lu joined CNCIC and started consulting research work in 1996. He has more than 25 years' experience in petrochemical and chemical consulting research, and has provided professional industrial consulting services to domestic and foreign enterprises for many years.

The scope of research includes trending petroleum/chemical products, new materials, coal, gas and salt chemicals, biochemicals, pesticides, organofluorine and organosilicon sectors, as well as energy, industrial and economic analysis.

Richard Tong – Chemical Compliance Department Deputy General Manager

15 years' working experience in the chemical industry and 10 years' working experience in the chemical compliance consulting industry. Mr Tong has lead and participated in the completion of 200+ regular registration projects of new chemical substances and provided chemical compliance services for hundreds of chemical enterprises. He has rich experience in regulatory response, testing, toxicology, ecotoxicology etc.

Minyan Liang – Chemical Compliance Department Project Director

Minyan Liang is a senior engineer with 19 years' experience in regulation consulting services. She is mainly responsible for domestic and overseas chemical regulations and policies, such as China's new chemical substance registration, chemical environmental risk assessment, social-economic benefit analysis, EU-REACH, K-REACH, etc.

She has led and completed 300+ general registrations and 1000+ simplified registrations of new chemical substances in China and has published many papers in various professional technical journals.

Amy Yu – Chemical Compliance Department Project Director

Amy Yu graduated from Beijing University of Chemical Technology in 2005, with 19 years' experience in China and overseas pesticides registration. She has led more than 300 pesticide registration projects and more than 30 new ingredient registrations.

She leads a professional team for agricultural chemicals compliance services and has extensive experience in domestic and foreign pesticide registration regulations.

Jing Qiao – Chemical Compliance Department Deputy Director

Jing Qiao graduated from Nagoya Institute of Technology. She is a senior engineer and the certified toxicologist of the China Toxicology Society. She has 10 years' chemical compliance management experience and 5 years' experience in cosmetic services. She is also a specialist in the filing and registration of new cosmetic ingredients in China.

Contacts	
Website	cirs-group.com
E-mail	service@cirs-group.com
Head office	11/E Bldg 1, Dongguan Hi-Tech Park, 288 Qiuyi Rd, Binjiang District, Hangzhou, China
Tel	+353 (1) 477 3710 (Ireland) +86 571 8720 6574 (China) +86 8720 6533 (fax)
Contact	David Wan
Directors	Lucy Li, President of CIRS Group; Walt Lin, Vice President of CIRS Group; Hangsik Yim, Managing Director of CIRS Group Korea; David Wan, Managing Director of CIRS Ireland and US
Ownership	Private company
Locations	China (Beijing, Hangzhou, Nanjing, and Shanghai), South Korea (Seoul), Ireland (Dublin), US (Arlington) and UK (London)
Founded	2007

Overview

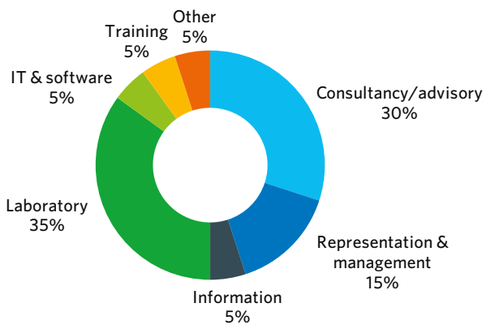
CIRS Group was established in 2007 and is a leading product safety and regulatory consulting firm. It is headquartered in Hangzhou, China with subsidiaries in the Republic of Ireland, South Korea, the US, and the UK. It utilises its technical expertise, resources, and international network to provide comprehensive compliance services across multiple industries including chemicals, cosmetics, food, FCMs, medical devices, and agrochemical products.

CIRS Group provides a variety of services including regulatory compliance, laboratory testing, R&D and data services to help clients gain a competitive advantage by reducing business risks associated with regulatory affairs.

Vital statistics 2022/23

Turnover: group	approx €30m
Turnover: chemical service provision	approx €15m
No of offices	9
No of countries represented	5
Staff: group	500
Staff: chemical service provision	approx 35%

Service area breakdown



Global Offices

CIRS China, CIRS South Korea, CIRS Europe, CIRS US, CIRS UK.

Services provided

Global GHS compliance

SDS and labelling services for:
- North America;
- EU;
- China; and
- Asia Pacific.

We also offer chemical consumer product labelling and 24hr emergency telephone number services for China.

Global chemical notification

Registration services:
- EU REACH (also OR services);
- China new chemical substances and hazardous chemical;
- K-REACH, KBPR and Kosha;
- Taiwan TCSCA, and OSHA;
- Turkey KKDIK; and
- India CMSR.

We also offer chemical notification in other regions including Japan, the Philippines, the US, and Australia.

Food and food-related product service in China

- Regulatory compliance for FCMs
- New food contact resin and additive (including GMO) registration
- New food raw materials registration
- Dietary supplement registration and filing
- Infant formula registration
- FSMP product registration
- China GACC overseas manufacturers registration for imported foods
- Formula and label reviews for pre-packaged food

Cosmetics and ingredients registration in China

- Cosmetics registration
- New ingredient registration
- Cosmetic ingredient safety information code application
- Toxicology safety assessments
- Formula and label reviews
- Customs clearance assistance
- Regulatory compliance testing services

Cosmetics and ingredients registration in South Korea

Provide notification and registration services for quasi-drug products and functional cosmetics. We also provide consulting services for GMR.

Cosmetic services in the EU and UK

- **Pre-clinical and clinical safety trials:** design and realise *in vitro* tests, providing reports with analysis and conclusion.
- **Hazard profiles and risk assessments:** comprehensive risk-based safety assessments of cosmetic ingredients and products.
- **Regulatory monitoring:** survey of cosmetic ingredients based on EU and UK cosmetic regulations, other local regulations and international rules.
- **Product information file (PIF):** provide a cosmetic product safety report (CPSR) and ensure the completeness of PIF.
- **Labelling and communication:** validate the text and regulatory notices on the packaging in French, Spanish and English. Compile the regulatory documents necessary for import/export. Notify cosmetic products on the European portal (CPNP).

Testing services

- China ecotoxicology
- SVHC list testing
- China RoHS
- *In vitro* testing
- Consumer goods safety testing.
- Hazardous chemical testing
- FCM testing (EU, US and China)
- Cosmetics efficacy testing

Corporate developments and achievements

2007	Founded in Hangzhou
2008	Europe subsidiary established
2010	China – first chemical safety report completed by CIRS
2011	Partnership with JEMAI and became JAMP member Nanjing subsidiary established
2013	CIRS Testing Centre (C&K Testing) established
2015	Beijing subsidiary established
2016	Completed 100th typical notification under China REACH
2017	US subsidiary established
2018	South Korea subsidiary established Partnership with Chemsafe
2019	Authored 100,000th global SDS Completed 3,000th K-REACH pre-registration Completed 10,000th China Cosmetics Registration Hosted the Asian Helsinki Chemicals Forum and the fourth Summit meeting on Chemical Regulations in Asia Pacific (HCF&SMCR 2019). Acquired full CNAS/CMA testing qualifications of FCM products
2020	UK subsidiary established
2021	CIRS Cosmetics efficacy testing centre established
2022	Unveiled new visual identity
2023	Shanghai subsidiary established

Accreditations

We are a China-certified SDS service provider. Our laboratory is CNAS, CMA, and CPSC accredited. We also hold a JAMP membership certificate.

Partners

Chemsafe, JEMAI, Eurofins, KTR, Flashpoint, ExperTox, Arcadis, Cafe24, SRICI, Cekindo, and Export Access.

Clients

We have worked with more than 20,000 clients and partners across multiple industries, including chemicals, cosmetics, biocides, agrochemicals, food, medical devices, and consumer goods. Our services are used by 70% of Chinese chemical companies. More than 600 international corporations are currently using our services to fulfil their product regulatory obligations around the world. 55% of clients have been working with us for more than five years and 80% for more than three years.

Staff selection

Yunbo Shi, Chief Operations Officer, Toxicologist, CIRS HQ

Yunbo has more than 15 years' experience in regulatory affairs, product safety, and product stewardship for multiple industries including chemicals, cosmetics and pesticides. He is a certified toxicologist (DCST), an executive council member of the Shanghai Society of Toxicology (SHSOT), and co-author of the book Chemical Product Safety Regulations and Risk Assessment (ECUST press, 2018).

He holds a BS degree in chemistry from the University of Science and Technology of China (USTC) and an MS degree in chemistry from the University of Maryland College Park (in the US).

Michael Chang, PhD – Chief Technical Officer, DABT, DCST, CIRS HQ

Michael graduated from the University of Science and Technology of China. He is a leading technical expert in the risk assessment of chemicals in China. Since 2011, his team has completed more than 300 REACH LR projects and has prepared more than 1,000 risk assessment reports for registration in the EU and China. All reports have been accepted by the authorities. His team has also compiled thousands of SDSs for global enterprises.

He is proficient in various chemical risk assessment software and QSAR models such as EPA-SUIT, QSAR toolbox, VEGA, IUCLID 6, and CHESAR.

Queenier Yang – Technical Director of Chemical Technology Sector, Toxicologist, CIRS HQ

Queenier has more than 13 years' experience in global chemical regulations including EU REACH, K-REACH, KKDIK, UK-REACH, US TSCA and Canada DSL/NDSL. Her expert use of QSAR and read-across instead of testing, successfully gains compliance with REACH-LIKE regulations. Her team has completed thousands of notifications/registrations covering China REACH and overseas chemical regulations.

April Guo – Personal Care Sector Manager/Senior Consultant, Toxicologist, CIRS HQ

April has more than ten years' experience. She leads the personal care team and helps globally renowned cosmetic companies and ingredient suppliers with regulatory compliance for thousands of products each year. She is frequently invited to imbue her extensive knowledge by providing training to foreign cosmetic companies at international regulatory conferences.

Cathy Yu – Food Sector Manager/Senior Consultant, Toxicologist, CIRS HQ

Cathy majored in food science and engineering at university. She has worked for the CIRS Group for more than ten years and leads the food business division to assist globally renowned food companies. She is very familiar with the food industry and has extensive experience with China's food-related laws and regulations.

Eric Xiong – Director of Industrial Chemicals Sector, CIRS HQ

Eric has 13 years' experience in product stewardship and regulatory compliance for the chemical industry in China, the EU, and other Asian Pacific countries. His team has provided solutions for hundreds of enterprises to achieve chemical regulatory compliance and helped clients place thousands of chemicals onto the market in China, the EU, and other Asia Pacific countries without barriers.

Bryan Zhou – Deputy General Manager/Senior Consultant, CIRS Europe

Bryan has eight years' of practical experience in global chemical and cosmetic regulations including the EU, the UK, China, South Korea, and other Asia Pacific countries. Together with his team, he has completed more than 1,000 projects covering EU REACH registrations, Poison Centre Notifications, UK REACH, K-REACH, KKDIK, Global GHS, and China chemical and cosmetic management.

Edwin Wen – Managing Director/Senior Consultant, CIRS Beijing

Edwin has 14 years' experience providing medical device regulatory services for CIRS. He leads a dedicated team to help global medical device companies develop regulatory compliance procedures for their products and formulate solutions for regulatory approval, clinical trials, quality assurance, and gaining a registration certificate or manufacturing/distribution licence in China.

Yasmine Boulanouar – Senior Regulatory Toxicologist, CIRS Europe

Yasmine has an MS in Toxicology, risk assessment and vigilance from the Farmacy University of Paris-Saclay. She has more than ten years' experience in the cosmetics and consumer products industries. She specialises in toxicology and risk assessment, as well as regulatory affairs. She is based in Paris and covers the European market.

Junho Lee – Director of CIRS Group South Korea

Junho has 17 years' of international experience, specialising in the field of chemical regulations, standards, and certifications in South Korea, China, and Europe. He has supported industry with major updates to chemical regulations around the world including EU REACH, and South Korea's K-REACH.

complymarket
TOTAL COMPLIANCE SOLUTIONS

Contacts	
Website	complymarket.com/
E-mail	info@complymarket.com
Head office	Tal 44, 80331 Munich, Germany
Tel	+49(0)1637819457
Contact	info@complymarket.com
Directors	Ms Shahd Jemmy
Ownership	Private company Private company, affiliated with: ComplyMarket UG (haftungsbeschränkt)
Locations	US, Canada, Europe, Asia, Africa
Founded	2023

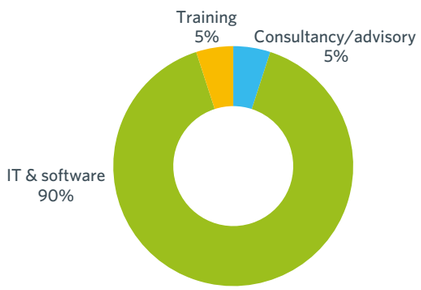
Overview

ComplyMarket is a Total Compliance Solutions provider, using the power of AI to identify compliance requirements and perform risk assessments. Our expertise extends to the development of the first-ever open-source software designed specifically for supply chain management. This groundbreaking tool enables the efficient collection of compliance and sustainability information from suppliers, empowering our clients to uphold the highest standards of regulatory compliance and environmental stewardship.

Vital statistics 2022/23

No of countries represented	Global
Staff: group	10-25
Staff: chemical service provision	5-10

Service area breakdown



Services provided

ComplyIntelligent

AI-powered software that can quickly identify compliance requirements, which saves time and resources.

A process that can cost companies thousands of dollars using normal consultancy. Now you can do business everywhere with low compliance costs. With ComplyIntelligent you save both time and money.

ComplyDoC

The first ever open-source code software for collecting compliance information within your supply chain, to perform SCIP notifications to the European Chemicals Agency, and to prepare PFAS information for reports in the US.

It also helps your company collect the necessary information for legislation similar to Supply Chain Due Diligence (eg Conflict Minerals legislation in the EU and US, the EU's proposed Corporate Sustainability Due Diligence Directive, Germany's Supply Chain Act, EU Deforestation Regulation, etc) and support sustainability reporting. Its open-source status enhances your company's financial attractiveness, proving to be a strategic asset in mergers and acquisitions.

ComplyPass

A Digital Product Passport will be mandatory for products you place in the EU market. ComplyPass provides:

- **For small businesses:** We offer a direct, server based DPP issuance service for easy compliance without extensive resources.
- **For large companies:** We create custom in-house DPP solutions that integrate smoothly with your systems, suited for complex, large-scale needs.

Advanced material compliance and sustainability training

This is a two-day intensive training course that builds your expertise in all topics of material compliance worldwide and teaches you how to build a material and sustainability compliance management system.

Supply chain communication

Our dedicated team can take over the process of contacting your suppliers and checking compliance evidence collected from them for correctness and quality requirements allowing you to focus on the business.

Compliance Management System according to ISO 37301

ComplyMarket Team can design and build your Product and Material Compliance System according to the requirements of ISO 37301 and IDW PS 980.

ComplyRisk

This tool analyses the probability of each substance being present in your bill of materials. It is developed based on scientific research conducted by materials scientists and incorporates cutting-edge artificial intelligence technology. The tool aims to minimise your laboratory costs to the minimum.

Corporate developments and achievements

2023	Founded in Germany as company headquarters Munich University of Applied Science incubation programme 'Start for Future' incubation programme Nvidia decided to support ComplyMarket under its 'Inception' programme Amazon Web Services decided to support ComplyMarket under its 'Loft' programme
2024	Microsoft decided to support ComplyMarket under its programme 'Microsoft for Startups'

Partners

Amazon Web Services, Microsoft for Startups, Nvidia inception programme.

Clients

ComplyMarket proudly serves a diverse array of international manufacturers, from regions such as the European Union, the United Kingdom, Canada, and the United States. Our clientele spans various industry sectors, including electronics, entertainment, automotive, chemicals, machinery, medical devices, and heavy equipment manufacturing.

We cater to companies specialising in electrical equipment and components, automation and control systems, appliances, and industrial machinery and equipment. This wide-reaching expertise underscores our commitment to addressing the unique compliance needs of each sector and facilitating global trade for manufacturers across these critical industries.

Testimonials

ComplyMarket has been instrumental in reducing our supply chain communication software costs by US$240,000. This significant cost saving has enhanced our competitive edge in the global market, enabling us to lower our product prices. Typically, achieving compliance is associated with increased product costs; however, ComplyMarket's open-source software has not only helped us cut costs but has also added value to our assets.

As an innovative startup launching new products, navigating the complexities of product compliance was daunting. We discovered that most service providers quoted us a minimum of US$5,000 per product for compliance assistance. Adopting ComplyIntelligent transformed our approach, saving us substantial amounts of money and significantly boosting our efficiency and speed in operational processes.

Case study 1

Transitioning to ComplyMarket for enhanced material compliance and cost efficiency

A renowned international manufacturer faced challenges with their existing software for collecting material compliance declarations of conformity. The software, provided by another company, was not only costly but also imposed significant fees for each regulatory update. Additionally, it lacked the flexibility to integrate various regulations, such as battery regulations, which required collecting similar information from the same suppliers.

Seeking a more efficient and cost-effective solution, the manufacturer turned to ComplyMarket's software for supply chain communication. This open-source platform offered a transformative advantage, allowing the addition of new regulations at no extra cost and enabling customisation to meet the manufacturer's unique needs. For the first time, all necessary declarations could be managed within a single software, eliminating the need for additional payments.

The open-source nature of ComplyMarket's software provided an unparalleled sense of security. It eliminated the risks associated with software changes or contract terminations and safeguarded against unexpected cost increases. Moreover, the competitive pricing of ComplyMarket's solution facilitated a smooth transition from the previous provider, demonstrating its superior value and flexibility.

Case study 2

Case Study 2: Streamlining compliance processes with ComplyIntelligent

A leading manufacturer, known for launching hundreds of new products annually, faced a significant challenge. Their engineers were required to dedicate a few days to research product compliance requirements for each new product in its target country. This time-consuming process not only delayed product launches but also increased the operational costs significantly.

The introduction of ComplyIntelligent marked a turning point for the manufacturer. By integrating this innovative solution, the company was able to drastically reduce the time spent on compliance research from days to just a few hours per product. This remarkable efficiency gain was a game-changer, allowing engineers to focus more on product development and innovation.

Case study 3

Enhancing material compliance and sustainability for global clients

In a focused, two-day workshop, we empowered our clients with the essential knowledge to navigate the complex landscape of global chemical regulations. This intensive session was meticulously designed to cover the intricacies of nearly all chemical regulations worldwide, providing attendees with the tools to ensure their operations align with international standards.

Moreover, our workshop delved into the construction of a compliance management system conforming to the rigorous requirements of ISO 37301 and IDW PS 980. By the end of the workshop, participants were not just familiar with compliance requirements but also equipped to implement a comprehensive compliance management system within their organisations.

Staff selection

Dr Mohamed Kassem – Director

Dr Kassem leads the scientific department at ComplyMarket in Germany, with a distinguished academic record from five international universities. His expertise spans three disciplines: Chemistry, where he has achieved a Bachelor's, Master's, and PhD; Industrial Management and International Business, with three master's degrees; and Computer Science, where he holds several diplomas akin to associate degrees.

With more than 15 years' experience, Dr Kassem has supported over 1,000 companies in meeting their compliance, regulatory and sustainability goals while reducing costs. He offers intensive training in material compliance and sustainability, and on building product compliance management systems according to ISO 37301 and IDW PS 980. His consultancy roles, including positions as a senior consultant for notable international firms, affirm his capacity to guide companies to safety in compliance matters.

Dr Kassem also contributes socially in Germany by organising events for international Erasmus students from all over the world, providing them with support during their exchange, and showcasing his commitment to both professional excellence and community engagement.

Engineer Doaa – Chief Technology Officer

As the Chief Technology Officer at ComplyMarket, Engineer Doaa leads the software and IT teams, focusing on enhancing supply chain communication and advancing artificial intelligence capabilities within the company. Her career spans over two decades, during which she has been instrumental in the research and development of new products, aiming to enhance the efficiency of ComplyMarket's clients and reduce their operational costs. Overseeing the cybersecurity team falls within her purview, ensuring the security and integrity of all operations and data.

Contacts	
Website	ebrc.de
E-mail	info@ebrc.de
Head office	Kirchhorster Straße 27, 30659 Hannover, Germany
Tel	+49 511 898389 0, +49 511 898389 10 (fax)
Contact	Torsten Grewe
Directors	Dr Rüdiger V Battersby
Ownership	Privately owned
Locations	Germany
Founded	1993

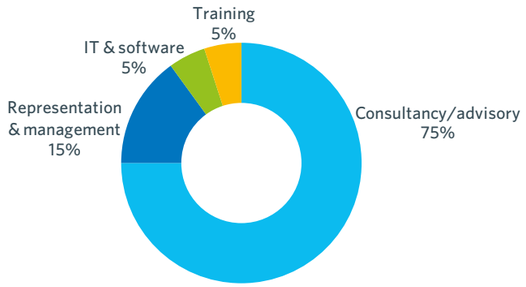
Overview

EBRC is a privately owned consulting organisation based in Hannover, Germany, providing consulting services with a focus on the chemical, biocidal and agrochemical industries. EBRC specialises in scientific experience in all key disciplines relevant to product safety with respect to human health and the environment. Taskforce management and coordination of industry consortia is another important aspect of our work.

Vital statistics 2022/23

No of offices	1
No of countries represented	1
Staff: group	68
Staff: chemical service provision	40

Service area breakdown



Global offices

EBRC Consulting GmbH: Kirchhorster Straße 27, 30659 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);
- generation of "read-across assessment framework" (RAAF) documents;
- PBT and vPvB assessment;
- technical dossier (IUCLID);
- identification of known uses;
- development of exposure scenarios for HH and ENV;
- risk characterisation;
- classification and labelling;
- safety data sheets;
- QSAR calculation and reporting (QMRF, QPRF);
- 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, formulation changes and mutual recognition;
- 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; and
- 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);
- taskforce/consortia management; and
- evaluation of substances – as specified for industrial chemicals and agrochemicals above.

Special services

- EBRC has inhouse 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 and achievements

1993	Foundation of EBRC (initial staffing: six people)
2024	Continual growth, leading to a current staff count of 68 Headquarters moved within Hannover

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) document. 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 the REACH Regulation (EC) 1907/2006.

In an integrated assessment of strictly controlled conditions (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 that 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

Rüdiger Battersby is the founder and director of EBRC. After his PhD in biochemistry, he took up a position as manager of contract research organisation IBR in Hannover, from which 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 risk assessment 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 Chemical Society's Expert Gremium for Chemicals Safety.

Arne Burzlaff – Senior Registration Manager Industrial Chemicals

Arne Burzlaff graduated as a chemist in 2000 and obtained a PhD in technical chemistry/biotechnology in 2005. He worked for the German Federal Institute for Occupational Safety and Health's 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 for 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 from the University of Hannover in 1984. After years of experience in biochemical analytics, with specific emphasis on the development and validation of immunoassays, he has been working for EBRC as registration manager for agrochemicals since 1999.

His main responsibilities at EBRC include the coordination 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

Silke Burger graduated as a biologist in 2000 and obtained a PhD in molecular biology/toxicology in 2004. Since 2006, she has been working for 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 from the University of Hannover in 2003. His main responsibilities for 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 human equivalent concentrations (HEC) approach.

THE
NON-CLINICAL
ENGINE

Contacts	
Website	www.erbc-group.com
E-mail	info@erbc-group.com
Tel/fax	+33 2 48230023/+39 06 91095263
Contact	info@erbc-group.com
Directors	Christophe Priou (CEO), Pascal Champeroux (CSO), Frank Visser (CCO)
Ownership	Privately owned
Locations	France (HQ) and Italy
Founded	2019

Overview

Born on 1 November 2019, when CERB (France) acquired the toxicology activities of RTC (Italy). By merging the complementary portfolios of pharmacology and toxicology a new full-service provider was created and renamed ERBC. ERBC is a European leader in non-clinical studies. It offers healthcare and chemical professionals a comprehensive range of experimental capabilities, preclinical models, regulatory pre-IND package and consultancy services to de-risk innovation and improve R&D productivity.

Based in Baugy, near Paris (France) and in Pomezia, near Rome (Italy), ERBC provides all services from preclinical proof-of-concept to market of any type of drug candidate or chemical compound. Each project is managed by a study director, relying on a multidisciplinary team of experts, notably in general, genetic and reproductive toxicology, carcinogenicity, pharmacology and safety pharmacology, non-clinical cardiology, electrophysiology and pathophysiology, also benefiting from a world class academic and private network.

Every year, study reports from our two centres are successfully used in support of the market authorisation of new product approval submissions around the world, including the European (EMA, ECHA), US (FDA and EPA) and Japanese (MHLW and MAFF) regulatory authorities.

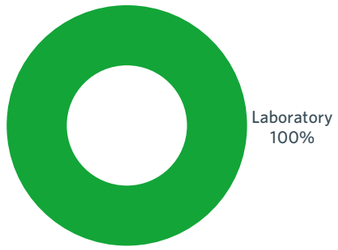
Investment in outstanding scientific and technical manpower, high-tech equipment and facilities are crucial cornerstones of our sound and organic growth. The quality and reliability of our performance is reflected by the many ongoing and long-lasting collaborations we maintain with leading international pharmaceutical and chemical companies.

ERBC is deeply engaged in animal ethics and welfare. ERBC supports the Basel Declaration, respects the 3Rs concept and continually improves its tools and procedures to maximise the balance between the benefit for health and the animal well-being.

Vital statistics

No of offices	6 (ERBCx2 in France and Italy, Novaxia, Bioprim, Voxcan + Oncofactory)
Staff: group	>350

Service area breakdown



Global offices

- ERBC SAS - Chemin de Montifault, 18800 Baugy, France
- Laboratoire Novaxia SAS - 6 Rue des Champs Godin, 41220 Saint-Laurent-Nouan, France
- Oncofactory SAS - 43 Boulevard Du 11 Novembre 1918 LAtrium, 69100, Villeurbanne, France
- Voxcan - 1305, route Lozanne. 69380 Dommartin, France
- ERBC SrL - via Tito Speri 12/14, 00071 Pomezia (Rome)

Services provided

- Genetic, *in silico* and *in vitro* toxicology
- General toxicology, carcinogenicity
- Reproductive toxicology and juvenile toxicology
- Preclinical proof-of-concept and early safety
- Safety pharmacology and general pharmacology (*in vitro* and *in vivo*)
- Analytical support (PK/PD and metabolism, analytical chemistry, bio-analysis, immunology, histo-pathology)

Infrastructure and team

- Animal facilities: dedicated facilities for each species (rodents, non-rodents including dogs, minipigs and non-human primates) with surgical suites and histopathological laboratories
- Analytical laboratories (small and large molecules) for GLP and non-GLP analyses
- Secured data centre
- Project coordination, project management and alliance management
- Full study reporting including SEND
- Multi-disciplinary team of experts: toxicologists, pathologists, pharmacologists, biologists, pharmacists, chemists, veterinarians and engineers

ERBC is continually investing in highly trained scientists and state-of-the-art technologies. The company has also established, and continues to set up, strategic scientific and technological partnerships both with academia and life-science companies.

Corporate developments and achievements

1972	Foundation of Italian facilities (RTC)
1973	Foundation of French facilities (CERB)
1987	First GLP certification
2012	AAALAC accreditation
2014	Start of cooperation between CERB and RTC
2019	CERB acquires RTC: foundation of ERBC
2021	ERBC acquires Bioprim
2022	ERBC acquires Laboratoires Novaxia ERBC acquires Oncofactory
2023	ERBC acquires Voxcan

Accreditations

- AAALAC
- GLP
- FDA approved
- ISO 14001:2004
- BSOHSAS 18001:2007
- EcoVadis

Partners

We collaborate with partner laboratories for ecotoxicology, physicochemical 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

ERBC works hand in hand with academic and industrial partners during the early stages of drug development to demonstrate the pre-clinical proof-of-concept of a test compound, ultimately aiming to convert it into a drug candidate.

ERBC performs a range of *in vivo* assays and offers numerous animal models of human diseases covering almost all therapeutic areas.

At ERBC, we consider this initial step of *in vivo* proof-of-concept studies as essential to minimising the risks of late attrition during clinical trials, remembering that the lack of clinic efficacy is one of main causes of late attrition during drug development. ERBC offers the clear advantage to run these pivotal studies under Good Laboratory Practice (GLP).

Very often, the development of new chemical entities (NCE) must be stopped following abnormal toxicity, safety margin issues, mutagenicity, cardiovascular or neurological adverse effects. To detect these deleterious events as early as possible, ERBC conducts exploratory safety programmes combining *in vitro* and *in vivo* toxicity assays (in rodent and non-rodent species) and predictive biomarkers.

To optimise costs and timing, the administrative work is minimised as much as possible, the experimental procedures are described in standard study plans, and all details specific to each study will be described in an information study sheet.

Optimised costs are also achieved through a reduction of animal numbers while sensitivity is maintained by using low variability models, appropriate statistical designs (biostatisticians in the team) and the application of very powerful approaches such as the probabilistic method. In the same way, a summary report including the results of each test in each model, the interpretation of results and a description of the experimental methods are issued just after the end of the final experimental phase (less than two weeks after the last experimentation).

With more than 200 validated methods and models, a facilitated access to patient samples and a world class academic and industrial network, ERBC is uniquely positioned to establish the preclinical proof-of-concept of any therapies.

Thus, by performing in vitro functional assays and custom-designed assays and assessing the therapeutic effect of a test compound in relevant anima models, ERBC converts next-generation therapeutics into validated drug candidates across almost all therapeutic areas and indications (except infectious diseases).

In addition, the company also conducts exploratory programmes that allow early detection of deleterious adverse effect and toxicity induced by new chemical entities.

Together, these translational studies contribute to clarify the mechanism of action of a drug candidate and, obviously, improve risk-taking and decision making.

To establish the toxicological profile of new compounds, or to extend the known profiles of an existing one (new indications, new formulations, new routes of administration ...), ERBC offers a full range of services from exploratory programmes to fully GLP-compliant toxicology studies. The latter range from acute and chronic toxicity - with different species and multiple routes of administration - to specialty toxicology. These data support human clinical trials and marketing authorisation approval around the world.

Today, the company is a leading innovator in the discipline. ERBC scientists develop advanced tools, assays and models that contribute to a reduction in the use of animals and improve data predictivity and they participate in interdisciplinary working groups that shape the future of toxicology.

Staff selection

Pascal Champeroux

Chief Scientific Officer, Senior Expert in Pharmacology (cardiovascular) and Safety Pharmacology

Silvana Venturella

Test Facility Manager and General Manager, ERBC Italy and France

Alexandre Bidaut

Client Solutions Director, ERBC Group

Raafat Fares

Associate Scientific Director, In Vivo Toxicology

Rosaria Cicalese

Expert in Reproductive Toxicity Studies, Senior Study Director

Catherine Botteron

Associate Scientific Director, Senior Pathologist

Francesca Calfapietra

Head and Expert, Analytical Chemistry Department

Nathalie Mokrzycki

Head and Expert, Analytical Chemistry Department

Marie-Laure Sola

Alliance Manager

Daniela Gallo

Head of Toxicology

Pascal Clayette

Immunologist, Virologist

Françoise Horand

Alliance Manager

Contacts	
Website	eurofins.com
E-mail	reach@eurofins.com
Head office	Brussels, Belgium
Tel	+49 89 899 650 0
Contact	Iris Pfisterer
Directors	Gilles Martin, Chief Executive Officer
Ownership	Listed at French Stock Exchange
Locations	900+ locations worldwide
Founded	1987

Overview

With more than €6.5bn annual revenues in 2023 and over 62,000 staff in more than 900 laboratories across 62 countries*, Eurofins is a global leader in the pharmaceutical, food and environmental testing market, and offers an unparalleled range of testing and support services for the chemical, agrochemical, biocide and cosmetic product sectors through a global network of companies.

As one of the most innovative and quality-oriented international players in the industry, the Eurofins network 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 solutions provider, capable of providing a full suite of services for clients in the chemical industry, we perform the required research services for government regulatory approvals around the world.

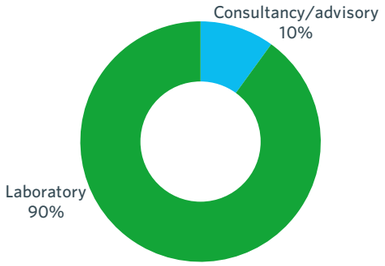
We connect global, multi-disciplined research capabilities with market-leading product expertise and technical support services to meet the regulatory needs of your business.

**reported in 2023*

Vital statistics 2022/23

Turnover: group	approx €6.5bn
No of offices	900+
No of countries represented	62
Staff: group	>62,000

Service area breakdown



Global offices

Eurofins, a global network of companies, has a presence in 61 countries. Our main testing facilities for chemical/REACH services are in Germany, UK, Asia, and the US.

Services provided

For the chemical, agrochemical, pharmaceutical, veterinary medicine, biocides, cosmetics and food industry, Eurofins offers a broad scope of biological safety studies, which meet international regulatory requirements and includes the following services:

Human safety assessment

Relevant toxicology services for chemicals, agrochemicals, biocides and novel food are carried out in collaboration with our AAALAC-accredited partner laboratories. This includes the classic studies from acute to repeated dose and teratogenicity studies. Emphasis is placed on *in vitro* testing with regard to the 3Rs strategy for refinement, replacement and reduction of animal studies. We have established a large range of *in vitro* assays for many endpoints.

Our services include:

- irritation/corrosion;
- sensitisation;
- dermal absorption;
- genetic toxicity;
- acute toxicity;
- repeated dose toxicity;
- reproductive and developmental toxicity (DART);
- toxicokinetics, ADME;
- carcinogenicity;
- neurotoxicity;
- endocrine disruptor testing; and
- mode of action studies.

Avian safety studies

With one of the largest and most respected avian safety laboratories in the world, we offer unparalleled skill in performing the full suite of acute and reproduction studies (radiolabelled and unlabelled) as well as custom-designed investigations in non-traditional species to meet client-specific needs.

Ecotoxicology and aquatoxicology testing

We offer the full suite of aquatic and terrestrial toxicology services required to assess the acute and chronic effects of chemicals on amphibians, earthworms, honeybees and select non-target insects, as well as freshwater and saltwater invertebrates and fish, in a GLP-compliant environment, and are capable of supporting a large number of concurrent studies. Our laboratories are uniquely equipped with temperature controlled custom-designed static, semi static and flow-through test systems. The test systems are designed to secure a high degree of precision and accuracy during the entire study.

Sediment toxicity and terrestrial plant testing

We provide 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.

Environmental fate and biodegradability testing

Our experts have unparalleled experience in the identification and quantification of the fate of test substances in soil, water and other complex environmental matrices, complemented by in-house radiolabelling and structural elucidation expertise. We offer biodegradation screening and testing (OECD 301, 310, 314, 303 etc.) and environmental fate testing (OECD 307, 308, 309, 106). All these studies can be performed, including metabolite identification.

Residue analysis

Providing unparalleled method development know-how in the challenging discipline of residue chemistry, Eurofins offers routine testing of a wide variety of sample types and their major metabolites under GLP, including method development and validation.

Radiolabelling and custom synthesis

We offer a full range of 14C custom radiolabelling services, the synthesis of unlabelled reference compounds (metabolites and impurities) and analytical chemistry services (including GLP certification if required).

Our expert chemists can prepare C-14 labelled molecules of almost any complexity and have a strong background supporting regulatory studies acquired over many years in the life science and chemical industries.

REACH services

Eurofins REACH services is comprised of a global network of Eurofins laboratories covering many fields of expertise.

This expert network provides the wide range of studies required to fulfil EU REACH requirements as well as other global regulations, based on the substance category. The suite of testing services begins with substance identification, moving on to physico-chemical properties and toxicological profiling, then on to assess impact on the environment through environmental fate and aquatic toxicology.

All services are tailored to your specific testing and regulatory needs, to ensure both accuracy and cost efficiency. We can support you with your complete registration requirements from the very beginning or based on additional demand/claim from ECHA for your existing registration.

Endocrine disruptor screening and testing

We have specific expertise in this field and offer the majority of anticipated studies related to endocrine disruptor screening and testing. We can provide histopathology services to evaluate the potential of chemicals to affect endocrine-sensitive tissues in fish, amphibians and frogs.

In vitro safety testing for chemicals and cosmetics

As a leader in safety testing without the use of animals, the Eurofins group of companies is deeply committed to the principles of the 3Rs of Replacement, Reduction and Refinement. With a set of alternative *in vitro* test methods, we are able to provide the full service to assess necessary toxicological data under GLP-compliance or not. For cosmetics, a complete service portfolio is provided, 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 many years of experience in regulatory studies, our experts offer advice not only for standard studies but also for individual study designs and testing strategies. All angles are considered; substance properties as well as the interdependency of many studies required.

A dedicated team of regulatory experts can support you through the agrochemical registration process, starting with data gap analysis through to dossier preparation as well as post submission support. For biocides, cosmetics and other chemicals, we offer regulatory consultancy expertise throughout the Eurofins group as well as through established external partners.

SVHC and restricted substances under REACH

Annex XVII 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.

SVHC testing on articles: 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, NMR, UV-vis, IR etc.), 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 (Bill of Materials) and BOS (Bill of Substances) assessment: We can help to manage and monitor your supply chain by helping to collect BOM/BOS from your suppliers. This information is essential in the process of controlling the occurrence of any SVHC through your supply chain. Based on the provided information, our experts can help to assess your product and evaluate the likelihood of it 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.

SCIP notification: SCIP is the database for information of substances of concern in articles as such or in complex objects (products), established under the Waste Framework Directive (WFD). Articles containing substances of very high concern (SVHC) on the Candidate List at a concentration above 0.1% (w/w) and placed on the EU market must be notified to ECHA via SCIP database. Eurofins can help manufacturers/producers, suppliers, importers and/or distributors with SCIP notification procedures as well as providing an automated SCIP submission solution.

Corporate developments and achievements

1987	Foundation of Eurofins Scientific Continuous growth and acquisitions
1997	IPO on the French Stock Exchange
2008-2009	Establishment of Eurofins REACH Services
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, medical device industry, pharmaceutical/biotech industry, personal care products and veterinary medicine.

Staff selection

Dr Helge Gehrke – Head of in vitro Pharmacology and Toxicology, Munich, Germany

Dr Gehrke has more than 10 years' experience working in scientific institutes and the contract research industry and drives the development of new in vitro assays within Eurofins.

David Carver – Synthesis, London, UK

David has more than 25 years' experience in the life-sciences industry and supports our clients with advice on 14C labelling and synthesis strategies for Eurofins Selcia.

Maja Willutzki – Scientific Coordinator REACH, Niefern, Germany

Maja has been with Eurofins since 2020 and is responsible for coordination of different REACH studies as well as analysing analytical chemistry studies.

fieldfisher

Contacts	
Website	fieldfisher.com
E-mail	claudio.mereu@fieldfisher.com koen.vanmaldegem@fieldfisher.com peter.sellar@fieldfisher.com gerard.mcelwee@fieldfisher.com
Head office	L'Arsenal, Boulevard Louis Schmidtlaan 29, Box 15,1040 Brussels, Belgium
Tel	+32 2 742 70 00
Contact	Claudio Mereu, Partner, Koen Van Maldegem, Partner, Peter Sellar, Partner, Gerard McElwee, Partner
Directors	Claudio Mereu, Partner, Koen Van Maldegem, Partner, Peter Sellar, Partner, Gerard McElwee, Partner
Ownership	Limited liability partnership
Locations	Netherlands (1), Spain (2), UK (5), Ireland (1), Italy (5), Germany (5), China (3), Belgium (1), Luxembourg (1), France (1), United States (1), Austria (1)
Founded	1835

Overview

Fieldfisher is a full-service European law firm with a network that spans more than 1,800 people across 26 international offices (in 12 countries). The EU Regulatory Group based in Brussels advises international clients on EU and national laws regarding the placing on the market of chemicals. It combines advisory advocacy consortia management and litigation work, thereby constituting the "go-to firm" for product defence in the EU.

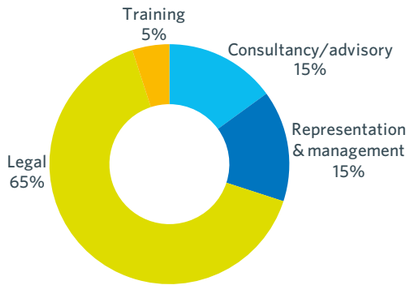
Our lawyers advise and represent clients on large and complex multijurisdictional matters arising out of a variety of EU products legislation, including chemicals (REACH), pesticides, biocides, cosmetics, medical devices, general product safety and eco-design requirements and, more broadly, EU environmental and market-access legislation. We address related data protection, competition and other business law issues that arise when, for example, drafting and negotiating commercial agreements or setting up and running REACH consortia and task forces.

We represent clients before the European institutions, member state authorities, scientific committees, ECHA Board of Appeal, and the European and national courts.

Vital statistics 2022/23

No of offices	26
No of countries represented	12
Staff: group	1800
Staff: chemical service provision	28

Service area breakdown



Services provided

Chemicals

We have more than 25 years' experience in EU chemical law. We provide a broad spectrum of chemicals-related advice and deal with the most significant REACH implementation and compliance issues relevant for companies or for groups of companies (industry associations, task forces or consortia). We provide support to more than 30 REACH Consortia and/or Lead Registrants, including calculation of letters of access, SVHC listing, authorisation and restriction issues, including challenges before ECHA Board of Appeal and the EU Courts.

We advise clients in the field of product regulation, on issues pertaining to the classification, packaging, and labelling of chemical substances and preparations, safety data sheets, marketing and use restrictions, authorisation and restrictions, chemicals grouping, workplace regulations, and product safety/liability related issues, as well as questions relating to the free movement of goods and parallel imports.

Agrochemicals/fertilisers/biostimulants

We advise international agrochemical companies on the European approval/renewal programme laid down under Regulation 1107/2009 as well as follow-up re-registration activity.

In this context, we provide legal assistance on a variety of issues, ranging from the formation of task forces, submission of dossiers, to follow up product registration issues, including zonal applications and mutual recognition across jurisdictions, as well as related negotiations and litigation before the EU and national courts.

We address these issues at both an EU-wide and member state level and are particularly active in challenging regulatory restrictions and negotiating data compensation agreements during the re-registration process, including relevant arbitration proceedings in several EU countries. We have negotiated many data sharing/compensation agreements and successfully handled arbitration and litigation cases in various EU countries relating to data access.

Biocides

We provide legal advice on data protection, data sharing, dossier submission and evaluation, regulatory requirements under the Biocidal Products Regulation (BPR) and we have set up and manage many taskforces. Our expertise also covers the overlap with other legislation, such as the REACH Regulation and legislation on medicinal products, cosmetics or medical devices.

We offer expert advice on the national member state regulations of biocidal active substances/product type combinations during the review programme and provide support in making biocidal product authorisation applications. We advise on data sharing/compensation agreements, as such or in the context of distribution/purchasing or other arrangements.

We have an in-depth knowledge of the free-rider and EU competition law issues at stake. We guide several active substance/product type combinations through the EU review programme for existing active substances.

We communicate with EU and member state institutions on our clients' behalf before legislation is adopted and, when necessary, represent their interests in related litigation before the European Courts and the courts of the member states.

Testimonials

2023 – Legal 500

Brilliant professionals. The support provided by Peter Sellar was excellent and superb. *Legal 500, 2023, EU Regulatory: Chemicals – Tier 1.*

Excellent knowledge and skills in multiple chemical regulatory sectors; very successful performance and high success rates; straight forward approach versus realistic and achievable goals; strong positive reputation at all levels like industry, national and European regulatory authorities, ECHA, EU COMM and many others.' *Legal 500, 2023, EU Regulatory: Chemicals – Tier 1.*

Exceptional depth in REACH and chemical regulatory law and procedure. *Legal 500, 2023, EU Regulatory: Chemicals – Tier 1.*

Claudio Mereu is widely regarded as a top chemical regulatory lawyer in Brussels. His depth of knowledge and experience in REACH is encyclopedic. Yet he is accessible and gives practical advice. *Legal 500, 2023, EU Regulatory: Chemicals – Tier 1.*

The FF team is extremely specialised in the review of chemical issues. It is a sector which is very technical and requires a strong understanding of scientific evaluations. It is not something that can easily be mastered. You need years of expertise. In this sense, once you have a deep expertise of the chemical industry, it is impossible to match.'*Legal 500, 2023, EU Regulatory: Chemicals – Tier 1.*

2023 – Chambers

They are always at the forefront of anticipating change in regulatory frameworks. *Chambers Europe-wide, 2023, Regulatory: Environment – Band 1.*

Fieldfisher provides clear responses written in such a way that people who are not legal based can understand. *Chambers Europe-wide, 2023, Regulatory: Environment – Band 1.*

Claudio Mereu is very specialised and can quickly understand the key issues and their potential commercial impact. *Chambers Europe-wide, 2023, Regulatory: Environment – Band 1.*

2022

Fieldfisher has an excellent team of lawyers highly experienced in advice and litigation in the field of EU regulations applicable to chemicals. They therefore understand the regulations and the chemical industry in much greater depth. *Legal 500, 2022, EU Regulatory: Chemicals – Tier 1.*

We had the pleasure to work with Peter Sellar, skilled, professional, available, and providing outstanding insight on our topics of interest. *Legal 500,2022, EU Regulatory: Chemicals – Tier 1.*

Claudio Mereu is a key legal expert who also possesses a good understanding of the often complex scientific issues at hand. *Chambers Europe-wide, 2022, Regulatory and public affairs: Environment – Band 1.*

2021

According to one of its clients, Fieldfisher is 'a one-stop shop for chemical companies navigating the complex field of EU regulation of chemicals and substances. They have unsurpassed depth and breadth of knowledge'. *Legal 500,2021, EU Regulatory: Chemicals – Tier 1.*

Claudio Mereu is the top of EU regulatory legal practice. He has personal unparalleled depth and breadth of experience on almost every issue facing the industry. *Legal 500,2021, EU Regulatory: Chemicals – Tier 1.*

Koen Van Maldegem, easily the most knowledgeable lawyer in the world in the EU Biocides sector. *Legal 500, 2021, EU Regulatory: Chemicals – Tier 1.*

Gerard McElwee, a highly capable and talented lawyer who brings humility, pragmatism, and common sense to any issue. *Legal 500,2021, EU Regulatory: Chemicals – Tier 1.*

They understand the technicalities and the scientific part. If you want chemical law advice, they're brilliant. *Chambers Europe-wide, 2021, Regulatory and public affairs; Environment – Band 1.*

Corporate developments and achievements

2007	Fieldfisher's office and EU Regulatory practice established in Brussels
2010	Interim Order from the President of the EU General Court won to suspend an ECHA decision regarding the REACH candidate list – the first of its kind
2011	First ever appeal filed before the ECHA Board of Appeal; successfully obtaining reversal of the ECHA decision
2012-2015	Groundbreaking annulment actions filed before the European General Court against Commission regulations adopted under REACH
2016-2023	Management of about 45 consortia under REACH, BPR and pesticides renewals

Clients

Major chemical/pesticides/biocides, medical devices and pharma companies, small innovative companies. Industry associations, task forces and consortia (more than 15 years' experience in consortia and task force management).

Case study 1

Centro REACH S.r.l. – Case A-005-2019

Fieldfisher successfully represented a group of nine companies in an appeal before the Board of Appeal of ECHA (BoA), as part of a data sharing dispute involving REACH & Colours Kft. The appeal concerned a decision by ECHA finding that our clients would have not made every effort in order to proceed with data sharing negotiations of vertebrate studies. In particular, the dispute revolved around the concept of sameness of substances and whether such concept is a mandatory prerequisite to start data sharing negotiations pursuant to the REACH Regulation.

On 15 December 2020, the BoA annulled the ECHA decision, rejecting an application by the appellants to refer to the vertebrate studies contained in the registration dossiers for numerous dyes.

Case study 2

Sharda vs BASF – Case A-006-2019

Fieldfisher successfully represented Sharda in a data sharing appeal before ECHA's BoA (A-007-2016). The BoA had ordered ECHA to grant access to the studies property of another company to our client, but ECHA decided to reassess the efforts made by the parties in the data sharing negotiations and concluded that Sharda should not be granted access as it did not make "every effort". As this conclusion and the reasons of ECHA were diametrically opposite to the first decision, we represented Sharda in a second appeal before the BoA.

On 17 November 2020, the BoA annulled ECHA's decision thereby allowing Sharda to refer to studies concerning the active substance alpha-cypermethrin, owned by BASF.

Case study 3

Solvay Solutions UK Limited vs. Dow Benelux BV – Case A-009-2019

Fieldfisher successfully represented Solvay Solutions UK in an appeal before ECHA's BoA, in relation to an ECHA decision granting Dow Benelux permission to refer to studies owned by the appellant concerning the active substance THPS.

On 7 March 2018, the BoA accepted a first appeal against ECHA's decision (Case A-014-2016) on the grounds that ECHA had failed to consider Dow Benelux's non-compliance with the contractual clause agreed between the parties to make data sharing subject to the establishment of chemical similarity between their sources. The BoA annulled the decision and referred the case back to ECHA.

On 6 May 2019, ECHA again granted Dow Benelux permission to refer to the studies. The appellant contested this second decision on seven grounds, including ECHA's breach of the appellant's right of defence by failing to hear the appellant before adoption of the contested decision. On 3 November 2020, the BoA annulled ECHA's decision, deciding that none of the criteria had been fulfilled.

Staff selection

Claudio Mereu – EU Regulatory Partner.

Koen Van Maldegem – EU Regulatory Partner.

Peter Sellar – EU Regulatory Partner.

Gerard McElwee – EU Regulatory Partner.

Contacts	
Website	fobig.com
E-mail	info@fobig.de
Head office	KlarastraBe 63, 79106 Freiburg i Br, Germany
Tel	+49 761 386080, +49 761 3860820 (fax)
Contact	Jan Oltmanns
Directors	Jan Oltmanns, General Manager
Ownership	Private company
Locations	Germany
Founded	1992

Overview

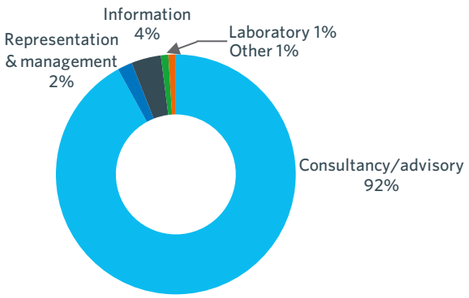
FoBiG is a privately owned consultancy specialising in toxicological and ecotoxicological risk assessment, with more than 30 years' experience in exposure assessment and risk characterisation. FoBiG's REACH experience dates back to 2001, participating in Cefic- and VCI-sponsored projects. FoBiG has successfully prepared numerous registration dossiers for phase-in and new substances and is currently engaged in updates of registration dossiers for several industry clients.

We have extensive experience in authorisation under REACH. FoBiG successfully prepared many authorisation dossiers for threshold and non-threshold Annex XIV substances and is continuously involved in authorisation projects, including many review reports. Further projects deal with providing support such as for substances targeted by ECHA dossier evaluations.

Vital statistics 2022/23

Turnover: group	€1m
Turnover: chemical service provision	€1m
No of offices	1
No of countries represented	Europe-wide
Staff: group	14
Staff: chemical service provision	11

Service area breakdown



Services provided

REACH registration

FoBiG offers full-scale scientific support to meet industry's REACH obligations:

- IUCLID 6 files (including literature searches, data gap analysis, evaluation of data reliability, application of read-across and category approaches and inquiry dossiers for new substances) covering 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).

FoBiG has prepared registration dossiers for hundreds of substances/categories for small and large companies and continues to support the chemical industry (updates and registration of new substances).

REACH authorisation

Together with our partner RPA Ltd, FoBiG prepares complete dossiers for submitting applications for authorisation with:

- CSRs according to authorisation requirements, including a refined exposure assessment to demonstrate implementation of suitable RMMs/OCs and acceptable remaining risks;
- analysis of alternatives (including substitution plan);
- socio-economic analysis;
- support for communication with ECHA during the process; and
- post-submission services (eg communication with ECHA and RAC/SEAC on submitted dossiers, trialogue meetings).

FoBiG has prepared initial applications for authorisations as well as review reports for about 20 substances and numerous uses for single companies, small and large consortia, including the large Aerospace and Defence Chromates Re-authorisation (ADCR) Consortium. The substances covered possess different properties (organic, inorganic, volatiles and non-volatiles) and represent different hazards (see case study 2 below).

In many applications, the exposure assessment is the most critical part of the risk assessment. Based on our extensive experience with exposure assessment specifically in the context of applications for authorisation, FoBiG provides support in the design and execution of monitoring campaigns and cooperates with accredited laboratories.

FoBiG drafted the first authorisation review report CSR granted a review period of 12 years.

REACH dossier and substance evaluation and restrictions

FoBiG provides scientific support to companies for substances targeted in dossier and substance evaluations or affected by restriction proposals. Services include problem analysis, dossier refinement and communication with competent authorities/committees. Substance and dossier evaluation decisions often require performance of new studies.

FoBiG provides support in comparing quotes from CROs and acts as study monitor for all kind of studies (physico-chemical endpoints, environmental fate and ecotoxicity and toxicity studies).

Biocidal product authorisation

FoBiG offers full-scale services for authorising biocidal products according to the Biocidal Products Regulation (BPR) scheme, including data gap analysis, preparation of the IUCLID-based dossier and communication with authorities.

FoBiG provides ample experience, for example, on authorising disinfection products and biocidal products with in situ-generated active substances.

Pharmaceuticals and medical devices

Scientific services for pharmaceutical companies and for manufacture of medical devices include:

- derivation of PDE (permitted daily exposure) according to EMA guidelines for residual substances (for example, for use in cleaning validation); and
- assessment of impurities, including application of TTC (threshold of toxicological concern) approaches.

Occupational toxicology

(Company-specific) occupational exposure limits (OELs) for threshold and non-threshold substances (the latter based on an analysis of exposure-risk relationships) support companies in their internal occupational safety and health evaluations. In various projects, FoBiG analysed the methodology to derive OELs and investigated possibilities for improvements, eg by using dose-response modelling and probabilistic approaches to hazard assessment.

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 and achievements

1986	Founded as personal company by Fritz Kalberlah
1992	Reorganised as private company with partners Fritz Kalberlah, Klaus Schneider, Martin Hassauer
2009	New company partner Jan Oltmanns
2018	Fritz Kalberlah and Martin Hassauer retired, Ulrike Schuhmacher-Wolz, Karin Heine, Eva Kaiser and Markus Schwarz entered as company partners

Partners

FoBiG established a successful partnership with RPA Ltd for REACH authorisation projects, providing full-scale services for preparing applications for authorisation. FoBiG cooperates with accredited laboratories, eg for workplace measurements (including biomonitoring), wastewater monitoring or migration studies.

Clients

Chemical and pharmaceutical companies (from multinational to small- and medium-sized). EU institutions (eg EFSA, several European Commission Directorates General). National and other authorities (eg BfR, BAuA, UBA, RIVM). Stakeholder organisations (eg VCI, trade unions).

Case study 1

PMT/vPvM and PBT/vPvM assessment

Commission Delegated Regulation (EU) 2023/707 introduced new hazard classes into the CLP Regulation. In addition to the new hazard classes for endocrine disruption, chemicals will require classification for PBT/vPvB and PMT/vPvM properties. While a PBT/vPvB assessment is required for many chemicals already under REACH, assessing PMT/vPvM properties is a new element for which guidance is not yet available. Furthermore, classification for these properties is also required for substances at low tonnages, for which a PBT assessment is not required under REACH and for which relevant experimental data may be missing.

FoBiG supports companies in developing approaches to address these properties with our broad experience in environmental fate assessments of chemicals. Specifically for mobility, different QSAR models may estimate log Koc as a key determinant, but applicability of the models for the specific chemical must be discussed in detail. For example, some QSAR models are not suitable for ionisable substances and generation of experimental data may be needed in some cases. With respect to bioaccumulation, a stronger focus on bioaccumulation in air-breathing animals is expected in the future, which may necessitate WoE approaches using different data for substances with high log Koa values. With increasing documentation requirements for WoE approaches since ECHA's 2023 provisions, addressing bioaccumulation in air-breathing animals may involve substantial work. Therefore, a refined persistence assessment may be the first choice for some substances, since it is relevant for both new hazard classes and development of a biodegradation testing strategy may constitute the most efficient way of addressing these new hazard classes.

Case study 2

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;
- documentation of implementation of suitable measures to reduce emission and exposure; and
- refinement of the exposure assessment to derive realistic exposure estimates to demonstrate minimisation of risks and to conclude on low remaining risks associated with the use for which authorisation is sought.

Experience from authorisation projects clearly shows that CSRs need to provide detailed descriptions of technical processes, RMMs and conditions of use. CSRs should generally include measured data (eg air and/or bio-monitoring measurements), which may be supported by higher tier modelling (eg by ART and RISKOFDERM), for successful applications. In addition to workers exposure characterisation, assessment of human exposure via the environment is essential for authorisation CSRs. In this context, realistic release estimates (eg based on measured data) and a critical appraisal of modelled exposures (eg recognising the limitations of EUSES) are key to a robust exposure assessment.

New challenges for authorisation come with the increased Annex XIV listing of PBT/vPvB substances and endocrine disrupting chemicals (EDC), for which no established assessment methodology exists. FoBiG developed suitable assessment strategies for these types of substances to inform the CSR/SEA interface. Therefore, FoBiG provides profound experience for all kind of authorisation endpoints (carcinogenicity, reproductive toxicity, PBT/vPvB properties, EDCs).

Case study 3

Dossier and substance evaluation: refinement of CSR and supply chain information

ECHA has increased the numbers and the scope of dossier evaluations from 2019 onwards, i.e. more and more substances are targeted by such evaluations. Updates of various parts of registration dossiers (regarding data requirements, exposure assessment, risk characterisation) might therefore become necessary. Requirements for additional studies are often based on ECHA's rejection of category approaches, which then need to be improved to comply with ECHA's requirements.

With regard to substance evaluation, companies with CORAP-listed substances should adopt a proactive position, communicate with the evaluating competent authority (CA), and try to reduce existing concerns.

FoBiG supports companies by providing study monitoring services, working on dossier updates and communicating with ECHA and CAs.

Staff selection

Klaus Schneider, PhD, DABT

Key areas: toxicological risk assessment, method development.

Jan Oltmanns, MSc, PgDip

Key areas: exposure assessment (workers, consumers, environment).

Ulrike Schuhmacher-Wolz, PhD, ERT, Fachtoxikologin DGPT

Key areas: reproductive toxicology and endocrine disruptors.

Karin Heine, PhD, ERT, Fachtoxikologin DGPT

Key areas: in vitro toxicology, computational toxicology, read-across.

Markus Schwarz, PhD, Fachökotoxikologe (GdCh/SETAC)

Key areas: environmental fate modelling and ecotoxicology.

Eva Kaiser, PhD

Key areas: hazard assessment, C&L, dose-response modelling.

Melanie Macherey, PhD

Key areas: environmental fate modelling and ecotoxicology.

Anne Bierwisch, PhD

Key areas: toxicological risk assessment, C&L.

Contacts	
Website	gbk-ingelheim.com
E-mail	gbk@gbk-ingelheim.de
Head office	Koenigsberger Strasse 29, 55218 Ingelheim, Germany
Tel	+49 6132 98 290 0, +49 6132 84685 (fax)
Contact	Ulrich Mann
Directors	Thomas Jost
Ownership	Private company
Locations	Germany and China
Founded	1986

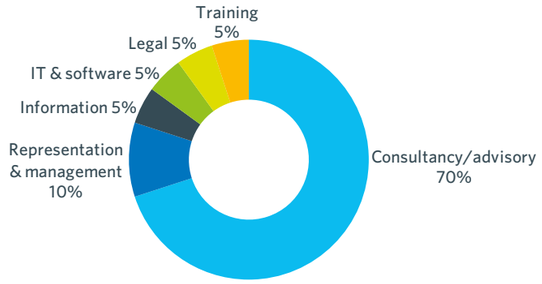
Overview

The GBK GmbH Global Regulatory Compliance is an international consulting company and full-service provider around the themes of environment, health and safety. Services include product registration in chemicals inventories in Europe, the US and Asia and the GBK-EMTEL® Emergency number for global transport of dangerous goods.

Vital statistics 2022/23

No of offices	3
No of countries represented	2
Staff: group	37
Staff: chemical service provision	20

Service area breakdown



Global offices

GBK GmbH headquarters based in Ingelheim, Germany.

GBK China Co Ltd in Shanghai, China.

Services provided

EMTEL® emergency telephone number

An emergency telephone number for dangerous goods transportation is mandatory in numerous countries including the US and Canada, and it is required by many air carriers (IATA). According to regulation 1907/2006/EC, this emergency number must be included on any safety data sheet. GBK's EMTEL® offers 24/7 immediate telephone assistance if problems occur during transport or handling of dangerous goods/hazardous materials. This comprehensive service ensures assistance in cases of spillage, fire or contamination, and medical advice for toxicological incidents.

Our EMTEL® service

- 24/7 access to a professional emergency call centre
- Emergency telephone number in 190 languages
- Fulfillment of your legal obligations
- Realisation of all airline and shipping company requirements
- Medical advice in case of poisoning
- Additional waste management service in the US
- Fulfilment of regional requirements for an emergency service
- Comprehensive support in case of accidents with chemicals

Your benefits

- You provide us with the required information and we will take care of the rest
- We take on your legal responsibilities
- You assume the responsibility to an external service provider
- It is valid for all deliveries to any destination worldwide

International EHS consulting/PCN notification

We help you with all issues around REACH, GHS, product registration and authoring of safety data sheets. Article 45 of the classification, labelling and packaging (CLP) regulation introduces European wide product registers. We can create the dossiers and complete the poison centre notifications (PCN) via the ECHA portal for you.

We guide you through the maze of laws and perform product registrations in chemical inventories in Europe, the US, Asia (Japan, China, Korea, Philippines) and Australia. We assume all duties associated with registration, including with regard to labelling and safety data sheets (SDS).

REACH services

- Substance/product registration in Europe, US, Japan, China, Korea, Turkey and Australia (other countries on request)
- Consulting services in connection with the registration

Your benefits

- Compliance together with reduced costs
- Legal responsibilities met by an external adviser
- Service with more than 30 years of professional experience
- Excellent price/performance ratio

Dangerous goods safety advisor/dangerous goods services

Because major accidents can occur during the transport of dangerous goods, Germany implemented a responsible person – the safety advisor – in each legal entity who takes over the responsibility for all issues concerning the transportation of dangerous goods. Safety advisers quickly became a success story. After its beginnings in Germany in 1989, the European Union then adopted this important role in the Safety Adviser Directive 96/35/EEC on 3 June 1996.

Since 2001, safety advisers have been mandatory in all member States that are signatories to the agreements on International Carriage of Dangerous Goods by Road (ADR) and International Carriage of Dangerous Goods by Rail (RID). All relevant training programmes have been surpassed in the US. The directive offers the option of transferring this activity to an external expert.

Service specification

- Taking over the responsibility of safety adviser for all modes of transport (road, rail, barge, sea)
- Classification/labelling of substances and preparations including evaluation of suitable packaging
- Ongoing consultation for your organisation
- Development of process-oriented checklists
- Regular training to ensure your employees always act in compliance with all applicable regulations
- Periodical audits guarantee to detect possible weak areas
- Providing IATA/DOT/IMDG compliance 24/7

Your benefits

- We take on your legal responsibilities
- Reduction of internal fixed costs
- Fully experienced advisers offering high quality services
- Legal and organisational consulting regarding EHS
- Fast and reliable responses adapted to your needs

Training, seminars and GBK online training

We offer a wide range of training and seminars, conducted by our worldwide experts. GBK GmbH is established in the market as an important and well-known company. An essential element is the organisation of instruction, training and conferences in the areas of chemicals, legislation, handling of hazardous materials and the transport of dangerous goods. A wide range of training courses are offered by experts from all over the world. All trainers are experienced professionals in their field providing state-of-the art training. For this reason many companies rely on the competence and high quality of our courses and seminars.

Some training courses (examples)

- Asian-Pacific and Chinese chemical legislation
- United States and Canadian hazard communication
- MSDS/SDS Authoring expert training
- Training for dangerous goods safety advisers
- Dangerous goods training

GBK Trusted Partner GmbH/TP1 – guideline for hazardous materials transportation

Process optimisation by switching to electronic transport documents for dangerous goods transport. In order to be able to use the electronic transport document, a guideline published in 2021 must be followed. The design guidelines from 2015 will finally have had their day in January 2023.

Subsection 5.4.0.2 RID/ADR/ADN allows the use of electronic data exchange to meet the documentation requirements of Chapter 5.4. The principle of the process described in this guide is based on three parties. The Trusted Party 1 (TP1) is the interface enabling data exchange of electronic transport document when transporting dangerous goods. The Trusted Party 2 (TP2) provides all relevant details regarding dangerous goods in the transport document (eg in the event of an inspection by the authorities or in the event of an emergency).

Significant cost savings and future-proof innovation, data security and data protection, among other things, through encryption on the server using state of the art technology. For all companies transporting dangerous goods this guideline is a great opportunity to optimise your process and to save costs.

Our GBK experts will help you to recognise this and integrate our GBK-TP1 portal into your daily process of transport of dangerous goods.

Your benefits

- Clearly reducing operating costs through optimising and completely switching the process to electronic document management, also now for dangerous goods
- Future readiness and innovation: this national step by step introduction is already a part of the European Union-wide and international targeted solution for the usage of electronic transport documents
- The data protection and encryption of transport documents on the TP-1 server is based on the latest technology

Corporate developments and achievements

1986	Foundation, Ingelheim, Germany
2008	Acquisition of GBK by Bjorn Noll and winner "German dangerous goods Award 2008"
2010	Co-founder of Compliance Footprint AG, Zurich
2012	Moves into the new GBK company building in Ingelheim
2017	Opening of GBK China Corp Ltd In Shanghai
2021	Takeover of Gefahrgut – Umweltschutz C. Giefer GmbH & Co KG
2022	Co-founder of GBK Trusted Partner GmbH

Accreditations

ISO 9001.

Partners

NRCC, CIRS, GIZ, BMZ, BVMW, CFP, IKW, VCI, VDSI, VCH, BGI, DLSV.

Furthermore, we can offer our customers global support via our network of collaboration partners, including governmental institutions and local regulatory specialists.

Clients

Our more than 1,450 customers include both medium-sized companies from the chemical industry and 73% of all German DAX-listed companies particularly in the fields of chemicals, pharmaceuticals and automotive.

Case studies

Based on our customer base, from different industries and verticals, we can offer a wide range of case studies that match your business or that are at least comparable. Further details available upon request.

Staff selection

Ulrich Mann – member of the senior management team

Ulrich Mann is a lawyer and specialist solicitor for transport-/logistic-law and within GBK, a member of the senior management team. He is responsible for consulting with companies dealing with hazardous materials

Since 1988 Mr Mann has been engaged with dangerous goods issues, as well as with chemicals legislation and has worked for companies such as Infraserv GmbH & Co. Hoechst KG and Infraserv Logistics GmbH, where he spent many years during his professional career.

Thomas Jost – Managing Director

Since May 2020, managing director of GBK GmbH in Ingelheim. The certified dangerous goods officer has extensive knowledge of new substances and product registrations, as well as the entire PCN notification process within the EU.

GBK team worldwide

The highly motivated, educated and experienced GBK team will provide you with excellent services and is dedicated to meeting your individual needs with a high level of quality and flexibility.

Our colleagues with degrees in different sciences are engineers or doctors in chemistry, law and further EHS fields. They can offer you our services in German, English and Chinese.

Landbell H2 Compliance

Contacts	
Website	h2compliance.com
E-mail	info@h2compliance.com
Head office	Unit 14D Nutgrove Office, Park Rathfarnham, Ireland
Contact	Kevin Hoban
Directors	Kevin Hoban, John Hayes, Grant Kinsman
Ownership	Part of the Landbell group of companies
Locations	11 (Chemical)
Founded	2006

Overview

H2 Compliance is a full-service chemical and environmental consulting firm dedicated to successfully introducing our customers' products onto global markets. We help our clients ensure compliance and market access by applying our breadth of knowledge to the business complexities related to REACH, UK REACH and REACH-like programmes, product stewardship, GHS implementation worldwide (SDS and labelling), PCN with the help of element1™ chemical management software.

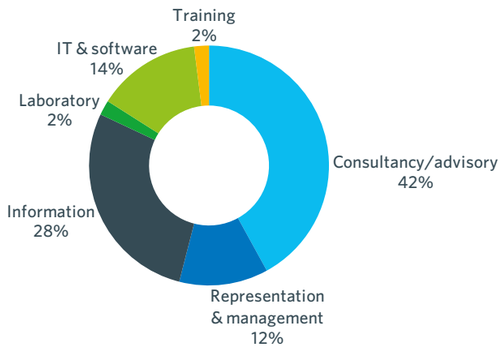
H2 Compliance has a global footprint with offices across Europe and the US and with a network of trusted in-country partners to assist in providing global support to our clients.

Being part of the Landbell Group expands our services into the environmental compliance and circular economy covering waste electronics (WEEE), batteries, packaging, and take back programmes.

Vital statistics 2022/23

Turnover: group	>€400m
No of offices	23
No of countries represented	18
Staff: group	350+
Staff: chemical service provision	45+

Service area breakdown



Global offices

Ireland (Cork and Dublin); **US** (Washington, DC and Michigan); **Poland** (Warsaw and Lodz); **UK** (London and Belfast); **Finland** (Helsinki); **Netherlands** (Amsterdam); **India** (Mumbai).

Services provided

REACH registration and dossier management

H2 Compliance provides a full range of lead, member, and intermediate REACH registration services. Besides building and submitting substance dossiers, we help determine alternatives and costs, oversee testing, and offer full project management to completion, as well as updates and additional support with REACH requirements.

Only representative service

Supporting numerous manufacturers and formulators in fulfilling the duties on behalf of their importers in another jurisdiction with our OR services in the EU, the UK, and through partners – in Turkey and South Korea. Our comprehensive service relies on deep knowledge and appreciation of complex supply chains, technical execution, financial management and communication with clients and their customers.

Stewardship, substances of concern and supply chain compliance

Substances of very high concern (SVHCs) and chemicals under restriction and authorisation are a potential business risk requiring early assessment and appropriate action.

H2 Compliance assists companies with building sustainable chemical management programmes that proactively address the growing list of regulatory and market requirements and supports companies in planning for the future. We utilise our proprietary element1™ substance tracking platform to review substances in our client's inventory and analyse which are, or may be, subject to regulatory measures, and advise on a plan of action.

UK REACH

With the UK's withdrawal from the EU, companies face a parallel set of REACH-like activities to remain on the market. H2 Compliance, with its UK legal entity, helps producers, importers, and downstream users navigate the complexities this presents.

Hazard communication: SDS, labelling, online sales

We author Safety Data Sheets (SDS) and review label contents for the EU and globally. With our toxicological, industrial hygiene and regulatory knowledge, we build and maintain hazard communication programmes for our clients and their specific product portfolios and offer technical solutions for supply chain communication. We provide comprehensive hazard communication support tailored to online sellers and marketplaces.

Notifications: PCN, C&L, SCIP

H2 Compliance helps companies determine and meet their EU notification obligations that are central to the safe management of chemicals:

- poison centre notifications (PCN) for hazardous mixtures;
- C&L notifications for hazardous substances; and
- substances of concern in products (SCIP) notifications for SVHCs present in articles.

Our customisable software platform enables submission and ongoing maintenance of notifications over time.

Regulatory strategies and market access assessments

We evaluate new substances, products, and target markets to produce a regulatory strategy and market access assessment to help clients scale-up production and get the products to market across the world.

Global compliance

We determine clients' obligations within existing supply chains as well as for new products placed on the market globally. We ensure timely execution of requirements and facilitate reusing clients' REACH assets and investments in non-EU jurisdictions, with particularly strong experience in South Korea, China, Japan, Switzerland, and Turkey.

Cosmetics

We offer full range of services to help clients comply with the Cosmetics Regulation:

- acting as the Responsible Person in EU/UK;
- providing toxicological profiles and Cosmetic Safety Reports;
- notifying cosmetics to the EU/ UK portals; and
- compilation and safe storage of Product Information Files (PIFs) using our element2 software.

Regulatory and extended producer responsibility (EPR) tracking

H2 Compliance tracks chemicals control regulations in over 45 countries providing regular overviews and expert analysis to the clients via our element1™ platform. We also prepare targeted assessments on how various regulations and their changes impact client's specific portfolios and supply chains.

As part of the Landbell Group, we have a comprehensive set of data on EPR as a regulatory tracking service for waste electronics (WEEE), batteries and packaging obligations for global markets.

element1™ software

element1™ is one of the leading platforms for managing chemical regulatory compliance, provided as a SaaS model. It offers managing chemical portfolios at substance and product levels, a secure private cloud platform, direct submission to regulators, advanced user management, and fully configurable workflows tailored to your organisation's needs.

element1™ platform supports the delivery of REACH and REACH-like compliance services, global supply chain compliance, tracking substances of concern, and meeting hazard classification and labelling obligations. It specifically supports dossier and tonnage management, supplier compliance, PCN and SCIP notifications, and similar duties in other jurisdictions.

Backed by a team of chemical stewardship experts, element1™ is your one-stop-shop for executing chemical and product compliance programmes globally.

Corporate developments and achievements

2006	Company established, Dublin office opened
2009	US activities and legal entity established
2016	H2 Compliance acquired by The Landbell Group, Germany
2017	Poland office opened to lead hazard communications services
2018	UK legal entity established to lead UK services
2022	North American services expanded
2023	Global compliance services expanded

Accreditations

Approved REACH Ready Gold Member. Director acting Vice President of Only Representative Organisation. Co-sponsor of the Green Alley Circular Economy Awards. Certified Professional Product Steward® (US).

Clients

Core clients are from the pharmaceutical, medical devices, petrochemicals, polymers, metals, and fragrances sectors. We support over 4,000 downstream users within the clients' supply chains, and some 30,000 within our Landbell Group family.

Testimonials

Stewardship services

"H2 Compliance was carefully selected to allow us to continue to meet the changing needs of our new and existing client base. We based decisions on their ability to provide all required regulatory support within one compliance organisation. With their assistance we have successfully met the REACH and SDS deadlines without issue. I have found the team to be highly flexible with our deadlines, effective with providing accurate information, and most importantly, focused on our needs." *Michael Goluszka, La-Go Industries, US.*

Dossier services

"H2 Compliance supported us for the construction of lead dossiers; which were submitted on time and to budget. The company bring a wealth of experience to this technical area and have a high quality of communication and project management. We have always found communications to have due regard for the confidential nature of the relationships within the consortia environment. We have found the relationship with H2 Compliance to be strong and we are happy to recommend the firm for this type of activity." *Diversified Chemical Industry, US.*

Case study 1

Online sales compliance

H2 Compliance helped an online sales platform assess their level of compliance with the hazard communication requirements, developed and implemented a programme for screening SDS, labels and online content to ensure consistency and compliance. This is a complex process of data extraction to prepare a real-time discrepancy report to allow measures to be put into place to minimise gaps. The programme also flags substances of concern where those are present in suppliers' products. This type of service is particularly timely given the CLP revision and enforcement focus on online sales.

Case study 2

Pharmaceutical and healthcare support and software solutions

H2 Compliance has immense expertise within the pharmaceutical industry, supporting all aspects of REACH, GHS and emerging global regulations. This understanding allows us to become part of the team, working in partnership to identify issues, determine impacts and manage required actions. H2 Compliance is known for its collaborative platform, element1™. Our clients enjoy the fixed price model we typically operate, flexibility in working hours and deep strategic thinking. "I wish all of our partners and consultants were as easy to work with as H2 Compliance" says a top ten pharmaceutical client.

Case study 3

A sustainable safety data sheet solution for proprietary substances

H2 Compliance delivers comprehensive toxicology and safety data sheet services to several multinational companies. The projects involve engagement with internal stakeholders to develop a framework and system for maintaining and updating products' SDSs by assessing available data and determining hazard classifications under GHS. This process is facilitated using H2 Compliance's bespoke software platform to ensure consistency, transparency, and repeatability. The H2 team ensures compliant SDSs are generated in a process underpinned by thorough documentation and peer review.

Staff selection

Kevin Hoban – Head Chemical Compliance

Co-founder of H2 Compliance. More than 30 years' experience in industry, business development, commercials, software activities as well as REACH only representative practice. Qualified MSc industrial chemist and environmental engineer.

Dr John Hayes – Head Environmental Compliance

Co-founder of H2 Compliance. With over 30 years' experience in the IT and Pharmaceutical industries and regulatory affairs, John is leading environmental consulting activities within the group. John is a qualified biotechnologist and doctor of physical chemistry.

Grant Kinsman – CEO

A mechanical engineer with over 35 years' experience in the IT and consulting industry. Extensive global technology, scale-up, finance, business and marketing experience.

RÉPUBLIQUE FRANÇAISE
Liberté Égalité Fraternité

INERIS
maîtriser le risque pour un développement durable

Contacts	
Website	**ineris.fr**
E-mail	**prestations-ineris@ineris.fr**
Head office	Parc Technologique Alata, 60550 Verneuil-en-Halatte, France
Tel	+33 (0)3 44 55 63 29 (Patricia Rotureau), +33 (0)3 44 55 66 55 (fax)
Contact	Patricia Rotureau, Business Development Manager
Directors	Anne Morin, Environment and Impact on Human and Biodiversity Division
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, to guide them in their actions with regard to health, safety and environmental protection.

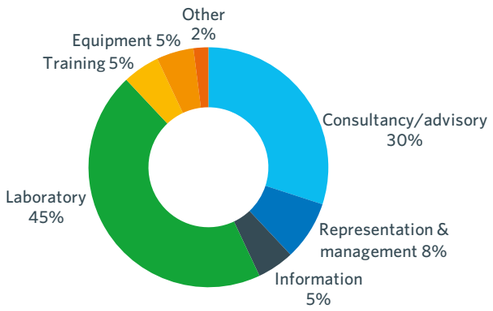
INERIS combines experimental approaches with expertise in modelling and risk methodology. It is equipped with physical/chemical analysis laboratories, GLP-compliant toxicology and ecotoxicology facilities, large-scale fire gallery and explosion platform, and test facilities that are among the best in 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 and in vitro (eco) toxicology, environmental fate and physico-chemical hazards in compliance with various regulatory needs (eg REACH, CLP and GHS notifications, biocides, waste (HP 14), transport of dangerous goods TDG, ATEX, etc), or in response to research and development needs.

Vital statistics 2022/23

Turnover: group	€64.5m
No of offices	4
No of countries represented	Global
Staff: group	510
Staff: chemical service provision	250

Service area breakdown



Global offices

France: main site in Parc Technologique Alata, Verneuil-en-Halatte (60550, north of Paris), waste recovery platform Ardevie in Aix-en-Provence (13592), centre for monitoring ground and underground risks in Nancy (54042), structural strength laboratory in Bourges (18020).

Services provided

Regulatory services

INERIS offers services according to the CLP and REACH regulations and their implementation. The testing capabilities and expertise permit a complete offer for the classification of substances according to CLP, GHS and TDG regulations and the registration of substances in accordance with the requirements of REACH.

It includes the development of the IUCLID dossier and the chemical safety report according to the exposure scenario and management measures to ensure a high level of protection for workers, the general population, and environment. In the context of 3R strategy, INERIS can also provide advice on the selection of the best alternative in integrated approaches for testing and assessment of your substance by using NAMs (QSAR, PBPK modelling and read-across, testing strategies).

INERIS can help industry with the selection of the best substitution option (**Practical Methodological Guide for Assessing Substitution Solutions for chemicals of concern** (SVHC, PFAS...). It can provide an integrated assessment of chemical alternatives covering regulatory, (eco)toxicological, safety dimensions, in order to avoid regrettable substitution by substances of concern.

Physico-chemical testing

INERIS has the equipment and facilities that allow an extensive range of experimental assays to study the physical and chemical properties of substances and mixtures.

For chemical characterisation and the determination of purity and stability of compounds, the in-house analytical techniques available include: GC-MS; GC with different detectors (FID, TSD, PFPD); LC with UV and fluorimetric detectors; LC-MS-MS; LC-HRMS; IC coupled to amperometric and conductometric detectors; and 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). INERIS is in the process of developing methods for analysing PFAS by LC-MS-MS in water, soils and air samples (stack emission).

A range of physical characterisation techniques are available, including: transmission and scanning analytical electron microscopy and X-ray; fluorescence for morphology and composition of materials, particles and aerosols; laser diffraction; quasielastic light diffusion; and centrifugal sedimentation for particle size quantification and tubular furnaces (from 50°C to 1500°C) for thermal degradation of substances and materials.

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 oxidizers, organic peroxides, self-reactive substances and explosives.

INERIS can also provide information for reactivity of substances (decomposition, chemical incompatibility) with molecular modelling and predictive data with QSPR methods.

Toxicological testing

INERIS provides customised, non GLP and regulatory GLP toxicology studies for chemicals (including nanoparticles, explosive substances, and fumes) and physical agents. The 1,500m2 *in vivo* facility is composed of mice and rat housing areas and innovative installations allowing exposure to chemicals by inhalation (nose-only and whole body) and to electromagnetic fields, and is set to perform behavioural testing, surgeries and *ex vivo* analyses. Based on the OECD test guidelines, our services include:

- skin and eye irritation/corrosion tests (OECD 431,439 and 492);
- acute toxicity testing (OECD 402,403, 423, 425 and 436);
- repeated dose 14-day preliminary tests (range finding assays);
- repeated dose 28-day toxicity tests (OECD 407 and 412);
- repeated dose 90-day toxicity test (OECD 408 and 413);
- developmental and reproductive toxicity tests (OECD 421,422 and 443); and
- toxicokinetics.

For inhalation toxicology testing, INERIS focuses on alternative methods to animal testing by the development of in vitro assays (such as in vitro air-liquid interface exposure systems for cell cultures and tissues) combined with in silico tools (PBPK modelling, QSARs).

In addition, as a service, INERIS makes available its facility, equipment, and expertise to external users for their own projects.

Ecotoxicological testing

INERIS provides non-GLP and GLP experimental assays and expertise in general ecotoxicity of chemicals and environmental matrices. It develops and performs biological assays to characterise the hazards towards the aquatic, benthic and terrestrial environments, as well as expertise on 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), and activated sludge respiration inhibition test (OECD 209);
- zebrafish embryo-based bioassays to assess the acute toxicity and developmental effects of test chemicals (OECD 236) as well as their potential estrogenic activity using the EASZY assay (OECD 250);
- terrestrial tests: dehydrogenase 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 developed expertise in the ecotoxicity of emerging substances including nanoparticles (sample preparation, nanoparticles characterisation, etc), ionic liquids, endocrine disruptors, PFAS 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, including sp-ICP-MS. It also participates 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, such as: 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 of 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 manufactured byproducts containing nanomaterials when subjected to external mechanical (abrasion, use), thermal (combustion, incineration), ultra-violet or chemical aggressions throughout their lifecycle.

Multi-disciplinary approach

INERIS's services include areas of expertise such as: 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 dangerous goods; authorisation to operate application hazards study (industrial sites and ICPE-class facilities).

INERIS 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 of 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 the industrial environment.

INERIS is compliant with good laboratory practice (GLP) in the areas of: toxicity testing, environmental toxicity studies on aquatic and terrestrial organisms, behavioural studies 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. (**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, including chemistry, paints and coatings, cosmetics, food, oil, gas and petrochemicals, automotive and heavy equipment manufacturers, construction, marine, consumer electronics, nanotechnology, etc.

Case study 1

Working with client on data for a REACH dossier

Unique importer of a substance, at a tonnage above 1 tonne/year (Annex VII), then above 10 tonnes/year (Annex VIII):

- validation of existing assay reports; *in silico* (read-across) feasibility evaluation and bibliographic expertise;
- guidance in providing physicochemical 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;
- realisation, 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

Patricia Rotureau – Business Development Manager

patricia.rotureau@ineris.fr

intertek assuris

Science Based Assurance in
Quality, Safety & Sustainability.

Contacts	
Website	intertek.com/assuris/chemicals/
E-mail	assuris@intertek.com
Head office	33 Cavendish Square, London W1G 0PS, UK
Tel	Head Office: +44 20 7396 3400 Assuris locations: **Canada:** +1 905 542 2900. **China:** +86 (21) 5339 7991. **Japan:** +81 3 4510 2595. **Korea:** +82 2 6090 9512. **France:** +33 (0)2 79 23 03 46. **Germany:** +49 711 27311 160. **India:** +91 8291 049593. **Italy:** +39 051 0562930. **Sweden:** +46 8750 00 00. **UK:** +44(0)161 245 8070.**US:** +1 302-287-3650. **Turkiye:** +90 212 496 46 46
Contact	Rose Passarella
Directors	Andre Lacroix, Chief Executive Officer; Colm Deasy, Chief Financial Officer
Ownership	Public
Locations	Intertek is an industry leader with more than 1,000 laboratories and offices in more than 100 countries
Founded	1996

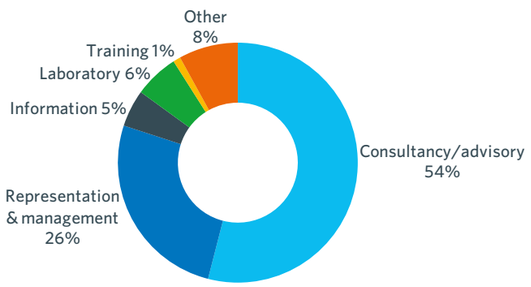
Overview

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke assurance, testing, inspection and certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Vital statistics 2022/23

No of offices	1,000+
No of countries represented	100+
Staff: group	40,000+
Staff: chemical service provision	5,000+

Service area breakdown



Services provided

Chemicals

Global notification and registration of new chemicals support

- Canadian New Substances Notification Regulations (NSNR)
- US Toxic Substances Control Act (TSCA) services
- Global REACH programme OR and technical support (UK, EU, Korea, Eurasia, Turkiye, India, China, Taiwan)
- Australian Industrial Chemicals Introduction Scheme (AICIS)
- China new chemical substance registration
- Pre-manufacture and pre-importation notification (PMPIN) in the Philippines
- New chemical substance notification under CSCL and ISHL in Japan
- Bureau of Indian Standards (BIS) Certification

Global chemical management

- Risk assessment and management
- Data gathering activities (Canada CMP; TSCA LCSA; Inventory nominations, updates, and resets)

Hazard communication (HazCom) services

- Workplace MSDS and label support
- Consumer chemical labelling (Canada and US)
- Dangerous goods transportation regulatory support
- Hazardous chemical registration (China SAWS Order 53)
- Globally Harmonized System (GHS) compliance (India and Gulf Cooperation Council (GCC) member states)

Biocides

- Pre-submission regulatory consultations
- Protocol development, study placement, and monitoring
- Dossier support and data review for biocidal active substances
- Liaison with pesticide regulators and submission shepherding
- Technical expertise and dossier preparation (product identity and chemistry, toxicology, efficacy, ecotoxicology and environmental fate)
- GLP, GMP, and GCP-compliant analytical laboratory testing services: physical and chemical parameters, quality/purity, residues, contaminants and shelf-life/stability

Global restricted substances

- RoHS: Supplier engagement, restricted substance control programmes, risk assessment, testing, technical file creation
- SCIP database: Supplier engagement, Intertek database solution for supply chain management, dossier preparation and submissions
- REACH: Product risk assessment, supplier engagement, SVHC screening
- California Proposition 65: Product and material risk assessment, analytical testing, exposure assessment

Cosmetics and personal care

- Toxicological safety assessments
- Toxicological profiles of ingredients
- Registration and notification of new cosmetic ingredients
- Registration and notification of domestic/imported cosmetic products
- Labelling reviews
- Literature review and data collection
- Regulatory dossiers
- Microbiology and stability testing
- Cosmetic packaging analysis
- Causality assessment

Food contact

- Global food contact regulatory compliance (EU, Mercosur, US, China, Japan, Korea, India and GCC)
- Preparation and submission of registration dossiers for EU (such as EFSA), US (FCN) and China
- Safety risk assessments
- Design and implementation of global testing strategies for compliance and registration dossiers
- Liaison with government regulatory authorities regarding submission and regulations interpretation
- Supply chain management review documentation and compliance
- Good manufacturing practices (GMP) implementation
- FDA no objection letter submissions for recycled plastics and recycled paper used in food contact applications
- Customised training

Sustainability

- Life Cycle Assessment (LCA)
- Ingredient transparency and health declarations
- Responsible sourcing
- Sustainable claims support
- Carbon footprint and water footprint
- Corporate sustainability reporting
- GHG emissions support services
- Sustainable Building Certification
- Management Systems Certification
- Recycled content verification

Corporate developments and achievements

2018	Intertek expands its Total Quality Assurance offering for sustainability with ATIC services global platform
2020	Intertek introduces CarbonClear certification programme, which brings unique clarity on the carbon impact of cradle-to-gate operations across all stages of oil and gas exploration and production
2021	Intertek launches Assuris to meet customers' fast-increasing need for science-based assurance in a changing world
2022	Intertek Assuris developed a process, including the US FDA challenge test, to support plastics recycling companies in obtaining an FDA no objection letter (NOL). Intertek also supports food, cosmetics, and medical packaging companies in selecting recycled plastics that best meet their product performance requirements, comply with government regulations, and are proven safe for their intended use

Accreditations

Mr Dan Bastien – Former Head Client Services Unit, Environment and Climate Change Canada and Government Representative at the at the ICG for the CEPA.

Dr Rose Passarella – Regular interaction with the US EPA to support clients in the reformed US Toxic Substances Control Act (TSCA) activities and implementation of the new policies; active member in the US Bar of Pennsylvania and New Jersey; founding member of STRIDE (Scientific Technical Research Institute of Delaware); and certified mentor for SCORE.

Dr Michael Leise – Board member of Only Representative Organisation (ORO) AISBL, representing credible REACH only representatives active within the European Economic Area.

Dr Rainbow Zhang – Member of Council of Chinese Society of Toxicology (CST) and a Committee Member of the Society of Toxicity Testing and Alternative Methods, CST.

Clients

Intertek Assuris adds value for finished goods companies and retailers by ensuring the safety, quality, and sustainability of materials, products, and processes throughout the supply chain, meeting compliance obligations. Our regulatory services primarily focus on the base of the supply chain, covering chemicals, raw materials, and ingredients used in finished formulations, medicinal products, processed foods, and manufactured articles.

Case study 1

A step-wise strategic approach to registration leads to higher success

The regulations governing the registration of biocides/sanitisers across the globe are complex and diverse, which requires a thorough understanding of the local legislations, ensuring the biocide/sanitiser product is well defined, and the claims are substantiated in accordance with these legislations.

To support the introduction of a new biocide/sanitiser product in multiple jurisdictions, Intertek's global team of regulatory and toxicology experts worked together in completing feasibilities assessments for the associated countries to identify roadblocks and develop a global test strategy to support the registrations, prior to submission of the applications to the competent authorities. Avoiding these roadblocks and aligning study placement saved the registrant time and money, as well as ensured that the submitted application successfully completed the full review process and resulted in approvals for sale and use.

Case study 2

Intertek's global network of experts helps clients achieve cost-effective registrations worldwide

Intertek was asked by a chemical company located in North America for help to understand and comply with the regulations to gain access to new markets in Canada, the US, Australia, the EU, China, Japan, South Korea, India and the Philippines. Sending chemicals into these regions requires compliance with the new chemical notification programmes in each of the jurisdictions and submission of sensitive product information by the local importer to the government agency for safety/risk assessment and pre-market clearance.

Intertek's global team worked seamlessly with the chemical company to develop and implement a smart global testing plan for each applicable new chemical to ensure that studies run were completed in a way that would maximise their acceptability across as many of these jurisdictions as possible.

TSCA's new requirements for affirmation, before a company can proceed to the US marketplace, are increasing the scrutiny of the assessments and offered additional challenges to address the requests for additional data and avoid the common extended timeframes using preliminary in-house screening approaches. Although the North American company agreed to provide the necessary data, they were reluctant to submit confidential information through the local customers. Intertek was able to work with both the client and their customers in each jurisdiction to prepare and submit robust dossiers, and act as local country agent/only representative in some of these countries, while maintaining the confidentiality of the data and reaching compliance for import/manufacture of the volumes required by the businesses.

We protect our customers' competitive advantage with efficient, economical and timely global market access.

Staff selection

Emilie Savides, Regulatory Affairs Specialist, France. Focus: chemicals, cosmetics and personal care – eight years' plus experience.

Amanacy Araujo, Sales & Project Coordinator, Germany. Focus: restricted substances, sustainability – seven years' plus experience.

Olga Casas, Regulatory Expert Project Manager, Spain and Portugal. Focus: chemicals, biocides, cosmetics and personal care – five years' plus experience.

Richard White, Operations Manager, UK. Focus: chemicals – 12 years' plus experience.

Alessandra Tagliani, Senior Regulatory Specialist, Italy. Focus: chemicals, biocides – 25 years' plus experience.

Basak Parlak, Regulatory Executive, Türkiye. Focus: chemicals, biocides, cosmetics and personal care – four years' plus experience.

Naeem Mady, Vice President, Regulatory Market Access, US. Focus: chemicals, food contact, sustainability – 50 years' plus experience.

Ellinor Nilsson, Senior Chemical Specialist, Sweden. Focus: chemicals, restricted substances, sustainability – 18 years' plus experience.

Dr Rainbow Zhang, General Manager, China, Japan and Korea. Focus: chemicals, food contact, cosmetics and personal care – 10 years' plus experience.

Rachel Kim, Senior Regulatory Consultant, Korea. Focus: chemicals, biocides – 15 years' plus experience.

Sunanda Kadam, Regional General Manager, India and Middle East. Focus: chemicals, food contact, restricted substances, sustainability – 20 years' plus experience.

Nick Jermstad, Senior Director, Toxicology, US. Focus: cosmetics and personal care – 18 years' plus experience.

KAHLBERG CONSULTING

Contacts	
Website	kahlbergconsulting.com
E-mail	info@kahlbergconsulting.com
Head office	KAHLBERG Consulting, Piazzale Bacone 7/A, 20129, Milan, Italy
Tel	+39 02 6700319, +39 02 67386811 (fax)
Contact	Vanessa Alberti
Directors	Michela Kahlberg, CEO
Ownership	Private company
Locations	Italy, UK and Turkey
Founded	2008

Overview

Kahlberg Consulting is a leading chemical consulting company based in Milan, Italy, and an expert in REACH, polymers, CLP, biocides, Turkish and UK chemical regulations.

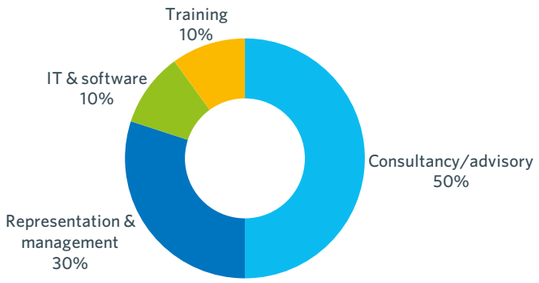
The highly skilled and experienced team provides fast and strategic solutions for all of its clients. The service delivered goes beyond what is expected and it always positively exceeds clients' demands.

Over the past decade, Kahlberg Consulting has grown and developed into a trustworthy partner for chemical regulations offering a complete and ever evolving selection of services. Our clients include the biggest players in the global market as well as small and medium-sized companies.

Vital statistics 2022/23

Turnover: group	>€1m
Turnover: chemical service provision	>€1m
No of offices	3
No of countries represented	>30 (worldwide)
Staff: group	22
Staff: chemical service provision	15

Service area breakdown



Services provided

Europe

REACH

- Regulatory and legal advice and registration strategy
- Full REACH registration dossier
- CLH dossier
- Management and logistical support to consortia/lead registrants
- Representation of customers in consortia
- Post-registration assistance and compliance checks assistance
- Study monitoring for eco and toxicological studies.
- Analytical characterisation assistance
- Chemical safety report preparation.
- Nanomaterials registration

Polymers

We are following the regulatory course of the REACH update proposal, including and focusing on polymers and REACH registration. We are already assisting companies to prepare for the new challenge with the following:

- regulatory updates;
- evaluation of impact;
- set up and management of working groups and consortia: definition of registration strategies and grouping;
- analytical support for polymers identification and laboratory management;
- verification of polymer status based on REACH Regulation criteria;
- definition of polymers portfolio; and
- definition of basic tests and physical-chemical properties.

Product safety

- Preparation, verification and update of safety data sheets, also extended with exposure scenarios
- Verification of dangerous goods hazard labels
- Verification of exposure scenarios and identification of the conditions that are not covered
- Preparation of downstream user reports and submission to ECHA, for unsupported uses
- UFI creation and poison centre notifications (PCNs)
- CLP requirements for substances and mixtures
- Dangerous goods safety advisor (DGSA) services and general consultancy for ADR, IMDG and IATA
- Auditing

Biocides

- Approval of active substances
- Authorisation of biocidal products
- Article 95 submission
- Managing and monitoring of laboratory tests
- Data-gap analysis
- Human health and environmental risk assessment
- Communication with regulatory authorities
- Mutual recognition in other EU member states

Turkey

KKDIK

Regulatory and strategic consultancy

- Only representative (OR) service
- Pre-registrations
- Registration strategy
- Full KKDIK dossier preparation services with CAE approve
- Management and secretarial support to consortia and/or lead registrants
- Technical and scientific translations.

Product safety

- Preparation/review and certification of safety data sheets
- Notifications based on SEA Regulation
- Labels

Biocidal products Regulation

Registration and consultancy services.

Turkey detergents Regulation

Consultancy services.

UK

UK REACH

- Registration, evaluation, authorisation and restriction of chemicals
- Only representative (OR) service

GB CLP

Classification, labelling and packaging of substances and chemicals.

Worldwide services

- Korea REACH
- Eurasia REACH
- Albania, Kosovo, Montenegro, North Macedonia and Serbia
- Latin America

Corporate developments and achievements

2008	Kahlberg Consulting is founded
2018	KKDIK unit is created
2019	UK REACH unit is created
2020	Worldwide REACH unit is created

Partners

Team Mastery srl

Case study 1

REACH polymers

Currently the REACH Regulation does not require registration or evaluation of polymers, but during the last three years the competent Authorities and ECHA have been working hard to help the Commission in presenting a proposal for updating REACH, including the registration of polymers.

Since the number and type of polymers on the European market are considerable, it is easy to see that the new registration obligation will be a great challenge for industry. Physico-chemical properties, toxicological and eco-toxicological data are not available on polymers; identity and grouping will require a big effort in time and resources. With this in mind, Kahlberg Consulting had started to work on polymers since the beginning of the discussion. Three webinars were held in the last two years, with more than 300 participants, in order to keep companies involved in this task updated.

We've created dedicated software to assist companies in storing and organising information efficiently. This software can perform calculations based on various criteria, group polymers with similar characteristics, and provides a notification tool that eliminates the need to re-enter information into other systems like IUCLID.

Past experience on substance registration has taught us that it is important to be proactive from the very beginning to avoid wasting of time on this challenging task. A specific consortium is currently being formed.

Case study 2

Compliance checks

According to Article 41 of REACH, ECHA can perform compliance checks on any registration dossier at any time. This means that several registrants face compliance checks every year and these processes can be very costly and complex to manage. We have supported many clients, both individually and at consortia level, in the compliance-check process with single substances or categories. What is common to all of these experiences is the invaluable help of an expert consultant who is able to analyse the situation from different perspectives. When receiving a draft decision from ECHA, we have noticed that several strategies can be applied, depending on the case.

The best solution lies in the evaluation of both technical and commercial concerns. Within 30 days of receiving the draft, the consultant has to be fast and efficient in preparing a reasonable strategy that suits the client's needs. An experienced consultant can see behind ECHA's reasoning and decision making, and suggest the most suitable solution for the client.

Being compliant is the end goal, but we offer solutions that go beyond the mere regulation and take into account the future of the substance and the business. Our varied experience tells us that investing time and resources during the draft process can save time and money in the long term.

Case study 3

KKDIK

Current REACH clients have asked for our support for different regulations around the world. We are always interested in growing and learning, therefore we have decided to expand our services to Turkey. Our background with the REACH Regulation is the added value our clients want when they face new challenges. The expertise of over a decade of work is crucial to understand the problems companies could face tomorrow, in two weeks, as well as in five years.

Most of the time, the past repeats itself and, having experienced these processes in Europe, we are sure we can better assist our clients in Turkey. It is normal for companies to have doubts and face difficulties when starting a new journey. More than 90 clients rely on our expertise and our ability to have a long-term view to accompany them into new markets.

Case study 4

Product safety

Sometimes small changes can make a huge difference. ECHA has increased controls on products arriving into Europe and the results have shown that many products were non-compliant. We are aware that many of our local clients could be heavily affected by these controls. Therefore, to anticipate any issues, we advised them to check what is in their warehouse. In our experience, we have noticed that sometimes clients have to pay a high price for small (avoidable) mistakes. We have provided all of our clients with a list of things to check about their substances within the realm of product safety. We strive to provide our clients with a 360-degree approach that anticipates future problems and supports them in daily tasks.

Staff selection

Kahlberg Consulting has a highly skilled and experienced all female team.

Michela Kahlberg – CEO

In 1998, after a degree in economics, and spending five years in research and marketing in London and Milan she took the control of the family company ORIGO, which had been representing Czechoslovakia's (now Czech Republic) chemical industry in Italy since 1951, enlarging in particular the organic dyes and pigments businesses. During 2008, she started following the REACH Regulation, particularly for organic dyes. Today, her companies are leading in different sectors and fields, inside and outside Europe.

Dr Elena Campagnoli – Senior Regulatory Affairs Officer

She earned a bachelor's degree in chemistry followed by a PhD in chemistry at Dublin City University and has more than ten years' experience with the REACH Regulation. Chemical safety assessor for the cosmetic products Regulation.

Vanessa Alberti – Senior Regulatory Affairs Officer

She has a bachelor's and master's degree industrial chemistry from Università degli Studi of Milano. Product safety expert, more than a decade of work with the REACH Regulation. Responsible for worldwide services, participant and exhibitor on events and trade fairs.

Dr Elif Dereli Eke – Regulatory Affairs Specialist

She has a bachelor's and master's degree in chemical engineering from Yildiz Technical University and Bogazici University. PhD in chemical engineering from Bogazici University. Previously a post-doctoral research fellow. Head of KKDIK department.

Ilaria Bruno – Regulatory Affairs Officer

Bachelor's degree in Chemistry and Master's degree in Organic and Biomolecular Chemistry. REACH Consultant Junior.

Giulia Martina Sitzia – Regulatory Affairs Officer

She obtained a Bachelor's degree in Toxicological Sciences and Quality Control and she is close to obtaining a Master's degree in Safety Assessment of Xenobiotics and Biotechnological Products, REACH Consultant Junior.

KFT
The CHEMICAL COMPLIANCE Company

Contacts	
Website	kft.de; kft.de/kft-academy; kft.de/kft-chemdoc24
E-mail	sales@kft.de
Head office	Im Leuschnerpark 3, 64347 Griesheim, Germany
Tel	+49 6155 8981 -400, +49 61 55 8981 – 500 (fax)
Contact	Marcus Rosenberger, Stefan Palla, Mario Andric
Directors	Marcus Rosenberger, Stefan Palla
Ownership	Wholly owned subsidiary of Infraserv GmbH & Co. Höchst KG
Locations	Griesheim, Headquarters, Germany Frankfurt a. M., Industriepark Höchst, Germany
Founded	1995

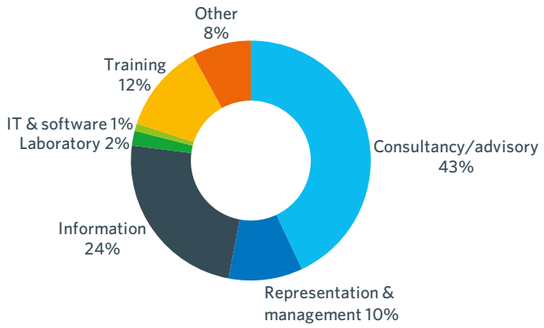
Overview

KFT Chemieservice's business is its competence in regulatory and product safety affairs. We ensure our customers' legal compliance for registrations, documentation as well as SDS, classification and labelling. Key elements are our experienced and well-trained staff, modern, sophisticated software and fair compensation for our services. Our responsiveness to individual customer needs is well recognised in the market.

Vital statistics 2022/23

No of offices	2
No of countries represented	1
Staff: group	39
Staff: chemical service provision	29

Service area breakdown



Services provided

KFT chemicals legislation:

REACH

KFT Chemieservice has been working with REACH Regulation (1907/2006/EC) since 2001. We have prepared a number of companies for REACH, devised practical solutions using our taskforces, and undertaken 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 IUCLID dossiers and CSR (chemical safety reports).

Our REACH and management services cover:

Impact analysis, strategic and operative REACH consulting, as well as supply chain communication consultation.

Our SIEF management provides:

Project management, cost calculation for clients and LoA prices and settlement, trustee services, support for new studies from the initial analysis to monitoring of the implementation and evaluation of the results, organisation of data sharing, communication with customers, authorities and competitors.

International regulations on chemical registrations

Many countries, such as the UK, South Korea and Turkey, have built up similar regulations to the EU with an obligation to register chemicals prior to marketing. Other countries have complex legal requirements containing of several laws, chemical inventories or obligations to notify products itself or the ingredients. With our local partners in all relevant countries we can enable you to fulfil all legal requirements.

Generation and maintenance of exposure scenarios

We generate exposure scenarios according to legal requirements. Furthermore, we create the necessary information for mixtures based on the methods LCID (lead component identification) and SUMI (safe use of mixture information).

Biocide substances

Consulting in the field of biocides and notification on a national level and labelling in EU countries.

Cosmetics

We check your formulas regarding permissible ingredients or compliance with permissible concentrations and we create the legally required labelling information and obtain approval of finished labels on your behalf.

In addition, we carry out product notification in the EU, draw up and verify existing safety assessments or complete product information files and finally, we will guide you through the jungle of 'borderline' products.

KFT product safety:

Safety data sheet management

Generation of safety data sheets (SDSs) worldwide in accordance with GHS and the country-specific requirements. Examples of countries and regions are the EU, Switzerland, Canada, US, all of Asia, South America and South Africa. We generate SDSs in more than 50 languages worldwide. We additionally support specific national certifications as required in Turkey.

A comprehensive concept of SDS maintenance packages has been successfully introduced, allowing customers to continuously update SDSs pursuant to statutory requirements. The total care service is completed by KFT SDS Control & Care, covering the management of supplier SDSs.

Raw materials management

Many of our customers have entrusted KFT with the management of their raw material data. This involves the registration and review of suppliers' safety data sheets, and communication with them to eliminate possible deficiencies.

Product notifications

Notification of products and articles pursuant to Article 45 of the CLR the German detergents and cleaning agents act (WRMG), and product notifications in all European countries and Turkey.

Remote data management

For more than 25 years, our customers have relied on our expertise and services for data research and maintenance. Protect yourself from potential liability and fines and trust us to maintain your chemical data.

We offer support in data maintenance remotely in the client's own system, such as SAP Environment, Health, and Safety Management. If desired, we cover the entire process – from management of the supplier safety data sheets (KFT Control & Care) to the clearance of your documents.

KFT Services – emergency response

Emergency numbers are important in two respects. First, they must be provided in safety data sheets according to GHS regulations. Second, legal regulations on transport, particularly by airlines, demand emergency numbers – usually on a carriage document or label. At KFT, we offer an emergency number service worldwide through our partners CHEMTREC, Giftinformationszentrum Nord and CIRS.

KFT Academy – seminars, training and coaching

The very popular and appreciated coaching support has been continuously developed to provide a broad spectrum of seminars around the compliance aspects of REACH, SDS, GHS/CLP and international chemical regulations.

Find the available selection at **kft-academy.com**. In-house training and customised coaching are available on demand at **academy@kft. de.**

A monthly webinar 'KFT chemical compliance live' can be accessed free of charge.

Corporate developments and achievements

1995	Foundation of KFT Chemieservice
1998	First registration according to the previous substances regulation 793/93/EC
2008	First only representative contract with Brazilian company
2010	Launch of **KFT-ChemDoc24.de** >3,000 pre-registrations, >60 substances registered, first biocide substance registered
2012	Introduction of SDS Control & Care (raw material management)
2013	Launch of KFT Chemical Compliance Live – a free web seminar 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	Cooperation with Lisam systems to market and implement ExESS software systems
2018	ISO-Certification DIN EN ISO 9001:201 5
2020	Wholly owned subsidiary of Infraserv GmbH & Co. Hbchst KG
2021	ISO-Certification DIN EN ISO 50001:2018

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

- LISAM Deutschland GmbH (ExESS chemical compliance software solution) KTR Europe GmbH (China and Korea New Chemical Substance Notification Service)
- Tradas Translations and Consulting Services
- Chemtrec/GIZ Nord (Security number services)
- CRAD (Cevre Risk Analiz Denetim), Turkey
- CIRS Chemical Inspection & Regulation Service Ltd

Clients

We provide our services to manufacturers, distributors, importers of chemical raw materials as well as finished products (including consumer products). Our clients range from SMEs to global companies from a wide range of industrial sectors.

Case study 1

Maintain marketability in Turkey

We support companies by working with them to answer the following questions:

- What are the options? Apply an exemption? Purchase of a letter of access (LoA)?
- Is the company a co-registrant or lead registrant and what data is needed?
- Which communication with other potential registrants is required?
- Are all substance data available? Have all the necessary chemical-analytical tests been performed? Should further studies have been conducted?
- Have some chemicals been forgotten or have additional products came up that should be pre-registered in a follow-up activity?

Case study 2

Marketability check Japan

We examine the marketability of consumer products for the Japanese market. Compilation of the applicable regulatory requirements including Chemical Substance Control Law (CSCL); Household Goods Quality Labelling Law; Measurement Law; Poisonous and Deleterious Substance Control Law (PDSCL): Law for the Control of Household Products Containing Harmful Substances: Food and Sanitation Law; and Fire Service Law.

We check for prohibitions and restrictions support in the implementation of labelling requirements.

Case study 3

REACH lead registrant support

We support our customers by:

- finding the existing data and identifying data gaps;
- undertaking negotiations with data holders and contracting testing labs to close the data gaps;
- supporting the transfer of the lead registrant role and organising with the previous lead;
- creating the IUCLID file and CSR and taking care of submission of the registration to ECHA, including all necessary communications;
- marketing the letter of access to other registrants and ensuring a legally compliant calculation on behalf of our client as the lead registrant;
- creating the SDS with appendix (exposure scenarios) in all EU languages: and
- providing a one-stop service for the client.

knoell worldwide registration

Contacts	
Website	knoell.com
E-mail	info@knoell.com
Head office	Konrad-Zuse-Ring 25, 68163 Mannheim, Germany
Tel	+49 (0)621-718858-100
Contact	Dr Michael Cleuvers
Directors	Felix Knoell, Dr Runar Eberhardt, Dr Marika Suhm-Tintelnot, Dr Michael Cleuvers
Ownership	Private company, majority-owned
Locations	Germany, United Kingdom, Switzerland, the Netherlands, Spain, Portugal, France, Italy, Poland, China, Thailand, Japan, South Korea, Taiwan, United States of America
Founded	1996

Overview

Worldwide regulatory consulting, substance and product registration services, compliance, services for chemicals, crop protection, crop nutrition, biocides, food contact materials and additives, novel food, cosmetics, medical devices as well as animal health-related products including special sustainability services triggered by the EU chemicals strategy for sustainability.

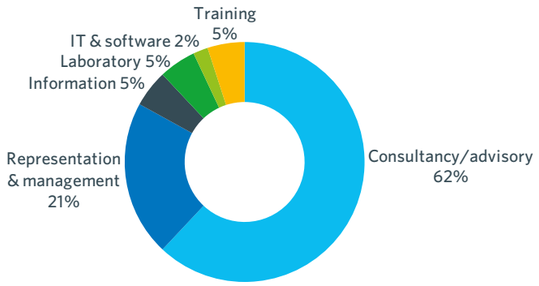
knoell: your go-to partner for registration and sustainable compliance, worldwide. Total outsourcing or individual solutions tailored to your needs. Benefit from our extensive regulatory and scientific expertise. We ensure that your substances, active ingredients and products are always in compliance with the latest regulatory requirements, the current developments with regard to sustainability and that you fulfil all obligations related to their safe handling: think globally, act locally.

With sites in Europe, Asia and North America and a well-established network of cooperation partners we support you to gain and maintain marketability, globally.

Vital statistics 2022/23

Turnover: group	~€60m
Turnover: chemical service provision	~€20m
No of offices	24
No of countries represented	15
Staff: group	~650
Staff: chemical service provision	>180

Service area breakdown



Global offices

Europe: Germany – Mannheim, Leverkusen, Berlin, Munster; UK – Cardiff, Bristol, Brampton; the Netherlands – Wageningen, Rotterdam; Switzerland – Basel; France – Lyon; Spain – Madrid; Portugal – Lisbon; Italy – Milan. **Asia:** China – Shanghai; Japan – Tokyo; Thailand – Chiang Mai; South Korea – Seoul; Taiwan – Taipei City. **North America:** US – Chadds Ford (PA), Research Triangle Park (NC).

Services provided

We offer solutions for every step in the regulatory process for various business areas in many jurisdictions. Whether you need complete outsourcing or customised solutions, our expert teams will work with you to develop the best strategy to achieve your goals.

Regulatory strategies for sustainability

- Strategic substance/product portfolio analysis: evaluation of substance portfolio regarding different sustainability aspects
- Watchdog service: always up to date with new regulatory developments and potential substance restrictions
- Sustainable chemicals by design: regulatory support, QSARS Eco-labelling
- Life cycle assessment: carbon footprint, water footprint
- Recycling: process authorisations, guidance on regulations
- Impact assessment: socio-economic analysis, biodiversity impact assessment

Strategic and regulatory consulting

- Latest information on the regulatory landscape in your target market
- Impact of applicable regulations on product portfolios, compliance check
- Review any regulatory changes and evaluate the need to update the impact assessment
- Development of appropriate registration and testing strategies, including alternative non-testing approaches such as QSAR, read-across and waiving
- Determination of customer roles under the different legal regimes in the world, analysis of communication within the supply chain

Representative services

- We can act as only representative (OR) in the EU, UK, South Korea, Switzerland, local agent in China or TPR in Taiwan
- We assist you as non-EU manufacturer in the REACH registration process by filing the required inquiries pursuant to Article 26 REACH, represent you in the different substance information exchange fora (Sief) and consortia, communicate with authorities, Sief members, consortia, downstream users and other involved parties as well as monitor the entire registration process
- We handle sensitive data confidentially, and hence can act as a trusted go-between – eg for consortia members

Submission support and document preparation

- Consortium and taskforce management
- Support with data sharing and letter of access negotiations
- Local in-country submission support – interaction with authorities and notified bodies pre- and post-submission (ie representing clients at authority meetings, handling submissions, applications and notifications) as well as with CROs and actors within the supply chain
- Dossiers and electronic submission (eg IUCLID, R4BR CADDY, VNeeS).
- TSCA registration including PMN support
- Preparation of technical reports, study summaries (eg OECD format) and tolerance petitions
- Declaration of compliance/conformity
- Design, risk management and usability documentation
- Expert statements and opinion letters
- Label finalisation

Hazard, risk and exposure assessments

- Toxicological and ecotoxicological hazard and risk assessments.
- Environmental exposure assessments
- Higher-tier exposure and risk assessments (eg model coupling, bee studies)
- Assessment of endocrine disrupting properties
- Assessments using computer-based (*in silica*) models (eg QSAR, read-across)

Technical and scientific support

- Literature search and evaluation
- Environmental fate of active ingredients and their metabolites
- Biological efficacy of your products
- Full data analysis, including gap analysis, check of completeness, technical equivalence, identity and physical-chemical parameter determination

Product safety and product stewardship

- Development and management of (extended) safety data sheets
- Poison centre notifications
- Classification and labelling: GHS, CLR OSHA HazCom and other schemes
- Workplace safety cards
- Exposure scenarios
- Dangerous goods: transport on road (ADR), rail (RID), inland waterways (ADN), sea (IMDG) and air (IATA/ICAO)
- Assessment of provided hazard data (classification as well as additional information), deriving the correct transport classification for the transport types of concern

Study management and monitoring

- Identification of studies needed for registration purposes
- Study concept management: request and quote negotiation with CROs
- Study organisation at CROs
- Technical contact for CROs and clients – from study plan preparation to the experimental phase and the final report
- Inclusion of endpoints and studies into dossiers (including summary preparation)

Quality management and audits

- Animal health products (quality assurance and audits for any stage of the product lifecycle – pre-clinical studies, clinical studies, pharmacovigilance or manufacturing)
- Food and food contact materials (Good Manufacturing Practices (GMP), in accordance with the Regulation (EC) No 2023/2006)
- Support for REACH inspections

Process automation

- Working in close collaboration with you, our dedicated team of IT specialists, scientist and regulatory affairs managers will support you in identifying areas where automation might help to increase the efficiency of your day-to-day work
- We will automate recurring tasks and processes and also speed up the way your reports and dossiers are created. We develop .NET-based tools and customised Microsoft Office add-ins (C#) based on your requirements
- Product design and development support for medical devices and animal health products (from manufacturing and quality projects to pre-clinical and clinical projects)
- Biological safety assessments and clinical evaluation of medical devices
- Clinical trial support and pharmacovigilance for animal health products (pharmaceuticals, immunologicals, feed additives)

Workshops and seminars

- Wide range of training programmes offered as seminars, training, web-seminars, e-learning and workshops by our knoell academy

Accreditations

Qualified Cefic – partner. Certifications: ISO 27001, EcoVadis.

Partners

SCAS Japan, SCAS Europe, Domo Salute, Cekindo, Mourao Henrigue Consultores Associados, CRAD, AgriThority, Chemical Watch.

Clients

We deliver flexible services to globally acting companies as well as to small- and medium-sized enterprises plus, we take care of large consortia and taskforces. Support is provided on- and off-site to meet our customers' specific local needs.

Corporate developments and achievements

1996	Foundation, Mannheim, Germany
2002	Office in Leverkusen, Germany
2007-to date	Continuous global growth by founding new entities (Switzerland, to date UK, the Netherlands, China, Thailand, Spain, Portugal, France, Japan, South Korea, Brazil, US), opening offices (Germany, Taiwan, Italy) and acquisitions (Cyton Biosciences Ltd, UK, Critical Path Services, LLC, PA, US, Shotwell & Carr, LLC, Carrolton, TX, US, Sitmae Reach Services, NL, Triveritas Ltd, UK)
2009	Launch of knoell academy, dedicated to providing training courses and bespoke in-house seminars, covering all our areas of expertise 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) Expand our portfolio to animal health consulting services – acquisition of Cyton Biosciences Ltd, Bristol, UK Extend regulatory affairs services from Europe to Japan and the Asia-Pacific region Successful preparation of more than 400 REACH dossiers and more than 100 chemical safety reports knoell is officially appointed as an institution for the training of experts in toxicology
2011	1st knoell Symposium on Chemical Control Regulations in Asia and the Americas
2018	Dr Knoell Consult GmbH becomes knoell Germany GmbH
2019	knoell joined the new, EU-funded LIFE CONCERT REACH project, aiming at improving the usability and acceptance of results from non-testing methods (such as QSAR models and read-across) for registration purposes
2020	Successful completion: knoell was tasked with testing the suitability of IUCLID software to handle pesticide and biopesticide dossiers and to fulfil the requirements of the Transparency Regulation coming into force in March 2021 in a pilot project commissioned by the European Food Safety Authority (Efsa) Full reports published by Efsa in the second half of 2020
2021	K-REACH: successful submission of more than 100 registration dossiers (>10 lead dossiers) and more than 4,000 pre-registrations UK REACH: successful submission of over 100 downstream user import notifications as well as around ten grandfathering dossiers
2021-2022	Establishment and extension of a dedicated team for sustainability services
2023	Two UK forces united in one brand 'knoell animal health', Cyton Biosciences Ltd. becomes knoell Animal Health Ltd

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.

Staff selection

Toxicology – more than 45 toxicologists.

Global regulatory affairs including consortium management and TPR – more than 80 specialists.

Environmental fate and modelling – more than 70 experts.

Ecotoxicology – more than 45 ecotoxicologists.

Contacts	
Website	**biopharma.labcorp.com/services/chemical-crop-protection.html**
Head office	**Headquarters:** 531 South Spring Street, Burlington, NC 27215
Tel	+1 336 436 3920
Contact	**Crop Protection & Chemical Division**
Directors	Don McKenzie (VP Global Head of Crop Protection & Chemical), Joanne Miller (Global Head of Sales, Crop Protection & Chemical, preclinical Medical Device)
Ownership	Publicly traded
Locations	US, UK, Korea, Japan, China, Germany, Switzerland, Spain
Founded	1969 for Labcorp – Legacy Chemical Testing Experience from 1931

Overview

Labcorp is a global leader of innovative and comprehensive laboratory services that is a premier laboratory partner offering human and environmental safety testing, physical chemistry, as well as, regulatory consultancy and other dedicated services that furthers the development of chemical and crop protection products from early discovery all the way to dossier preparation and regulatory submission.

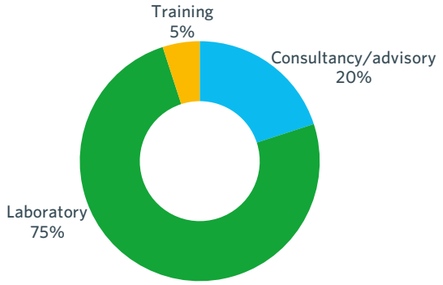
Labcorp continues to innovate with chemical and agrochemical advancements through our experienced team of dedicated experts and consultants, our compliant infrastructure, an unparalleled testing portfolio and industry-leading consulting support.

Together, we can improve human health and environmental safety by offering testing solutions for a healthier tomorrow.

Vital statistics 2022/23

No of offices	35
No of countries represented	100
Staff: group	>67,000
Staff: chemical service provision	<1,000

Service area breakdown*



*Crop Protection and Chemical breakdown only

Global offices*

United States (Greenfield, IN; Madison, WI). **United Kingdom** (Eye; Huntington; Shardlow; Harrogate). **Japan** (Tokyo). **Korea** (Seoul). **Spain** (Valencia). **Switzerland** (Fullinsdorf).

** Regions that have crop protection and chemical sites only.*

Services provided

Physical chemistry

- Technical active ingredient characterisation
- Physical and chemical properties of AI properties
- Physical and chemical formulation properties
- Formulation and stability

Human safety

- *In silico*
- *In vitro* safety assessment
- *In vivo* safety assessment
- General toxicology
- Genetic toxicology
- Inhalation toxicology
- Development and reproductive toxicology (DART)

Environmental safety

- Ecotoxicology
- Environmental fate and metabolism
- Field trials
- Residue analysis trials
- Endocrine disruptor screening programme assays

Regulatory consultancy

- Regulatory consultancy
- Global regulatory support
- Classification, labelling and safety data sheets
- Registration and submission
- Community Rolling Action Plan (CoRAP)
- Biocides
- Biopesticides
- (Q)SARs

Industries we serve

- Crop protection products
- Industrial chemical products
- Nicotine products
- Biopesticides
- Biocides
- Nanomaterials
- Food and feed additives
- Cosmetics and fragrances

Accreditations

We maintain a number of laboratory certifications based on location. As a value-added service to our clients, we provide access to the current laboratory certification documents for each of our laboratory sites.

Accreditations and Certifications

Clients

Industrial and agrochemical companies that develop and manufacture chemical and agrochemical products for the open markets around the world.

Corporate developments and achievements

1931	Harlan Labs established (Legacy crop protection and chemical focused lab)
1951	Huntington Life Sciences lab established
2015	Huntingdon Life Sciences, Harlan Laboratories, GFA, NDA Analytics and LSR associates merged into Envigo Labcorp completes its purchase of Covance
2019	Labcorp acquires Envigo CRS – expands CP&C portfolio of offerings
2021	Labcorp expands US footprint with CP&C capabilities in Greenfield, IN
2024	As a leading lab partner that offers human and environmental safety testing and consulting services for the CPC industry, Labcorp offers a global network of sites across four global regions (North and South America, EU (UK) and APAC)

Case study 1

Navigating nanomaterials through REACH – Chemical Services case study

Labcorp was approached by a client with a synthetic graphite nanotube used in specialised applications who needed to register it in the European Union under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) regulation.

Although graphite is already registered under REACH, these tubules were clearly nanomaterials and therefore required a specialised REACH registration.

Navigating Nanomaterials Through REACH – Chemical Services Case Study, Aug. 03, 2021 (labcorp.com)

Case study 2

Planning for OECD TG 443 Changes by Generating History – Chemical Services Case Study

Keeping up-to-date on regulatory changes and performing sufficient groundwork to allow rapid implementation of new testing requirements is crucial to providing exceptional service to our our clients.

This proactive approach was needed when the Organization for Economic Co-operation and Development (OECD) introduced test guideline (TG) 443 – Extended One-Generation Reproductive Toxicity Study (EOGRTS) and the EC and ECHA preferred the OECD 443 to the OECD TG 416.

Planning for OECD TG 443 Changes by Generating History – Chemical Services Case Study, Jun. 14, 2021 (labcorp.com)

Case study 3

Safety first: Your guide to the Toxic Substances Control ACT (TSCA)

All governments are keen to ensure that the chemicals produced, manufactured and used within their countries are safe for consumers and used appropriately.

The 2007 European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation has become a model globally and is hazard based. In contrast, the US Environmental Protection Agency (US EPA) takes a risk-based approach to regulation under TSCA.

Safety First: Your Guide to the Toxic Substances Control ACT (TSCA), Jan. 31, 2022 (labcorp.com)

Staff selection

Sabitha Papineni, DVM, PhD – Global Head, Science & Strategy, Crop Protection & Chemicals Regulatory Consulting

- Mammalian toxicology subject matter expert on crop protection and chemical regulatory programmes
- Crop protection and chemical industry regulatory experience
- Strategic planning for development and maintenance of new active substances and plant protection products to ensure successful registrations with global regulatory authorities
- Review of data requirements and testing strategy development, such as waiver rationales, endocrine disruption and carcinogenicity weight of evidence assessments and mode of action studies and position papers
- Country-specific regulatory approaches and strategies to USEPA, PMRA, ANVISA (Brazil) and EU

Lesley Creighton – Regulatory Strategic Lead (Chemicals), CPC Regulatory Consulting

- Chemicals EU REACH and UK REACH
- Global notification of new chemical substances in North America, Australia, Asia Pacific region and developing regulatory regions
- EU REACH Only Representation, UK REACH Only Representation and Korea REACH Only Representation
- EU poison centre notifications (PCN), Harmonized Offshore Chemical Notifications (HOCN)

David Mayfield, MS, DABT, BCES – Expert Consultant, Crop Protection and Chemicals Regulatory Consulting

- Subject matter expert on human health toxicology, ecotoxicology, and risk assessment in relation to regulatory programmes
- Extensive experience performing toxicological assessments for international regulatory compliance programmes (eg TSCA, REACH, GHS).
- Strategic planning for development and maintenance of new chemical substances to ensure successful registrations with global regulatory authorities
- Supports development of Environmental Risk Assessments (ERAs) and strategies for related ecotoxicological testing supporting new Pharmaceutical Drugs

Steven Renaut – Associate Study Director, DART

- Chemical registration and drug development
- Safety assessment
- Study design and conduct
- Reproductive toxicology
- Crop protection and chemical studies
- Embryo-fetal development
- Male and female fertility
- Pre-and post-natal development
- Juvenile toxicity
- Scientific and regulatory compliance
- Regulatory and scientific strategy
- REACH guidelines

David Arrowsmith, Regulatory Consultant – Lead Project Manager (Biocidal Products), Crop Protection and Chemicals Regulatory Consulting

- Biocides: EU BPR, UK BPR and K-BPR
- Strategic planning and project management for approval/renewal of active substances and biocidal products to ensure successful registrations with regulatory authorities
- Review of data requirements and testing strategy development for product family authorisations, read-across justifications and efficacy testing requirements for disinfectant products
- Prepares biocidal regulatory dossiers, including product authorisation, active substance approval, article 95 applications, technical equivalence, and transitional notifications
- Project manages and provides regulatory consultancy to Task forces/ Registration Groups

Contacts	
Website	lisam.com
E-mail	info.eu@lisam.com
Head office	Rue Jean Jaures 5, B-7190 Ecaussinnes, Belgium
Contact	Michel Hemberg
Directors	Michel Hemberg, Owner and CEO/CIO Lisam Global Thierry Levintoff, Owner and CFO Lisam Global
Ownership	Private company
Locations	Belgium, France, Germany, UK, Romania, US, India, Turkey, Brazil, China, Luxembourg, South Africa, Italy, the Netherlands, South Korea, Australia, Argentina, Spain, Mexico, Poland, Canada, Bulgaria
Founded	1999

Overview

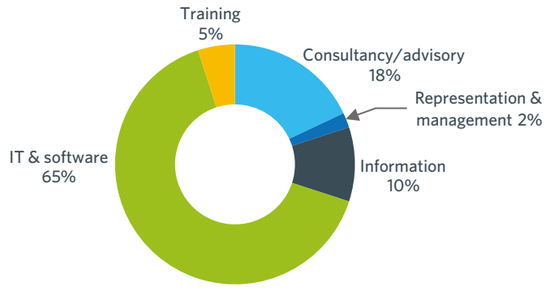
Founded in 1999, Lisam is a global provider of environmental, health and safety (EH&S) compliance management software solutions and services, operating from offices worldwide. By combining an easy-to-use, flexible technology built on the Microsoft .NET platform, with the latest regulatory content, Lisam 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, speciality chemical, cosmetics, aromas and flavourings, detergents, paints, coverings, coatings, plastics and energy industries. Today, thousands of customers 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 56 languages. With the opening of offices in Australia, Lisam can provide support and regulatory services for all five continents.

Vital statistics 2022/23

Turnover: group	€65m
Turnover: chemical service provision	€43m
No of offices	22
No of countries represented	25
Staff: group	480
Staff: chemical service provision	270

Service area breakdown



Services provided

Regulatory advisory services

For the past 25 years, Lisam has been a strategic partner to the chemical industry offering advanced environment, health and safety software and services. With practical knowledge and experience, we will guide your strategic decision making and bring support in:

- **safety data sheets:** creating quality SDSs in compliance with REACH and other regulations specific to your activities;
- **exposure scenario authoring:** preparation and translation in the latest standard format;
- **product portfolio compliance** relating to REACH, worldwide GHS, CLR (e) SDS, transport of dangerous goods, and many other regulations;
- **poison centre notifications** (Annex VIII to CLP);
- **regulatory monitoring:** general and customised;
- **biocides:** declaration of biocidal products and quantities, composition validation, study monitoring and environmental fate assessment, marketing authorisation, inclusion on list of authorised active substances and labels;
- **EU and UK REACH registration:** data collection, data gap analysis, test strategy, study monitoring, dossier preparation and submission (more than 400 dossiers);
- **EU and UK REACH only representative:** REACH compliance for non-EU and non-GB manufacturers; and
- **EU and UK REACH third-party representative:** Lisam acts on your behalf for data submission and data sharing.

Lisam will act as your trustee whenever necessary to maintain the protection of your or your suppliers' CBI. Our regulatory department also includes IT experts to advise you on the most adequate IT environment, install Lisam' 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 label 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's Chemical Substance Control Law;
- **regulatory content:** cost effective, integrated regulatory content such as DEL lists, EU GHS and REACH databases, 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 our own provider, WikiChemia, for the monitoring and fast integration of global regulatory content; and
- **more solutions** for waste management, risk assessment, detergents, fragrances, cosmetics, gas incidents and audit management, compliance calendar and tasking, air emission calculations, and chemical management etc.

Our solutions also include a compliance suite, integrating an SDS distribution and archival application, a chemicals inventory and document generation tool based on the SDSCOM xml format.

Training, services and support

Our services are offered in several languages:

- **regulatory training and consulting:** EU and UK REACH, GHS, CLR IUCLID, (e);
- SDS, poison centre notifications, biocidal products regulations;
- introduction and extended training on ExESS applications;
- **regional training:** EU, US, China, Japan;
- **technical training:** API, ERP integration, customisation;
- a helpdesk answering you on the phone or via email;
- version patches and updates of ExESS issued three times a year guarantee a system aligned with latest regulatory changes: and
- free user conference twice a year to discuss the latest implementations.

Corporate developments and achievements

1999	Creation of Lisam 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 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 Montreal, Quebec
2014	Lisam Deutschland opens in Berlin Wikichemia, LISAM start-up dedicated to the management of regulatory lists, opens in Luxembourg
2015	Lisam opens offices in Turkey, Romania and Brazil
2016	Lisam opens offices in China and the Netherlands
2017	Lisam opens offices in Italy and South Africa
2018	Lisam opens offices in Australia and South Korea
2019	Lisam opens offices in the Netherlands
2022	Lisam opens in Spain

Accreditations

REACH Ready certification. Full member of ORO (REACH Only Representative Organisation). EIGA preferred solution. Microsoft Gold Partner. PARTNERS. EIGA, WikiChemia, Emori, JCDB.

Partners

EIGA, WikiChemia, Emori, JCDB.

Clients

With premises and partners around the globe, Lisam applications and regulatory advisory services are adopted by more than 2500 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 21 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 and its 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 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 confidentiality 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 share a centralised database, while others use their own, lack of synergy
- SDS and labels layouts all differ, no efficient work method

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 has been supporting successfully global actors in cosmetics, detergents, fine chemicals, industrial and speciality chemicals, consumer products formulators with:

- ingredients, raw materials and product compliance under REACH and CLP;
- under other regional regulations;
- regulatory monitoring and early regulatory qualification processes;
- preparation and submission of inquiries as well as individual and joint REACH registration dossiers; and
- 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. He took over the CEO position in June 2012, managing the global expansion of the company. Michel obtained a civil engineering degree in 1986 and has worked for 25 years as a 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 obtained a civil engineering degree in 1985 and has more than 20 years' experience in software engineering, consultancy and product management in EH&S.

Maxime Juste, ChE, Head of Delivery and Support

Maxime has a civil engineering 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 as project manager for major industry actors.

Makersite

Contacts	
Website	makersite.io
E-mail	team@makersite.de
Head office	Munich, Germany
Contact	Julian.weitz@makersite.de
Directors	Neil D'Souza
Ownership	Private company
Locations	Stuttgart
Founded	2018

Overview

Makersite is a software-as-a-service company based in Stuttgart, Germany. Our software gives manufactures with highly complex products transparency and confidence in their supply chains, to ensure regulatory compliance and accelerate every phase of product development.

We do this using machine learning and automation to regenerate data from your disparate systems and integrate it into our data foundation of global materials, processes, and suppliers. Creating instant, granular, and accurate product models for your entire portfolio.

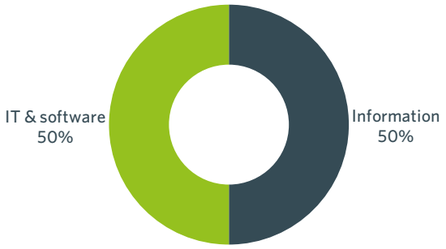
Our artificial intelligence connects the internal product data of our customers with data from more than 140 external supply chain databases that converge in our software. This gives customers an overview of their products and supply chains across the entire lifecycle of the product and over 40 categories, such as sustainability, cost, regulatory, etc.

Currently, we work for customers like Microsoft, Cummins Inc, Barco, P&G, Philips, Vestas, Bayer, and more. Clients mostly use Makersite to implement their Net Zero projects, design more ecologically and purchase more sustainably.

Vital statistics 2022/23

No of offices	4
No of countries represented	Global
Staff: group	60+

Service area breakdown



Global offices

UK, Germany, Norway, India.

Services provided

Makersite offers the following fully integrated solutions. All data, including proprietary third-party data, is included in our subscriptions.

Makersite Compliance: to manage quality and regulatory requirements, faster.

Compliance teams can use Makersite to harmonise material master data across the organisation to support timely and accurate compliance management. Product requirements including requirements for testing, quality and certification, and hazard communication can also be managed in an integrated manner. Makersite can help identify and mitigate compliance risks as an early warning system providing interactive and regionalised visualisations.

Extremely hazardous substance (EHS) chemical incident monitoring and substance tracking for compliance against control of major accident hazards (COMAH), Sevesco Directive, etc are also possible. Teams can also track compliance status against REACH, RoHs, Prop65, etc as well as custom lists and future regulation, and collaborate with suppliers with integrated surveys or standard exchange formats. Makersite offers flexible reporting including business intelligence (BI) integration for centralised dashboards.

Makersite Sustainability: for more sustainable products, faster.

Sustainability teams can use the integrated lifecycle analysis functionality to understand drivers of the product's environmental footprint orders of magnitude faster than traditional software. Makersite also enables engineering teams to design for environment and circularity with material lookups and AI-powered improvement suggestions, scenario analysis, and decision support functionality.

Makersite Costing: to calculate and optimise costs across your product's lifecycle, faster.

Makersite helps procurement teams implement their purchasing strategies by enabling them to should-cost purchased parts. Teams can quickly identify cost drivers and create a basis for supplier discussions. Makersite centralises cost data for the business and simplifies product costing for everyone. This enables engineering teams to design for cost and compares design alternatives, even early designs.

Makersite offers the following fully integrated solutions. All data including proprietary third party data is included in our subscriptions.

Makersite combines the best of all our products and provides a centralised intelligence platform that can integrate, harmonise, and gap-fill data from multiple systems. Together with our scenario analysis and decision support tools, this reduces friction between departments and helps to arrive at solutions faster.

Makersite also supports change and configuration management to reduce costly errors and the need for rework by understanding the impacts of changes in real-time.

Implementation and other services can be provided through us or our partners.

Accreditations

- The International Organization for Standardization (ISO)
- TISAX® is the world's leading automotive-specific information security standard

Partners

More than 140 data integrations, four integration partners, and three academic and industry partners (Berkeley and Durham University, Society of Cost Engineers).

Clients

Microsoft, Cummins Inc., Barco, Bayer, Vestas, Schaeffler, and approx 30 more.

Corporate developments and achievements

2018	Founded in Munich Launched the platform with product sustainability and costing applications
2019	Top ten startups in Europe by Innovation Radar Launched compliance applications and integrated more than 100 data providers
2022	€18m Series A investment Partnership with Autodesk, leader in product design software One of five finalists for the German Sustainability Award Partnership with Beroe to build more resilient supply chains
2023	Expansion to include team in North America Included as an example in AI segment in Gartner W Leverage Technology Ecosystems to Improve Sustainability Capabilities report for 2023 Included as a sample vendor in Forrester's "Supply Chain Imperatives For 2023" Named in Spend Matters 2023, Spend Matters 50 to Watch Named top 10 vendors advancing ESG and Sustainability Performance by Verdandix Named top 100 of 2023 by ProcureTech Named top 21 circular economy start-ups of 2023 by Circulaze Secured Partnerships with EcoInvent, Hitachi Solutions, PTC Windchill, and Suppliers Partners for the Environment and others

Case study 1

Advancing sustainability in industry: A conversation with Cummins

Cummins Inc.'s Mousumi Mukhopadhyay, Manager of Circular Economy & Life Cycle Leader, takes us through their journey with product level LCAs and supply chain insights.

Cummins were looking to take the next step in their sustainability journey. For them, this included keeping pace with the growth in annual ESG reporting obligations (including scaling their reporting capabilities to handle 27 ESG reports annually), standardising their data and enhancing supply chain transparency through digitisation.

Makersite helped Cummins to digitise their supply chains to show multitiered data aggregation layers, including data assurance, traceability and transparency as well as the collection and inspection of specific domains.

With Makersite's solution, Cummins was able to show how a product was generated, trace its journey through the supply chain and translate that information into the required sustainability reports.

Case study 2

Barco create multiple LCAs and PEFs on the fly

Barco faced challenges in efficiently reporting SKU-level environmental data due to data being siloed and scattered across the supply chain, resulting in slow and costly manual efforts.

Makersite provided Barco with automated Life Cycle Analysis (LCA) and Product Environmental Footprints (PEFs) at the SKU level, allowing them to accurately offset their emissions, comply with EU taxonomy reporting requirements, and implement more targeted eco-design principles across their product portfolio.

Barco was able to consolidate and enrich their data, perform comprehensive environmental reporting, and make data-driven decisions to minimise their environmental impact.

Case study 3

Schaeffler: Toward a climate-neutral supply chain with Makersite

How Schaeffler came one step closer to their target of a climate-neutral supply chain with the help of Makersite.

To achieve a climate-neutral supply chain by 2040, the company aims to reduce the carbon footprint of its raw materials by 25% by 2030. The challenge is that 90% of the raw materials used to make their electric motors are sourced from China with little to no deep-tier insight into emissions.

By teaming up with Makersite, Schaeffler can run ad-hoc automated analyses of environmental impacts from various supply chains in scope, eg for use of materials enabling the comparison different product scenarios from a sustainability perspective. By evaluating a range of sustainable supply chain alternatives in a pioneering pilot project, Schaeffler won the Global Innovation Award.

Case study 4

Microsoft's LCA methodology with Makersite

To transform their LCAs from being a purely directional modelling process to a more supply chain-specific environmental impact accounting process, Microsoft has invested in an innovative approach leveraging internal software engineering teams and Makersite to power sustainable products and supply chain decisions at scale.

The new approach was created to automate and scale the modelling of complex electronic products with an unprecedented level of primary data coverage. The key differentiation from common practices is that Makersite's artificial intelligence analyses the bill of material (BOM) of each device and the material composition from full material declarations (FMD) collected from suppliers to automatically model each part, component and sub-assembly down to its actual chemical composition.

A model of a representative manufacturing process is associated with each part in the BOM using data from Makersite, IDEA, and Ecoinvent, cutting out much of the manual effort and providing our LCA practitioners a running start. Effective scaling up of this modelling is enabled by the integration of Microsoft's product data management system with Makersite.

While their LCA experts are still involved in the process, they can now focus on completing the model with suppliers' primary data, performing the quality analysis, and ensuring the model is representative.

Staff selection

Neil D'Souza – CEO

Neil is an industry veteran and has previously been CTO at Thinkstep, the leader in product and corporate sustainability solutions. With more than 13 years' experience of building products, leading teams and directly helping customers through his technical consulting work, he founded and built the Makersite technology platform.

Fabian Hassel – COO

Fabian is an expert in lifecycle assessment, product sustainability and EHS. After an extensive career at Thinkstep and Emisoft AS, Fabian is now in charge of services and data at Makersite. He has conducted more than 100 LCA studies with international companies such as Kraft Foods, Mondelez, Hartman AG, Volkswagen, Mann und Hummel and has been involved in the development of the French ADEME database, the German Okobau.dat and other intentional lifecycle assessment databases.

Roy D'Souza – Data Science Lead

Roy is an expert in data science with a PhD in physical organic chemistry, while previously working in the fields of nanotechnology, biotechnology, and food chemistry, where he made several discoveries of new materials, unknown natural products, and new cocoa-based consumer products (ruby cacao). Currently, Roy works for Makersite as a data science lead building data model for sustainability, compliance, and risk in the manufacturing industry.

RAMBOLL

Contacts	
Website	ramboll.com
E-mail	rudolf.wilden@ramboll.com
Head office	Copenhagen, Denmark
Tel	+49 1 52 2258 1047
Contact	Dr Rudolf Wilden, Product Safety & Stewardship Lead Europe
Directors	Dr Martina Vosteen, Dr Benedikt Fischer (Germany) Dr Meera Cush, Thomas Griffiths (UK) Erin Tesch, Dr Lisa Navarro (US) Dr Cécile Rousseau (France) Nicklas Gustavsson (Sweden) Dr Andrea Pegoli, Giovanni Talamini (Italy) Dr Rosa Cirera (Spain) Willi Muenninghoff (Asia Pacific) Julian Reddy (Australia and New Zealand)
Ownership	Private company
Locations	300 offices worldwide
Founded	1945

Overview

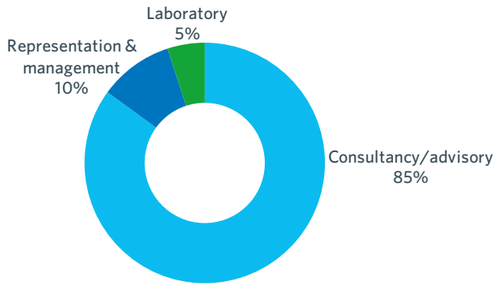
Ramboll is a leading engineering and consultancy company employing more than 17,000 experts. Our presence is global, with representation across continental Europe, the UK and the Nordic countries, North America, the Middle East and Asia Pacific. We constantly strive to achieve inspiring and exacting solutions that make a genuine difference to our clients, end users and society at large.

Our globally recognised environmental and health practice has earned a reputation for technical and scientific excellence, innovation and client service. Advances in science and technology and evolving regulatory, legal and social pressures create increasingly complex challenges for our clients. We evolve to keep pace with these changes – by adding new services, contributing to scientific advances or expanding geographically.

Vital statistics 2022/23

Turnover: group	€2,284m unaudited
Turnover: chemical service provision	€30m
No of offices	300
No of countries represented	35
Staff: group	>17,000
Staff: chemical service provision	250

Service area breakdown



Services provided

Ramboll 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;
- consumer;
- cosmetics;
- medical devices;
- food safety; and
- food contact applications.

We balance clients' technical, regulatory and commercial interests with 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 audits 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 also acts as a consortium manager, only representative and responsible person, and is independent from testing facilities.

Global chemical notifications and regulatory compliance support

Ramboll evaluates obligations and provides support for regulatory approvals required to market products globally. We assess new market opportunities, substance notification and regulatory obligations, classification and labelling (GHS) and packaging. Our established global network covers all sectors and geographies.

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;
- socio-economic analysis;
- product vigilance; and
- technical 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.

Testimonials

"Ramboll has assisted the CTACSub Consortium for more than ten years with its REACH authorisations of certain uses of chromium trioxide. Ramboll continues to provide support for the submission of the review report for prolongation of the granted authorisation. Ramboll's insight and knowledge of the metal plating and surface treatment industry is unique and very valuable." *Ursula Schliessner, Jones Day, consortium manager of the ChACSub Consortium.*

"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 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 timeframe requested." *Michelle T Quinn, associate general counsel, regulatory affairs and general litigation, Catalent Pharma Solutions.*

Corporate developments and achievements

2020	Ramboll launches Health Sciences Spearhead, bundling product safety and stewardship, occupational and building health, risk assessment and community health, expert services and science for regulatory support
2022	Ramboll launches 'The Partner for Sustainable Change' strategy and opens new offices in Japan and South Korea
2023	Ramboll has signed a licence agreement with Clean Production Action (CPA) to conduct comparative chemical hazard assessments under the GreenScreen® methodology. This is part of Ramboll's integrated service offering combining product compliance and product sustainability

Clients

Clients span all industrial sectors, including industrial and speciality chemicals, pharmaceuticals, petrochemicals, agrochemicals, food and food packaging, cosmetics, medical devices, electronics, manufacturing, aerospace and defence, apparel and consumer products.

Case study 1

REACH registration and evaluation

We prepare robust substance dossiers, 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. We have extensive experience of both dossier and substance evaluation, and support through the appeal process.

Case study 2

PFAS restriction support

We developed two dossiers for an industrial client to respond to the recent public consultations launched in relation to the EU PFAS Restriction Proposal. The dossiers encompassed different technical areas, such as toxicological evaluation of the PFAS in scope, industrial emissions and mitigation strategies, analysis of the alternatives known in literature and a socio-economic impact analysis along the supply chain.

Case study 3

Risk Management Option Analysis (RMOA)

Technical support to help an industry sector develop and justify to policy makers a more credible and effective RMO 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

Proposal to reclassify as CMR

An industry association asked Ramboll to advise on the basis and technical merits of EC proposals to reclassify a substance as CMR and provide support for technical advocacy for appropriate risk management measures.

Case study 7

Product stewardship

Our comprehensive emissions and exposure model characterised releases of the substance across Europe, providing a firm basis for discussions regarding risk management options.

Case study 8

Endocrine disruption

Identification and comprehensive evaluation of all available data using a weight of evidence approach to assess whether a substance had endocrine disrupting properties. Presentation of the evidence to authorities to inform policy making.

Staff selection

Dr Martina Vosteen – Principal, Global Division Director, Health Sciences

Twenty years' experience in risk assessment and product-related regulatory support for chemicals, biocides and consumer products, including RMOA, restriction (eg PFAS) and authorisation for REACH.

Erin Tesch – Principal, Director Health Sciences, US

More than 25 years' experience of regulatory guidance and advocacy for clients seeking approval of chemical related products.

Willi Muenninghoff – Principal, Director Health Science, Asia Pacific

Thirty years' experience in product-related regulatory support for chemicals, biocides and consumer products, including consortium management and enabling data sharing globally.

Dr Lisa Navarro (DABT, ERT) – Principal, Health Sciences, Product Safety & Stewardship, Global Key Account Program Lead (focus Americas)

US board-certified and EU registered toxicologist with more than 25 years' experience providing strategic guidance for the approval, ongoing compliance, and stewardship of consumer goods including food ingredients, cosmetic ingredients and food packaging materials.

Dr Rudolf Wilden – Principal, Product Safety & Stewardship Lead

More than 20 years' experience in supporting clients maximising the value of product-related HSE compliance and product sustainability.

Dr Robert DeMott – Principal, Product Safety & Stewardship

A Board-certified toxicologist with more than 25 years' expertise evaluating health effects from chemical exposures in the workplace and community.

Julian Reddy – Principal, Global Regulatory Affairs Manager

Thirty years' experience as regulatory project manager providing strategic guidance and supporting clients and consortia in meeting their global regulatory obligations for industrial chemicals, consumer products and biocides.

Dr Thomas Ruecker – Principal, Regulatory Toxicology

A board certified toxicologist (ERT/DABT) with more than 20 years' expertise in assessing hazards and risks from chemical exposures.

Dr Cécile Rousseau – Principal, Product Safety & Sustainability Lead

More than 15 years' experience between the French Competent Authority for REACH and Biocides, French Chemical Sector Organisation and supporting local to global clients optimising their products and minimising their impacts.

REACH Global Services

Contacts	
Website	reach-gs.eu
E-mail	info@reach-gs.eu
Head office	Rond Point Schuman, 6 Box 5, B-1040 Brussels, Belgium
Tel	+32 (2) 234 77 78, +32 (2) 234 79 11
Contact	Anna Figlarek
Directors	A. Ecmel Yorganci – Global Offices CEO Adil Pelister – Chairman of the Board
Ownership	Private company owned by Chemicals and Chemical Products Exporters' Association (IKMIB)
Locations	**Headquarters:** Brussels, Belgium **Subsidiary:** Istanbul, Türkiye
Founded	2008

Overview

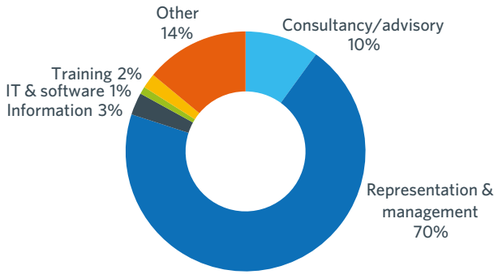
Brussels-based REACH Global Services SA (RGS) and its Turkish subsidiary RGS Danışmanlık A.Ş are professional regulatory consulting companies advising clients in the chemicals and allied industries to comply with EU, Türkiye and worldwide REACH-like chemicals legislations. RGS Group's experienced staff supplies services to a diverse array of global companies, operating across a range of chemical industry sectors in over 60 countries.

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 Only Representation, consortia management and Responsible Person services as core businesses for EU/Turkish REACH and EU Cosmetics Regulations included but not limited to; company specific consultancy services, general consultancy on regulatory compliance issues, training on specific legislation compliance, audits or due diligence projects.

Vital statistics 2022/23

No of offices	3
No of countries represented	5
Staff: group	25
Staff: chemical service provision	21

Service area breakdown



Global offices

RGS SA Brussels, Belgium. RGS Istanbul Liaison Office, Istanbul, Türkiye. REACH Global Danışmanlık A.Ş Istanbul, Türkiye. ChemAdvocacy. Kimyasallar Danışmanlık Ltd. Sti (CATR) Istanbul, Türkiye.

Services provided

EU REACH Compliance Services

According to Article 8 of the REACH Regulation, it is compulsory for non-EU manufacturers that export chemicals on their own or in preparations to the EU, to appoint an Only Representative (OR) for compliance. The EU importer benefits from being a downstream user and RGS, acting as an OR, fulfils the obligations of the manufacturer.

Our OR and consultancy services cover:

- preparation and submissions for inquiry and registration dossiers;
- SIEF/consortia representation;
- tailor-made tonnage tracking IT system and certification for compliance of the downstream user (DU)/importer; and
- general consultancy services for EU-based companies on substance registration, and interactions regarding authorities' requests/inspections.

EU Cosmetics Regulation Compliance Services

According to Regulation (EC) No 1223/2009, notification of a cosmetic product must be submitted prior to placing the cosmetic product into the EU market. Companies manufacturing outside of the EU must appoint an Responsible Person (RP). RGS acts as an RP and has notified thousands of products to the CPNP portal since 2013. RGS' experienced team of consultants assist manufacturers to compile cosmetic product information files (PIFs) to comply with the legal requirements.

Our services cover:

- EU legal representation (Responsible Person);
- preparation and verification of PIF;
- cosmetic product safety report parts A and B (CPSR); formulation and claims review;
- review and guidance on borderline cases;
- review and guidance on required corrections on labelling;
- cosmetic product notification to CPNP;
- scientific and laboratory services (claim tests, etc); and
- regulatory compliance support.

Turkish REACH (KKDIK) Compliance Services

Turkish-REACH (KKDIK), was published on 23 June 2017. KKDIK is almost a copy and 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 the Turkish language. However, the spirit of Article 8 of the EU REACH remains identical under the Turkish KKDIK Regulation (Art. 9).

RGS acts as a Turkish OR through its branch office, with its consultants highly experienced in the EU REACH Regulation and fluent both in English and Turkish. It is critical for non-Turkish manufacturers to choose a well-experienced professional OR in Türkiye to successfully comply with the Turkish national legislation.

According to the Turkish bylaw on the Classification, Labelling and Packaging of substances and mixtures (CLP), hazardous substances and hazardous polymers placed on the Turkish market should also be notified to the MoEUCC regardless of their volume.

RGS represents international companies putting hazardous chemical substances and mixtures onto the Turkish market under the Ministry of Environment Urbanisation and Climate Change (MoEUCC) database since 2010.

Consortia/SIEF Management Services

RGS and CATR staff, are experts in the REACH and KKDIK implementation processes and management of Consortia, in particular, the Data Sharing and LoA cost calculation procedures, and have a strong background from working in or for the chemical industry.

RGS is transposing all experience described above into KKDIK and play a role of interface between our EU REACH consortia management experience and KKDIK, including an efficient outreach to the Turkish chemical industry players and national authorities.

SDS Services

Within the scope of the regulation 2020/878 of the REACH legislation 1907/2006 in the EU, and within the scope of KKDIK regulation dated 23/06/2017 and numbered 30105 in Türkiye, it is an obligation to prepare Safety Data Sheet (SDS) for hazardous products.

With Article 64 of Turkish KKDIK; the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures (GBF) dated 13 December 2014 has been repealed. As of 31 December 2023, SDSs must be prepared by a chemical assessment expert (KDU) according to KKDIK Annex II.

RGS, with its experienced expert staff holding certifications from the accredited institutions, offers services for SDS and e-SDS preparation, update and validation in Turkish compliant with KKDIK and in 54 different languages compliant with EU REACH Regulation for your company-specific needs.

General Consultancy Services

RGS offers tailor-made training sessions on REACH, Turkish Chemical Regulations and the EU Cosmetics Regulation. Should your company require expertise in regulatory compliance or related industry legislation then please do not hesitate to contact us.

Assessment and certification services are also offered to companies having difficulty proving compliance during exports into the EU.

Other Global Chemicals Legislations

RGS offers services to manufacturers ensuring compliance with other chemical regulations in Korea, China, Japan and Taiwan. The scope of work includes, but is not limited to, local OR services, consortium management, submission of notifications and registrations in the local language with required data, regulatory update monitoring and annual reporting, and liaising with the authorities when required etc.

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.

All RGS staff are certified as Chemical Safety Assessors (KDU) and SDS Authors in conformity with the provisions of KKDIK.

Standardisation, certification and professional liability

- ISO 9001-2015 Quality Management Systems
- ISO 10002-2018 Quality Management – Customer Satisfaction
- ISOIEC 27001-2013 Information Security Management
- Compliance with EU GDPR and Turkish equivalent KVKK

Both RGS legal entities are covered by respective professional liability insurances of €2,5m and USD2m.

Clients

RGS' client portfolio (1100+ clients in 60 countries) 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.

Corporate developments and achievements

2008	REACH Global Services SA. established in Brussels, Belgium Istanbul Liaison Office established in Türkiye
2010	Appointed as an OR for more than 220 companies by the end of the year, representing 80% of the Turkish chemicals export volume in addition to manufacturers' from US, Japan, India, China, Indonesia etc. before the first EU REACH registration deadline
2011	Notified over 2000 substances under the Turkish bylaw on inventory and control of chemicals on behalf of +150 worldwide manufacturers
2013	Successfully completed REACH registrations in 2013 Started providing product information file (PIE) preparation services and introduced responsible person (RP) services according to the EU cosmetics Regulation
2015	Notified 1,500+ hazardous substances under the Turkish CLP (SEA) Regulation
2016	Established REACH Global Services Danışmanlık A.Ş in Istanbul, Türkiye Successfully notified 2,000+ cosmetics products into the cosmetics products notification portal (CPNP) by 2016
2017	Based on 12 years' experience in EU REACH and Turkish KKDIK regulation, extended its activities in Korea, China, Japan, Taiwan
2018	Completed 11 years' of REACH registration period with 2,000+ pre/registration for more than 450 manufacturers
2019	Pre-registered and notified 4250+ substances under KKDIK as OR/TPR, and SEA as trustee Preliminary preparations of SIEF/consortia establishment for Türkiye in direct communication with the EU REACH Consortia Extending activities in UK, and Eurasia
2020	Pre-registered more than 10,000 substances under KKDIK as OR/TPR for more than 350 manufacturers and notified 4,000+ substances for SEA. Leads SIEF/consortia activities within Türkiye Representing companies under UK REACH through strategic partners
2021	Commenced working on SIEF/consortium management in Türkiye, financial management and data sharing, letter of access agreements to provide services to the EU consortia and lead registrants
2022	Successfully submitted 50+ lead registration dossiers. Acts as the pioneer company on SIEF management for more than 6,000 co-registrants under KKDIK
2023	Successfully submitted 600+ registration dossiers. Acts as the pioneer company on SIEF management for more than 12,400 co-registrants under KKDIK

Staff selection

RGS Board Members and management have more than 30 years' chemical industry experience and international regulatory affairs practice. The RGS technical team consists of chemists, chemical engineers, and environmental engineers with Master's degrees from five to 15 years' experience. Our consultants are experienced within the areas of regulatory management of chemicals both in the EU and Türkiye, with extensive practices 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 tailor-made and cost efficient solutions and corrective actions to the companies in urgent need for compliance.

REACHLAW
COMPLIANCE. SUSTAINABILITY.

Contacts	
Website	reachlaw.fi
E-mail	sales@reachlaw.fi, info@reachlaw.fi
Head office	Aleksanterinkatu 19, 00100, Helsinki, Finland
Tel	+358 9 412 3055/+358 9 412 3049 (fax)
Contact	Frederik Johanson, Partner, Sales
Directors	Jouni Honkavaara, CEO, Partner. Frederik Johanson, Partner, Sales
Ownership	Private company
Locations	Finland, Belgium, UK, Turkey, India, South Korea
Founded	2006

Overview

As a leading expert in registration, authorisation, and notification of chemical substances, inside and outside the EU, REACHLaw provides chemical regulatory compliance and sustainability solutions to fit customer's needs. We help companies gain market access for their chemical products and support them with compliance with different chemical regulations such as EU REACH and EU CLP, Turkey KKDIK and SEA, UK REACH and GB CLP, K-REACH and GHS, India BIS, India REACH and many more.

Furthermore, REACHLaw is also committed to supporting companies with their sustainable growth. As part of the EU's Green Deal objectives, we guide businesses in understanding the implications of ongoing developments related to EU REACH Revision, ESPR and EU Chemicals Strategy for sustainability.

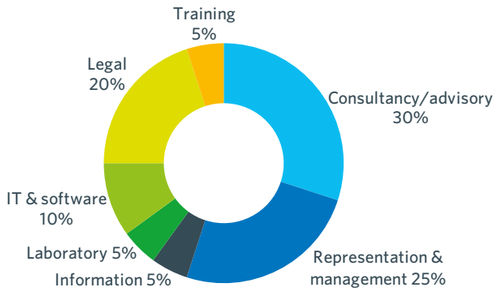
REACHLaw serves its clients in the following languages: English, Finnish, French, Spanish, German, Hindi, Hungarian, Italian, Russian, Swedish, Turkish and Ukrainian.

REACHLaw collaborates with several industry associations and has a network of partners in all the key areas globally.

Vital statistics 2022/23

No of offices	6
No of countries represented	60+
Staff: group	50+
Staff: chemical service provision	50+

Service area breakdown



Global offices

Helsinki, Brussels, Manchester, Istanbul, New Delhi, and Seoul.

Services provided

Global chemical regulatory compliance services

REACHLaw provides a comprehensive range of chemical regulatory compliance services to help companies adapt to changing regulatory requirements and provides full support with notification, inquiry/ pre-registration, registration, and authorisation of their chemical substances placed within and outside the EU. We serve our clients as their only representative and service provider through our offices in Helsinki, Brussels, Manchester, Istanbul, New Delhi, and Seoul.

Our support covers EU REACH and CLP, UK REACH and GB CLP, Turkey KKDIK and SEA, K-REACH and GHS, India BIS, Ukraine REACH & CLP and many more.

To date, REACHLaw has prepared 200+ lead registrations, 3,000+ registrations, including updates, 30+ authorisation applications, 8 000+ Turkey KKDIK pre-registrations, 500+ UK REACH downstream user import notifications, 500+ K-REACH pre-registration, and many more.

REACH authorisation and restriction support services

REACHLaw provides a range of services relating to substances of very high concern (SVHCs). These include technical and legal support in providing input into public consultations for entries proposed for inclusion on the candidate list, restriction proposals and recommendations for entries to be included on the authorisation list. We prepare applications for authorisation for our clients to enable them to continue their use of substances listed in Annex XIV.

We assist our clients at every step in the process, from strategy development to the collection, compilation and analysis of the information needed for the application, to its documentation in the format of the four reports to be submitted to ECHA. Post submission, we also assist with preparing responses to questions from ECHA's committees, responding to input from alternatives providers and commenting on draft committee opinions. We have prepared more than 30 applications for more than 40 uses that include individual and joint applications, and consortia for upstream and downstream applicants.

Legal support, public affairs and advocacy services

REACHLaw legal services provide support on a wide set of legal issues from legal analysis, data and cost sharing, consortia management to disputes and Board of Appeal cases. We help our clients develop and implement strategies to influence policy developments, raise awareness of their positions and interests, and build constructive relationships with key decision-makers and opinion leaders.

We provide tailored advice and support on all chemical legislation (eg REACH, CLP) and related sustainability concepts (eg SSbD, Essential Uses), and much more. We monitor and analyse the relevant legislative and political early-stage developments, expert analysis, prepare position papers, briefing notes, stakeholder identification and engagement and management. We also develop custom strategies for public affairs and advocacy efforts. REACHLaw has a proven track record of delivering successful advocacy outcomes for our clients.

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.

Clients

Major industry sectors served: oil, chemicals, petrochemicals, specialty chemicals, pulp and paper and metals. Downstream users in the chemical, electronics, defence, and space sectors. Our customers are manufacturers, importers, traders, downstream users, retailers, industry associations and governmental.

Corporate developments and achievements

2006	Established in Helsinki
2008	Partnerships with 20+ local partners in Asia, Europe, Latin America, the US and India established. 3,000+ REACH pre-registrations submitted
2009	REACHLaw received internationalisation award from the president of Finland. Brussels and New Delhi offices opened
2010	300+ REACH registrations submitted. REACHLaw launched global compliance services outside the EU
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
2013	REACHLaw supported several hundred REACH registrations, numerous authorisation projects, lead registrant cases
2014	Delivered several REACH lead registrations and a large number of authorisation projects
2015	Provided IT management solutions especially related to supply chain compliance and risk management
2016	The European Defence Agency (EDA) commissioned REACHLaw to carry out a study to examine the impact of the EU's chemicals regulations – mainly REACH and CLP – on the defence sector
2017	Supported several REACH registrations. Working on EU country specific product notifications
2018	Prepared many REACH 2018 lead and co-registrations Supported several companies with their 2019 applications for authorisation and KKDIK pre-registrations
2019	Prepared several large-scale joint applications for authorisation Supported EU 27 and UK companies to maintain access to the EU/ EEA market as well as to the UK market Prepared large number of KKDIK pre-registrations REACHLaw London office was established
2020	Prepared and submitted thousands of KKDIK pre-registrations Helped article suppliers with their SCIP notification obligations Helped UK and EU companies to address Brexit related impacts Helped industry with India BIS applications REACHLaw YouTube channel – REACHLAW TALKS – launched
2021	Supported industry with UK REACH registration requirements and provisional measures: downstream user import notifications, grandfathering and more Helping companies with their KKDIK lead registrations
2022	Supported companies with the preparation and submission of late DUINs, UK REACH lead and co-registrations, and the NRES process. Continue helping companies with their KKDIK lead and co-registration-related processes Provided support with data sharing regarding REACH-like regulations
2023	Continue to help companies with Turkey KKDIK lead registrations and co-registrations Helping companies understand the obligations under the proposed REACH Revision, ESPR and the Chemicals Strategy for Sustainability. REACHLaw Korea Ltd was established in Seoul
2024	Helping companies to comply with K-REACH registration requirements as their Only Representative through our Seoul office

Testimonials

"REACHLaw has been a true partner to Stepan Company as an Only Representative. The expertise the team has brought to the table has helped Stepan effectively navigate the complex regulatory landscape by enabling efficient portfolio and opportunity management, as well as management of lead and co-registration efforts. REACHLaw has been an asset in helping our customers to meet their needs." *Chris Hammond, Stepan.*

Case study 1

Global regulatory compliance – one-stop-shop

Data sharing is key to success in developing the lead dossier for the joint submission. It is imperative that the same information is, as far as possible, used across different chemical regulations to ensure that deviation in the data as submitted will be as little as possible. This will ensure that authorities will not find "arbitrage" opportunities between regulations. REACHLaw has, as part of providing lead registration services, currently most prominently for Turkey KKDIK purposes, assisted several of our clients in the re-utilisation of existing data as much as possible.

Typically, such data emanates from the EU REACH registration process and related tests as performed, but, in some cases, data has also been acquired from sources not previously used as endpoint data, typically for read-across purposes. In such cases, it has been important to keep potential deviations to a minimum from the EU REACH dosser. REACHLaw utilises its long experience gained from the EU REACH registration process in assuring the result for data sharing and related cost sharing is as optimal and cost efficient as possible.

REACHLaw uses its knowhow both for the scientific as well as administrative part of the data sharing process for the best results for both the client and regulatory compliance.

Case study 2

K-REACH Only Representation

REACHLaw helps its customers to comply with South Korea K-REACH and K-OHSA for both new and existing substances as their Only Representative. Using the experiences from being an Only Representative for EU REACH, UK REACH and Turkey KKDIK successfully for many years, REACHLaw applies the same proven compliance management processes in South Korea, and in doing so, helps our customers to learn about the complex requirements for chemicals in Korea and how to plan their product portfolio for optimal market access.

REACHLaw also supports customers with changing their Only Representative for REACHLaw Korea which was a hard process in the past, before 2024. Companies can now easily change for a better Only Representative instead of being stuck with their original one.

Staff selection

Tim Becker, MA (law) – Senior Legal Advisor

Sini Suomela MSc (organic chemistry) – Chief Operating Officer (COO)

Dr Bernadette Quinn PhD (chemistry) – Head of Authorisation Practice

Sibel Kiliç PhD (organic chemistry) – Director, REACHLaw Turkey

Pietro Di Tondo BSc (Hons) MPhil (chemistry) – Director, REACHLaw UK Ltd

Gagan Kumar MTech and BTech (chemical engineering) – Director, REACHLaw India Private Ltd

Julien de Cruz, LLM (Law) – Head of Advocacy Services

Sami Vesikansa, MSc (Biochemistry) – Head of Lead Registration Practice

Contacts	
Website	cia.org.uk/reachready
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
Locations	London, UK
Founded	2006

Overview

REACHReady offers a confidential and comprehensive service to help businesses fulfil their specific chemical regulatory compliance needs for both the UK and EU REACH, CLP and BPR regulations.

Through REACHReady's robust training and consultancy services, businesses have access to expert ongoing technical helpdesk support and are kept up to date with chemical regulation developments through regular technical alerts and regulatory guidance documents on the member's area of our website.

Our webinars and face-to-face meetings, as well as services provided via our Approved Service Provider "Matchmaker" programme, give global manufacturers, importers, retailers and formulators access to a broad network of technical expertise within the chemical industries.

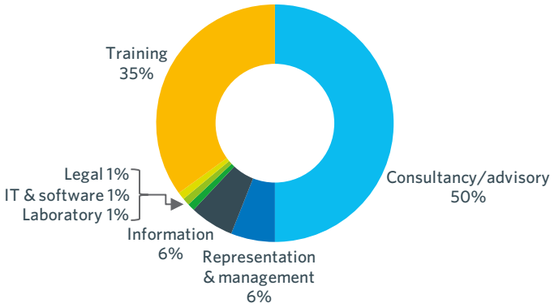
Our strong reputation and extensive experience of the chemical and downstream industries makes us the best choice for REACH, CLP and BPR services. Our understanding and knowledge of legislation stems from the in-depth involvement of our parent organisation, the Chemical Industries Association, in its development at every stage.

Contact us today. **cia.org.uk/reachready**

Vital statistics 2022/23

No of offices	1
Staff: group	2-5
Staff: chemical service provision	2-5

Service area breakdown



Global offices

Westminster, London, UK.

Services provided

In the REACHReady focus areas of REACH, CLP and Biocides for both the UK and the EU, we provide the following services:

- technical helpdesk;
- training – public and bespoke;
- consultancy including on site REACH Assurance days;
- safety data sheet and label reviews; and
- preparation of IUCLID dossiers.

In addition to our core services, our Matchmaker service allows us to put you in touch with our Approved Service Providers who can assist in areas such as:

- only representatives services under REACH;
- laboratory testing services;
- performing scientific data searches/gap analysis;
- assessment of data packages eg toxicological/ecotoxicological; and
- legal and commercial assistance.

Clients

Helpdesk, Consultancy, Training, Matchmaker.

Testimonials

"Overall REACHReady is a fantastic resource. Their helpdesk for REACH/CLP/BPR is very helpful and provides detailed responses with fast turnaround times (and welcome follow-up queries). Their Technical Alerts are also informative." *Yannick Gama, Chemical Regulatory Affairs Associate at Bartoline Limited*

"I think REACHReady are fantastic in what they do, when I have required assistance, I have received a professional and detailed response. The highly skilled team are polite, friendly, and always willing to help. The training courses they offer are excellent and very detailed." *Michael Howard, Monitoring and Compliance Executive at Leading Solvent Supplies Ltd*

"REACHReady delivered a professional and bespoke event for the Scotch Whisky industry, cost-effectively. Their technical expert explained the implications of REACH for our industry and helped us to identify a clear course of action to ensure REACH compliance." *Julie Hesketh-Laird, former Director of Operational and Technical Affairs, Scotch Whisky Association*

"I found the training both of academic and practical use, with real examples to illustrate the point(s) being made. The course tutor was proactive in ensuring that what you put into the training you also got back out, re: interaction and sharing best practice and ideas."

Case study 1

Helpdesk

A GB-based company exporting products to the EU faced a requirement previously not needed; to declare a "Y-code" to customs to explain the products' restriction statuses under REACH. They were not able to find sufficient information to inform their choices, and their shipping agent was unable to provide clarification.

After contacting the REACHReady Helpdesk, we explained to the company the meaning of all relevant Y-codes for REACH restriction status, the background and reasoning for the new codes, and the appropriate situations in which to use each code. After discussion with the helpdesk consultants, the employee in charge of export control felt far more confident in assigning these new customs codes to each of their products.

Case study 2

Helpdesk

An EU-based organisation contacted the REACHReady helpdesk to understand their obligations surrounding Section 1.4 of the SDS, the provision of an emergency contact number, and when it was mandatory to include the number of the poison centre for the relevant EU27 Member State.

In addition to answering the above, the REACHReady helpdesk clarified on the provision of third-party contact details, whether these could be located outside the UK, and what additional information should be included alongside the emergency contact. Following the correspondence, the REACHReady Gold member was satisfied that they now understood the requirements for emergency contacts in EU REACH compliant SDS.

Staff selection

Our technical team members are REACHReady's key resource for delivering our training, consultancy and Helpdesk services.

Nishma Patel

Nishma has been working in the area of chemicals management since 2012 providing advice on regulatory issues around REACH, CLP, Safety Data Sheets and transport. As part of the REACHReady team Nishma spends much of her time on the helpdesk and writing technical articles for the REACHReady Review newsletter.

Roger Pullin

Roger joined the REACHReady Team in 2019 bringing over 12 years of experience in chemicals management and workplace health regulatory policy areas. Roger has a PhD in chemistry and is actively involved with policy developments in these areas here in the UK as well as the EU. He works on the Helpdesk and provides input to the REACHReady Review newsletter. Other experience includes product development within the chemical industry and working for the Chemical Hazards & Poisons Division of the former Health Protection Agency (now Public Health England).

Mark Selby

Much of Mark's work involves dealing with the complex issues raised by REACHReady customers, with a particular emphasis on the practical aspects of the regulation, carrying out risk assessments and the interpretation of data.

A major part of his work includes acting as a trainer for academic institutions, government agencies and industry (including health care and fine-chemical suppliers) covering areas such as applied toxicology, physico-chemistry and ecotoxicology in relation to regulatory requirements. This includes regular training work with the Chemical Hazards Communication Society for the classification and labelling of chemicals and preparation of Safety Data Sheets. Recent training programmes include involvement in the European Commission Twinning Project with Poland.

Silvia Segna

In her helpdesk role, Silvia advises companies on legislative compliance in relation to REACH, CLP and the BPR. She is also involved in policy developments surrounding REACH and BPR. Silvia holds a Master's Degree in Materials Engineering. Previous experience includes the position of Technical and Regulatory Affairs Manager in the engineering plastics business unit of a chemical company, where she was responsible for managing the technical customer service and ensuring products' compliance with technical standards as well as chemicals management policy in different market sectors such as automotive, electric/electronic, food contact.

Kirsty Eley

Joining REACHReady in 2022, Kirsty's previous experience includes regulatory and compliance advisor roles within the paints and coatings industry, with a heavy focus on the automotive market sector. In her role as consultant, she provides support through the helpdesk on UK and EU CLP, REACH and BPR regulations. Kirsty also manages the Technical Alert and contributes articles to the REACHReady Review.

Contacts	
Website	rpaltd.co.uk
E-mail	post@rpaltd.co.uk
Head office	Suite C, 2nd floor, The Atrium, St Georges Street, Norwich, Norfolk, NR3 1AB, UK
Tel	+44 1603 558442, +44 1508 520758 (Fax)
Contact	David Carlander
Directors	Matthew Lambert, Teresa Fenn, David Carlander, Eliza Kritikos
Ownership	Employee owned
Locations	UK, Italy, Czechia, Lithuania
Founded	1990

Overview

Risk & Policy Analysts Ltd (RPA), established in 1990, is an independent B-Corp certified employee-owned 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 market leader in the development and application of socio-economic analysis (SEA) for chemical risk management and is particularly proud of its reputation in preparing applications for authorisation of SVHCs under UK and EU REACH for industry clients.

RPA offers services on the assessment of socio-economic impacts from the CLP hazard classification of substances that are subject to the provisions of the biocidal products and cosmetic products Regulations. Following Brexit, RPA is offering its services also under the UK (GB) REACH legislation.

RPA has worked with industry clients since 2001 on the implications of the EU regime for chemical risk management. We have worked closely with the European Commission and the European Chemicals Agency (ECHA) on the development and implementation of REACH and many other regulations relating to chemical risk management, including recent reports on nanotechnology and UN GHS.

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 more than 50 high-profile chemicals. RPA's multinational staff routinely work on detailed analysis and consultation with industry and regulators in most European languages.

RPA is a B-Corp and is ISO9001 certified.

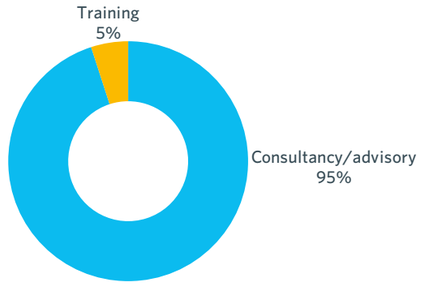
Vital statistics 2022/23

Turnover: group	€4m
Turnover: chemical service provision	€2m
No of offices	4
No of countries represented	Focus on EU-27, EEA, UK and candidate countries
Staff: group	50
Staff: chemical service provision	25

Global offices

RPA: UK; **RPA Europe:** Italy, RPA-Prague, Czechia.

Service area breakdown



Services provided

REACH Authorisation

RPA assists industry clients with the development of applications for Authorisation of SVHCs under REACH (UK and EU), as well as REACH Authorisation strategies more broadly.

These studies involve detailed analyses of supply chains, of alternatives and preparation of SEAs and substitution plans.

REACH Restriction and CLP Classification

RPA assists both industry clients and regulators with the collection and analysis of use/exposure data of chemicals, their alternatives and the preparation of SEAs. This data may be used to inform restriction dossier development or support industry in defending substances for which harmonised hazard classifications or restrictions without derogations 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 EU REACH revision, PFAS, nanomaterials, OELs, WEEE/RoHS, CMRs at work, toy safety, cosmetics, biocides, drinking water and WFD.

Partners

RPA works with FoBiG, Okopol, Field Fisher, Bureau Veritas, Triskelion, Milieu, DHI, RIVM, Arche Consulting, IEH Consulting, AQC/Logika and Anthesis, among others.

Clients

OECD, European Commission (including DG Grow, DG Environment, DG Employment and DG Justice and Consumers).

National authorities (UK, Germany, Sweden, Denmark, France, Norway and the Netherlands).

European Chemicals Agency, European Food Safety Authority, European Environment Agency, Executive Agency for Small and Medium-sized Enterprises.

European/international industry/trade associations and groups (including AISE, Apeal, Cefic, Cosmetics Europe, DEHP ATF, Etinsa, Eurocommerce, Eurometaux, European Plastics Recyclers, IAEG WG5, ICMM, IMnI, International Zinc Association, Lead Development Association, Nickel Institute and UKWIR).

A range of companies (from multinationals to SMEs) and consortia, including Bayer Pharma AG, Dow Chemicals, Eli Lilly, Grupa Azoty, Huntsman, H&R Group, Lanxess, Rolls-Royce, Airbus, Leonardo, Nouryon, Spolana.

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."

"Your expert knowledge alongside your conscientious, accommodating and flexible approach made it a pleasure to work with you on this project. The resulting outputs have provided us with a detailed 'How-to' guide for monitoring and evaluating UK REACH over the coming years."

"[Client] is very satisfied with the deliveries of the projects and found the outcome very useful. We are also very happy with the continued support and the professional and open communication with RPA."

Corporate developments and achievements

1998	RPA wins major framework contract for the UK authorities on chemical risk management
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 support applications for authorisation under REACH with a focus on SEA work
2012	RPA completes three studies for DG Environment reviewing the first years of REACH implementation
2014	RPA clients obtain the first granted REACH authorisations
2016	RPA leads the EC fitness check for chemicals legislation (excluding REACH)
2017	RPA supports DG Employment in major revisions of the CMD and RPA clients submit first ever authorisation review reports
2018	RPA Europe established as an EU legal entity to ensure continuity of services within the EU post-Brexit
2019	RPA leads a team of consultants in providing technical services to the Aerospace & Defence Chromates Reauthorisation Consortium (ADCR). This team is also supported by Fieldfisher, FoBiG and Bureau Veritas
2020	RPA selected to lead fifth study for DG Employment assessing the socio-economic impacts of potential revisions to occupational exposure limits (OELs). RPA supporting UK DEFRA in UK REACH monitoring
2021	RPA and RPA Europe complete a report on behalf of ECHA on the current state of knowledge regarding chemical recycling of waste
2022	RPA supports private clients on PFAS substances. Submission of ADCR dossiers in EU and UK
2023	RPA leads sixth study for DG Employment on assessing the socio-economic impacts of potential revisions to occupational exposure limits (OELs). RPA selected to assist with development of REACH Regulation for the Isle of Man

Case study 1

Provision of analysis of alternative (AoA) and socio-economic analysis (SEA) support services

RPA has provided REACH Authorisation support to several consortia of manufacturers and users of SVHC substances. This includes preparation of analyses of alternatives, supply chain communication, preparation of socio-economic analyses and substitution plans.

Most recently, RPA is acting as the lead consultant on the Aerospace and Defence Chromates Reauthorisation (ADCR) Consortium, preparing applications for authorisation for the sector across a range of uses for eight chromates. This includes reauthorisation in the EU and new applications for authorisation under UK REACH.

Case study 2

Market analysis of PFAS on behalf of authority and industry clients

RPA conducted an analysis on the manufacturing and processing of PFAS in Europe on behalf of RIVM, the Dutch National Institute for Public Health and Environment. This was used by RIVM to understand the possible impacts of a proposed restriction for these substances. Following this, RPA has supported several private clients with socio-economic analyses of PFAS across many sectors.

Case study 3

Sixth study on Occupational Exposure Limit Values (OELs)

RPA recently completed a sixth study for DG Employment, assessing the socio-economic impacts of potential revisions to OELs under the Chemical Agents Directive and the Asbestos at Work Directive. We are currently working on the sixth study for OELs. This includes performing socio-economic analysis of possible OELs to assess the costs and benefits.

Staff selection

David Carlander – Director, Chemicals

David, a board member of RPA, has more than 23 years' experience from academia, public administration and the private sector. He holds a PhD in Clinical Chemistry, and an MSc in Biotechnology. For the past 15 years, David has been working on risk assessments in food and chemicals, including nanomaterials. David has been supporting regulatory submissions of food contact materials under the EU and US legislations, and given numerous presentations at national and international events, including regular attendance at Echa Stakeholder and OECD meetings.

David Lever – Technical Director

David Lever, brings more than 20 years' experience from the metals, mining, and industrial minerals sector. He has held a number of technical and commercial positions and has extensive experience in market analysis, project leadership, market development, and business process improvement. At RPA David has worked on a number of projects in the Chemicals and REACH space, including Regulatory Management Options analysis and Restriction proposal.

Max La Vedrine – Principal Consultant

Max works on REACH applications for authorisation conducts site visits, performs literature reviews, and develops client's analysis of alternatives, socio-economic analysis and chemical safety reports. Max has worked on several studies looking at the impact of EU chemical legislations.

David Fleet – Technical Director

David is an economist, with more than 15 years' experience leading RPA's work on impact assessment and evaluation work as well as SEA for REACH authorisations. David is fully familiar with EU's Better Regulation guidelines and with relevant ECHA guidance.

Russell Norman – Senior Consultant

Russell has more than 25 years' experience as an industrial chemist. Areas of expertise include surfactant-based cleaning, re-odourising and biocidal products, and REACH. The main focus of Russell's work is identification and compilation of information for the purposes of applications for authorisation under REACH.

Marco Camboni – Director RPA Europe S.R.L

Marco is an environmental economist with more than 15 years' experience in policy advising.

Daniel Vencovsky – Director RPA Europe Prague s.r.o.

Daniel has significant research and project management experience.

SCC
WE CARE FOR YOUR SUCCESS

Contacts	
Website	scc-gmbh.de
E-mail	scc@scc-gmbh.de
Head office	Am Grenzgraben 11,55545 Bad Kreuznach, Germany
Tel	+49 671 298 46-0, +49 671 298 46-100 (fax)
Contact	Dr Thomas Roth (Head of Chemicals)
Directors	Florian Pistel, Dr Monika Hofer
Ownership	Private company
Locations	Berlin, Germany. Japan, United Kingdom
Founded	1989

Overview

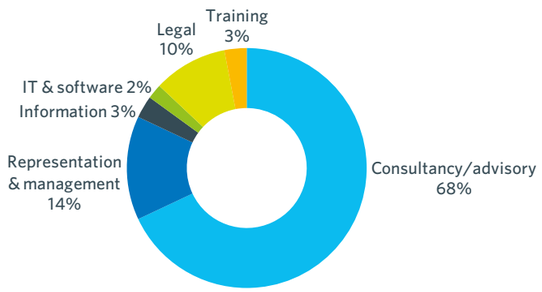
Since 1989, SCC – Scientific Consulting Company – has been supporting the industry with tailored strategic solutions for their regulatory and scientific needs focusing on international registration and in-market compliance services.

Our key areas include chemicals, cosmetics, consumer products, plant health and nutrition products, biocides, medical devices and pharmaceuticals, feed additives, food contact materials and GLP archiving.

Vital statistics 2022/23

No of offices	4
No of countries represented	3
Staff: group	160
Staff: chemical service provision	60

Service area breakdown



Global offices

Headquarters Bad Kreuznach (Germany), Office Berlin, SCC Japan and SCC UK.

Services provided

Regulatory and scientific support for chemicals – EU REACH and international regulations

SCC provides strategic expert counselling, registration services and lifecycle support for chemicals at international level.

We successfully filed more than 1,000 lead dossiers and more than 50 PPORD notifications, hundreds of member dossiers and more than 1,000 CLP notifications. Beyond Europe, we notified new and existing substances in many international markets, such as the UK, Türkiye, China, Japan, South Korea, Australia, Canada and Eurasia.

We have well-established relations with competent authorities in the EU and abroad and are recognised as a competent and reliable partner both by authorities (eg ECHA) and industry organisations (eg Cefic). For all types of substances and across all industry sectors, we can provide you with:

- professional advice on registration and testing strategies for chemicals and polymers;
- organising and monitoring of studies;
- preparation of inquiry and registration dossiers including submission to competent authorities;
- literature search, data review and identification of data gaps;
- development of grouping/category approaches (read-across);
- estimation of substance properties and data generation via QSAR prediction tools, such as QSAR Toolbox, EPI Suite and Ecosar;
- human health and environmental risk assessments, including exposure modelling (such as Euses, Risk of Derm, ConsExpo, EasyTRA, ART and Stoffenmanager);
- safety data sheet (SDS) support, including preparation of the annex to extended eSDS;
- C&L support (CLH dossier according to Annex XV Rac evaluation);
- defence support for chemicals under authority evaluation or scrutiny (EU: Corap, SVHC, compliance checks, restriction, authorisation procedure);
- comprehensive solutions for substances of concern, eg endocrine disrupting substances and nanomaterials;
- scientific/regulatory support at EU expert meetings;
- only representative support and trustee service for supply chains (non-EU, EU);
- joint submission and consortia support/management; and
- poison centre and SCIP notifications.

Strategic and regulatory services for agrochemicals, biopesticides, adjuvants, biostimulants and fertilisers

In the field of plant health and nutrition, we look back on several decades of experience, being well-versed in all aspects of registration and regulatory support for both chemical and biological substances and products under plant protection and fertiliser regulatory frameworks.

We have successfully defended more than 90 chemical and biological active substances both within and outside Europe and compiled hundreds of PPP dossiers for national markets in the EU, Asia-Pacific and NAFTA.

Our experts have been involved in the assessment of the endocrine disrupting properties of more than 15 substances in line with the ED guidance document (ECHA and EFSA, 2018) after its enforcement in 2018.

Together with our international partners, our expert teams stay at the forefront in strategic planning and defence, providing cutting-edge expertise in the fields of:

- data-gap analysis, study monitoring and dossier preparation;
- exposure modelling and risk assessments for human health and environment;
- conceptual work on higher-tier approaches (eg *in silico* (eco)toxicology, population modelling);
- assessment of potential ED, including MoA analysis, AOP concepts and WoE approaches;
- preparation of expert statements and position papers;
- classification and labelling support (CLH dossier preparation and defence during Rac process);
- MRL/import tolerances and Codex MRLs; and
- independent expertise in product performance and efficacy testing and assessment.

Registration of biocides

We have long-lasting experience and a proven track record in the regulatory and scientific area. Our biocides experts have successfully submitted and defended dossiers for more than 25 biocidal active substances in nearly all product types (>70 active substance dossiers) as well as renewal dossiers and numerous dossiers for biocidal products and product families in line with BPR (Regulation (EU) No 528/2012).

Our team of 30 experts provide regulatory support in the EU and UK and task force/consortium management covering all disciplines, eg physical-chemical hazards and analytics, identity, efficacy, environmental science, ecotoxicities, human health toxicology including exposure, and risk assessments.

Regulatory and strategic solutions for medical devices

We have a profound knowledge of quality- and admission-relevant standards and regulations, helping you ensure the compliance of your medical devices with MDR (EU) 2017/745, (US) FDA or other regulations. We offer full-scale support in quality management in line with ISO 13485, 21 CFR Part 820 (FDA) or other QMS standards and national legal requirements.

We assist you in preparing or updating your technical files and have experience in risk management (ISO 14971), biological evaluation (study selection and evaluation in line with ISO 10993-1), and clinical evaluation (MDR (EU) 2017/745 and related guidance) as well as qualification and validation. We offer comprehensive support for nanomaterials and substances of concern.

Authorisation of feed additives and food contact materials

Hands-on expertise paired with keeping abreast of the recent developments in EU regulations is the vital basis for our regulatory and scientific support allowing us to look back on more than 50 successful (re-)authorisations for feed additives. Our expertise and good standing with the authorities and industry partners enable us to sustain the optimal balance of scientific data and expert statements for your products.

We professionally guide you through the hurdles of the food contact material (FCM) authorisation processes in the EU, covering all aspects of the framework Regulation (EC) No 1935/2004, specific European and national product regulations (such as for plastics, active and intelligent materials) and a variety of directives for other product categories (such as printing inks).

Notification of cosmetics and consumer products

We have been successfully supporting the cosmetics and consumer product industry for more than two decades. With in-depth knowledge of the relevant EU regulations (eg for cosmetics or detergents) and applicable national regulations, we help our clients master various challenges, such as the animal testing ban for cosmetics. We have successfully prepared more than 60 safety dossiers for challenging cosmetic ingredients like hair dyes, UV filters, preservatives, nanomaterials, botanicals and CMR categorised substances.

Regulatory/scientific and GLP archiving

With three decades of experience in the storage of regulatory and scientific data, we offer you sustainable and inclusive concepts for all your regulatory needs ensuring quick and cost-effective access to all regulatory data, including electronic documents and submission details, at any time and from any location.

We also offer secure archiving of GLP raw data. In 2004, we were successfully certified as the first GLP contract archive in Germany. Since then, we are regularly inspected by the German GLP monitoring authority, successfully maintaining this status.

Accreditations

- GLP archive since 2004
- Full Member of the Only Representative Organisation (ORO)
- Member of the "Helix Team" (Fieldfisher, Risks Policy Analysts, SCC and EU Focus Group): 'One-stop-shop' REACH services with focus on project management, socio-economic analysis, scientific assessment, legal support, advocacy and communications

Partners

In cooperation with our global network of CROs, local regulatory experts and scientists, we can offer our clients support in key markets across the world.

Corporate developments and achievements

1989	GmbH founded Agrochemicals, Biorationals and Regulatory Science business units
1996	Chemical and Consumer Products business unit Biocides business unit
2004	GLP archive certification
2007	Liaison Office Japan founded
2014	Office Berlin founded
2018	SCC Japan founded
2019	Medical Devices business unit SCC Legal founded
2020	SCC UK founded

Clients

Small to large (global) companies in the areas of chemicals, plant health and nutrition products, biocides, cosmetics and consumer products, feed additives, food contact materials, medical devices and pharmaceuticals.

Testimonials

Many of our clients are longstanding, some going back to the start of our company. New clients are often recommended to us via existing clients.

Case study

Grouping for complex substances under REACH

For a demanding class of 30 plus highly unstable and reactive substances, many in the higher tonnage bands, we managed to set up a category grouping approach, enabling us to minimise the overall cost and avoid unnecessary animal testing. The key difficulty was to develop complete testing packages based on meaningful bridging studies where many compliance check decisions were already in place.

We successfully established a comprehensive picture for the entire group through intelligent testing strategies, having waived a number of higher-tier tests.

Staff selection

Dr Thomas Roth

Dr Roth has a PhD in food chemistry and is a certified toxicologist. He has been with SCC for more than 15 years, and head of Chemicals since 2017. He previously worked for a large multinational chemical company, having gained considerable professional experience in the evaluation and registration of consumer products and chemicals worldwide.

Dr Jens Schlirf

Dr Schlirf has a PhD in Solid State Chemistry. He joined SCC in mid-2023 as a Team Lead Regulatory Affairs Chemicals. With more than 15 years' experience in the explosive, cosmetic and fragrance industries, he draws on firsthand experience across different industry sectors.

Dr Ingo Walter

Dr Walter has a PhD in food chemistry and is a certified toxicologist. He has been with SCC since 2008, focusing on risk assessments, C&L and eSDSs.

Dr Mathias Rietzel-Roehrdanz

Dr Rietzel-Roehrdanz has a PhD in chemistry and joined SCC in 2017. He focuses on international registration of chemicals and cosmetics.

Contacts	
Website	www.scymaris.com
E-mail	hello@scymaris.com
Head office	Brixham Laboratories, Freshwater Quarry, Brixham, Devon, TQ5 8BA, UK
Tel	+44 (0)1803 659170
Directors	Private limited company
Ownership	UK
Locations	2016
Founded	2000

Overview

Scymaris is a specialist CRO providing high quality aquatic ecotoxicology, environmental fate and analytical chemistry services to the global agrochemical, human pharmaceutical, industrial chemicals, biocides, cosmetics and animal health industries. Our extensive state-of-the-art laboratory facilities are equipped with controlled temperature rooms, freshwater and seawater treatment and processing capabilities, controlled air-flow and conditioning, security and back-up systems to provide a comprehensive suite of world class capabilities in regulatory (GLP) and non-regulatory laboratory testing, including:

- ecotoxicology (freshwater and marine), acute and chronic exposure and bespoke study designs;
- endocrine disruptor tests including FSTRA/FSDT/FFLC/FELs/AMA/LAGDA/ZEOGRT;
- biodegradation and higher tier radiolabelled and cold Environmental Fate studies;
- analytical chemistry services: product characterisation, Metabolite ID, complex chemical analysis (LC-MS/GC-MS), routine sample analysis, ILV's; and
- regulatory laboratory testing compliant to GLP, OECD, OCSPP, ISO, OSPAR and licensed to work with radiochemicals (14C & 3H).

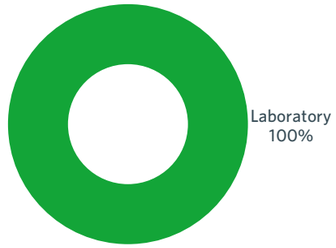
We are known for successfully and efficiently solving the challenges associated with the risk assessment and global registration of many different chemical types in the fields of agrochemicals, human pharmaceuticals, biocides, industrial chemicals and veterinary medicines. In addition to standardised regulatory testing, we also offer customised and bespoke study designs and will take the lead in proposing valuable testing strategies for often complex and challenging circumstances.

Our multidisciplinary team of scientists have many years of experience with different types of test compounds including complex substances. By design, our scientific teams are highly integrated across ecotoxicology, analytical chemistry and environmental fate/biodegradation enabling open and prompt communications and actions to ensure the timely completion of studies.

Vital statistics

No of offices	1
Staff: group	77
Staff: chemical service provision	58

Service area breakdown



Global offices

UK and US.

Services provided

Ecotoxicology

Aquatic, Freshwater and Marine.

Analytical Chemistry

Environmental Fate

Biodegradation

Radiolabelling

Corporate developments and achievements

2023	The King's Award for Enterprise – International Trade

Accreditations

- GLP Certification
- Radiological Permit
- Home Office ASPA Licence

Clients

We support clients from around the world: Europe, North America, Asia and South America.

Testimonials

"Deep scientific knowledge, great communications and timely execution of studies."

Case study 1

Designing a bespoke multigeneration fish study to support the derivation of an Environmental Quality Standard (EQS)

After extensive discussions with the regulator, a client approached Scymaris to discuss possible study design options for a long-term multigeneration fish study using the Fathead Minnow. Previous studies had not fully addressed the regulators' requirements in respect of the Environmental Quality Standard (EQS) for the substance which member states will need to monitor and comply with.

Approach:
After consultation with the client and an academic scientific advisory panel, a draft study design was submitted to the regulator for comments and feedback. A final study design was agreed using a combination of relevant OECD test guidelines, utilising the OECD TG 210, OECD TG 234 and OECD TG 229. The study starts with embryos as the F0 generation, taking them through to breeding adults employing the OECD TG 229. The embryos collected from the OECD TG 229 are retained within the study to assess the effect of the test compound on the F1 generation. The design of the multigeneration study was well received by the regulatory authorities.

The planning of this study required several pre-tests to determine a suitable concentration range and pH level of the dilution water to represent European waters. We modified the OECD TG 236 for the Fathead Minnow to assess the effects of pH and toxicity of the substance on the embryos. This study type was employed to minimise animal numbers and employ the 3Rs principles.

Case study 2

Identification of unlabelled transformation products in environmental fate studies

The position of the radio-label for environmental fate studies should necessarily be in a stable location on the molecule. However, this location is not always the location of interest in terms of activity or toxicity. Metabolite identification is only triggered by radio-labelled transformation products, which could result in a misleading profile of non-toxic metabolites. In this project, a screening method for the identification of transformation products containing a specific active centre by accurate mass LC-MS/MS using in-source fragmentation was utilised.

Approach:
A range of reference standards were analysed for common fragments that contained or indicated the presence of the target functional group. As the upper limit on the ratio between precursor m/z and the lowest trapped fragment ion is restricted for FTMS, in-source fragmentation rather than data dependent scanning had to be employed. The most useful fragment ions were found to have masses lower than the dynamic range of the trap.

Suggested structures were assigned to each fragment and likely candidates were chromatographically extracted in study samples with a mass accuracy of ±10mmu (limited by the processing software). Peaks in the extracted ion chromatograms were then reviewed to determine if mass conformed to the fragment ion with an accuracy of ±5ppm. Without the use of data dependant scans, parent ions are not immediately apparent. Modern processing software was also found unhelpful when reviewing data collected by in-source fragmentation. However, it was possible to determine parent ions by comparison with full scan data collected with no in-source fragmentation. Control samples, not typically prepared for radio-labelled environmental fate studies, were also vital to confirm the source of suspect peaks.

Outcome:
Along with the identification of triggered (<10% of the applied radio activity) radio-labelled transformation products, it was possible to observe additional transformation products containing the targeted active centre. Although the data is qualitative it is considered helpful to determining the need for further quantitative determination.

Case study 3

Using a fluorescence spectroscopy method to determine the cell density of the cyanobacteria Anabaena flos-aquae

Anabaena flos-aqaue is a species of filamentous cyanobacteria used in ecotoxicology testing. It forms long chains of cells, which makes some methods of cell density determination either extremely laborious (manual) or impractical (automated particle counting).

Approach:
Literature showed that using a fluorescence spectrometer to measure cyanobacteria or algal cell density was a reliable and accurate method. The absorption of fluorescence by the fluorophore phycocyanin (a fluorescent blue pigment protein found in cyanobacteria and some algae) was found to be a suitable surrogate to more direct cell counting methods. Data was readily available on the excitation and emission wavelengths for phycocyanin, which we used to run growth trials and a reference toxicant study, where a chemical with a known toxicity level is used to test the efficacy and effectiveness of a test method. The test was run for 72 hours with samples taken at each 24-hour interval for cell density determination.

It quickly became clear that the method worked well for the 48- and 72-hour sampling occasions. But due to the relatively low concentration of cells at the 24-hour time point, measured values were not always discernible from the background readings and were not within our planned calibration range. It was thought that the filamentous nature of *A. flos-aquae* contributed to this as it was difficult to obtain a homogenous sample. Disruption of the cell chains using an ultrasonic bath was undertaken, leading to shorter chains comprised of fewer cells, increasing the homogeneity of the samples. Alongside this, we tested increasing the initial cell density of *A. flos-aquae* inoculated into each test vessel at the start of the test at several different levels to determine what was most effective and able to grow exponentially over the whole test period and achieve the highest cell density at the 24-hour time point. Having increased the homogeneity of our samples, we were also able to extend our calibration range to cover much lower cell densities.

Outcome:
After some trial and error, we were able to successfully determine the cell density of test samples at the 24-, 48- and 72-hour sampling occasions and meet the validity criteria detailed in an internationally recognised test guideline (OECD 201, 2011) for several regulatory studies.

Staff selection

Edward Hayward – Director of Laboratory Operations.

Helen Garcia – Head of Ecotoxicology.

Gemma Andrews – Head of Environmental Fate.

Marina Santos – Head of Analytical Chemistry.

Simon Lock – Director of Quality & Regulatory Compliance.

Glyn Horner – Global Head of Business Development.

Contacts	
Website	sphera.com
E-mail	marketingoperations@sphera.com
Head office	130 East Randolph St, Suite 2900, Chicago IL, 60601, US
Tel	+1 312-796-7160
Contact	Shyam Khagram
Directors	Paul Marushka, President and CEO, Jim Pieper, Chief Financial Officer
Ownership	Privately held
Locations	USA, Canada, France, UK, India, Japan, Germany
Founded	2016 (previous division of IHS)

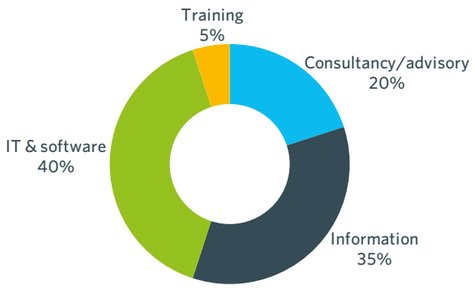
Overview

Sphera is the leading provider of environmental, social and governance (ESG) performance and risk management software, data and consulting services focusing on environment, health, safety and sustainability (EHS&S), operational risk management and product stewardship. For more than 30 years, we have served over 7,000 customers and a million-plus users in 80 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.

Vital statistics

	2022/23
No of offices	14
No of countries represented	Global
Staff: group	1,000+
Staff: chemical service provision	150

Service area breakdown



Global offices

UK: 24 Greville Street, London, EC1N 8SS. **Germany:** Hauptstrasse 111-113, 70771 Leinfelden-Echterdingen.

Services provided

Sphera provides product stewardship solutions 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 enterprise resource planning (ERP) and product lifecycle management (PLM) systems enabling consistent support for business compliance processes.

Our comprehensive chemical management and product compliance 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. Sphera supports your company's compliance programme with these powerful information management capabilities:

Chemical management

Ensure universal access to safety data sheets, manage the approval, physical arrival and departure of chemicals on site and easily report on all of your chemical data. Our chemical management solutions, including on-site inventory services, offer integrated regulatory data and chemical approval functionality. With access to one million unique product profiles, global capabilities, automated SDS updates and compliant reporting and labelling tools, you can ensure worker safety and compliance.

Product compliance

Our SDS authoring solution 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 declarations and compliance analysis

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 the data flow for end-to-end business processes by effectively connecting to other key systems, such as ERP, PLM, LIMS and formulation management applications.

Sphera also offers a product compliance solution for SAP® EHS
As an official SAP® partner, 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 behaviour 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.

Clients

For more than three decades, Sphera's portfolio of solutions has been trusted by thousands of enterprise-level clients worldwide across a vast array of industries, including chemicals, life sciences, fragrances and flavours, industrials and automotive, CPG, paints and coatings, technology and manufacturing, oil and gas, and utility.

Case study 1

Horiba

Based in Japan, Horiba is a multinational manufacturer of measuring and control instruments. It specialises in manufacturing emission measurements systems, environmental measuring instruments, medical diagnostic analysers and a wide range of scientific analysers. The company has locations in over 25 countries and sells in multiple markets across the globe.

Corporate developments and achievements

2011	IHS acquires Dyadem. IHS creates Operational Excellence & Risk Management (EHS) Division
2015	Verdantix – Smart Innovators badge
2016	Verdantix – Green Quadrant Leader Sphera Solutions founded from previous IHS EHS Division
2017	Sphera Solutions acquires Rivo Software Verdantix – market leader, chemical and hazardous waste management. Environmental Leader – project of the year
2018	Sphera acquires SparesFinder and Petrotechnics
2019	Sphera acquires SiteHawk and ThinkStep Verdantix – #1 Provider, Chemical Management. Sustainability and Product Stewardship Excellence
2021	Blackstone acquires Sphera Solutions
2022	Sphera acquires riskmethods
2023	Verdantix – Green Quadrant: Leader: Enterprise Carbon Management Software. Verdantix – Green Quadrant ESG Reporting and Data Management Software. Verdantix – Green Quadrant: Leader: EHS Software Sustainability Leader
2024	Sphera acquires SupplyShift

In 2012, with the increased pressure to comply with regulations like the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the need to author safety data sheets (SDSs) in country-specific languages, Horiba realised it needed an SDS authoring software and began to evaluate its options. Horiba quickly realised that there weren't any Japanese software solutions available that could support all the languages it required. One of Horiba's overseas group companies recommended Sphera's Intelligent Authoring solution and offered to help the team in Japan establish internal processes and operations for implementing it. Sphera's extensive language offering coupled with the fact that Horiba's group company was already using the solution made Intelligent Authoring the clear choice.

Case study 2

Blaser Swisslube

For more than 85 years, family-owned Blaser Swisslube has produced a comprehensive range of reliable, high-quality and high-performance metalworking fluids for a variety of industries. Blaser Swisslube makes it a priority to deliver solutions with measurable added value while being gentle to people and the environment. The company has two production facilities, 46 international agencies and 13 subsidiaries across the globe.

In 2021, Blaser Swisslubes's leadership recognised that the company needed a better way to author compliant SDSs for the global markets into which they sell. The solution they were using was from a small regional player that was not keeping pace with rapidly changing global regulations. Additionally, they were spending a huge amount of time manually re-authoring SDSs in different languages. The Blaser team narrowed their search to three software providers, but ultimately chose Sphera's Product Compliance software to reduce their risk of non-compliance and improve transparency for their customers.

Case study 3

Northrop Grumman

Northrop Grumman, a leading global aerospace and defence technology company, realised that their homegrown tool for managing SDSs was no longer working for them. It was a very manual process, much of the old data could not be queried and it required the team to manually enter data into their ERP system. When ECHA REACH came out in the early aughts, they knew it was time to look for a better solution.

When the team at Northrop Grumman made the decision to implement a true chemical management solution, they launched an official RFQ process with three major vendors. During this process, Sphera's Chemical Management solution rose to the top as the clear choice for their team. The ability to connect to their ERP system, the amount of data Sphera indexes and the ability to query and join information, including GHS status, were top reasons for their decision. Sphera's Chemical Management was initially deployed at 12 Northrop Grumman sites and, over the years, has expanded to serve 50 sites.

Case study 4

Yara

Meet Yara, the world's largest fertiliser company and a leading chemical manufacturer, specialising in ammonia and nitrate production, with operations in 50 countries supporting sales in over 150 countries. To sell its solutions for sustainable agriculture in international markets, the company must ensure that its products are always in full compliance with a multitude of health, safety and environmental (HSE) regulations and standards.

Yara had to tackle the introduction of the REACH and GHS-EU legislation in Europe, therefore they re-examined the software tools for the authoring of SDSs with the aim to create an integrated system with SAP. Yara's business is SAP-based and Sphera offers an application called Compliance Engine for EHS, which is complimentary to the SAP offering, so they were able to leverage Sphera's solution with an SAP EHS background platform.

Staff selection

Carrie Decatur, Manager Regulatory Content

Carrie has been with Sphera for over 17 years. In her role as manager regulatory content she is responsible for the analysis and implementation of global chemical regulations into the Sphera Product Stewardship offerings and the web based Intelligent Authoring (AI) training programme.

Rosemary Feiter, Managed Regulatory Services

Rosemary has more than 25 years' experience in a variety of fields that are correlated to product stewardship activities such as R&D, chemical production and distribution, quality control and hazards assessments. She leads Sphera's Managed Regulatory Services team that provides clients with SDS authoring and consulting services.

Scott Amoroso, Compliance Engine and SAP

With a prior background in product stewardship in the chemical industry as well as computer science, Scott assists our SAP EHS customers to implement and customise our product safety solutions with ease. He oversees several sustainment agreements for these customers, ensuring that our customers stay focused and up-to-date with the ever-changing regulations.

Michelle Atherley, Regulatory Content

Michelle has been with Sphera for over 17 years. She has more than 25 years' experience related to regulatory affairs in EHS and sustainability. As a senior regulatory analyst, her experience provides practical input for the implementation of global chemical regulations in Sphera's products, including Intelligent Authoring (AI) and product compliance for SAP.

Katie McGee, Regulatory Content

Katie is a global regulatory expert with more than 19 years' experience. She is a registered specialist in SDS and label authoring. Her role as a senior regulatory analyst includes managing regulatory content, training/education, monitoring and analysis of changes to regulations and serving as an internal and external subject matter expert for Sphera's Chemical Management and Product Compliance solutions.

Ruth Donlon, Regulatory Content

Ruth is a global regulatory expert in Chemical Management and Product Compliance with more than 19 years' experience. With her deep background and expertise, she has been a key driver behind chemical data and product compliance strategies within Sphera, focusing on chemical management services, SDS authoring, and regulatory compliance.

Staphyt
empower science together

Contacts	
Website	staphyt.com
E-mail	contact@staphyt.com
Head office	**Regulatory Affairs head office (new address)** Le Rodin – 26 Rue Louis Blanc, Lyon 69006, France **GLP Laboratory (new address)** 12 Avenue des Langories, Plateau de Lautagne, Valence 26000, France **Staphyt head office** 23 rue de Moeuvres, Inchy en Artois 62860, France
Tel	+33 (0)3 21 21 45 21
Contact	**Regulatory Affairs Director:** Aurély Beghin (abeghin@staphyt.com). **GLP Laboratory Director:** Jean Christophe Boissinot (jcboissinot@staphyt.com)
Directors	Regulatory Affairs Director: Aurély Beghin GLP Laboratory Director: Jean Christophe Boissinot
Ownership	Staphyt Group
Locations	Europe, Brazil, Morocco

Overview

Staphyt Regulatory Affairs Division provides comprehensive technical expertise, multiple language skills and in-depth regulatory knowledge on plant protection products, fertilisers, biostimulants, biocides and REACH, throughout Europe, UK, Brazil and in many other countries.

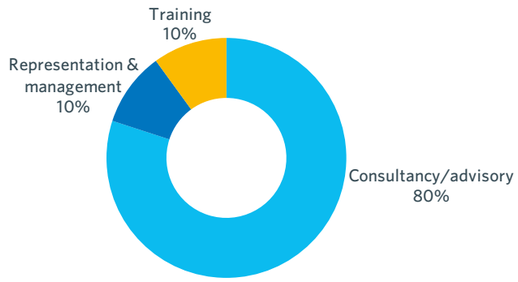
Our regulatory consultants help our clients to meet all aspects of their chemical and biological regulatory obligations, to achieve authorisation for the production, marketing and sales of their new or existing substances or products in their target countries. We will also keep you informed of changes in the regulatory landscape as they emerge.

Staphyt GLP laboratory generates all the data for ecotoxicology, environmental fate, physical-chemistry, residue, analytical support. We help you to screen, test and evaluate your substances and products. The Staphyt laboratory works in accordance with OECD guidelines and in compliance with ISO and OPPTS standards and national and international regulations. Tests may be performed under Good Laboratory Practice or for R&D purposes.

Vital statistics 2022/23

Turnover: group	€44.7m
No of offices	**Europe and Brazil:** 10 regulatory offices **France:** 1 ecotox/efate/analytical lab
No of countries represented	>40
Staff: group	>700
Staff: chemical service provision	>150

Service area breakdown



Services provided

Areas of expertise

Sectors covered: plant protection products, fertilisers, biostimulants, biocides, chemical substances (REACH & CLP).

Regulatory affairs services

- Regulatory advice and strategy
- Data gap analysis
- Technical equivalence
- Field and laboratory study monitoring (GLP and/or GEP)
- Dossier preparation for active substances and products
- Literature search
- Task force/consortium management
- Risk assessments for operators, workers and bystanders, birds and mammals, other terrestrial and aquatic organisms, consumers, environment
- Modelling
- CLP classification, SDS and labelling
- Poison control centre notifications (PCN)
- Expert statements and Efsa compliant literature searches
- Regulatory support in all European countries, Brazil, Australia and many more
- Technical and regulatory training
- Update service Regulatory Watch (newsletter by subscription)
- UK-REACH and GB-CLP support
- Only Representative support (EU or UK)

GLP Laboratory services

- Ecotoxicology (terrestrial and aquatic, endocrine disruptors assessments, bee studies)
- Environmental fate
- Physical Chemistry (substance properties and characterisation, storage stability)
- Analytical support (Residue analysis, Active Substance monitoring, Degradation products, Biomarker screening)

Corporate developments and achievements

1989	Creation of Staphyt
2015	Acquisition of Ambrosi Scientific Consulting France
2018	Acquisition of TB Agrartechnik Austria
2018	Acquisition of APC UK
2020	Setting Regulatory Affairs office in Brazil
2020	Acquisition of Rovaltain Research Laboratory in France
2022	Acquisition of Plurie and Leisor, Regulatory consultant companies in Brazil

Partners

In addition to our in-house teams, we also work with a network of third parties (laboratories and local external consultants) across many continents, providing a comprehensive offering of regulatory and scientific expertise at both the national and European level. This network supports us by extending our language skills and by having consultants who have formed close relationships with regulatory authorities in their own areas.

Clients

From SMEs to multinationals, our clients are chemical and biological product manufacturers, formulators, importers or distributors. We work with many well-known larger clients, well established small to medium-sized companies, and with startups. They specialise in one or more of the following types of business: biocides, industrial chemicals, plant protection products, adjuvants, fertilisers and biostimulants.

Accreditations

GLP, GEP, Research Tax Credit accreditation and training.

Testimonials

Client 1

"For us working with Staphyt is effortless. As well as open and collaborative communication, their expertise takes the burden of requiring specialists in each area off our shoulders. Working together provides us with space to focus where our internal value lies, confident our partners Staphyt are fully managing technical aspects to meet our particular needs.

Client 2

"Working with Staphyt for several years has shown us that we can count on them for project development. Communication is simple and proactive, being able to have specialists with high competence and knowledge, and with a very high commitment to achieve the set objective."

Client 3

"The assistance we received from the ecotoxicology experts on the ED studies for our active substance was great. We received quick and reliable feedback on the study progress and the options to continue, so we could weigh these off and choose the best solution to proceed with the study."

Case study 1

Biocides Sector

Thanks to its extensive experience in the preparation of dossiers for active substances, products and product families under most PTs, the Staphyt team managed and submitted in parallel nine single product dossiers and three product family dossiers for the same deadline. We prepared all dossier sections including all risk assessments. Tailored strategies for human risk assessment were proposed to our clients. Specific refinements were developed, including dermal absorption studies monitored by our toxicologists. We successfully obtained the biocidal product Regulation authorisation for all products in many EU countries.

Prior to this regulatory deadline, our team was in charge of transitional registrations of these products across Europe. More specifically, new products were registered according to national regulations in countries such as the Czech Republic, Greece, Latvia, Romania, Slovakia, Slovenia, Switzerland, Poland, Denmark, Lithuania and Belgium.

In the framework of the renewal of some authorisation dossiers, we are currently dealing with the update on biocidal product family regulation, taking into account the change of our clients' products.

Case study 2

Plant Protection Sector

A draft Registration Report was prepared for the renewal of authorisation of a product in different member states across the EU.

The product was used on a wide range of crops, which involved a complex environmental risk assessment. As a first step, our 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 subsequently tailored to support the revised rates and timings, in order to gain the maximum number of crops for renewal of the authorisations. In the environmental fate and ecotoxicity sections, 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 modeling. These solutions were successful and the product was approved by the zonal Rapporteur member state.

Case study 3

Plant Protection Sector

One of our clients wanted to data match against protected active substance data held by another company. The substance was to be used in insecticide products and there were many complex metabolites and some very challenging environmental issues. We assisted our client in negotiations to secure access to protected vertebrate studies with the primary data holder. We also provided a robust justification waiver of the date requirements negotiated on other areas with the EU RMS. We were able to save our client more than €1m as they no longer needed to generate all of the data themselves. Our client was therefore able to maintain all their existing national registrations at a cost significantly below what was initially expected.

Case study 4

Chemicals – REACH

Our experts have prepared many lead registration dossiers under REACH, including UVCB registrations. Our experts worked closely with ECHA to confirm substance identity, prior to submitting a successful inquiry dossier. To upgrade the inquiry dossier to a new substance lead registration, our technical specialists completed a detailed data gap analysis to identify end-points where additional data would be required. Following completion of a targeted literature search, the project manager provided the client with a strategy for addressing remaining data gaps, which included commissioning new testing, alongside securing access to read across 'source' substance data.

The PM managed the laboratory appointed to conduct the new testing, drawing in technical specialist support where necessary. Through the One-Stop-Shop offer (Laboratory + Regulatory), an optimised timeline has been proposed for all the phys-chem and ecotoxicological studies, with specific prices and services.

In parallel, the PM negotiated read across letters of access for the additional source substance studies. The IUCLID dataset, accompanying read across justification (in accordance with ECHA's Read-across assessment framework – RAAF) and CSR, including exposure assessment, was then prepared by specialists across a range of disciplines, including toxicologists, ecotoxicologists, environmental fate and physchem specialists, as well as human health/environment risk assessors. Timely dossier preparation enabled the client to place the substance on the EU market quickly, submitted as an 'only representative' registration.

Staff selection

Our large, highly qualified and experienced scientists and regulatory consultants teams have expertise in all areas. Our experts are drawn from regulatory authorities, industry, professional organisations, others testing facilities and consultancies companies, providing Staphyt with a varied and comprehensive offering to our clients.

Aurély Béghin – Regulatory Affairs Director

With more than 12 years' experience in consultancy, Aurély has held several senior leadership positions in biocides business development, in regulatory and scientific teams' management. These roles involved supporting clients in their strategic projects, managing business change and building team expertise.

Garth Drury – Principal Consultant

Garth Drury joined our team in 2021. With more than 30 years' experience in the agrochemical business, Garth has previously held senior positions at Bayer, Rotam and Arysta, plus he was President of the European Crop Care Association. Garth's considerable experience further strengthens the existing Staphyt team and he is available to assist with high-level strategic advice and support.

TEAM mastery

Know the rules, play your market.

Contacts	
Website	team-mastery.eu
E-mail	info@team-mastery.eu
Head office	Via G. Ferrari 14/B, 22100 Como, Italy
Tel	+39 031 269513
Contact	monicalocatelli@team-mastery.eu
Directors	Monica Locatelli
Ownership	Private company
Locations	Italy
Founded	2008

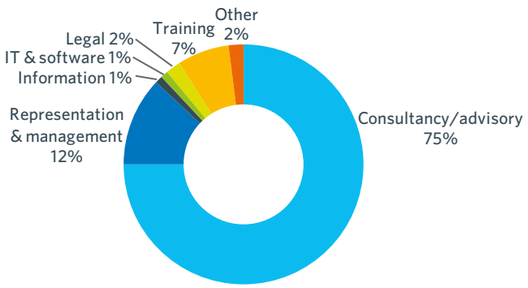
Overview

TEAM mastery is a premier service provider in chemical regulatory affairs, covering REACH, plant protection products (PPP), Biocidal Products Regulation (BPR), medical devices (MD), and more. Our expert staff specialises in chemistry, toxicology, and environmental risk assessment, committed to aiding clients throughout the supply chain. We leverage our industrial experience to enable cost-effective compliance with European and global chemical regulations. Our strategy integrates advanced, innovative solutions with scientific and regulatory insights, optimising benefits for the industry and end-users.

Vital statistics 2022/23

Turnover: group	€2.2m
Turnover: chemical service provision	€2.2m
No of offices	1
No of countries represented	1
Staff: group	28
Staff: chemical service provision	28

Service area breakdown



Services provided

REACH services: REACH registration dossier

TEAM mastery has substantial expertise in creating REACH registration dossiers, handling updates like tonnage band adjustments, responses to specific ECHA inquiries, and more. We excel in updating dossiers to meet ECHA's latest requirements, ensuring full compliance.

Read-across justification

TEAM mastery excels in providing read-across justifications to meet regulatory standards, successfully submitting numerous dossiers that leverage read-across to obviate the need for demanding *in vivo* tests. This process is enhanced by our use of QSAR modelling and *in vitro* testing.

Testing and *in vitro* strategy development, QSAR modelling

An integrated testing strategy is key for cost optimisation and justifying waivers. Our recognised expertise in QSAR modelling plays a crucial role in discussions with national authorities and scientific working groups.

Authorisation dossiers

TEAM mastery has acquired in depth expertise in developing comprehensive authorisation dossiers including the assessment of alternatives and socio-economic analysis.

Consortia management

We can provide legal advice, agreement documents, meeting location, cost calculation, managing of letters of access (LoAs).

Test monitoring

If new tests are necessary, TEAM Mastery will manage the selection of the most suitable laboratory, review the protocol, conduct lab audits, and verify results.

Risk assessment

TEAM mastery specialises in preparing Chemical Safety Reports (CSRs), including the addition of new uses or crafting downstream user-specific CSRs. We conduct exposure modelling using recognised tools such as EUSES, ECETOC TRA, EASY TRA, ART, CONS EXPO, and RISKofDERM.

REACH registration of polymers

With the upcoming REACH revision, the registration of certain polymers will be required. While awaiting the new draft, TEAM Mastery provides support in gathering essential information. We offer access to a dedicated software designed to efficiently organise information, aiding in the determination of the necessity for polymer registration.

Assessment and characterisation of nanomaterials

TEAM mastery offers assistance in the registration of nanomaterials following an analytical evaluation and (eco)toxicological assessment.

PPP services

Full dossier preparation for active substance and products. TEAM mastery offers comprehensive expertise to cover all aspects of a Plant Protection dossier, ensuring successful submissions across European zones. Our PPP team includes dedicated specialists, featuring leading European experts in Environmental Fate Modelling.

- Testing strategy development
- Study monitoring
- Risk assessment
- IUCLID compilation
- Finalisation and discussion with national and EU authorities
- Post-submission support

CLP/GHS services

Data collection and assessment of classification and labelling. SDS/eSDS compilation. UFI and PCN submissions. SCIP notification for articles. Exposure scenarios scaling and translation. CLH dossier. Supply chain communication.

Biocidal Products Regulation (BPR), services

Full dossier preparation for active substance and products. Technical equivalence. Testing strategy development. Management of biocidal product family (BPF) and of BPF *in situ* generated active substances. Study monitoring. Risk assessment. Endocrine disruptor properties evaluation. Evaluation of co-formulants endocrine disruptor properties. Finalisation and discussion with national and EU authorities. Post-submission support. Compliance procedures post Brexit.

Medical device services

Medical devices. Human health and environmental risk assessment. Determination of the permitted daily exposure (PDE). Assessment of mutagenic impurities.

Feed and food registration

Dossier preparation. Risk assessment. Test monitoring. Assistance to customers in case EFSA calls for data.

EU cosmetics Directive

Regulatory compliance support. Cosmetics ingredient profiles. Product information files. Cosmetic product safety reports.

World services

UK, Turkey, Korea, Eurasia, China, Japan, US, Canada and Brasil.

Corporate developments and achievements

2008	Foundation of REACH mastery
2010	About 120 successful registrations for the first REACH deadline
2012	Implementation of the BPR business unit
2014	Preparation and submission of the first application for REACH authorisation
2015	Implementation of the group to comply with the needs of the BPR 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 dossiers after Article 95 disputes on biocides and two authorisation dossiers
2018	Oversight of technical management and implementing dossiers for Italy's largest taskforce for the national authorisation of sodium hypochlorite New company name as TEAM mastery
2021	The new business unit "WORLD mastery" is born
2022	New Quaternary Salts task force for Biocidal Product national authorisation and implementation of a strategy for REACH polymer registration
2023	11 REACH applications for authorisation, 3 active substances dossiers The new business unit "TEAM academy" is born

Partners

Kahlberg Consulting S.r.l., Centro REACH S.r.l., network with local industry associations and consultants for health and safety requirements at work sites. Research projects in collaboration with many universities. Collaboration with Centre of Alternatives to Animal Testing (CAAT) Europe.

Clients

We work with some 500 customers around Europe; they are manufacturers, distributors, downstream users, from SMEs to international chemical companies involved in industry sectors including fertilisers, leather, textile, paper, pharmaceuticals, galvanic, food, cosmetic, polymers and many others.

Case study 1

REACH compliance check

The group is highly regarded in Europe for managing all aspects of REACH dossiers. TEAM mastery has prepared numerous lead dossiers, complete with monitored study plans. We specialize in UVCBs and complex substances, adapting many dossiers to meet ECHA's increasing compliance checks, thereby enhancing exposure scenarios, read-across justifications, and dossier quality.

Case study 2

Application for authorisation

After the incertitude of the chromium trioxide authorisation presented at consortium level, several companies decided to apply for their own applications. TEAM mastery helped many companies to successfully comply with the authorisation requirements.

Case study 3

Quaternary salts biocides consortium

TEAM mastery is working with Centro REACH for the organisation of the biggest Italian Task Force for the National Authorisation of Biocidal Products based on quaternary salts. Several families have already been established.

Case study 4

Nanomaterials

TEAM mastery aids in identifying and characterising nanoforms and defining eco(toxicological) testing strategies, including nanoform grouping for read-across. We've helped numerous clients comply with EU Regulation 2018/1881, updating REACH with new nanoform information requirements.

Case study 5

New Approach Methodologies (NAMs)

The increasing interest in New Approach Methodologies (NAMs) for chemical toxicological assessment is fuelled by EU Cosmetic Regulation compliance, ethical considerations, and the limitations of traditional animal testing. TEAM Mastery collaborates with universities and CROs to offer advanced NAM strategies, encompassing protocol development, result interpretation, and dossier preparation.

Staff selection

Dr Monica Locatelli – ERT, Founder and Director

After a degree in chemistry, ten years in R&D and a specialisation in toxicology applied to risk assessment, Monica has been working in regulatory and implementation of REACH regulation since 2001. The cooperation with many specialists within international companies and universities allowed her to specialise in consortia management and dossier preparation. She founded TEAM mastery in 2008 and since then she managed to grow the company which is now leader in the chemical regulatory area at international level.

Dr Costanza Rovida – ERT, Senior Regulatory Toxicologist

Graduated in chemistry, after 15 years' experience in analytical chemistry, she is now responsible for the management of global customer assistance. She is part of the CAAT-Europe team with participation in the integrated EU project RiskHunt3R, focused on NAMs.

Dr Chiara Marelli – REACH Regulatory Specialist

PhD in Organic Chemistry, about 10 years' experience in pharmaceutical R&D, Chiara is now responsible of the REACH division of TEAM mastery and reference person for the authorisation dossiers.

Dr Elena Borsini – Product Safety Regulatory Specialist

PhD in Organic Chemistry, Elena is responsible for global customer assistance in their daily needs as downstream users.

Dr Arianna Fazio – Regulatory Affairs Specialist

After graduation in environmental sciences, Arianna is now a Regulatory Affairs Specialist, head of the Biocides division of TEAM mastery.

Contacts	
Website	toxicon.it
E-mail	info@toxicon.it
Head office	Via Robolini 1, 27100 Pavia, Italy
Tel	+39 0382 1938015
Contact	Raffaella Butera, MD
Directors	Raffaella Butera, MD
Ownership	Private company
Locations	Italy
Founded	2010

Overview

Toxicon provides a wide range of consultancy and regulatory services in the areas of toxicology, pharmacology, occupational medicine, products regulatory compliance and consumer safety for companies, institutions and for the general public.

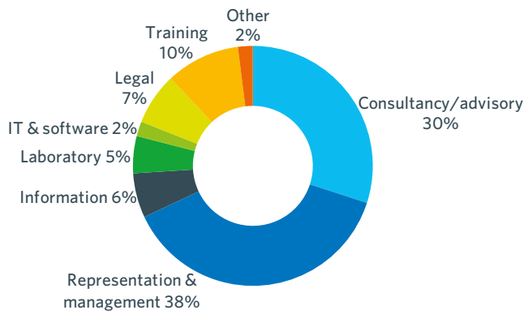
Toxicon offers clients its know-how based on solid academic training in risk assessment and a deep understanding of clients' needs. Toxicon provides consulting services to both large companies and SMEs; approximately 40% of these activities are performed for international customers. Moreover, Toxicon works in partnership with institutions, industries and associations on R&D and compliance projects.

The team of specialists consists of toxicologists, pharmacologists, physicians, biologists, chemists, economists and lawyers: the core belief in Toxicon is that complex problems can be successfully and qualitatively solved through teamwork.

Vital statistics

	2022/23
No of offices	3
No of countries represented	1
Staff: group	9
Staff: chemical service provision	7

Service area breakdown



Services provided

We have always been active in the area of toxicology and risk assessment; therefore, we have the expertise to enable enterprises to handle chemicals properly and safely. We want to make our in-depth professional knowledge available to companies and stakeholders. We have personally experienced the evolution that led to the current regulations, we know the keys to interpreting them correctly and applying them appropriately.

We bring to companies our unique expertise that no other consultancy firm can offer: before we were at Toxicon, we managed tens of thousands of cases of poisoning and accidental ingestions, adverse drug effects, occupational diseases due to workplace exposure, spills, chemical accidents and maxi-emergencies.

Therefore, when the ultimate aim of regulations is the protection of human health and the environment, we know what we are talking about. We know this concretely and we put this concreteness into all the activities and assessments we carry out for companies.

Overall services

- Support for companies and guidance on regulatory interpretation
- Strategies and project management for regulatory compliance
- Auditing
- Support for dialogue with the authorities

Toxicological risk assessment

- Expert advice and consultancy
- Human and environmental toxicological risk assessment reports for chemicals, products, consumer exposure, workplace exposure and plant emissions

REACH

- Consortia management and data sharing agreements
- Data gap analysis and testing strategy for substances and groups of substances
- REACH registration dossiers (all types of dossiers, eg lead or member registrant, substances, intermediate, PPORD)
- Chemical Safety Assessment and Chemical Safety Report (CSR)
- Full support during substance and dossier ECHA evaluation
- REACH authorisations dossiers including SEA
- REACH restrictions compliance
- SCIP database notifications

Safety Data Sheets (SDS) and Exposure Scenarios (ES)

- Management of SDS flow in the company organisation, development of checklists and procedures
- Elaboration of SDS and e-SDS, ES for mixtures
- Compliance check with ES, scaling, CSR-DU development
- Check of existing SDSs to improve document quality

CLP and GHS

- Hazard assessment of substances and mixtures, classification and labelling
- Notification to ECHA C&L Inventory and to PCNP for emergency health response on mixtures
- Labelling of products

Biocidal products

- Transitional measures to BPR (ie assessment and management of national requirements)
- Preliminary assessment of formulae to check substances of concern and ED assessment of coformulants
- Product preliminary risk assessment report, including risk assessment for human health, animals and environment
- Data sharing agreements for authorisation
- Support for dossiers of active substances
- Biocidal products authorisation at national and EU level, including support in testing (phys-chem, efficacy, methods), risk assessment report, IUCLID dossier and Summary of Product Characteristics
- Support for dialogue with the authorities during dossier evaluation

Cosmetics

- Preliminary assessment of formulae
- Advice on testing
- Safety assessment, product information file (PIF), labelling
- CPNP notification

Food contact materials

- Advice for materials and products testing
- Assessment of risks due to with constituents transferred to food
- Declarations of compliance

RoHS

- Compliance assessment along the supply chain
- Advice for materials and products testing

Toy safety

- Compliance with essential and particular safety requirements with special reference to chemical properties
- Advice for product testing and risk assessment of relevant chemical constituents

Medicines

- Common Technical Document (CTD) for non-clinical and clinical modules
- Genotoxic impurities assessment
- PDE assessment
- Provisional OELs and OEBs for APIs and other chemicals
- Environmental risk assessment

Medical devices

- Chemical and biological characterisation, biological evaluation
- Extractables and leachables assessment

Occupational medicine

- Risk assessment and management (CAD, CMRD)
- Provisional OELs for unregulated chemicals

Legal advice

- Intellectual property
- Data sharing
- Protection of confidential business information
- Contract management and contract editing
- Support for dialogue with clients and suppliers
- Counselling and support to companies in case of enforcement

Education

- Training and education for companies, universities and institutions

Corporate developments and achievements

2010	Established as a private limited company, both senior and junior professionals converge in Toxicon to provide companies with toxicological risk assessments and services for REACH and CLP
2011	In partnership with a prestigious law firm, Toxicon sets up the Legal Business Unit
2013	Toxicon services extend to cosmetics and food contact materials
2015	The Biocides Business Unit is fully operational
2018	Toxicon activities in product safety, medical devices, healthcare and pharma areas are further enhanced
2020	During the most acute phase of the COVID-19 pandemic Toxicon – in addition to its regular activities – serves the numerous requests coming from manufacturers and users of disinfectants. Toxicon schedules daily educational webinars on toxicological and regulatory issues that become a regular meeting time for clients and partners to stay in touch even during the lockdown period

Case study 1

United we stand: when the creation of a Consortium strengthens companies compliance with chemicals regulations

Toxicon catalysed the aggregation of more than 40 manufacturers and importers of similar substances, channeling the commitment of players in a complex supply chain unfamiliar with the REACH Regulation. The identification of solid scientific criteria to support the appropriateness of including these substances in a single category has allowed a testing and evaluation strategy (shared with ECHA) with an economic advantage for all consortium members at equal data value.

The close cooperation between the companies in the climate of technical trust that was created made it possible to successfully address and resolve each potential issue with the full knowledge of the companies. Particularly noteworthy is the involvement in the activity of many SMEs whose awareness of the importance of the European chemicals strategy for safe management is growing day by day.

Case study 2

Successful legal litigation with the support of Toxicon expertise

The presence of an undesirable substance in a raw material used for a medical device could have created a severe problem for the manufacturing company. Toxicon performed a targeted and thoughtful assessment, identifying the allowable exposure level according to scientific literature and substance behavior in animals and humans, and by comparing such level with the amount detected in the medical device.

This made it possible to resolve the issue, reconciling the requirements of the regulations, the safety for the end consumer, the benefits to his health and, last but not least, the company's business on this product. We were glade to support the company in this situation, because we had the opportunity to give appropriate consideration to the needs of all stakeholders in the full respect of business, regulations, science and health.

Staff selection

Raffaella Butera

Founder and Director of Toxicon, physician, she offers to clients more than 30 years' experience in medical toxicology and regulatory affairs. "In Toxicon we provide companies with a unique point of view in the application of chemicals regulations: that of someone who – concretely – knows what it means to protect human health."

Arianna Brunoro

Senior Consultant, biologist, she offers to client highly qualified toxicological and regulatory consultancy. "Compliance with regulations is a crucial aspect in ensuring and improving the high quality of the environment and the human life, a fundamental key to a healthy future generation."

Fabio Lunghi

Senior Consultant, chemist, he offers to clients an in-depth regulatory knowledge and a rigorous approach to risk assessment. "In our work at Toxicon, the objective of evaluating a product is to identify and describe the conditions under which the risk can be controlled."

Massimo Zen

Senior Consultant, chemist, he offers to clients an extensive laboratory experience and expertise in risk assessment. "In our evaluations, the interpretation of the significance of the laboratory data gives depth and value to the analytical effort."

Daniele Campi Martucci

Senior Consultant, economist, he offers to clients a high sensitivity to small enterprises needs."The attention to small and medium-sized enterprises is crucial: at Toxicon we have developed SME-friendly services and activities to ensure proper chemical management even in the smallest enterprises."

Federica Butera

Senior Consultant, architect, she offers to clients a key reference point for the management of their regulatory projects with Toxicon. "The world of enterprise is all around us: we exchange needs, we experience, we build relationships, thanks to and with enterprises. Business is about bringing people to people."

Salvo Dell'Arte

Senior Partner of Law Firm Dell'Arte, lawyer and professor at the University of Turin, he offers to clients its profound expertise on commercial, industrial and copyright law. "The European Data Sharing Regulation has provided clarity, establishing in law the principles and rules that we ourselves had advocated since the early days of REACH."

tsg

Contacts	
Website	tsgconsulting.com
E-mail	info@tsgconsulting.com
Head office	TSG Consulting, Concordia House, St James Business Park, Grimbald Crag Court, Knaresborough, North Yorkshire, HG5 8QB, UK
Tel	+44 (0) 1423 799 633
Contact	Vicky Atkinson
Directors	Daryl Thomas
Ownership	Science Group plc
Locations	Global, with offices in France, Germany, Spain, UK, USA, Canada
Founded	1990

Overview

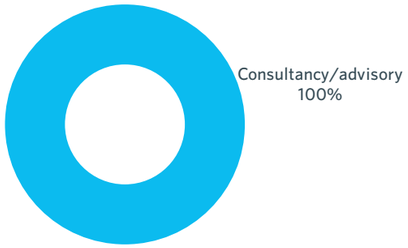
At TSG Consulting, our top priority is helping clients address regulatory hurdles and stakeholder demands to successfully bring their products to market across multiple jurisdictions. We understand the technical and regulatory challenges they face and provide comprehensive support for compliance, stewardship and sustainability.

With our scientific expertise and regulatory knowledge, we help clients navigate the complex and ever-changing regulatory landscape across the globe, while also taking into account local nuances. Our aim is to provide clients with robust evidence bases to achieve product goals and provide confidence for the future.

Vital statistics 2022/23

Turnover: group	>£113m
Turnover: chemical service provision	>£30m
No of offices	>10
No of countries represented	Worldwide regulatory support
Staff: group	>700
Staff: chemical service provision	>100

Service area breakdown



Global offices

UK (Epsom, Knaresborough, Cambridge, Bristol, Portsmouth, London). **Continental Europe** (Paris, France; Goslar, Germany; Oviedo, Spain). **North America** (Washington DC, US; London, Ontario, Canada). **Asia** (Shenzhen, China).

Services provided

Our services encompass the expert offerings below. We provide specific services for different needs.

These include literature reviews, data gap analysis and strategies for developing optimal evidence bases. Expert human health and environmental risk assessment of products, chemicals, contaminants, impurities and breakdown products, preparation of expert reports, waivers and rebuttals.

We offer insight into emerging science, endpoints and issues such as endocrine disruptors, persistent and mobile substances, PFASs and polymers.

Product compliance

- Compliance assessments
- Representation and liaison with state, federal, national and supranational authorities
- Consortium management and only representative services, taskforce management
- Due diligence audits

REACH and CLP

- Registration, evaluation, authorisation, restriction and classification
- Data and dossier optimisation
- Chemical safety and read-across reports
- Policy and science positions

Biocides

- Strategic advice and general consultancy: EU and GB BPR, and international expertise
- Data gap analysis, study choice, design and management
- Dossier preparation (active substance approval/renewal and product (family) authorisation/renewal)
- Human health and environmental risk assessment; endocrine disrupting assessment (active substance and co-formulants)

Cosmetics

- Compliance with cosmetics regulations (EU, GB and international) and assistance with responsible person (RP) duties
- Ingredient, formula, and product claim reviews
- Electronic notifications (Cosmetic Products Notification Portal), cosmetic product safety reports. (CPSRs), product information files (PIFs)
- Toxicological safety assessments

Food contact materials

- Notification of new FCMs to regulatory authorities
- Declarations of compliance (DOC), QA/QC and associated documentation
- Risk assessment and migration testing
- Support with food packaging alerts and product recalls

Food additives and ingredients

- Global regulatory advice and technical support
- Food additives and novel foods, including support with dossier preparation
- Food and nutrition labelling, nutrition and health claims, artwork label checks
- Pet food regulatory advice

Plant protection

- Practical and strategic advice on all aspects of the active substance and product approval process, including preparation of dossiers for new and existing projects
- Preparation of IUCLID dossiers for MRLs and active substances, new and renewal, projects
- Data gap analysis vs submission requirements
- Both preliminary and full risk assessments services, including any additional national risk assessments requirements

US federal and state regulations

- Regulatory, scientific and compliance support for US federal and state regulations
- ERA, FIFRA, TSCA, California Proposition 65, FFDCA
- Antimicrobial efficacy: test methods, project planning, data development, pre-submission support
- State pesticide registration and renewal services, including tonnage reporting for animal feed and fertilisers

Product stewardship

- Mapping use and impact of substances in the value chain
- Emerging issues
- Technical advocacy
- Claims, labelling and reporting

Product sustainability

- Horizon scanning
- Assessing alternatives and trade-offs, clarifying essential use, and substitution planning
- Safe and sustainable design and NAMs
- Lifecycle impact assessment

Corporate support

- Compliance audit programmes
- Portfolio management
- Product due diligence and management systems
- Science, policy and regulation planning

Partners

We're proud to be part of Science Group plc, an organisation committed to applying science to help companies successfully navigate product innovation, commercialisation and market requirements. Our team works hand in hand with our sister companies, Leatherhead Food Research and Sagentia Innovation, to deliver innovative and sustainable solutions.

Clients

We work with clients worldwide, from multinational corporations to start-ups, across a wide range of industries including chemicals, pharmaceuticals, food and beverage, and more. We also collaborate with industry groups, trade associations, and law firms to provide tailored solutions that meet our clients' unique needs.

Case study 1

Clarifying the science

We step in when companies need to present detailed technical evidence, to authorities to inform policy, regulation and decisions. For example, we developed a detailed case to present to ECHA Rac in relation to a request for extensive new data requirements for a SVHC at the ECHA REACH Committee and Board of Appeal.

Case study 2

Reliable evidence base

When our client needed a fast response to prepare for a new regulatory position, they called us to help prepare the evidence base. We worked closely with the client to define a strategy, and prepared a safety assessment, alternatives assessment and socio-economic analysis on a fast track, making a timely submission.

Case study 3

Safe and sustainable

When the regulator proposed a new harmonised classification for a substance, a major manufacturer wanted to find a safer alternative. TSG worked with the manufacturer to assess potential alternatives based on consideration of all available data, including information on analogous substances, with the aim to avoid new testing.

Our research provided the confidence to proceed with a major investment and a refined process for evaluating new products.

Case study 4

Verifying compliance

When a multinational chemicals manufacturer wanted to ensure compliance with REACH and other related regulations, they called TSG to develop a sound approach. TSG's experts collaborated with stakeholders to develop the audit methodology, assess compliance for hundreds of chemicals and manufacturing operations, identify gaps, and propose solutions, all while managing confidential business information.

Staff selection

Sue Bullock – Head of Chemical Compliance, Stewardship and Sustainability

Over 30 years' experience in human health and environments consultancy. Provides expert strategic and technical advice to chemical producers, downstream users and product manufacturers world-wide.

Amy Burrows – Head of Biocides and Cosmetics

Certified Agile Project Management practitioner with over ten years' experience providing scientific and regulatory support across the plant protection, biocides and cosmetics industries and 21 years in total managing multi-disciplinary scientific projects.

Iain Watt – Head of Plant Protection

Thirty five years' experience in the crop protection sector. Record of achieving successful regulatory outcomes, including applications for new active substances, and renewals of existing active substances.

Bruce Callow – Head of Environmental Sciences

More than 25 years' experience providing expert regulatory advice on the environmental fate of agrochemicals, chemicals and biocides, including representation and negotiation with EU regulatory authorities.

Stephen Ruckman – Head of Human Health

Over 35 years' experience in mammalian toxicology and human health risk assessment. Specialises in endocrine disruptor assessment, substance defence and advocacy.

Mariko Kubo – Head of Scientific and Regulatory Affairs

Over 15 years' experience in international food and beverage regulations, specialising in strategic and compliance projects.

Abigail Wacek – Managing Director, TSG North America

Specialist in pesticide compliance, with expertise in residual disinfectants, inert ingredient petitions, treated articles, and products that integrate nanoscale materials, especially silver.

Kelly Rahn – Executive Vice President, Business Development

Over 30 years' experience. Expert in the registration and ongoing compliance of pesticides at the US state and federal level, with an emphasis on antimicrobials and conventional chemicals.

Contacts	
Website	tuvsud.com/de-reach
E-mail	REACH@tuvsud.com
Head office	TÜV SÜD Industrie Service GmbH, Westendstr 199, D-80686 Munich, Germany
Tel	+49 89 5190-5990/+49 89 5791-1174 (fax)
Contact	Ing. Rupert Scherer
Ownership	TÜV SÜD Holding AG
Locations	TÜV SÜD Group employs more than 26,000 people in 60 countries in ca. 1,000 locations
Founded	1866

Overview

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/CLP 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.

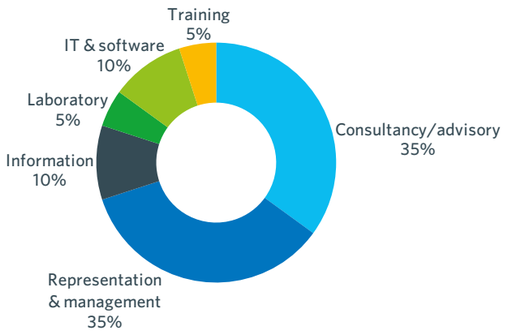
TÜV SÜD developed a service package custom tailored for small and medium sized enterprises (SMEs) as well as for global players.

An increasing focus is to support companies in securing their supply chain management in conjunction with chemicals legislations.

Vital statistics 2022/23

Turnover: group	€2,600m
No of offices	1,000
No of countries represented	60
Staff: group	26,000
Staff: chemical service provision	80

Service area breakdown



Global offices

Japan, Singapore, China, India, Croatia, Indonesia, Thailand, Vietnam, Ukraine, South Korea, US, UK, Spain, Turkey.

Services provided

Only representative

TÜV SÜD Industrie Service acts as reliable and impartial OR to numerous manufacturers and formulators of substances and mixtures established outside the EU community.

The obligations of an OR, outlined in Article 8 of the REACH Regulation, comprise not only registration but also all those obligations for importers.

Calling in an OR has the following advantages: importers need not become active themselves, and manufacturers/formulators established outside the EU can bundle notifications and do not have to address each importer individually. We find that manufacturers often come to us when their previous OR failed to act to their satisfaction or did not fulfil its obligations.

In 2021, our OR service expanded to UK REACH.

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 and tailored according to their specific role under REACH;
- workshops to create solutions under the guidance of an experienced expert;
- helpdesk function for the ad hoc solution of characteristic problems; and
- REACH audits to review the implemented REACH obligations from an inspector's point of view.

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 kinds 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.

We offer poison centre notification (PCN) and full safety data sheet services.

Accreditations

GLP.

Clients

Due to confidentiality we cannot name individual clients. Our clients are active in all industrial and professional sectors in more than 30 countries, ranging from manufacturers of chemicals to producers of articles. 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 products (substances, mixtures and articles).

Corporate developments and achievements

1866	Established in Mannheim
1926	Introduction of the TÜV SÜD mark/stamp in Germany
1960	Establish 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	Establish REACH services. Founder member of the BUSINESSEUROPE REACH Implementation Network

Case study 1

Consortium management

A consortium with representatives from five countries took over registration of a series of substances. The role as a lead registrant was shared alternatively among the individual members. The main bodies of the consortium are the steering committee, technical committee and the secretariat. TÜV SÜD provided consortium management to all bodies. Technical REACH consultancy and financial consultancy were part of the services delivered.

Case study 2

Support in REACH implementation

An EU manufacturer of articles and substances required support in implementing a REACH process for the entire company. The tasks focused on communication in the supply chain, registration, SVHCs, training and organisation building. A team was formed to give continuous assistance; the core team fully integrated with the client's activities onsite.

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; elaboration of exposure scenarios; communication within consortium; preparation of safety data sheets; cost calculation of letter of access; and 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 of data sharing is one of the crucial issues of negotiations in SIEF. High-quality data will be more costly than data of low quality. Some data gaps were filled by QSAR and read-across. Others had to be filled through a meaningful test strategy.

Case study 5

SVHC

An EU-based group with legal entities in several member states was seeking support in making an inventory of SVHCs in articles placed on the market, as well as in implementing a system to comply with the duties to communicate information on them. TÜV SÜD offered an integrated approach over all affected legal entities in order to avoid duplication of work.

Representative articles were selected for chemical analyses in the case of uncertainty on the presence or concentration of a SVHC. Analysing the presence and concentration of SVHCs was performed in TÜV SÜD's own chemical laboratory.

As a result of the investigations and consulting, a unified system was implemented across the entire group. The system ensured full compliance with REACH Articles 33 to 36. Furthermore, supply contracts were amended to increase legal certainty, to avoid the risk of lawsuits and reputational damage.

Case study 6

Only representative

TÜV SÜD acts as OR for many non-EU manufacturers. In several countries this is performed by involving local offices. This approach guarantees direct contact with the end client and avoids language barriers where applicable. This means smaller non-EU manufacturers can benefit from OR services although not conversant with English and technical terms.

Staff selection

Ing. Rupert Scherer

Rupert Scherer is an engineer and certified REACH multiplicator with more than 20 years' professional experience.

Dr Yvonne Fery

Yvonne Fery is a food chemist, European registered toxicologist and certified REACH multiplicator with about 15 years' professional experience.

Dr Bratislav Djordjevic

Bratislav Djordjevic is a chemist with 13 years' professional experience in REACH and consulting service.

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.

UL Solutions

Contacts	
Website	ul.com
E-mail	UL.supplychain@ul.com
Head office	333 Pfingsten Road, Northbrook, IL 60062, US
Tel	North America (US): +1 800 572 6501 Europe (UK): +44 115 965 1888
Directors	Ben Cronin
Ownership	UL Solutions, LLC
Locations	Global
Founded	1894

Overview

At UL Solutions, we help companies manage compliance and sustainability for products throughout both their lifecycle and complex global supply chains. For over 40 years, our customers have relied on us to meet the chemical compliance requirements of governments, NGOs, retailers, and consumers, while protecting intellectual property throughout all nodes of the supply chain. UL Solutions provides integrated and scalable chemical data and compliance management solutions that allow companies to:

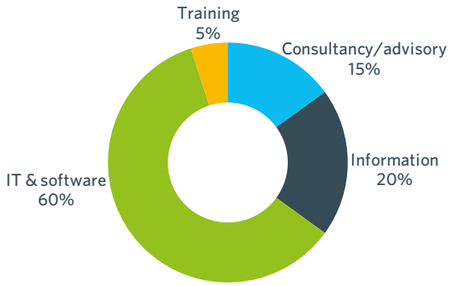
- manage their ingredient and product data;
- assess and meet regulatory compliance obligations for market entry;
- achieve sustainability goals; and
- proactively mitigate risks to ensure business continuity.

With best-in-class software solutions, the most robust regulatory data, and backed by a team of global regulatory experts, we help our customers establish chemical management policies, access actionable and insightful data for decision-making and policy enforcement, and automate their hazard communication, so they can proactively manage their regulatory and sustainability challenges with confidence.

Vital statistics

2022/23	
No of offices	160
No of countries represented	130
Staff: group	15,000
Staff: chemical service provision	820

Service area breakdown



Global offices

Brussels, Belgium; Ballerup, Denmark; Krefeld, Germany; Cabiate, Italy; Nottingham, UK; Northbrook, Illinois; Overland Park, Kansas; Latham, New York; Pittsburgh, Pennsylvania; Shanghai, China; Tokyo, Japan; Seoul, South Korea; Sao Paulo, Brazil; Melbourne, Australia.

Services provided

Chemical data management and SDS authoring software

Whether you require SDS authoring, a complex bill of materials, regulatory reporting, or distribution and workflow management, you can leverage industry-leading expertise, technology and data from UL Solutions for an integrated compliance solution to meet your needs.

Our powerful SDS authoring and chemical data management software allows you to manage your product stewardship and regulatory compliance obligations with:

- software options for every size of business and budget;
- platforms that are configurable and flexible, and can be integrated with other business systems (such as SAP);
- compliance data acquired by industry experts monitoring more than 8,000 regulatory lists; and
- solutions supported by an experienced, global network of scientists, consultants and regulatory experts.

Global market access and advisory services

It does not matter if you are a small business that needs compliance knowledge to grow, or a large corporation that needs surge capacity for the latest regulatory deadline, UL Solutions has the expertise and experienced staff to provide the advisory services you need.

Our team of 70+ regulatory experts provide support services to assist with:

- product development and product launch;
- verifying and maintaining product compliance;
- training staff on global regulations and best practices;
- regulatory data and information;
- technical and industry-specific issues;
- hazard communication and risk assessments;
- product or component registration/notification (eg REACH, CLP and TSCA):
- site audit and process reviews; and
- chemical policy development.

Supply chain transparency software

As consumers demand safer and cleaner products, retailers and product manufacturers are moving beyond regulatory compliance to deliver products that avoid chemicals of concern, utilise sustainable input materials, and exhibit other green attributes, such as waste reduction.

Our comprehensive supply chain data management and transparency platform enables data collection, evaluation and analysis of materials and products against custom evaluation frameworks that can be tailored to an organisation's specific sustainability goals.

Supply chain compliance

By facilitating secure data exchange throughout the most complex product supply chains, UL Solutions is the trusted third party for providing risk mitigation and data transparency. Whether it is securing the makeup of raw materials, the proprietary formulation from the leading manufacturers, or providing retailers with the critical data necessary to comply with local or national regulations, we can help you manage your compliance needs with confidence.

Accreditations

ISO 27001 (Latham, New York).

Clients

More than 15,000 UL Solutions customers worldwide use various product compliance products and services across industries such as adhesives, automotive, plastics, consumer products, flavours and fragrances, life sciences, paints and coatings, consumer electronics, building products, petrochemical, pharma, retail, and specialty chemicals.

Corporate developments and achievements

2013	UL Solutions acquires The WERCS, global supply chain software specialist
2016	UL Solutions acquires leading chemical EH&S regulatory compliance provider Safeware Quasar
2017	UL Solutions acquires ChemADVISOR®, a world leader in chemical regulatory compliance and data solutions
2018	UL Solutions launches search tool Product IQ®, for verifying UL certifications of products and components
2019	UL Solutions launches Illuminator®, a first-of-its-kind software tool enabling online access to industry-leading ChemADVISOR data
2022	UL Solutions launches ChemADVISOR® content for SAP® EHS with expert rules, templates, data and phrases for SDS authoring
2023	UL Solutions launches specialised PFAS content enhancement package, allowing companies to collect product data, identify PFAS in their portfolio and access insights to manage compliance and keep updated when regulations change.

Case study 1

Innovative data automation facilitates commerce and regulatory compliance

A global leader in analytical technologies was faced with improving the management and distribution of its equipment that shipped with limited hazard materials so the purchased items reached the customers as scheduled. With limited internal regulatory resources and constantly changing global regulatory requirements, compliance was an overwhelming task. This company needed an adaptable and scalable solution that would address its data migration needs and provide regionally compliant, multilingual documents to meet its global regulatory requirements quickly and effectively.

By leveraging our innovative suite of software solutions and extensive regulatory expertise, this company was able to improve its current business processes and integrate regulatory data into its existing ERP, meet chemical handling requirements and deliver equipment as promised to customers while improving cash flow.

Benefits

- Generated 130,000 compliant safety documents in weeks vs. months to meet regulatory deadlines
- Product data is now managed, updated and processed in a timely manner
- Products and their related hazard communications are compliant and easy to maintain
- Seamless translation of safety data sheets into multiple languages in a matter of minutes

Case study 2

Helping manufacturers and retailers meet regulatory requirements

Due to increasing regulatory demands and complex global supply chains, retailers and manufacturers were looking for ways to meet compliance and organisational sustainability requirements, while protecting confidential business information (CBI) and enabling commerce. The securing and exchange of chemical data along with regulatory expertise is necessary to ensure proper handling, transportation, storage and disposal of chemical containing products.

UL Solutions became the trusted third party to collect, process, protect and provide the data transparency needed between supply chain nodes to mitigate risks surrounding products containing chemicals or substances of concern. Our unique capability allows for the collection of essential chemical formulation data from manufacturers while applying critical regulatory insights to advise retailers on product stewardship without slowing down commerce for either party. While safeguarding proprietary information, our powerful engine allows manufacturers to register their products once and meet the needs of multiple retailers.

Today, UL Solutions helps more than 20,000 manufacturers and 125 major, multinational retailers, meet their product compliance and product stewardship needs.

Benefits

- Trusted third party to facilitate the secure transfer of product composition data and protection of critical CBI
- Automation of GHS compliant safety data sheets (SDS) and labelling documentation
- Risk mitigation and brand protection

Case study 3

Supply chain transparency and risk mitigation for consumer electronics

A leading global technology company expanding into augmented reality (AR) and virtual reality (VR) devices required information on the products upstream in its supply chain to effectively deliver finished products into the marketplace, comply with regulations and minimise potential risks.

Like most consumer electronics, this company was managing a component inventory of more than 400,000 SKUs (stock keeping units (SKUs)) with high inventory turnover, that represented more than 7,000 chemicals. It did not have expertise to collect and evaluate product data to protect its employees, the environment and to effectively transport its products globally.

With the overwhelming complexity of regulations and supply chains, this tech giant enlisted UL Solutions to help it navigate this new frontier. As a trusted third party in securing and protecting confidential component and chemical data, UL Solutions was able to secure data on all components and their complex bills of materials (BoMs), and quickly identify challenges and implement solutions to mitigate them. The powerful combination of software, data management, regulatory compliance knowledge and industry expertise allows UL Solutions to manage the full scope of the product stewardship journey – from material sourcing to product disposal.

Benefits

- Supply chain transparency and accurate component data for complex consumer electronics
- Risk mitigation with regulatory compliance and proactive chemical and material management software
- Comprehensive product stewardship from material sourcing to disposal
- Seamless creation of BoMs for finished goods with multilingual support
- Regulatory expertise and support for handling, transportation, use and disposal of hi-tech electronics

Staff selection

Darlene Susa-Anderson – Senior Regulatory Affairs Manager

With more than 40 years of global regulatory compliance experience, Darlene's expertise is deep in many areas. She has held several leadership positions within UL Solutions, and currently serves as a senior regulatory affairs manager. Darlene is often a requested regulatory speaker and presents on a variety of regulatory topics at events including DGAC, SCHC, AICHE and ChemCon.

Dr Bill Pease – Chief Scientist

Bill is responsible for the scientific methods and informatics services used by manufacturers and retailers to rate materials and products on their health, environmental and social impacts. He works with major US retailers and manufacturers to develop chemical policies and restricted substances lists.

He also helps design the standards used to identify environmentally preferable products and to implement software systems to collect data from their supply chains.

Andrew Brooks PhD, DGSA – Senior Manager, Chemicals

Andrew is a chemical regulatory expert, coming from the chemicals industry. Predominantly focusing on REACH, CLP and preceding European Directives, he has assisted many companies with differing product portfolios during the transition to GHS, enabling businesses to adapt and succeed with compliance. He is also a qualified dangerous goods safety adviser.

chemicals compliance consulting **UMCO**

Contacts	
Website	umco.de
E-mail	umco@umco.de
Head office	UMCO GmbH, Georg-Wilhelm-Strasse 187, 21107 Hamburg, Germany
Tel	+49 (0)40/555 546 300, +49 (0)40/555 546 357
Contact	Jan Moenster
Directors	Anika Biehl, Peter Duschek, Ulf Inzelmann
Ownership	See directors
Locations	Germany: Hamburg, Rhineland
Founded	1982

Overview

UMCO GmbH is your partner for chemicals compliance consulting. Since 1982, the consulting company has been guiding its clients from the chemical, industrial, pharmaceutical and logistics sectors safely through the complex regulations governing chemicals.

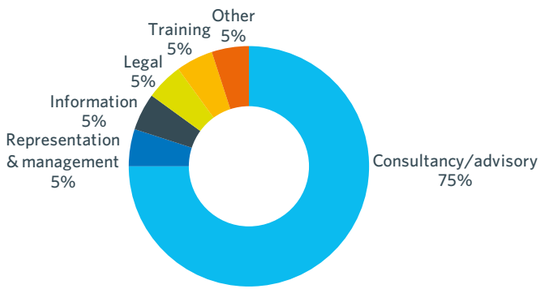
We support our clients with an interdisciplinary team of 90 engineers, scientists, and legal experts, who are committed to ensuring the economic viability, quality, timeliness, and success of our clients' projects. Through our many years of experience, we know exactly what our clients need in their day-to-day business: expert knowledge, legal certainty, and practical relevance.

Our service portfolio includes: Global chemicals management; safety health environment management; dangerous goods management; regulatory compliance and audits; digital efficiency solutions; emergency management; professional seminars and training. We are certified according to ISO 9001.

Vital statistics 2022/23

No of offices	2
No of countries represented	1
Staff: group	90
Staff: chemical service provision	45

Service area breakdown



Services provided

Hazardous substances management

- Determination of the status of all chemical products used or traded by your company regarding their marketability worldwide
- Auditing and advising on 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 European and international chemical and dangerous goods legislation
- Authoring and monitoring SDS and exposure scenarios (for all European regions/languages using UMCO's UHCS software for SDS – UMCO Hazard Communication System)
- International SDS compilation and monitoring performed in cooperation with our network partners
- Support with worldwide chemicals management, including analysis of national requirements for marketing and use of chemicals and notification/registration in cooperation with our network partners
- Notification of hazardous mixtures according to Article 45 CLP including Third Party Solution for non-EU companies
- Permanent monitoring of substance and product data with regard to legislative amendments or changes to customer recipes, including the updating of all necessary documents (SDS, eSDS, labels)
- Customised interfaces to generate the automatic import and export of data in standard XML format into/from UMCO's UHCS software for SDS
- Web services for customer specific evaluations, for example current stock or dangerous goods lists and functions; CLP-compliant online calculation tool
- Automated data export for printing CLP/GHS labels
- Consulting and support with inhouse hazardous substances management
- Compliance service for restricted/banned substances in mixtures/articles
- Data maintenance for hazardous substances, raw materials and products in the SAP EHS system of our customers
- Own data warehouse for all types of substance and product related information, data and documents

EU-REACH management (REACH Regulation (EU) No 1907/2006): Comprehensive support for lead registrants

- Project management
- Substance characterisation (so-called Sameness test) including communication with laboratories
- Preliminary study on data requirements, literature research and data gap analysis
- Study management and monitoring
- Preparation of all relevant documents for registration, eg chemical safety report (CSR), hazard/use/risk assessment, technical dossier in IUCLID and implementation of the LR registration
- Joint submission management and letter of access (LoA) management
- Communication with co-registrants and preparation of contractual arrangements for data and cost sharing
- REACH registration dossier follow ups: support during dossier and substance evaluations, including dossier updates

Registration management for co-registrants

- Support with joint registration: communications regarding substance sameness and LoA
- Compilation of inquiry/registration dossiers and (pre-)submission to ECHA.
- Dossier updates (including increasing tonnage bands or changing the registration type)
- Support during ECHA compliance checks
- Monitoring of incoming messages related to the registered substance (eg from REACH-IT, lead registrants, consortia) incl. recommendation for action, if necessary

Representative services

Only representative (OR) for non-EU manufacturers/formulators according to Article 8 EU-REACH.

Communications in the supply chain

- Strategies for the communication with suppliers and customers
- Support with identification of uses (use mapping)
- Implementation of exposure scenarios in daily practice
- Consultation on substances of very high concern (SVHCs) in mixtures and/or articles

Strategic consulting

Consultation and evaluation of organisations and structures aimed at ensuring EU-REACH compliance, for example restriction (annex XVII), authorisation (annex XIV) as well as support with participation and argumentation in public consultations and other communications with authorities.

Biocides management (Biocidal Products Regulation (EU) No 528/2012) Strategic consulting

- Consultation and evaluation of organisations and structures aimed at ensuring BPR compliance
- Advising on borderline and dual use products

Active substance approval and biocidal product authorisation (EU and UK)

- Coordination of the entire approval/authorisation process including communication with authorities and laboratories
- Definition of the appropriate strategy
- Literature research, data evaluation and data gap analysis
- Identity technical equivalence and physicochemical parameters
- Toxicology and human exposure, environmental fate and ecotoxicological evaluation
- Assessments of endocrine disruptors (ED)
- Development of test strategies for effectiveness
- Study management and monitoring
- Data management/study summary and expert statements
- Preparation of technical dossier in IUCLID including all necessary submission forms (PAR, CAR, etc) and submission
- Preparation of application documents for national notifications (transitions period for actives applicable)
- Support for Art. 95 listings
- Marketability of the treated articles including differentiation from the biocidal product and verification of the labelling information in accordance with Art. 58 of the BPR

Safety health environment management

- Provision of an SHE manager/officer.
- Provision of external company advisors/officers for the fields of occupational safety, emissions protection, water pollution control, waste, hazardous incidents
- Management of approval procedures
- Advice on storage of hazardous materials
- Explosion protection consultation
- Preparation of operating instructions and risk assessments
- Compilation of safety reports and further hazardous incident documentation, such as safety management systems and corporate alarm and hazard control plans
- Training and instruction (executives, contract workers, employees)
- Management systems: ISO 14001, 45001
- Compliance organisation
- Compliance checks (SHE legal compliance)
- Conducting internal audits and remote audits

Dangerous goods

- Provision of an external dangerous goods safety advisor (DGSA)
- Establishment of a customised dangerous goods organisation and analysis to optimise procedures
- Inventory and dangerous goods audits
- Dangerous goods consulting
- Checklists and working and operating instructions
- Verification of correct classification and labelling
- Instruction and training courses
- Document checks
- Information about legal changes
- Special topics, such as the transport of explosive and radioactive substances, as well as lithium batteries
- Project management

Emergency services

Emergency telephone number for EC SDS (all European poison centres) as well as GlobalChem24: 24-hour emergency number for dangerous goods transports and SDS worldwide (together with RICARDO/NCEC).

Training

Training, workshops, seminars in-house or online provided across all services as well as working and process instructions.

Corporate developments and achievements

2006	Co-founder of the Global Chemical Consulting Network (GCCN), an entity that provides 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 customer ERP systems
2016	Customised online training for employees about occupational safety and related areas. These trainings can be tailored to company requirements
2020	Expansion of the offering on training to webinars and online

Partners

Global Chemical Consultant Network, RICARDO/NCEC and REACH24H.

Clients

Our clients include more than 1,000 national and international companies – all along the chemicals value-added chain: manufacturers, producers and formulators; distributors and importers; warehouses, storage operators and transshipment companies; logisticians; users of chemical products, articles and commodities; service providers and many more.

Testimonials

We, as A Lackfabrik (paints and lacquers factory), have been working successfully together with UMCO for many years. Over time, this cooperation has developed into an indispensable factor regarding hazardous substances, biocides, and dangerous goods. A common data exchange via import tables has been established so that we can react quickly to changes in formulations, new raw material installations or amended raw material data sheets. This means that our labels, safety data sheets and transport documents are always up to date. As a medium-sized company, we feel professionally well looked after at all times and look forward to further cooperation to master the constantly growing tasks together.

ISL-Chemie is a system provider for the plastics and lacquer industry with over 3,000 colour pastes and special lacquers in its range. With our partner UMCO/GlobalChem24 we are optimally positioned to guarantee the worldwide valid legal transport regulations of chemicals for our customers.

Case study 1

Chemical product management

Compilation of SDSs for different chemical traders and producers of chemical mixtures. More than 60,000 SDSs compiled and regularly updated.

Case study 2

Business process outsourcing

Handling product stewardship and legal chemical products services for paint companies, including determination of classification and labelling for products in all EU regions and languages and compiling SDS and CLP/GHS labels.

Case study 3

REACH consortium management

Financial management, supervision of subcontractors, trustees. Registration, SIEF and LoA management.

VelocityEHS®

Contacts	
Website	**EHS.com**
E-mail	**Velocity@ehs.com**
Head office	222 Merchandise Mart Plaza, Suite 1750, Chicago, IL 60654 US
Tel	+1 866 919 7922
Contact	**EHS.com**
Locations	Chicago, Illinois; Ann Arbor, Michigan; Tampa, Florida; Oakville, Ontario; Perth, Western Australia; Cork, Ireland
Founded	2001

Overview

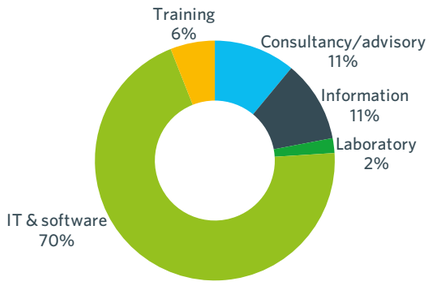
Trusted by more than 10 million users worldwide, VelocityEHS is the global leader in true SaaS enterprise EHS and ESG technology. Leveraging the VelocityEHS Accelerate® Platform, the company helps global enterprises drive operational excellence by delivering best-in-class capabilities for chemical management, safety, environmental compliance, training, operational risk, and environmental, social and corporate governance (ESG).

The VelocityEHS team includes unparalleled industry expertise, with more certified experts in health, safety, industrial hygiene, ergonomics, sustainability, the environment, AI, and machine learning than any EHS software provider. Recognised by the EHS industry's top independent analysts as a Leader in the Verdantix 2023 Green Quadrant Analysis-VelocityEHS is committed to industry thought leadership and to accelerating the pace of innovation through its software solutions and vision.

Vital statistics

	2022/23
No of offices	7
No of countries represented	5

Service area breakdown



Global offices

US, Canada, UK, Australia, Ireland.

Services provided

Chemical management

The award-winning VelocityEHS Chemical Management Solution is the industry gold standard. Its system's multi-language capabilities and ease-of-use empower workers, wherever they are, to be active participants in assuring the success of their company's chemical management, environment, safety, health and sustainability programmes. Their team can help you:

- take command of your chemical footprint;
- centralise and streamline regulatory reporting;
- achieve greater control of your chemical inventory on the container and ingredient level;
- identify ingredient level of concern with machine learning-driven ingredient indexing;
- ensure alignment with global hazcom regulations;
- crosscheck products against international hazardous substance lists;
- access industry's best database of Safety Data Sheets (SDSs) for 80+ countries;
- provide mobile SDS right-to-know access, available online and offline; and
- deploy secondary workplace labelling (GHS and more).

Authoring and regulatory consulting services

VelocityEHS is known for having deep domain expertise throughout its product offerings and each is backed by a deep bench of certified professionals. Its team is available to assist companies with:

- meeting global compliance requirements (eg OSHA HCS, EU CLP, WHMIS, 65+ GHS-aligned standards) and other corporate product stewardship and sustainability goals;
- classifying, authoring, translating, and reviewing chemical-product documents;
- preparing hybrid SDSs and certified business information (CBI)/trade secret claims;
- performing ingredient substitution assessments;
- creating custom container labels;
- staying compliant with the latest EU and UK SDS formats;
- providing toxicological and regulatory subject matter expertise; and
- consulting on global transportation.

Emergency response services

VelocityEHS Emergency Response Services provide customer access to a 24-hour toll-free phone line that connects to the globally recognised chemical emergency call centre, providing support in more than 200 languages.

Through this service, customers receive unlimited use of the hotline for:

- listing on hazardous materials shipping papers and manifests (to meet DOT, FAA, IMDG, IATA and other global hazmat shipping requirements);
- listing on SDSs (to meet Section 1 emergency number requirements for OSHA HCS, Health Canada WHMIS and other hazard communication standards);
- chemical exposure support;
- escalated chemical incident reporting;
- SDS back-up access by phone, email and fax; and
- lithium battery shipping support.

Chemical management services

VelocityEHS offers a range of services to complement its chemical management software that enable customers to streamline critical safety and chemical management tasks. A sample of services includes:

- emergency response services – 24-hour SDS back-up and exposure support hotline;
- onsite chemical inventory audit;
- building of an SDS online library;
- SDS library back-up; and
- SDS indexing – where VelocityEHS inputs desired data from SDSs, such as but not limited to, GHS pictograms, hazard statements, ingredients, PPE, and target organs into customers' chemical management account to facilitate the generation of secondary workplace container labels and a variety of useful inventory reports.

Industrial hygiene

VelocityEHS IH solutions help both certified industrial hygienists and EHS professionals new to the field achieve expert results through a comprehensive solution that makes it easy to:

- assess and control workplace stressors;
- simplify sampling and data entry;
- drive IH programme management;
- enhance the visibility of workplace risks;
- perform sample management, equipment tracking, medical surveillance, and respirator fit tests; and
- leverage the Global Chemical/OEL database for accurate data and insights.

Risk management

VelocityEHS Operational Risk software gives enterprises unparalleled visibility and control of EHS risks. The software's core capabilities help companies easily:

- perform hazard studies, such as JSA/JHA/PHA and bowtie assessments;
- deliver control verification and assurance monitoring;
- perform semi-quantitative analysis;
- generate LOPA, PLL, CBA Analysis; and
- manage change and minimise risks.

ESG: Climate Change & Environmental Compliance

VelocityEHS software supports enterprise-wide sustainability and resiliency efforts related to ESG and Environmental Compliance, such as:

- simplifying the collection, validation, and reporting of greenhouse gas, energy, and materiality data;
- tracking, managing, and reporting air emissions, water quality, and waste compliance data; and
- strategically aligning stakeholders organisation-wide.

Corporate developments and achievements

2021	SASB Licensed Corporate Reporting Software
2022	Ecovadis Sustainability Awards – Silver Rating
2022, 2023	OH&S Industrial Hygiene Awards – Risk Assessment and Management; Respiratory Protection; Hazard Communication; Education and Training; Control of Work Solution
2022, 2023	Top Product – Environment + Energy Leader Awards – Global Enterprise ESG Solution
2021–2023	Verdantix Green Quadrant Report Industry Leader – Process Safety Management; Enterprise Carbon Management; ESG Reporting and Data Management Software; EHS Software

Accreditations

Company: SOC 2 and GDPR compliant.

Staff accreditations include: toxicologist, chemical engineer, chemist, CSP, CIH, PMP (project management professionals), CEP (certified ergonomics professionals) Bachelor's and Master's degrees in biotechnology, environmental law, MPH (Master's in public health).

Partners

Service Partners: WSP, Trinity, JS Held, Fit for Work.

Other Product Partners: Arcadia, GRI, Snowflake.

Clients

Microsoft Corporation, Toyota, Kraft Heinz, Ashland, 3M, Coca-Cola.

Testimonials

"VelocityEHS [chemical management] software is so easy to use." *Ikea, North America*

"Using the Velocity software has helped our performance. We're tracking things better, eliminating extra work, and plants are already seeing improvements in their numbers." *Jessica Skrehot, Coprorate EHS Manager, Global Construction Solution Manufacturer*

"Flexible, convenient, easy to use and explain to the employees. Great time saver over the old paper system that had. I am very happy with the experience; from building the file to the roll out to the employees." *Cope Plastics, Inc*

"I have found VelocityEHS [chemical management] software to be a great resource and I was glad that my predecessor had selected you folks. With the GHS change, your software was way ahead of other companies in providing information and training." *Eastern Pennsylvania electronics manufacturer*

"Your [chemical management] software has made it really easy for anyone to access what onsite chemicals we have, and in what departments. Especially in a multiple location environment, this thing is extremely efficient. It saves time for our administrators; they can check anything they need to check, location by location. I access it remotely, and so do many of our line managers, on their iPads or iPhones." *Ron Odell, Cactus Feeders*

Case study 1

MAG Automotive USA

MAG Automotive USA – a leading supplier of machine tools for global automakers like Ford, Cummins Diesel, and Fiat Chrysler – turned to VelocityEHS and its SDS/Chemical Management Solutions to simplify management of safety data sheets across their dynamic workforce. As a business that must regularly adjust the size of their full-time and contract workforce based on the size of the project, MAG needed a quick, easy, and effective way to manage their worksite chemical safety and access a large amount of safety data sheets – especially in the face of ever-evolving compliance requirements.

VelocityEHS Cloud-based Chemical Management Solution and extensive mobile SDS database was the answer. With robust tools for tracking the location, status, and risk associated with chemicals used, and a mobile app with offline access capabilities, MAG now had real-time access to their library of SDSs and chemical inventory information online, becoming part of their culture of emergency preparedness and response. As a result, MAG has been able to drive efficiency and productivity across their organisation while keeping their workplace safe, compliant, and running smoothly.

Case study 2

Compass Health

Compass Health, a leading manufacturer of life-enhancing home healthcare products, transformed their chemical management programme with VelocityEHS. Previously reliant on cumbersome paper binders for safety data sheets (SDS), Compass Health shifted to VelocityEHS, driven by a third-party audit that underscored the need for better employee access to safety data sheets.

With over 100 employees at their Sioux Falls facility handling a unique suite of more than 400 chemicals, VelocityEHS Chemical Management solution was the perfect fit. The solution had everything Compass needed for the chemicals they use, and offered not just compliance with OSHA regulations, but also a sense of security knowing that VelocityEHS software would help them stay compliant, even in the face of regulatory change.

In short, VelocityEHS Chemical Management solution and SDS software was a game changer. It saved significant time for Compass' safety staff – eliminating manual SDS lookups and binder updates – and the system's auto-update feature greatly simplified the management of their extensive chemical library. Compass Health now looks forward to expanding their use of other VelocityEHS capabilities, including container tracking, GHS secondary labelling, ingredient indexing, regulatory reporting, and more.

Staff selection

Matt Airhart, CEO

Prior to joining VelocityEHS, Matt led KMI, an Oakville, Ontario-based EHS software provider acquired by VelocityEHS in 2014. He spent seven years in the chemical manufacturing industry and two years with an EHS systems consulting company. His passion is building high-performing teams and solving complex business challenges. Matt holds a Bachelor's degree in Chemistry and Environmental Studies from Ohio Wesleyan University.

Contacts	
Website	vitisregulatory.com
E-mail	info@vitisregulatory.com
Head office	Office 59, Canterbury Innovation Centre, University Road, Canterbury, Kent, CT2 7FG
Tel	+44 (0)1227 470901
Contact	Dr Oliver Warwick
Directors	Oliver Warwick, Louise McLaughlin, Rosalind Wildey
Ownership	Limited company
Locations	**UK:** Canterbury, Kent. **Belgium:** Etterbeek, Brussels. **Germany:** Bockenem, Lower Saxony
Founded	1995

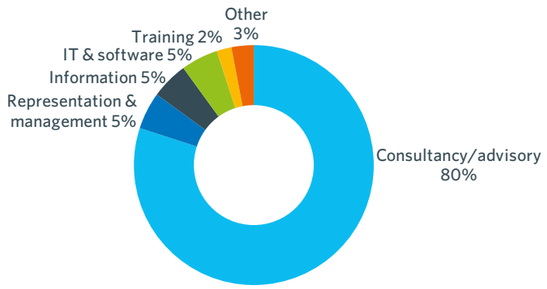
Overview

We are scientific experts in regulatory and research support for the management of chemicals, our services rely on our scientific approach. We work with you to comply with regulations, develop policy, strategy, research and solutions to the problems that you have, by understanding the data.

Vital statistics

	2022/23
No of offices	3
No of countries represented	3
Staff: group	35
Staff: chemical service provision	30

Service area breakdown



Services provided

Vitis Regulatory Limited, SRL and GmbH colleagues work together to offer expert advice and support on:

Regulatory compliance

REACH (EU and UK): development of all aspects of technical dossiers for registration, including substance identity and classification and labelling, and response to regulatory evaluation. Technical support for applications for authorisation (AfA) and restriction proposals.

Biocidal products: compiling product authorisation dossiers for the EU biocidal products Regulation and similar regulations in the UK, understanding of the complex needs of the regulations for active substance and product assessment, applying expert knowledge of chemistry, degradation in the environment, toxicology and ecotoxicology.

EU Cosmetics Regulation: understanding of chemistry, degradation in the environment, toxicology and ecotoxicology to develop a cosmetic product safety report (CPSR) for notification.

Environmental safety: exposure modelling at all steps of the supply chain, quantifying how the environment and humans may be exposed to a chemical throughout its lifecycle. Assess exposure in depth for specific locations, using modelling to help plant managers identify operational controls they can apply to minimise environmental footprint.

Scientific research

Predictive methods: filling data gaps for regulatory submissions including quantitative structure-activity relationships (QSAR), read across and alternative methods to testing.

Modelling development: standard and bespoke modelling methods and programmes for assessment of environmental exposure and fate, worker and consumer exposure, including impact of market changes. Working with clients and laboratory-based partners to validate models using measurements from workplace monitoring, effluent and environments monitoring data and experiments.

Data interpretation: substance identity and sameness evaluation for regulatory purposes. Characterisation of complex substances such as UVCBs from both natural and synthetic sources.

Literature reviews and screening assessments: on a wide range of regulatory endpoints including use pattern, fate, toxicity and endocrine disruption.

Study design and management: designing and monitoring testing programmes and studies that are fit for purpose. Understanding and managing the challenges associated with testing "difficult" substances.

Chemical policy

Policy development for chemicals management: development and analysis of policy for chemicals management. Understanding the risk of substances and the impacts they have, such that the consequences of regulatory actions can be quantified, and the costs and benefits understood.

Corporate developments and achievements

1995	Peter Fisk Associates established
2006	Incorporated as a UK private limited company
2016	Belgian subsidiary firm established
2020	Existing directors buyout and change of ownership to Oliver Warwick, Louise McLaughlin, and Ros Wildey
2021	Company rebrand to Vitis Regulatory
2022	German subsidiary firm established

Partners

We partner with others to complement our skill set and enhance the offer to our clients. We have close established collaborations on areas such as socio-economic analysis and specific scientific/regulatory areas (eg biocidal efficacy).

Clients

Vitis Regulatory has a wide range of clients from both industry and regulatory organisations. Testimonials can be provided upon request. We support:

- SME chemical companies up to major multinationals:
- manufacturers, importers and downstream users;
- single companies to large consortia; and
- regulatory authorities and government organisations.

Accreditations

Vitis Regulatory Limited: ISO 9001 Quality Management System, ISO 14001 Environmental Management System, ISO 27001 Information Security Management System. **Vitis Regulatory SRL:** ISO 9001 Quality Management System.

Case study 1

REACH registrations

Vitis Regulatory has been supporting our clients with EU REACH since the publication of the Regulation back in 2006 and we have been involved with the successful submission of more than 300 REACH technical dossiers including both phase-in and non-phase-in substances. Our portfolio includes a wide range of organic and inorganic substances, UVCBs, industrial chemicals and those with widespread uses.

Vitis Regulatory's approach to compliance is centred around the science that underpins the regulatory requirements, starting from a sound understanding of substance identity, physico-chemical properties, fate and hazard through to best practice in exposure science and risk characterisation.

We continue to support our clients with their ongoing compliance obligations for previously registered substances as well as new substance registrations, assisting with dossier quality improvement initiatives across a range of industry sectors and with proactive preparation for upcoming changes in the requirements for registration.

Case study 2

Polymers

In 2019, Vitis Regulatory and Wood plc were selected by the European Commission to provide " Scientific and technical support for the development of criteria to identify and group polymers for registration/evaluation under REACH and their impact assessment". The resulting report, presented at the 35th Caracal meeting, considered the potential risks to human health and the environment posed by polymers and highlighted the prospect of polymers requiring registration under REACH in the near future.

Challenges included defining complex substance identity and adapting testing methods for polymers. The strategy involves minimising the number of polymers for REACH registration (PRRs) by defining their composition and grouping them, thereby reducing animal testing through read across and other regulatory adaptions. This preparation will assist clients in understanding their substance portfolios, determining data needs, and planning for regulatory compliance and product stewardship.

Understanding polymers and how they fit in the current regulatory landscape at EU or global level will be pivotal for the industry. The team at Vitis Regulatory has the expertise and creativity to help businesses of any size develop a strategy for polymers and navigate forthcoming regulations effectively.

Case study 3

REACH application for authorisation – technical support

Vitis Regulatory has provided the technical support for applications for authorisation (AfA) under both EU and UK REACH regimes. This has involved supporting our client on all aspects of the AfA: preparation of specific and detailed exposure scenarios, including the assessment of exposure monitoring and modelling data, and the assessment of impacts to workers and the general population.

We worked closely with our client to produce a detailed analysis of an alternatives and substitution plan. We also collaborated closely and successfully with socio-economic analysis (SEA) specialists to produce the SEA. We supported our client throughout the process in meetings and in interactions with the authorities from the pre-application information session and at follow-up meetings, through to assistance with written responses to opinions and recommendations.

Case study 4

OECD workshop

In October 2023, the OECD hosted a workshop on Valuation of Environmental Endpoints in the Context of Chemicals Exposure to seek a common understanding and agreement of the attributes to value for chemicals related environmental endpoints and the relevant valuation scenario(s) to consider in the development of a valuation methodology and subsequent pilot study. The meeting heard from regulatory economists/ risk managers, regulatory ecotoxicologists and academic environmental economists on what:

- valuation information regulators need for environmental cost/benefit assessment;
- comes out of a regulatory risk assessment regarding environmental impacts and chemicals; and
- the challenges are in linking these with environmental valuation approaches.

A presentation was held on the potential use of approach to combining a valuation scenario with expert elicitation, followed by a discussion on potential use of a valuation scenario in which various environmental attributes related to chemicals exposure are linked to regulatory risk assessment outcomes through extrapolation via an expert elicitation protocol.

Vitis Regulatory was invited by the OECD to be a discussant for this item as well as participating in the other discussions over the two-day workshop.

Staff selection

Oliver Warwick PhD – Managing Director

Oliver joined the company in 2010 having previously worked in consulting and prior to that in government and industrial research. He has more than 20 years' experience leading scientific and multi-disciplinary teams to successful completion of technical projects on EU chemical (eg REACH, BPR) and other environmental legislation (eg EIA, Seveso). He works with directors and project managers to ensure the delivery of high quality scientific and technical support for clients across industry and government.

Louise McLaughlin – Director

Louise joined the company in 2002. She has a background in analytics chemistry and previously worked in regulatory and analytical departments for a major CRO. She is project manager across all technical areas including chemical property data, use pattern and lifecycle information, exposure assessment and risk assessment.

Rosalind Wildey – Director

As an environmental chemist, Ros has more than 20 years' experience in chemicals exposure assessment in a regulatory context, working on projects for both industrial and regulatory authority clients. Regulatory compliance experience includes development and maintenance of data sets, hazard and risk assessment, as well as project management.

Joanne Massey – Principal Toxicologist

Joanne brings more than 20 years' expertise in hazard assessment of industrial chemicals in the regulatory context, biocides, food additives, soil contaminants and air pollution. Joanne has taken the lead toxicologist and substance leader roles in preparing complex, REACH registration dossiers monitoring various study types, and planning targeted testing and read-across strategies.

Emma Jack PhD, LLM – Principal Consulting Scientist

Emma possesses over 20 years' experience in ecotoxicology and natural resource protection within regulatory and policy frameworks. With a focus on multi-stakeholder team coordination and management, she excels in regulatory compliance, including hazard and risk assessment and project management of up to US$1m. Emma also manages a range of dossiers under REACH registration.

Helen Disley PhD – Principal Scientist

Helen is a chemist with 14 years' experience assessing chemicals under the REACH regulation. She specialises in understanding substance chemistry and its impact on hazard and risk profiles. Helen's expertise extends to non-experimental data gap filling methods like QSAR and read-across. Helen is closely involved in substance identity, physiochemical property assessment, and data management/analysis.

Contacts	
Website	yordasgroup.com
E-mail	info@yordasgroup.com
Head office	Lancaster Environment Centre, Lancaster University, Lancaster LA1 4YQ, UK
Tel	+44 (0) 1 524 510278
Contact	Malcolm Stewart
Directors	Jonathan Lutwyche, Dr Sandra Meijer, Adam Rowntree
Ownership	Privately owned
Locations	UK, Germany, Turkey, Canada., Japan
Founded	2007

Overview

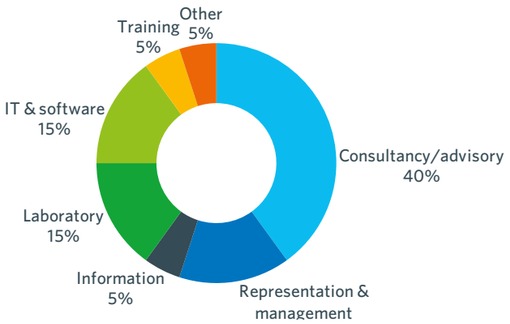
Yordas Group is a leading provider of scientific, environmental, and global regulatory and sustainability consulting services. With international capability (representation in North America, Asia, Latin America and Europe, and commercial activities around the world) and offices in the UK, Germany, Turkey and Canada, Yordas Group is structured to support companies globally.

Our collaborative approach is designed to build strong working relationships over time, allowing us to create a customised and integrated service specifically tailored to the needs of each customer.

Vital statistics 2022/23

No of offices	5
No of countries represented	Global
Staff: group	113
Staff: chemical service provision	71

Service area breakdown



Global offices

Yordas Group is headquartered in the UK with offices in Canada, Germany, Japan and Turkey.

Clients

Our global customer base includes manufacturers, distributors and retailers across a broad variety of industry sectors, along with trade associations and government bodies.

Services provided

Regulatory compliance

- Global notifications, including EU REACH, UK REACH, US TSCA, China MEP Order No 7, Korea ARECS (K-REACH), Taiwan TCSCA and OSHA, Japan CSCL and ISHL
- Cosmetics: scoping assessments and responsible UK and EU persons
- Environmental permitting: HOCNF, OSPAR
- Product regulations: toys, detergents, aerosols, RoHS
- Nanomaterials: regulatory compliance and safety
- Global biocides product regulations and claim substantiation
- Hazard communication: global safety data sheets (SDS), classification and labelling to GHS, CLP and other global classification systems, exposures scenarios, and poison centre notification

Product stewardship and sustainability

- Global regulatory monitoring
- Regulatory and supply chain audits
- SCIP database reporting
- Custom data services
- Sustainability strategy and reporting
- Product substitution and 'green chemistry'
- Integrated management systems, such as ISO
- PFAS services
- Management systems and auditing
- Lifecycle assessment (LCA)

Scientific expert and analytical services

- Chemical characterisation
- Chemical safety assessment and reporting
- Analysis of nanomaterials
- Hazard and risk assessment of substances and products
- Data acquisition, testing and management
- Assessment of alternative chemicals and substitution strategies
- Assessment of endocrine disrupting properties
- Systematic review
- Expert assessments: polymer status, exemption from registration, physchem and (eco)toxicological endpoint
- Read across justification and QSAR toolbox
- Expert witness services and litigation support

Training

Yordas Insight provides integrated training solutions that are relevant, up-to-date and interactive. Our training delivers knowledge, tools and methodologies that you can apply to your business. Our experts share their knowledge through case studies and interactive learning methodologies so that you can use your learning for business risk management and strategy.

Accreditations

Our training courses are approved by the Royal Society of Chemistry.

- ISO 9001:2015 Quality management
- ISO 14001:2015 Environmental management standard
- ISO 27001:2013 Information security management standard

Corporate developments and achievements

2007	Founded as The Reach Centre
2017	Rebranded to Yordas Group and formed a Group of Companies
2018	Yordas GmbH (Germany) Yordas Limited (Canada) established
2020	Yordas Danigmanhk Limited Şirketi (Turkiye) established
2022	Yordas K.K (Japan) established

Case study 1

GRMS2 – Regulatory radar for the automotive industry

Yordas was contracted to develop, populate and maintain the GRMS2 (Global Regulatory Monitoring System of Chemical Substances) tool on behalf of ACEA (the European Automobile Manufacturers Association). Our industry-focused GRMS2 solution covers the majority of chemical regulatory management needs for the automotive industry including global regulatory impact assessments for the sector. In this project, we were able to combine our extensive regulatory knowledge with our software development capabilities and make use of the chemical substance data and updates from our in-house database Yordas Hive.

GRMS2 contains hundreds of fact sheets. Scripted by experts at Yordas Group, these provide key information on new and existing global legislation impacting the automotive sector, including their impact on the manufacture, import, and after-sales of both articles and process chemicals.

yordasgroup.com/case-studies/grms2

Case study 2

Using Yordas Hive to create and populate substance scorecards

The challenge

A strategic client contracted Yordas to provide them with a timely and cost-effective solution to automate the population and monitoring of their regulatory scorecards, which are used to evaluate the health and environmental risks of substances used during the development of their products. Using a colour coding system, the scorecards help to forecast the hazards, regulatory status and stakeholder concerns for substances critical to their business, while building confidence in the future use of low-risk substances.

Work completed by Yordas included:

- establishing a list of relevant regulations;
- defining categories for different substances;
- automatic generation of scorecards;
- population of each scorecard with the regulatory information; and
- ongoing monitoring of regulatory changes.

Using Hive Notifier, Yordas continues to provide ongoing monitoring to inform the client of any immediate or upcoming business risks in relation to hazardous substances in their products.

yordasgroup.com/case-studies/substance-scorecards

Case study 3

Global biocides and cosmetic regulatory project support

The client

Our client wanted to market several hygiene products in the following 19 countries: Canada, France, Italy, Japan, Saudi Arabia, South Korea, Spain, Belgium, The Netherlands, Qatar, UAE, Australia, Hong Kong, Poland, Romania, Brazil, Israel, Mexico and Singapore. The client needed to identify their regulatory obligations and costs for compliance to determine their next steps.

Scoping assessment

Using our team of experts we conducted a regulatory scoping assessment for each country of interest. The client wanted to understand which regulation would apply to their products if registration was required in each country and the costs, timelines and requirements if applicable. The assessment included reviewing the client's products, their composition presentation and claims to define the country-specific biocidal/ cosmetic product regulations applicable to their products.

yordasgroup.com/case-studies/global-cosmetic-regulations

Case study 4

The flexible extension to your regulatory compliance team

The regulatory challenge

Our client is an international home improvement company who is required to comply with the chemical regulations for their products. They also aspire to reduce hazardous substances in their products beyond the minimal level that is required.

Our solution

We provide a number of services to the client, including regular notifications of changes to the chemical regulations that affect their products, and horizon scanning for future changes in the pipeline, to allow them to act quickly to substitute substances in good time, and sell through stocks before they must be removed from the shelves. In addition, we act as the flexible extension to their regulatory team, by providing advice on and interpretation of the chemical regulations, producing communications documents regarding chemical compliance to distribute through their supply chain, and contacting the regulatory authorities on their behalf to clarify requirements in cases where the regulations are ambiguous, such as borderline products. We have also provided training to the client on product compliance for various product types used within their business and have produced product compliance assessments and hazard scorecards for various products.

yordasgroup.com/case-studies/extension-compliance-team

Staff selection

Sandra Meijer – Chief Data Officer

A recognised expert on chemicals management and product stewardship, Sandra has built up the Yordas Group's highly regarded product stewardship services package, which includes the Yordas Hive suite of regulatory compliance tools for industry. Sandra's extensive knowledge on how global chemicals regulations impact on supply chains, and her work with Yordas Hive has helped us to deliver tailored compliance solutions for large companies in the automotive, aerospace, and retail industries.

Rosalinda Gioia – Chief Scientific Officer

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. 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, and risk assessments in the aquatic environments.

Alex Paul – VP Enterprise and Partnerships

Alex develops Yordas' partnerships around the world. Since 2014, Yordas has established partnerships in China, South Korea, Thailand and Taiwan, and Alex leads this expansion as further South-East Asian and Latin American countries implement new chemical notification systems.

Neil Hunt – Principal

Neil heads Yordas Group's services for nanomaterials, substance substitution, exposure scenarios and authorisation, running the training courses for the last two topics. Neil has been appointed to be a member of ECHA's Partner Expert Group for the revision of the REACH guidance documents on recommendations for nanomaterials.

Chem Academy

Contacts	
Website	chem-academy.com
E-mail	info@chem-academy.com
Head office	Bahnhofsplatz 2, D-16321 Bernau bei Berlin, Germany
Tel	+49 3338 75157 0
Contact	Dr Bjoern Nehls
Ownership	Private company
Locations	Germany
Founded	2007

Overview

Chem-Academy provides conferences, seminars and workshops on current topics in the chemical industry and those related to it. Experienced speakers from operational practice, government/authorities and academia deliver the latest findings on current issues in their respective fields. Experts from the entire pipeline from manufacturing to downstream users as well as manufacturers of articles and service providers are represented at our events. Chem-Academy delivers specialist answers and advice that go beyond the general helpdesks, FAQ pages or complex legal texts.

Services provided

Hybrid conferences and courses on chemical regulation and implementation.

Clients

A wide variety of clients and delegates from industry, authorities and service providers.

HEITMANN com for chem

Contacts	
Website	com4chem.de/en/about/
E-mail	info@com4chem.de
Head office	Chilehaus A, Fischertwiete 2, 20095 Hamburg, Germany
Tel	+49 1736176387, +49 40 320 052 00 (fax)
Contact	Kerstin Heitmann
Ownership	Kerstin Heitmann
Locations	Hamburg
Founded	2020

Overview

We deal with issues relating to chemicals legislation on a daily basis. We have been involved with REACH, CLP and other regulations since 2001, when the first drafts for a new European Chemicals legislation were developed. During the course of our consultancy work, we can draw on many 'best practice' examples. We are also aware that company-wide solutions and cooperation agreements are becoming increasingly important. We can help, acting as a moderator and a coordinator.

European chemicals legislation is not a rigid structure. New or adapted concepts for restrictions and authorisation such as the "essential use concept" are expected with the upcoming REACH Revision. Furthermore, polymers shall become subject to notification and registration obligations. Other developments relate to legal provisions for individual substances, for example classification, restriction and authorisation.

Com for Chem follows up these developments and discusses them with our extensive interdisciplinary network.

Services provided

- Technical and regulatory support for registrants, including lead registrants, consortia, co-registrants
- Chemical safety assessment (registration, DU CSR, application for authorisation)
- Strategic REACH consultation, compliance monitoring for substances, PPORD
- Substances in articles, SVHC and SCIP notifications
- In-house seminars, webinars and workshops

Clients

- REACH Selenium and Tellurium Consortium
- Metals producers and distributors including associations
- Paint manufacturers
- Polymer producers
- Producers of medical devices
- Chemicals distributors

Coracle

Contacts	
Website	coracle.global
E-mail	info@coracle.global
Tel	+44(0)1484 866777
Contact	Claire Clarke
Ownership	Private limited company
Locations	UK
Founded	2015

Overview

Experts in complex chemistry, regulatory affairs and project management. We specialise in complex substance identification, analytical interpretation and problem solving.

We design and carry out testing to respond to ECHA compliance check requests as well as general REACH and biocide inquiries. For example, testing protocols to demonstrate how substances degrade under simulated toxicological and environmental conditions.

Our analysis goes beyond the simple fail/pass parameters to provide detailed interpretation and suggest solutions to problems.

We use the expertise and facilities of a number of laboratories complemented by other partners with a background in industrial chemistry, research and development, and bioinorganic chemistry.

Services provided

- Complex analytical interpretation
- Substance identification
- IUCLID dossier preparation
- REACH/BPR
- Process development
- Product stewardship
- Batch testing
- Purity analysis/screening
- Designing bespoke testing protocols
- SDS reviews and authoring
- Supplier audits

econetta sustainable solutions since 1995

Contacts	
Website	econetta.com
E-mail	Daniel.egger@econetta.com
Head office	Ifangstrasse 11, 8952 Schlieren, Switzerland
Tel	+41 44 732 92 90
Contact	Daniel Egger
Ownership	Private company
Locations	Switzerland
Founded	1995

Overview

Econetta combines scientific consulting with laboratory expertise offering flexible and efficient solutions. Our experts support clients from private and public sectors to comply with chemical legislation and promote sustainability, ensuring responsible product placement.

Services provided

Benefit from Econetta's global partnerships, which ensures expert assistance for European and Swiss chemical legislation, but also for compliance with legislation such as China REACH, UK REACH, TSCA and more. Econetta's portfolio includes:

Sustainability: Strategy for Safe and Sustainable by Design (SSbD) Assessment, Ecolabel, Lifecycle Assessment (LCA), Green Chemistry.

Chemical management: Strategic consulting, regulatory tracking and compliance, monitoring of critical substances, data management, quality assessment.

REACH Registration: Data-gap analysis, test management including study monitoring, dossier including exposure scenarios and risk assessment.

REACH Authorisation: Strategy development, dossier including Analysis of Alternatives, Socio-Economic Analysis and Chemical Safety Report.

CLP/GHS: Hazard assessment, Classification and Labelling (C&L), SDS (eSDS), C&L inventory, PCN notifications.

Biocides: Strategy development, data sharing agreements, active substance and biocidal product authorisations, transitional authorisations.

Swiss legislation: Regulatory compliance, SDSs and cover sheets, new substance notifications, RPC notifications, SVHC-authorisation.

Laboratory services: Efficient ordering of all relevant test types, GLP compliant in-house ecotoxicity and biodegradability studies according to OECD guidelines.

Clients

Econetta serves a diverse clientele ranging from multinational companies to dynamic SMEs and regulatory bodies. Our expertise caters to a wide spectrum of industries including pharmaceuticals, (petro)chemicals, fragrances, paints and coatings, biocides, and cosmetics. Together with our international partners, we deliver tailored solutions to drive success in every sector.

eSpheres CLOUD HSE

Contacts	
Website	espheres.com
E-mail	Philip.capel@espheres.com
Head office	rue des Pères Blancs 4, 1040 Etterbeek, Brussels, Belgium
Tel	+32 (0)2 740 43 36/ +32 (0) 473 58 14 73
Contact	Philip Capel
Ownership	Private
Locations	Belgium
Founded	2011

Overview

eSpheres, a Solvay spin-out, delivers health, safety and environment (HSE) software services and solutions to international businesses. Our combination of specialised services, consulting and IT solutions, expertise on SAP®EH&S and SAP®Product Compliance, and our partnership's help companies to improve their chemical product compliance. We can support directly with you or via your ICT solutions and services provider.

Services provided

SAP®EHS Consulting: eSpheres supports projects and strengthens corporate EHS and IT departments with adequate resources to maintain, support, operate and implement SAP®EHS into any organisation. Experts in SAP®EHS and HSE data management, we have developed IT-tools to facilitate the use of EHS systems. eSpheres implements and supports the SAP®EHS(M) modules; maintains Regulatory Contents, implements SAP Poison Centre Notification software applications (3ENotify, Opesus EPN), SAP Product Compliance for S4HANA and helps to meet the requirements of Regulations (PCN, SCIP, GHS, CLP...). Expertise in SDS authoring, product safety, product stewardship, vendor SDS management, label management, dangerous goods management, substance volume tracking, recipe management and recipe development.

Outsourced EHS regulatory content update (3ECompany, Sphera CE) for SDS authoring with SAP Product Safety or SAP Product Compliance.

SAP®EHS Training: Expert Rules and WWI templates creation, tailored SAP®EHS programs to modify, export and import EHS data from SDS.pdf into XML, JSON, CSV files, facilitating HSE data management with SAP®EHS.

Clients

Specialty chemicals, pharmaceuticals, paintings, steel and alloys, pulp and paper, polymers, microelectronic, semiconductor, chemicals distributors, SAP ICT service providers.

Kerona Scientific Ltd.

Contacts	
Website	kerona.ie
E-mail	info@kerona.ie
Head office	14 Thomas Hand Street, Skerries, Co Dublin K34 A375, Ireland
Tel	+353 (0)1 8495284
Contact	Dr. Irene McGrath
Ownership	Private Company
Locations	Ireland ,Spain, Portugal and the UK
Founded	2014

Overview

With offices in Ireland, Spain, Portugal and the UK, Kerona Scientific is an award-winning regulatory consultancy providing a wide range of services for the registration of biocides, plant protection products, plant biostimulants, fertilisers, chemicals and cosmetics throughout the EU.

Services provided

Kerona provides a full range of services to support client registration in Europe, including strategic regulatory advice on new product introductions, and maintenance and expansion of existing product ranges. Our clients benefit from our multilingual and multidisciplinary team of experts in analytical chemistry, toxicology, environmental fate, ecotoxicology, microbiology and biochemistry.

We assist with all aspects of data generation and dossier preparation, such as data gap analysis, data review, study commissioning, dossier preparation, technical equivalence, and risk assessments for human health and the environment. We also provide a wide range of support services, for data access negotiations, representation with EU authorities and consortia, only representative, preparation of SDS/label/SPC, CLP/GHS, SDS authoring and literature searches. Drawing on our experience of more than 40 years in regulatory management, we advise on the most efficient and expeditious pathway to success for national and regional authorisation, under transitional arrangements and after active substance approval.

Clients

We are proud to work with all our clients and delighted that many of the leading companies worldwide have chosen to work with us. Our clients include global multinationals and SMEs from the biocides, chemicals, plant protection, cosmetics, plant biostimulant and biopesticide sectors.

Eurideas LANGUAGE EXPERTS

Contacts	
Website	eurideastranslation.com
E-mail	translation@eurideastranslation.com
Head office	Square de Meeûs 35, 1000 Brussels, Belgium
Tel	Tel +32 (0)2 808 4406
Contact	Kristina Bitvai
Ownership	Private company
Locations	Belgium, Germany, Hungary
Founded	2007

Overview

Eurideas Language Experts provides professional translation and interpreting services. We specialise in chemical, technical and medical translations, but cover other fields such as EU legislation, law, environment, health and more. Our native speaker chemical translators are experts in the REACH, CLP and BPR Regulations and other related EU, international and local legislation. We have extensive experience in translating SDSs, SPCs and other regulatory documents. We have developed our own unique methodology through years of translating chemical documents, and are therefore able to offer 60% discount for any repeated work.

Services provided

We provide translation, certified translation, machine translation (AI) with human post editing, proofreading, editing and layout services in all European and in many Asian, African and Latin American languages. Our linguists are always native speakers of the target languages and have background in the field of the translatable document. We translate SDSs, exposure scenarios, SPCs, labels, dossiers, reports, patents and marketing materials.

Clients

We have worked on REACH, BPR and other chemical-related projects for Arkema, Cefic, FEICA, Ecolab, Cidlines, Helleniq Energy Holdings, Solenis Switzerland, Glencore International, HELM AG, Rio Tinto, Wintershall, International Lead Association, Nickel Institute, Syngenta, DonauChem, JCDB Japan Chemical Database, Nissan Chemicals, Agrolab and many more.

INFOTOX

Contacts	
Website	infotox.pt
E-mail	info@infotox.pt
Head office	INFOTOX Lda, Rua de Moscavide 6D, Parque das Nações, 1990-160, Lisbon, Portugal
Tel	+ 351 218 063 659
Contact	Elsa Casimiro
Ownership	Private company
Locations	Portugal and UK
Founded	2004

Overview

Founded in 2004, INFOTOX is a specialist consulting company providing chemical regulation compliance, human health and environmental risk assessment and advisory services to the private and public sector.

Services provided

Our regulatory services include expert support for the biocidal products Regulation (BPR) cosmetic products Regulation, detergent Regulation, medical devices Regulation, Ecolabel, REACH, CLP/GHS, ADR and PIC in terms of:

- dossier data gap analysis;
- IUCLID dossier preparation for BPR and REACH;
- electronic submissions and updates (CPNP, PCN, ePIC, R4BP and REACH-IT);
- (eco)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;
- BPR specific services, including transitional period biocidal product registrations in the EU/UK, product assessment report (PAR), consortia for biocidal products and Article 95 listing of active substances;
- poison center notifications in the EU/UK;
- Ecolabel dossier preparation and submissions;
- REACH specific services, for example only representative services and production of chemical safety reports (CSR); and
- cosmetic products specific services, including responsible person services, product information file (PIF) review and compilation and cosmetic product safety reports.

The services listed above are also available for UK regulations and submission platforms.

We also provide a wide range of environmental health services, including health impact studies for environmental impact assessment (EIA), soil clean-up, climate change projects and the Tobacco Products Directive.

Clients

Our clients include regulators, professional organisations, multinational companies and SMEs.

LKC

Contacts	
Website	LKC-ltd.com
E-mail	LKC@lkc-ltd.com
Head office	Postfach 167, Hauptstrasse, Fuellinsdorf, Switzerland
Tel	+41 61 906 8503
Contact	Matthew Kane
Ownership	Private company
Locations	Switzerland, UK and EU
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. Speciality chemical manufacturing clients benefit from our range of scientific, technical and regulatory services to achieve the successful registration of substances and products for crop protection, biocides, veterinary medicines and industrial chemical uses.

Services provided

Technical and scientific: pre-and post-submission discussion with authorities, data assessment and compensation, registration success forecasting, maintenance and defence.

Regulatory: data gap analysis, data evaluation, data waiving, justifications, 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 approval, product dossiers for national registrations, provisional and union authorisations and mutual recognition. CADDY.XML dossiers, IUCLID dossiers, registrations, renewals, PPPAMS, label extensions, EU import tolerances/ MRLs, REACH and CLP dossiers.

Clients

LKC's clients are international speciality chemical and biochemical manufacturers that benefit from technical and regulatory services to compete and grow in major competitive market sectors including crop protection, public health, veterinary medicines and chemicals.

Safety Assessment Solution Co., Ltd.

Contacts	
Website	safety-as.com
E-mail	info@safety-as.com
Head office	3F, 311, Sinbanpo-ro, Seocho-gu, Seoul, 06532, Republic of Korea
Tel	+82 (0)2-754-0600
Contact	info@safety-as.com
Ownership	Limited company
Locations	South Korea
Founded	2018

Overview

Safety Assessment Solution is a consultancy specialised in managing chemical substances and products. SAS staff includes more than 40 qualified experts including MS or PhD. Annually, SAS successfully registers and approves over 200 cases under K-REACH and K-BPR.

We have five of our own-IT platforms called Sol-T Series, a chemical regulatory web service that performs regulatory implementation and customer response processes more efficiently. In particular, with the specialised focus of Sol-T. EX on monitoring the test production for two-generation reproduction toxicity, teratogenicity, as well as 28-day and 90-day repeated dose toxicity, we annually produce 2,000 test materials.

We also have specialised polymer-related know-how through experience in analysis, test design, and technical consultation on special polymers.

SAS promises to provide reliable consulting services by responding accurately and quickly based on expertise, experience, and technical skills.

Services provided

Regulatory compliance

- K-REACH: OR service, consortium management, registration and updates, CSR preparation.
- K-BPR: OR service, consortium management, approval and updates for active substances and products, risk assessment.
- K-OSHA(SDS): OR service, SDS authoring and submission, CBI non-disclosure approval.

Multi-site test management service

A one-stop solution for testing-related tasks such as: test strategy creation; selection of reliable and affordable CRO; monitoring and review; and test data production.

Training for companies

Clients

Chemical and associated industries: BASF, Ecolab, Kemira, Lotte Chemical, Merck, Sigma Aldrich, SK Chemical, Solvay, etc.

JongeriusConsult

Contacts	
Website	jongeriusconsult.com
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 is a small-scale consultancy firm with great expertise and experience in the field of European and Dutch legislation on hazardous substances, such as REACH and CLP. We support companies and industry sectors to use their products safely in the supply chain and in the workplace through effective implementation of REACH and CLP in a logical connection with the Occupational Safety and Health and Environmental legislation.

Onno Jongerius has been a recognised expert in REACH and CLP regulations since 2007, valued for his ability to engage with customer-specific business cases and to provide personalised attention.

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 free call.

Clients

Our clients are companies and sectors that want to deal efficiently and effectively with REACH, CLP and related legislation up to safe use of chemicals and in alignment with their business needs. We are proud of our strategic partners, satisfied customers and many satisfied participants who attended our REACH workshops. We'll continue to focus on providing added value and making REACH and CLP work for industry.

ATC GmbH

Angewandte Tox-Consult

Contacts	
Website	tox-consult.de
E-mail	info@tox-consult.de
Head office	Hülser Straße 283, 47803 Krefeld, Germany
Tel	+49 (0)2151 / 78 42 563
Contact	Dr Joachim Haselbach
Ownership	Private company
Locations	Germany
Founded	2004

Overview

ATC GmbH (Applied Tox-Consult) is an independent consulting company that was founded by Dr Joachim Haselbach in 2004. Our core competence is to support our clients in the evaluation of all kinds of ecological/toxicological safety issues relevant for humans and the environment. Our goal is to provide comprehensive yet personalised solutions that fulfill essential legal obligations for ensuring product safety.

Services provided

Our strength lies in our extensive service capabilities based upon our competence in all ecological/toxicological disciplines. We are focused on various legal areas and assess the safety, and if needed, the marketability of all kinds of consumer and industrial products. These include, cosmetics, medical devices, detergents and articles for daily use, ie sanitary hygiene products, clothing and packaging materials.

Our greatest strength lies in fostering trusting collaboration with our clients, leading to optimal and high-quality solutions tailored to individual needs. We cover:

- consumer goods and articles;
- cosmetic products, personal hygiene products;
- medical devices;
- detergents;
- extractables and leachables;
- novel food;
- food contact materials;
- recycled plastic materials;
- and REACH and CLP.

Clients

We operate both domestically and internationally, serving individuals, small businesses, medium-sized enterprises, large corporations, public institutions, as well as law and insurance firms.

Our staff comprises chemists, biologists, toxicological experts (expert toxicologist ("Fachtoxikologe") of the German Society of Pharmacology and Toxicology (DGPT), publicly authorised experts ("Sachverständiger") for Toxicology and Toxicological Risk Assessments.

Siam

Contacts	
Website	siam-it.com
E-mail	sales@siam-it.com, usa@siam-it.com
Head office	Ortega y Gasset 17 bajo, 26007 Logroño, Spain
Tel	+34 941 28 67 49
Ownership	Private company
Locations	Europe and North America
Founded	2007

Overview

Siam develops software for the classification and management of safety data sheets under CLP and GHS Regulations. We provide a highly versatile software platform for preparing multilingual SDS and chemical products labelling. Our Chemeter software and SdSArea tool can offer much time saved, with features suited to the current and evolving safety regulations in more than 60 countries. The software is built up in a modular fashion to suit your exact needs at a given time.

Services provided

Chemical data management: a solid substance database is available and constantly under review.

SDS authoring software: Chemeter generates compliant and multilingual SDSs for more than 60 countries.

EU Poison Centre Notification format: automatically and quickly creates all PCN dossiers for harmonised notifications, taking the data needed from Chemeter.

Label editor: an innovative tool for designing CLP and GHS labels.

SDS efficient management and distribution: SdSArea takes care of sending SDSs to your customers, notifying them in compliance with REACH regulation.

Updated software: new features are constantly developed and legislative updates implemented.

Integration with your system: possibility of automation for issuing and sending of updated SDS process.

Further documents: extended SDS (e-SDS), dangerous goods documents and sector-specific paperwork.

Clients

A wide variety of clients, from small-sized to global international companies, are using our software to make their safety data sheets and labels. Today we have a well-established international presence through our worldwide sales network. Our clients are companies that manufacture and distribute all kinds of chemical products in many sectors, such as: cleaning, paints and coatings, rubber, detergents, adhesives and sealants, flavours, fragrances, water treatment etc.

SWECO

Contacts	
Website	sweco.fi
E-mail	sds@sweco.fi
Head office	Finland
Tel	+358 20 739 3000
Contact	Emilia Lier, +358 50 4119387
Ownership	Public company
Locations	Finland, Sweden, Belgium, Germany
Founded	1898

Overview

Sweco plans and designs the built environment and industry of the future. We offer our customers the right expertise for every need. Sweco is Europe's leading engineering and architecture consultancy with 18,000 employees and net sales of €2bn. There are more than 30 experts in the compliance team.

Services provided

- Chemical safety
- Product safety
- REACH
- Safety Data Sheets (SDS), CLP, Exposure Scenarios (ES)
- Biocides, BPR
- Toxicological and ecotoxicological risk assessments
- Cosmetics safety assessments
- Medical device compliance
- Food safety
- Contact material safety
- Legal advice
- Regulative services
- Process safety
- Machine safety
- Functional safety
- Risk analyses (HAZOP)
- SIL-verification

Clients

Industry. Brand owners. Retail. Public organisations.

SCAS Europe

Contacts	
Website	scas-eu.be
E-mail	scaseurope07@scas-eu.be
Head office	SCAS Europe (Sumika Chemical Analysis Service), Leonardo da Vincilaan 19A Bus6 (MC Square Offices) B 1831 Diegem, Belgium
Tel	+32 (0)2 719 0475
Ownership	Sumika Chemical Analysis Service, Tokyo, Japan
Locations	For parent company: Japan, China, Singapore, Taiwan, South Korea
Founded	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.

SCAS is a major analytical service provider with laboratories in Japan, China, Korea and Singapore. Founded in 1972, SCAS has consistently satisfied its customers' requirements 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

Our clients work in many sectors, with manufacturers and downstream users in industries including chemicals, petrochemicals, electronics, pharmaceuticals, automotive, paint, ink, rubber, fibre and others.

wsp

Contacts	
Website	wsp.com
E-mail	REACH@wsp.com
Head office	70 Chancery Lane, London, UK
Tel	+44 161 200 5101
Contact	Mick Goodwin
Ownership	Private company
Locations	UK, Europe, worldwide
Founded	8 April 1987

Overview

WSP is one of the world's leading professional services consulting firms, working across the chemical industry and their downstream users to identify, manage and mitigate current and future risks and liabilities. Companies benefit from opportunities presented through regulatory and environmental compliance, EHS improvements and sustainability aspirations.

Services provided

Our experts possess a rich understanding of the chemicals and related sectors, which we combine with our multidisciplinary services to support clients throughout the lifecycle of their processes and projects. We actively engage with our clients to help identify and provide solutions to the challenges they face. For example, our product stewardship team offers a turn-key chemical regulation and compliance service. Clients benefit from easier access to market, increased reputation, and reduced reporting obligations.

Services include:

- EU REACH, UK REACH and worldwide registration and authorisation dossier preparation and submission
- only representative (OR) services for EU and UK, strictly controlled conditions and REACH audits and REACH training
- SDS, exposure scenario and chemical safety report preparation and management
- CLP harmonised poison centres notification management and SCIP notifications
- dangerous goods safety advisor services
- support with EU and UK cosmetic regulations and biocidal product regulations
- support with chemical regimes outside of the UK and Europe (including China, Australia, Korea and US TSCA)
- support for POPs, PIC and Stockholm protocol
- advice for conflict minerals
- testing monitoring; and
- alternative testing support.

Clients

WSP supports a wide range of companies across the chemical industry and downstream users across the globe. Company sizes range from single site SMEs to large multinational corporations covering all aspects of the supply chain. Specialising in helping companies respond to their business challenges and effectively manage compliance allows WSP to remain at the cutting edge of knowledge in the chemical industry.

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		Germany	US	25-50	2-5	●	◗	◗			◗	◗		
24-7 Response		UK		50-100	10-25	●					◗	◗		
3E		US	US, Canada, Europe, Asia	100-500	100-500	◗				◗	◗			
3S-SafelyServingScience		Greece		2-5	2-5	●	◗					◗		◗
Accenture		Belgium		5,000 plus		◗	◗			◗	◗	◗		
Acta	**66**	**US**	**UK, Belgium**	**25-50**	**25-50**	◗	◗	◗			◗	◗		
Active Steward		UK	Belgium	25-50	25-50					●				
Aegis Regulatory Inc		Canada		2-5	2-5	●								
Aequor, Inc.		US	US, UK	2-5	2-5	◗						◗		◗
AG-HERA		UK	UK	2-5	2-5	●	◗					◗		
AGREXIS AG		Switzerland		5-10	5-10	●								
Alchemy Compliance Ltd.		UK	UK	1	1	●	◗					◗		
Alemare Solutions Limited		UK		2-5	1	●					◗			
ALSTER Consulting > Chemical Compliance		Germany		1	1	◗	◗				◗	◗		◗
Altertox Academy		Belgium		2-5	2-5	◗	◗					●		◗
Altox a/s		Denmark		2-5	2-5	◗	○	◗				◗		○
AMEC (now Wood plc)		UK	Germany, Netherlands, US	2,000-5,000	25-50	◗	◗		◗		◗	◗		◗
Anderson Materials Evaluation, Inc.		US		2-5	2-5	○			●					
Annray Test Co., Ltd.		China		25-50	10-25	◗			●		◗			
Antea Group		US	Europe, Colombia, Africa	5,000 plus	100-500	●	◗			◗	◗	◗		◗
Anthesis Group		UK	Europe, N. America, China, Philippines	100-500	5-10	●	◗			◗				◗
Apeiron-Team NV	**68**	**Belgium**		**10-25**	**10-25**	●	◗				◗	◗		◗
Arcadis	**72**	**The Netherlands**	**Belgium, US, China**	**5,000 plus**	**50-100**	●	◗			◗	◗	◗		
Arcerion GmbH	**72**	**Germany**		**10-25**	**10-25**	◗	◗		◗	◗	◗	◗		
ARCHE Consulting	**74**	**Belgium**		**25-50**	**25-50**	●	◗			◗		◗		
Arrow Regulatory Ltd	**76**	**UK**	**Ireland, Austria**	**10-25**	**10-25**	●	◗				○	○		
Artemisa d.o.o.	**78**	**Slovenia**	**Slovakia, Poland, Hungary, Croatia, Romania**	**10-25**	**10-25**	●	○				○	○		
Asia Inspection (now QIMA)		Hong Kong	China, US	1,000-2,000	50-100				●					
Assent Compliance		Canada	United States, Amsterdam, Kenya, Malaysia	100-500	100-500	◗	◗			◗	◗	◗		○
asseso AG		Germany		5-10	5-10	◗	◗	◗				◗		
ATC GmbH (ToxConsult)	**164**	**Germany**		**5-10**		●	◗				◗	◗		
ATOMIUM		Croatia		2-5	2-5	◗	◗	◗		◗	◗	◗		
ATOUT REACH		France		2-5	2-5	◗	◗							◗
Auxilife Scientific Services Pvt. Ltd		India	No	10-25	10-25	●	◗				◗	◗		
Ayansan Chemical Consultancy Ltd. Co.		Turkey	Hungary	5-10	5-10	◗	◗	◗	◗		◗	◗		
Battelle UK Ltd		UK	Switzerland, US	100-500	100-500	◗			●					
Baytouch Ltd		UK	US	5-10	5-10	◗				●				
Beijing BoardingCard Chemical Consulting Co., Ltd.		China		10-25	10-25	◗	◗		●		◗			
Benchmark Digital		US		100-500						◗	◗	◗		
Beveridge & Diamond, PC		US		50-100	10-25				●					
bibra toxicology advice & consulting		UK		10-25	10-25	●	◗				○	○	○	
BIG vzw		Belgium		25-50	25-50	◗	◗	◗		◗	◗	◗		
BioDetection Systems bv		Nederland		10-25	5-10	◗			●			◗	◗	
BioGenius GmbH	**80**	**Germany**		**25-50**	**10-25**	◗			●					
BioQuanta		France	Japan, Thailand, US	25-50	10-25				●					
BIOVIA, Dassault Systemes		US		25-50	25-50					◗	◗			
Bird & Bird LLP		Belgium		500-1000	2-5			●						
Blue Frog Scientific Limited		UK	France	10-25	10-25	●	◗							
bluesign technologies ag		Switzerland	Germany, HK, representatives globally	50-100	5-10	●	◗				◗	◗		
Bootman Chemical Safety Ltd.		UK	Republic of Ireland	2-5	2-5	●	◗					◗		◗
Borenius & Kemppinen, Attorneys at law Ltd		Finland		100-500	5-10			●						
Bristol Environmental		US		100-500	100-500									●
Buckman		US		2,000-5,000		◗	◗	◗	◗	◗	◗	◗		
Bureau for Chemical Engineering TB-Klade		Austria		1	1	●								
Bureau Veritas		Denmark	China, Hong Kong, France, Germany, US	5,000 plus	50-100	◗		◗	◗	◗		◗		◗
Burges Salmon LLP		UK		500-1000	2-5			●						
Butterworth Laboratories Ltd		UK		50-100	50-100				●					
CAAT-Europe		Italy	Germany	10-25	5-10	●						◗		
Cambridge Environmental Assessments		UK	Republic of Ireland	5,000 plus	25-50	●	◗		◗			◗		
Cardno ChemRisk		San Francisco, CA, US		100-500	100-500	◗		◗				◗		◗
CE way		Slovenia		2-5	2-5	●			◗					
Cefas		UK		500-1000	25-50	◗			●					
CEHTRA		France	Belgium, Germany, Spain, UK, India, Canada, Luxemberg	50-100	25-50	●	◗	○		◗		◗		
Centro Reach Srl		Italy		2-5	2-5	◗	◗	◗			◗	◗		
CERM		US		5-10	2-5	◗	◗				◗	◗		
CGI		Canada	US, France	5,000 plus	100-500	◗	◗			◗		◗		
Charles River		US	UK, Netherlands, France, Hungary	5,000 plus	100-500	◗			●					
CHD Global		Turkey		5-10	5-10	◗	◗			◗	◗	◗		
Chem-Academy	**162**	**Germany**	**Germany**	**10-25**	**5-10**							●		
ChemAlert (RMT)		Australia				◗				◗	◗	◗		◗
CHEMDOX	**82**	**Austria**	**US**	**50-100**	**10-25**					●		◗		
Chementors Ltd		Finland	China, Vietnam	50-100	5-10	◗	◗	◗	◗	◗	◗	◗		
Chemex Environmental International Ltd		UK		10-25	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
1cc GmbH	■				□			■		□				□			■	■	■	■	□	□				■		□					**1cc-consulting.com**
24-7 Response																	□	□	■	■		□	□										**24-7response.org**
3E	■	■	■	□	□	■	□	□	■	□	■	□	■	□	■	□	■	■	■	■	□	□	■		■	■	□	□		□	■		**3Eco.com**
3S-SafelyServingScience	■	□	■	□	■	■							■			■	□	■	■	■		■	■	□									**3s-chem.gr**
Accenture	■	■	■	■	□	■	□										■	■	■	■		□	□										**accenture.com**
Acta	■	■	■	□	■	■	■	□	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	**actagroup.com**
Active Steward	■	□		□	□	□							□		□		■	■	■	■	□	□	□	□	■						□		**activesteward.com**
Aegis Regulatory Inc	■				□	□											□	□	■	■	□		□										**aegisreg.com**
Aequor, Inc.	■	■	■	■	■	■	■			■		■	■								■	■		■								■	**aequorinc.com**
AG-HERA	■	■	■	□	■	■	■										■	■	■	■	□	■	■	■									**ag-hera.com**
AGREXIS AG		■			■														□	□		■		■									**agrexis.com**
Alchemy Compliance Ltd.	■																■	□	■	■	□	□	□								□	□	**alchemycompliance.com**
Alemare Solutions Limited	■	■			■								■				■	□	■	□		■									□		**alemare.co.uk**
ALSTER Consulting > Chemical Compliance	■			□	□												■		□	□	□	□											**alster-consulting.eu**
Altertox Academy	□	□	□	□	□	□	□						□	□			□	□	□	□	□	□	□	□	□								**academy.altertox.be**
Altox a/s	■			□	■	■		□	■	■	□	■	■	□	■	■	■	□	■	□		■	■		□	■	■	□				□	**altox.dk**
AMEC (now Wood plc)	■	□	□	□	■	□			□								■	□	□	■	□	■		□									**woodplc.com**
Anderson Materials Evaluation, Inc.	■	□	□	□	□	□	□	□	■	□	■	□	□	□	□	□							□	□		□	■						**andersonmaterials.com**
Annray Test Co., Ltd.	■			■		□											■	□															**annraytest.com**
Antea Group	■	■	■	□	□	□											□	□	□	□	■			□									**anteagroup.com**
Anthesis Group	■	□			□	□		■	□	■	□	■	□	□	□		■	■	■	■	□	■	□		■	□	■	□	□	□	□	■	**anthesisgroup.com**
Apeiron-Team NV	■	□	□		■	□		□	□	□	□	□	□	□	□	□	■	□	■	□	□	■	□		■	□	□		□	□			**apeiron-team.eu**
Arcadis	■	■	■	■	■	■	□	■	□	■	□	■	■	□	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	**arcadis.com**
Arcerion GmbH	■	□	□		■	□		□	□			■	■			■	■	■	■	■	□	■		□		■		□	■	■	■		**arcerion.com**
ARCHE Consulting	■	■	■		■	■	□			□		■	□	■			■	□	■	□	■	■	■			■		□					**arche-consulting.be**
Arrow Regulatory Ltd	■	□	□	□	■	□	□					■	□	□	□	□	■	■	■	□	■	□	□	□				□			■	□	**arrowregulatory.com**
Artemisa d.o.o.	□	■		■		■		□					■	■			□	□	■		■		■					□					**artemisa.si**
Asia Inspection (now QIMA)	□	□			□		■	■			■	□		■	□		■					□		■	■	■							**qima.com**
Assent Compliance	□		■	□			■	□	■	□	■	□	■	□			■	■			■	■		■	■	■	■						**assentcompliance.com**
asseso AG	■	□			□	□	■	□	■	□	■		□	■	□		■	■	■	■	□	□		■	■	■	■			□	□		**asseso.eu**
ATC GmbH (ToxConsult)	■	□	■	□	■			■			■	■	■	■	■		■	□	■	□		■				■	■						**tox-consult.de**
ATOMIUM	■	□	■	□	■	□	■	□	■	□	■	□	■	■			■	■	■	■	■			■		□			■	□	■	□	**msds.com.hr**
ATOUT REACH	■																■	■	■				□										**atoutreach.fr/service-atout-reach**
Auxilife Scientific Services Pvt. Ltd	■	■	□		■	■				□		■		□	□	□	■	□	■	□	□			■	■				□	□	□	□	**auxilife.com**
Ayansan Chemical Consultancy Ltd. Co.	■	□	□		■	■	□	■	■			■	□	□	□	□	■	■	■	□	■	□	■	□	■	■	□						**ayansan.com**
Battelle UK Ltd	□	■	□	■	■												□				■			■									**battelleuk.com**
Baytouch Ltd	■	□	□	□	□	□	□										■	□	□	□	□	□	□	□									**baytouch.com**
Beijing BoardingCard Chemical Consulting Co., Ltd.	■	□	□	□	□	□												■		■													**bjboardingcard.com**
Benchmark Digital	■	■	■														■	■		■	■						■						**benchmarkdigitalesg.com**
Beveridge & Diamond, PC	■	■	■	■	■	□											■	■	■	■	□	□	■										**bdlaw.com**
bibra toxicology advice & consulting	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	□	**bibra-information.co.uk**
BIG vzw	■	□	□		■	□		□	□	□	□	□	□		□		■	■	■	□	■	□	■										**big.be**
BioDetection Systems bv	■	■	□	■	□	□	□	□				■	□	□	■	□	□	□	□		□	□		□	□	□							**biodetectionsystems.nl**
BioGenius GmbH	■	■			■	□	□				□	□		□		□	□	□	□		■	□	■	□									**biogenius.de**
BioQuanta	■	□	■	■		■																											**bioquanta.net**
BIOVIA, Dassault Systemes	■	■	■	■	■	■											■	■	■	■	■	■	■										**3ds.com/products-services/biovia**
Bird & Bird LLP	■	■	■	■	■	■											■	□	■	□	■	■	■										**twobirds.com**
Blue Frog Scientific Limited	■	■	■		■	■								□			■	□	■	□	■	■	■										**bluefrogscientific.com**
bluesign technologies ag												■		■	□	□	□	□															**bluesign.com**
Bootman Chemical Safety Ltd.	■	■	□		■	□											■	□	■	■		■	□	■						■	■	■	**bootmanchem.com**
Borenius & Kemppinen, Attorneys at law Ltd	■	■	■	■	■	■	□										■	□	■	□	□	■	■	□									**borenius.com**
Bristol Environmental	□			□																	■	□											**bristolenvironmental.com**
Buckman	■	■		■	■												■	□	■	□	■	■	□	□									**buckman.com**
Bureau for Chemical Engineering TB-Klade				■						□		□		□	■		■			■													**tb-klade.at**
Bureau Veritas	■	■		□	□	□	□	□	□	□	■	□	■	□	■	□	■	■	■	■	□	□	□	■	■	■	■				□	■	**bureauveritas.dk/en**
Burges Salmon LLP																	■	■	■	■	■	■	■	■									**burges-salmon.com**
Butterworth Laboratories Ltd	■	□	■	□	■	□	■	□		□	■	□	■	□	■																		**butterworth-labs.co.uk**
CAAT-Europe	■	■	■	■	■	■			□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	**biologie.uni-konstanz.de/leist/caat-europe**
Cambridge Environmental Assessments	■	■	□	■	□	■	□	■	□	□		□	■	□	■	□	■	■			■	■	□	■	□	■	□	■	□		□		**cea-res.co.uk**
Cardno ChemRisk	■	□	■	□	■	□	■	■	□	■	□	■	■	■	□	■	□	■	□	■	□	■	□	■		■			□	■			**cardnochemrisk.com**
CE way					■																	■											**ceway.eu**
Cefas	■	■	□		□	■	□	■		□	■	□	■	□	■	□				■	□		■	■									**cefas.co.uk**
CEHTRA	■	■	■		■	■				■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	**cehtra.com**
Centro Reach Srl	■		□		■	□			■		■	□	■	□	□		■	□	■		□	■	■			□		□					**centroreach.it**
CERM	■	■									■		■		■						■				■								**Cermonline.com**
CGI	■	□	■	□	□	■	□	■	□	■	□	■	□	■	□	■	■	■	■	■	■	■	□	■	□	■	□	■		■	■		**cgi.com/en**
Charles River	■	■	■	■	■	■	■		■				■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	■		**criver.com**
CHD Global	■	■	□		■	□	■						■				■	□	■	□	□	□											**chd.com.tr**
Chem-Academy	■	■	■	■	■		■	□		□	■	□	■	□	■		■	■	■	■	■	■	■	■	□	■	□	■					**chem-academy.com**
ChemAlert (RMT)														■	□	□	■			■												■	**rmtglobal.com**
CHEMDOX	■			■			■	■	■	■	■		■		■	■	■	■	■	■						■			■	■	■	■	**chemdox.com**
Chementors Ltd	■	□	□	□	■	■				□	□	□	□	□	□	■	■	■	■	■	■	□	■	□	■	□	■						**chementors.fi**
Chemex Environmental International Ltd	■	■	■		■	■	■						■																				**chemex.co.uk**

Key: Icons above represent the percentage breakdown of services provided by each company 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)
ChemFORWARD		US	None	5-10		◗				◗	●			
ChemHaz Solutions		Ireland		1	1	●						◗		
Chemical Check GmbH		Germany		50-100	25-50	●	◗	)	)	◗	)	)	)	)
Chemical Compliance		DE	Germany	1	1	●								
CHEMICAL COMPLIANCE CA INC.		Canada		2-5	2-5	◗	◗			◗		◗		
Chemical Safety Consulting		Germany		1	1	●						◗		
CHEMLEG		Turkey		50-100	50-100	◗	◗			◗	◗	◗		
ChemManage		Turkey		2-5	2-5	◗	◗	)		◗	◗	)		
ChemPharmaServe Ltd		UK		2-5	2-5	◗								◗
ChemRegs (UK) Ltd		UK		2-5	2-5	●						◗		
ChemRisk		US		50-100	50-100	●								
Chemsafe Srl	**84**	**Italy**		**25-50**	**5-10**	◗	◗	◗	◗		◗	◗		
Chemservice	**86**	**Germany, Luxembourg, Korea**	**Switzerland, Spain, UK, US, Turkey**	**50-100**	**50-100**	◗	◗			◗	◗	◗		◗
ChemService Srl Controlli e Ricerche		Italy	Agent in China	25-50	25-50	◗		●				◗		
Chemtopia Co., Ltd.		South Korea	EU, US, Canada, China, Thailand, Japan, Vienam, Malaysia	50-100	25-50	◗	◗	◗	◗	◗		◗	◗	◗
CHEMTREC	**88**	**US**	**United Kingdom**	**5-10**	**5-10**	◗	◗			◗	◗	◗		●
Chemwatch		Australia	US, Europe, Asia	100-500	100-500	◗				◗	◗	◗		
CHESSOL B.V.		The Netherlands	Belgium, France, Italy	5-10	2-5	●				◗				
China National Chemical Information Center Co., Ltd.	**90**	**China**	**US**	**100-500**	**50-100**	●	◗		◗		◗			)
ChIR – Chemical Innovation and Regulation		Portugal	Spain, Italy, UK	5,000 plus	50-100							●		
Chymeia ApS (part of EcoOnline)		Denmark	Denmark	10-25	5-10	◗				●		◗		
CIDP		Mauritius	Brazil, Romania, India, Singapore	100-500	10-25				●					
Cindax BV		Netherlands	Cloud based chemical information service provider	2-5	2-5	◗		●						
CIRS	**92**	**China**	**Ireland, US, South Korea, UK**	**100-500**	**50-100**	◗	◗		◗	◗	◗	◗		◗
Citoxlab (part of Charles River)		France	Hungary	1,000-2,000	100-500	◗			●					◗
CJV Consulting Ltd		UK		1	1	●	◗	◗				◗	◗	
Clariant		Italy		5,000 plus	100-500	◗		◗	◗					◗
Compliance for Chemicals	**162**	**Germany**		**1**	**1**	◗	◗					◗	◗	
Compliance & Risks		Ireland	US, UK	50-100	50-100	◗				●				
Compliance Footprint AG		Switzerland	global offices	5-10	5-10	◗				◗				◗
Compliance Services International		US	UK	10-25	10-25	●	◗		◗			◗	◗	
Compliance-Footprint AG		Switzerland		2-5	2-5	◗	◗			◗		◗		
ComplyMarket	**94**	**Germany**		**10-25**	**5-10**	◗				●		◗		
Concept Life Sciences		UK				◗			●					
Consortia Management GmbH		Germany		10-25	10-25	◗	●							
CONUSBAT Regulatory Services		Germany		Globally	5-10	●	◗							
Coracle	**162**	**UK**		**5-10**	**5-10**	◗	◗		◗	◗	)			
Cosanta		The Netherlands	The Netherlands, Germany, Austria, Belgium, Finland, Denmark, Sweden, UK, Poland, Spain, France, Italy, Portugal.	10-25	5-10	◗		)		◗	◗	◗		
CRAD		Turkey	Representatives in EU, UK, US, Japan, Korea	10-25	10-25	◗	◗			◗	◗	◗		
Crowell & Moring		US		25-50	5-10	◗	◗	◗						
CS Regulatory Ltd		UK	Republic of Ireland	5-10	5-10	●	◗					◗	◗	
CSB Compliance Group		Germany	US, United Kingdom	25-50	25-50	◗	◗				◗			
Currenta GmbH & Co. OHG		Germany		100-500	25-50	◗	◗	◗	◗		)	)		
Cyprotex		UK	US	100-500	25-50				●					
Danger and Safety srl		Italy		5-10	5-10	●	◗				◗	◗		
dangerousgoods.com		US	Europe – China	10-25	10-25	◗	◗	◗	◗		◗	◗		
Danish Technological Institute		Denmark		100-500	25-50	◗			◗			◗		◗
Datalab		US		2-5	1									●
de ViB fabriek		Netherlands		2-5	2-5	●						◗	◗	
DEKRA Assurance Services GmbH		Germany		25-50	5-10	●	◗					◗		
DEKRA Consulting GmbH		Germany	France, Hungary, Turkey, UK	100-500	50-100	●	◗					◗		◗
DEKRA Process Safety		UK	8+ globally	5,000 plus	100-500	◗	◗		◗			◗	◗	
Dell Tech Laboratories Ltd.		Canada		5-10	2-5	◗			◗	◗				
Delphic HSE		United Kingdom	Hong Kong, Netherlands, China, Australia	50-100	25-50	◗	◗	◗		◗	◗	◗		
Dentons		US	Belgium	100-500	10-25	◗	◗	◗				)		◗
DHI		Denmark	26 offices worldwide	1,000-2,000	10-25	●	)		◗			)		◗
DIPHEX Ltd		UK		5-10	2-5	◗						◗		●
DORUKSISTEM		Turkey		25-50	25-50	◗	◗	◗	◗	◗	)	◗	)	
Dr. Andrea Volpato		Italy		1	1	●								
DXC Technology		US	Germany	5,000 plus	50-100	◗				●				
Eagle Environmental		South Africa		2-5	1	◗								●
EBRC Consulting	**96**	**Germany**		**50-100**	**25-50**	●	◗			◗		◗		
ECD Compliance		Canada		2-5	2-5	◗	◗		◗		◗	◗		◗
ECETOC		Belgium		5-10	5-10									●
Ecolab		US		5,000 plus	50-100	)								●
Ecomatters BV		The Netherlands	Spain	5-10	2-5	●				◗		◗		
EcoMole Ltd.		UK	Czech Republic	5-10	5-10	◗	◗			◗	◗	◗		
EcoMundo		France	Canada, Korea, US (New-Jersey)	25-50	25-50	●	◗			◗	◗	◗		
Econetta AG	**162**	**Switzerland**		**50-100**	**5-10**	◗	◗		◗	◗	◗	◗		

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
ChemFORWARD	□					■		■			□	□	□		■																		chemforward.org
ChemHaz Solutions	□		□														■		□	□		□											chemhazsolutions.com
Chemical Check GmbH	■	□	□			■	□		□	□	■	■	□	■	□	□	■	■	■	■		■	□		□	□	□	■				□	chemical-check.de
Chemical Compliance	■					□	□		■	□	■	■	□	□		■	■	■	■	■	□	□	□		■	□	■		□	□			pl-chemical-compliance.de
CHEMICAL COMPLIANCE CA INC.	■	■	■	■	□	□	□											■	□	■	□												chemicalcompliance.ca
Chemical Safety Consulting	■	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	■	□	■	■	□	□	□	□	□	□	□	□	□	■	■	■	chemicalsafetyconsulting.com
CHEMLEG	■	□	□	□	■	■	□						■	□	□		■	■	■	■		■	■					■					chemleg.com
ChemManage	■	■			■	□	□		□	□		□	□				■	■	■	■		■	□	■			□						en.chemmanage.com
ChemPharmaServe Ltd	□	□	■	■													□																chempharmaserve.com
ChemRegs (UK) Ltd																	■	■	■	■		■	□										chemregs.co.uk
ChemRisk	■	■	■	□	□	■	□										■	□	■	□	■	□	□	■									chemrisk.com
Chemsafe Srl	■	■	■	■	■	■	□	■	□	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■					chemsafe-consulting.com
Chemservice	■	□	□	■	■	□	□	■	□		■	□	■	□	■	■	■	■	■	■	■	■	□	■	□	■	□	■	□	□	□	□	chemservice-group.com
ChemService Srl Controlli e Ricerche	■	■			■	□	□										■	□	■			■	□	■								chemservice.it
Chemtopia Co., Ltd.	■				■			■		■		■	■		□	■	■	■	■	■	■	■	□		□	■	■						chemtopia.net
CHEMTREC	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	□	□	□	□	□	□	□	□	□	□	□			■	■	chemtrec.com
Chemwatch	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	chemwatch.net
CHESSOL B.V.					■								□		■	□	■	■	■	■	■												chessol.nl
China National Chemical Information Center Co., Ltd.	■	■	■		■	■	□								■		□	■	■	■	□	■		■	■								chemhse.com/english
ChIR – Chemical Innovation and Regulation	■	□	■	□	□												■		■	■	□	■	□	■		■				■	□		emmcchir.org
Chymeia ApS (part of EcoOnline)	■				□	□							■			■	□		■	□		□	□								■		ecoonline.com/chemical-safety/sds-authoring-software
CIDP			■	■		■											□						□										cidp-cro.com
Cindax BV																																	cindax.com
CIRS	■	■	■	□		□	■	□	■	■			■	■	■	■	□	■	■	■	■	□	■	■	■	■	■	■				■	cirs-group.com
Citoxlab (part of Charles River)	■	■	■	■		■	■						■	■	■		□	□	□			□		□									criver.com
CJV Consulting Ltd	■	□			■	□											■	□	■	■	□	■	□										cjvconsultingltd.wix.com/cjvconsultingltd
Clariant																	■	■	■	■	■	■											clariant.com
Compliance for Chemicals	■					□		□		□	□	□	□	□	□	□	■	□	■	□	□	□		□		□			□	□			com4chem.de
Compliance & Risks	□			□	■	□		■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■		■	■	■	■				■	complianceandrisks.com
Compliance Footprint AG	■	■															■	□	■	■													compliance-footprint.com
Compliance Services International	■	■	□	■	□	■	□						□	■																			complianceservices.com
Compliance-Footprint AG	■	□			□									■	□	■	■	□	■	□	■	□	□			■							compliance-footprint.com
ComplyMarket	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	complymarket.com
Concept Life Sciences																																	conceptlifesciences.com
Consortia Management GmbH	■	□			■	□								□			■	■	■	■	□	■	□	■	□								consortia-management.com
CONUSBAT Regulatory Services		■		■		□	■																■										conusbat.com
Coracle	■	□	□			■	□		□		■	■		□			■	■	■	□	□	■	□	■	□	■	□						coracle.global
Cosanta	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■							□		■	■	■			stoffenmanager.com
CRAD	■	■	□	□	■	□	■	□		□	■	□	■	□	■	□	■	□	■	□	■	□	□	□	■	□							crad.com.tr
Crowell & Moring	■	■	■	■	■		■		■	■	■				■	■	■	■	■	■	■		■				■						crowell.com
CS Regulatory Ltd	■			□		□			□	■	□		□		■	■	■	■	■	■	□			□	□					□	■		csregulatory.com
CSB Compliance Group	■			■	■				■		■		□		■	■	■	□	■	■	□			■							■		csb-compliance.com
Currenta GmbH & Co. OHG	■	■	■		□	■	□								■	■	■	■	■	■	□	■	□	■									currenta.de
Cyprotex	■	■	■	■	■	■	□		□		■	■	■		■	■	■	■	■	■	■	■	■				■	■			■	■	cyprotex.com
Danger and Safety srl	■				■	■									■	■	■	■	■	■	□	■	■										dangerandsafety.it
dangerousgoods.com	■	■	■	■	■	■	■		□					■	□	□	□	□	□	□	□	□	□										dangerousgoods.com
Danish Technological Institute	□	■	□	■	■	□	□		□	□	■	■	■	■	■	□		□			■	■	□	■	□	■	□	■	□				dti.dk/biocides
Datalab	■																																datalabsj.com
de ViB fabriek	■	■	□	□	□	■	□					■	■	□		□	□	□	■	■	□	□	□	□	□	□						■	devibfabriek.nl
DEKRA Assurance Services GmbH	■	□	□	□	□	■	□								■	□	■	■	■	■	□	□	□										dekra-consulting.de/de/chemikalienverordnung-reach/
DEKRA Consulting GmbH	■	□	□			■									■	□	■	□	■	□	□	■	□										dekra.com/en/consulting
DEKRA Process Safety	■	■	■	■	□	■	■	□	■	□	■	□	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	dekra-uk.co.uk/en/process-safety-overview
Dell Tech Laboratories Ltd.	■	■	□	■	■	□	■										□	□	■	□		□											delltech.com
Delphic HSE	□			■	■			■			■	□	□		□	■	■	■	■	□	■	□	□	□	■		■	■	■	■	■	■	delphichse.com
Dentons	■	□	■	■	■	■	□								■	■	■	■	■	■	■												dentons.com
DHI	■	□	■	□	■	■	■	■	■			■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	dhigroup.com
DIPHEX Ltd	■	■	■	■		■																											diphex.com
DORUKSISTEM	■	■	□	□	■	■	■	■	■		■	■			■	■	■	■	■	■	■	■			■	■					■		doruksistem.com.tr
Dr. Andrea Volpato	■	□			□		□		□		□				■	■	■	□	■		□		■		□		■						andreavolpato.it
DXC Technology							■		■			□			■	□	□	□	□	■	■				■	■			■				public.cdxsystem.com/en/web/cdx/home)
Eagle Environmental																																	eagleenv.co.za
EBRC Consulting	■	■	■		■	■		■		■	■		■	■	■	■		■	■	■						■		■					ebrc.de
ECD Compliance																	■			■													ecdcompliance.com
ECETOC	■	■	■	■	■	■	■																										ecetoc.org
Ecolab	■				■										■	■	■	■	■	■	■	■											ecolab.com
Ecomatters BV	■	□			■	■					■				■		■			■	■	□											ecomatters.nl
EcoMole Ltd.	■	□	□	■	□	□			■	□	■	■	□	□	■	□	□	■	□	□	■	□	■	□	■	□	□						ecomole.com
EcoMundo	■				■	■				■		■	■	■	■	■	■	■	■	■	□	■	■			■						■		ecomundo.eu
Econetta AG	■	■	□		■	□		■		□	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■						□	econetta.com

Key: Icons above represent the percentage breakdown of services provided by each company 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)
Economics for the Environment Consultancy Ltd. (eftec)		UK	Belgium	10-25	10-25	●						◗		◗
EcoOnline		Norway	Sweden, Finland, Denmark, Switzerland	50-100	5-10	◗				●	◗	◗		
Ecotox Services Australia		Australia		5-10	5-10				●					
ECT Oekotoxikologie GmbH		Germany		25-50	25-50	◗	◗		●					
Edif ERA (now Rina)		UK		100-500	5-10	●								
EHSCareers		US		5-10	2-5									●
elc group		UK	Czech Republic, India, Romania	50-100	10-25	◗	◗		◗	◗	◗	◗		
Elements Advisory		Belgium		2-5	2-5	●	◗					◗		
Elemica		US	Europe, Asia	100-500	100-500					●				
Envigo		US	Offices in 14 countries worldwide	2,000-5,000	500-1,000	◗			●					
Enviresearch		UK		10-25	10-25	●	◗		◗	◗				
Enviresearch Ltd		UK	Portugal	10-25	10-25	●								
Environmental Assessments		Germany	Sweden	2-5	2-5	◗	◗				◗	◗		
Environmental Science Group		UK		2-5	2-5	◗				◗		◗		
EnviroPlanning AB		Sweden		5-10	2-5	●								
epos Software & Service AG		Germany		25-50	10-25	◗				●		◗		
EPP		UK		25-50	25-50				●					
EquiTox		France		5-10	5-10	●	◗					◗		
ERBC	**98**	**France**							●					
ERM		UK	Worldwide offices	5,000 plus	100-500	●	◗			◗		◗		
eSpheres	**163**	**Belgium**	**Finland, Germany**	**5-10**	**5-10**	◗				◗	◗			
ETC		Slovakia		10-25	5-10	●	◗				◗	◗		
EUPHOR		US		50-100	10-25	◗				●				
Eurideas Language Experts	**163**	**Belgium**	**Hungary, Germany**	**10-25**	**10-25**	●								
Euro Safety and Health		UK		2-5	2-5	●	◗					◗		
Eurofins	**100**	**Belgium**	**Germany, UK, Denmark, US, China, India & Australia**	**5,000 plus**	**5,000 plus**	◗			●					
Eurofins Air Toxics		US	Denmark, Germany, France, China	5,000 plus	2,000-5,000	◗			●					
Eurofins Consumer Product Testing UK		United Kingdon				◗			●					
Eurofins EAG Laboratories		US	China, France, Germany, Japan, Singapore, Taiwan	1,000-2,000	100-500	◗			●					
Eurofins Product Testing A/S		Denmark	Europe, China, US	5,000 plus	100-500	◗			●					
Eversheds Sutherland		UK	Europe, Middle East, Asia	2,000-5,000	25-50			●						
Exitss		Belgium		10-25	2-5	◗	◗	◗		◗	◗	◗		◗
Exponent International Limited		UK	US, Ireland, London, Switzerland, China	500-1,000	50-100	●	◗			◗	◗			
f_OXYDE GmbH		Austria		5-10	2-5	●	◗							◗
Fanwood Chemical, Inc		US	Germany	2-5	2-5	●								
Fera Science Ltd		UK		100-500	25-50	◗			●			◗		
Fieldfisher (Belgium) LLP	**102**	**UK**	**Belgium, France, Germany, Italy, Spain**	**1500-2000**	**10-25**	◗	◗	●				◗		
FinnREACH		Finland		2-5	2-5	◗	◗	◗	◗					◗
Flashpoint srl		Italy		10-25	5-10	●						◗		
FoBiG	**104**	**Germany**		**10-25**	**10-25**	●	)	)	)	)				)
Foodchain ID		US	Germany, Thailand, Chile	50-100	10-25	◗				●				
Formulator Software LLC		US		5-10	5-10					●		◗		
Fraunhofer ITEM		Germany		100-500	25-50	◗	◗		●			◗		◗
GAB Consulting (SynTech Research Group)		Germany	Italy, Cyprus, Slovenia, Spain, Poland	50-100	50-100	●	◗			)	)			
GBK GmbH Global Regulatory Compliance	**106**	**Germany**		**25-50**	**10-25**	●	◗	◗		◗	◗	◗		
GHD		US	Australia, Canada, Chile, New Zealand, UK	5,000 plus	100-500	●								
GHS-expert Ltd		Hungary		1	1	●				◗		◗		
Global Product Compliance		Sweden	India, South Korea, UK, Australia, Turkey, China and Russia	100-500	100-500	◗	◗	◗	◗	◗	◗	◗		
GlobalMSDS		UK		5-10	5-10	◗				◗	◗			
GLTaC, Inc.		US		10-25		◗		◗		◗	◗	◗		
Gradient		US		100-500	50-100	●								
GreenSoft Technology, Inc		US	Taiwan, Japan, China, Spain	50-100	50-100					◗	◗			
Greenwich Chemical Consulting		US		1	1	●								
Grow Smart Chemical Compliance		Romania	-	2-5	2-5	◗	◗	)	)	)	◗	)		)
H2 Compliance	**108**	**Ireland**	**US, UK, Poland, Finland, India**	**100-500**	**25-50**	◗	◗	)	)	◗	◗	)		
Haley & Aldrich, Inc.		US		500-1000	10-25	●						◗	◗	
HAZMAT Ltd		Israel	UK	25-50	10-25	●	◗				◗	◗		
Herbert Smith Freehills		UK		2,000-5,000	2-5			●						
Hibiscus Plc		UK		25-50	25-50					◗				◗
Hohenstein		Germany	Bangladesh, China, Hong Kong, US, India	1,000-2,000	100-500	◗		)	●	◗	◗	◗		◗
Hunton Andrews Kurth LLP		Belgium	US	5,000 plus	1,000-2,000			●						
I+K AG, Compliance-Footprint AG		Switzerland		2-5	2-5	◗	◗			◗		◗		
ibacon GmbH		Germany		100-500	100-500	◗			●			◗		
ICB Pharma		Poland		50-100	25-50	◗			◗					◗
ICF		US	Belgium, Brazil, China, Russia, India	2,000-5,000	50-100	●								
IDRG (International Development of Regulatory Globalization)		Germany		2-5	2-5	◗						◗		
IES Ltd		Switzerland		50-100	2-5	◗			●					
imds professional GmbH & Co. KG		Germany	France Italy Spain Brazil	25-50	5-10	◗					◗	◗		
INERIS	**110**	**France**		**500 – 1,000**	**100-500**	◗	◗		◗		◗	◗	◗	)
INFOTOX	**163**	**Portugal**	**UK**	**5-10**	**5-10**	●	◗					◗		
INSCX exchange		UK	US, Turkey	5-10	2-5	◗	◗				◗			
International Cosmetics & Chemical Services Ltd		US	UK	5-10	5-10	●	◗					◗		

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
Economics for the Environment Consultancy Ltd. (eftec)	■	■	□	□	■	■	□	□	□	□	□	□	□	□	□	■	■		□	□		■	□						■		□		eftec.co.uk
EcoOnline	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	ecoonline.com
Ecotox Services Australia	■	■	■	■	■	■	□	□																									ecotox.com.au
ECT Oekotoxikologie GmbH	■	■	■		■	■	□	■									■		□			□		□									ect.de
Edif ERA (now Rina)								■		□				□			■		□			□	□			■	□	■						rina.org/en
EHSCareers																																		ehscareers.com
elc group	■	□	■	□	■	■	□										■	■	■	■	□	□	■	□									elc-group.com
Elements Advisory	□	□	□		■	■	□						□	□	□		□	□	□			■	□	■	□			□					elements-advisory.be
Elemica	■	■			■	■											□	□	□	□	□	□	□	□									elemica.com
Envigo	■	■	■	■	■	□	■										■	■	■	■	■	■	□	■									envigo.com
Enviresearch	■	■	■		■		■						□				■	□	■	□	■	■		■		□							enviresearch.com
Enviresearch Ltd	■	■	□		■		□						□	□			■	□	■	□		■		■									enviresearch.com
Environmental Assessments	■	□	□	□	■	□											■	■	■	■	□	■	□	■									enas-online.com
Environmental Science Group	■	□	■		□												■	□	■	■	□	□											envsciencegroup.com
EnviroPlanning AB	■		□		■	■											■		■			■											enviroplanning.se/en
epos Software & Service AG	■	■	□	□	□	□		□	□				■	□	□	□	□	□	■	□		□	□		□	□	□	□					gefahrstoff.com
EPP	■	■	■		■		■																										eppltd.com
EquiTox	■		□	□	■	■							□	□	□		■		■	■		■	■					□					equitox.eu
ERBC	■	■	■	■	■	■	■							■	■	■																	erbc-group.com
ERM	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	erm.com
eSpheres	■	□	■	□	■	■		□		■	□		□				■	■	■	■	■	■	■	□		■							espheres.com
ETC	■				■	□											■	□	■			■	□										ekotox.sk
EUPHOR	■	□	■	□	■	□	■	□	■	□	■	□	■	■	■	■	■	□	■	□	■	□	■	■	□	■	□	■	□	■	□	■	euphoreach.com
Eurideas Language Experts	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	eurideastranslation.com
Euro Safety and Health	□	□	□			□	□	■	□	■	□		□		■	□	□	□	□										■	■			eurosh.com
Eurofins	■	■	■	■	■	■	■	■	■		■	■	■	■			□	□	■	■	□	■	■	■	■	■	■	■	■	■			eurofins.com
Eurofins Air Toxics	□	■	■	□	■	■											■	■	■	■	■	■	■										airtoxics.com
Eurofins Consumer Product Testing UK	■	□	□		■	■	□	■	■		■	■	■	■	■	□	■		■			■	■	□	■	■	■	■					eurofins.com/consumer-product-testing
Eurofins EAG Laboratories	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	□	□	□	□	■	□	■	□	■		■		■					eag.com
Eurofins Product Testing A/S	■	■	■	■	■												■	■	■	■		■	■	■									eurofins.com/galten
Eversheds Sutherland	■	■	■	■	■	■	□										■	■	■	■	□	■	■	■									eversheds-sutherland.com
Exitss	□																■	□	■	■		□											exitss.eu
Exponent International Limited	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	exponent.com
f_OXYDE GmbH	□				■																	■											foxyde.at
Fanwood Chemical, Inc	■																■																fanwoodchemical.com
Fera Science Ltd	■	■	■	■	■	■	■					□	■		■		■	■			□	■	□	■	■								fera.co.uk
Fieldfisher (Belgium) LLP	■	■	□	□	■	■	■	■	■	■	■	■	■	■	■	□	■	■	■	□	■	■	■	■	■	■	■	■	■	■	□	□	fieldfisher.com
FinnREACH	■			■	■												■		■	□		■	■										finnreach.com
Flashpoint srl	■	□	■	□	■	□	■										■	■	■			□	□										flashpointsrl.com
FoBiG	■	□	□		■	□		□	□	□	□	□	□	□	□	■			■	■		□	□	□	□	□	□	□	■	■			fobig.de
Foodchain ID	■	□	□		■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	□	□	□	foodchainid.com/decernis
Formulator Software LLC	■	■	□	■	■	■	□		□	□	■	□	■		■		□	□	■	□	■	□	□	■									formulatorus.com
Fraunhofer ITEM	■	■	■	■	■	■	■		□	□		■	■	■	■		■	□	■	□	■	■	■	■	■	■	■	■	■	■	□	■	item.fraunhofer.de/en.html
GAB Consulting (SynTech Research Group)	■	■	□		■	■	□						■	□	■		■	□	■	□	■	■	□	■									gab.syntechresearch.com
GBK GmbH Global Regulatory Compliance	■	■	■	■	□	□	□	■	■	■	■	■	■	■	■	■	■	■	■	■	□	□	□	□	□	□	□	□	□	■	□	■	gbk-ingelheim.com
GHD											■									■	■			■					■		■	■	ghd.com
GHS-expert Ltd	■			■	□												■		■	■	■												ghs-expert.com
Global Product Compliance	■	■	□	■	■	□		■	■	■		■	□	■	□		■	■	■	□	■	□	■	□	■	□	■	□	■				gpcgateway.com
GlobalMSDS	■	■	■	□	■	□											■	□	■														globalmsds.co.uk
GLTaC, Inc.	■	■	■	■	■	■											■	□	■	□	□	■	□										gltac.com
Gradient	■	■	□	□	■	■		■			□	■	■	■	■	□	■		■	■													gradientcorp.com
GreenSoft Technology, Inc	■	□	■	□		■											■	■	■	■		□											greensofttech.com
Greenwich Chemical Consulting	■	□															□	■	■	■													grcci.com
Grow Smart Chemical Compliance	□	□	□		■	■	□		■		■		■	■	■	□	□	■			■	■	■	■			■	■					produsebiocide.ro
H2 Compliance	■	□	■	■	□	■	□	■	■	■		■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	h2compliance.com
Haley & Aldrich, Inc.																																	haleyaldrich.com
HAZMAT Ltd	■	■	□	■	□	■	□										■	□	■	□	■	□	■										hazmat.co.il
Herbert Smith Freehills	■	■	■	■	□	■	□										■	■	■	□	■	□	■										herbertsmithfreehills.com
Hibiscus Plc	■	□	□		□		□						□						■	■													hibiscus-plc.co.uk
Hohenstein	□		□	■	■	□		□	□	□		■	□		□		■					□	□		□	□							hohenstein.com
Hunton Andrews Kurth LLP	□																■								□								huntonak.com/en/
I+K AG, Compliance-Footprint AG	■	□			■									□	■	□	■	□	■	□	■	□	■	□		□							i-k.ch_complinace-footprint.com
ibacon GmbH	■	■	■		■	□	■										■					■	□	■									ibacon.com
ICB Pharma		■			■	■	■						■	■																			icbpharma.com
ICF	■	□			■												■		■	■	■												icf.com
IDRG (International Development of Regulatory Globalization)		■			■																		■	■									idrgplantprotection.eu
IES Ltd	■	■	■		■	□	□										□	□		□		□	□	□									ies-ltd.ch
imds professional GmbH & Co. KG					■		□		■								■	□	■			■				■							imds-professional.com
INERIS	■				■	□			■	□		■	□		■	□	■	□	■			■		□									ineris.fr
INFOTOX	■				■	■			□		■	□	■	■			■	□	■			■	■		□		■	□					infotox.pt
INSCX exchange	■	□															■				■												inscx.com
International Cosmetics & Chemical Services Ltd	□		□	□		■	□	□	□		■	□	□	□	□	□	■	■	□	■		■		□	□	□	□		□				intlcosmetics.com

Key: Icons above represent the percentage breakdown of services provided by each company 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)
Intersolia		Sweden	Germany, UK, Denmark, Serbia	100-500	10-25	◗				●		◗		
Intertek	**112**	**UK**	**11+ Countries**	**5,000 plus**	**5,000 plus**	◗	◗		◗	◗	○	○	○	◗
IOM		UK	Singapore	100-500	10-25	●	◗	◗	◗	◗				
IPO O/Pszczyna		Poland		50-100	50-100				●					
iPoint-systems gmbh		Germany	Austria, France, Benelux, Sweden, UK, US, Japan, China, South Korea	100-500	25-50	◗				●		◗		
Jones Day		Belgium	North America, Europe, Japan	5,000 plus	50-100			●						
Jongerius Consult BV	**164**	**The Netherlands**		**1**	**1**	◗	◗	◗		◗		◗		
Joseph Sabol		US		1	1	●	◗				◗	◗		
JRF Global		India	United States,					●						
K J Bray & Associates		UK		1	1	◗	◗							
K&L Gates LLP		Belgium		1,000-2,000	25-50			●						
KAELTIA Compliance Services		Spain		5-10	5-10	●	◗			◗	◗	◗		
Kahlberg Consulting	**114**	**Italy**	**United Kingdom and Turkey**	**10-25**	**10-25**	◗	◗			◗		◗		
Kalium solutions inc.		Canada	Canada	5-10	2-5	◗						◗	◗	
Keller and Heckman LLP		US	Belgium, France, China	100-500	25-50	◗	◗	●						
Kelley Drye & Warren		US	Brussels	100-500	25-50						●			
Kerona Scientific Ltd	**163**	**Ireland**	**Spain**	**5-10**	**5-10**	●	◗				◗	◗		
KFT Chemieservice GmbH	**116**	**Germany**		**25-50**	**25-50**	◗	◗		○	○	◗	◗	◗	◗
Knoell	**118**	**Germany**	**UK, the Netherlands, Switzerland, France, Spain, Portugal, Italy, China, Japan, Thailand, South Korea, Taiwan, North America**	**500-1,000**	**100-500**	●	◗		◗	○	◗	◗		
Konica Minolta Business Expert, Inc		Japan		2,000-5,000	10-25	◗	◗	●						
Kotiti Testing and Research Institute		South Korea	China, Vietnam	50-100	2-5	◗	◗	◗	◗	◗	◗	◗	◗	◗
KREATiS		France		2-5	2-5				●	◗				
Krogerus Attorneys Ltd.		Finland		100-500	2-5	◗	◗	●				◗		
Kumi Consulting Ltd		UK		5-10	2-5	●								
Labcorp	**120**	**United States**	**UK, US, Korea, Japan, Spain**	**5,000 plus**	**5,000 plus**	◗			●			◗		
LAUS		Germany	France, US and UK	50-100	25-50	◗	◗		●					
LG CNS		South Korea	Asia, South America, Europe, US, Middle East	5,000 plus	50-100	◗	◗	○	○	◗	◗	○		○
LGC		UK		1,000-2,000	50-100				●					◗
Linge Agroconsultancy		The Netherlands		10-25	10-25	●								
Linmark Consulting GmbH		Switzerland	UK, Malta	2-5	2-5	●	◗							
Lisam	**122**	**Belgium**	**US, Canada, UK, France, Germany, Romania, India, Turkey, Brazil**	**100-500**	**100-500**	◗	○			●	◗	◗		
LKC Switzerland Ltd	**164**	**Switzerland**	**UK, Ireland**	**5-10**	**5-10**	●	◗		◗		◗			
Logic SDS		UK	France	2-5	2-5	◗				●		◗		
Logscale Ltd		Finland		2-5	2-5	◗	◗	◗				◗		
Makersite GmbH	**124**	**Germany**	**Munich, Berlin, London, Bergen**	**25-50**	**5-10**					◗	◗			
Manatt, Phelps & Phillips, LLP		US		100-500	25-50				●					
MB Research Laboratories		US		25-50	2-5				●					
Mediator A/S		Denmark		10-25	5-10	●	◗					◗		
Mercer		US	Asia-Pacific, EMEA, Americas	100-500	2-5					●				
Mérieux Nutrisciences		US	Italy, Brazil, France, China	2,000-5,000	1,000-2,000	◗	◗		●		◗			
Miami Chemical (now Shrieve)		US		10-25	5-10	◗	◗							
Micromeritics Analytical Services		US		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	◗	◗	◗	○	◗	◗	◗		
MSDSWriter LLC		US		2-5	2-5	●								
National Chemical Emergency Centre (NCEC)		UK			25-50	●	○		◗		○			
National Physical Laboratory (NPL)		UK		500-1000	100-500	◗			●			◗	◗	
Neuralog, LP		US	Canada	25-50	10-25					●				
Nexreg Compliance Inc.		Canada		10-25	5-10	●					◗	◗		◗
NimkarTek Technical Services Pvt. Ltd		India	Sri Lanka, Bangladesh	10-25	10-25	◗						●		◗
NOACK Laboratorien GmbH		Germany		50-100	50-100				●					
Noerr LLP		Germany		1,000-2,000	10-25			●						
NORMACHEM S.r.l		Italy		25-50	10-25	◗	◗		◗	○	◗	◗		
NovaTox		Canada	Ireland, UK	2-5	2-5	●								
NRM Solutions		Trinidad & Tobago	Guyana, Barbados, St. Lucia, Antigua and Barbuda, St. Vincent and the Grenadines, and Suriname (The Caribbean)	2-5	1	●	◗			◗				◗
OCI		China		10-25	5-10	◗	◗		◗	◗	◗	◗		
Olon Ricerca Bioscience		US		500-1,000	500-1,000	◗	◗		●					
ONLY CORE CHEM		Portugal	Portugal	10-25	10-25	◗			◗			◗		
PACA GmbH		Germany		5-10	2-5	◗			◗					●
Pace Regulatory Services		US		2,000-5,000	100-500	●								
Pengin Oy		Finland		1	1	●	◗					◗		
Penman Consulting		Belgium	UK, The Netherlands	5-10	5-10	◗	◗				◗	◗	◗	
Peter Fisk Associates		UK	Belgium	25-50	10-25	●	◗				◗	◗	○	○
PFA-Brussels		Belgium	UK	5-10	5-10	●	◗				◗	◗	○	○
Polgar ACRO		Hungary	Belarus, Kazakhstan, Moldova, Russia, Ukraine	10-25	5-10	●						◗		
Pöyry Finland Oy (now AFRY)		Finland		2,000-5,000	10-25	●						◗	◗	
Prefusion LLP		UK	China	5-10	5-10	◗	◗				◗	◗	◗	
Primetra Global Regulatory Consultants		Canada		1	1	◗	◗						◗	
Proactima AS		Norway		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%

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
Intersolia	□	□	□		■	□		□	□	□	□	□	□	□	□	□	■	□	■	□	■	□	□	□	□	□	□			■		intersolia.com
Intertek	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	intertek.com
IOM	■	■	■	■	■	■	■										■	■															iom-world.org
IPO O/Pszczyna	■	■	■	■	■		■										■	□	■	□	■	□	■		■								ipo-pszczyna.pl
iPoint-systems gmbh	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	□	■	■	□	□	□	□	ipoint-systems.com
Jones Day	■	■	■	■	■	□	□										■	□	■	□	■	□	■	□	■								jonesday.com
Jongerius Consult BV	■	□	□			□							□			□	■	□	■	□		□											jongeriusconsult.com
Joseph Sabol	■	□	□	□	□	□	□	□		■	□	□	□	□	□		□	□	□	□	□	□		□	□		■						chem-consult.com
JRF Global	■	■	■	■	■	■	■						□		□		■	■			■	■	■	■									jrfglobal.com
K J Bray & Associates	■				□												■	□	■	□		□											
K&L Gates LLP																	■		□	□		□	■	□									klgates.com
KAELTIA Compliance Services	■	■	■	□	■	■	■		■			■	■	■			■	■	■	■	■	■	■	■	■	■	■	■	□	□	■	■	kaeltia.com
Kahlberg Consulting	■	□	□	□	■	□					□	□	□	□			■	■	■	■	■	□	□	□	□		■	□	□	□	□	□	kahlbergconsulting.com
Kalium solutions inc.	■	□	□	□	■	■	□		□	□	□	□	■		□	□	□	□	■	□	■	■		□				□	□	□	□	□	en.kaliumsolutions.com
Keller and Heckman LLP	■	■	■	■	■	■	□	■			□	□	□	■	□	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	khlaw.com
Kelley Drye & Warren	■				■	□		■	□	■	□	■	■	■	■	■	■	■	■	■	■	□		■	■	■	■					■	kelleydrye.com
Kerona Scientific Ltd	■	■			■	■	□					□	■		□		■	■	■	□	□	■	■	□	■								kerona.ie
KFT Chemieservice GmbH	■	□			■	■		□	□	□		□	■	□		■	■	■	■	■	□	■	■			□		■	■	■	■	■	kft.de
Knoell	■	■	■		■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	knoell.com
Konica Minolta Business Expert, Inc	■				□												□	■	□	■	□												konicaminolta.com
Kotiti Testing and Research Institute	□					□											■	■	□	□			■										kotiti-global.com/en/index.do
KREATiS	■	□	□	□	□	□	□										■	□	□	□		□	□	□									kreatis.eu
Krogerus Attorneys Ltd.	■	■	■	■	■	■		□	□	■	□	■	□	■	□	■	■		■			■	■		■	■	■	■	■	□			krogerus.com
Kumi Consulting Ltd								□	□	□																							kumi.consulting
Labcorp	■	■	■	■	■	■	□						■	■	■	■	■	■	■	■	■	■		■	■			■					biopharma.labcorp.com/services/chemical-crop-protection.html
LAUS	■	■	■		■	■	■						■	■	■		□	□	□	□	□	□	□	□	□	□	□	□					laus.group
LG CNS																	□	□	□	□	□	□	□	□									lgcns.com
LGC	■	■	■	■	■	■	■										■		■				■	■									lgcgroup.com
Linge Agroconsultancy	■	■			■													■		■		■		■									lingeagroconsultancy.nl
Linmark Consulting GmbH	■	■	□	□	■	□	■	□	□	□	■	□	■	□	□		■	■	■	■	■	■	■	□	□	□	□	□	□	□			linmarkconsulting.com
Lisam	■	■	■		■	■	■	■	■	■	■		■		■	■	■	■	■	■	■	■	■	■	■	■	■	■			■	■	lisam.com
LKC Switzerland Ltd	■	■	■	□	■	■					■	■	□	■	□	■	■	■	■	■	■	■	■	■				□			■		LKC-ltd.com
Logic SDS	■	■	■	□	■	■	□		■	□	■	□	■				□		■	■	■	□										■	logicsds.com
Logscale Ltd	■	■	■	□	■	□				■		■		□	■	□	■	■	■	□	■	□							□	■	□		logscale.fi/en/
Makersite GmbH	■	■	□			■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	□	□	□	■	■	□	□	□	□	□		makersite.io
Manatt, Phelps & Phillips, LLP	■	■	■	■	■	■		■			■		■		■	□				■					■	■							Manatt.com
MB Research Laboratories	■	■	■	□		■	□		□			□	■	■		■	■		■	■	□		■	■				■					mbresearch.com
Mediator A/S	■	■			■	■	■					□	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■				■	mediator.as
Mercer	■																□																mercer.com
Mérieux Nutrisciences	■	■	■	□	■	■	■										■	□	□	□	□	□	■	■									merieuxnutrisciences.com
Miami Chemical (now Shrieve)	■																																shrieve.com
Micromeritics Analytical Services	■	□	■	□		■											■																micromeritics.com/particle-testing
Modern Testing Services (Global)	■	□	□	□	■	□											■	■	■	■	■	□	■	□									mts-global.com
MSDS Europe	■	■	□	■	■	□											■	□	■	■	□	■	□	■									msds-europe.com
MSDSWriter LLC	■	■	■	□	■	■	■	□	□	□		■		□	□	□	■	□	■	□	■	□	□	□	□		□				■	■	msdswriter.com
National Chemical Emergency Centre (NCEC)	■	■	■	□	■	□	■	■	■	■	■	■	■	□	■	□	■	□	■	□	□	■	□		■					■			the-ncec.com
National Physical Laboratory (NPL)	■	■	■	■	□	■	■	■	■	■	■	■	□	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■					npl.co.uk
Neuralog, LP																	□			■	□												neuralog.com
Nexreg Compliance Inc.	■	□	□		□	■	□			□	■		■	□	□		□	□	■	■	□	□	■	□	■		□					■	nexreg.com
NimkarTek Technical Services Pvt. Ltd																	□	□	■	□	□												nimkartek.in
NOACK Laboratorien GmbH	■	■	□		■	□	■						□	□			■	■			□	■	□	■				■					noack-lab.com
Noerr LLP	■	□	■	□	■	■	□										■	□	□	□	□	■	■	□									noerr.com
NORMACHEM S.r.l	■	■	■		■	■		■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	normachem.it
NovaTox	□	□	■	□	■	□	■										□	□	□	□	□	□	■	□									novatox.ca
NRM Solutions	□	■																						■									nrmsolutions.org
OCI	■	■	□	■	■	■	□	□	□	□		□	■	■	■	■	■	■	■	□	■	■	■	□		■					□	chinaoci.com
Olon Ricerca Bioscience	■	■	■	■	■	■											■	□	□	□	■	□	■										olonricerca.com
ONLY CORE CHEM	■			■													■	□	□	□	■												onlycorechem.com
PACA GmbH	■	□			■	□			■			■	□	□	□			■	■	□	■		□				■			■	□		paca.de/sicherheitsdatenblatt-erstellen
Pace Regulatory Services	■	■	□	□	□	□	□	□	□	■	□	□	□	□	□	□	■	■	■	□	□	□	□	□	□	□	□	□					pacelabs.com/scientific-professional-services/regulatory-services/
Pengin Oy	□				□		■	■	□	□	□		■		■	□	■	■	□	■	□		□			■	□	□					pengin.fi
Penman Consulting	■				□												■	■	■	■	■		□										penmanconsulting.com
Peter Fisk Associates	■			■	■												■	■	■	■	□	■	■	□		■							pfagroup.eu
PFA-Brussels	■			■	■												■	■	■	■	□	■	■	□		■							pfagroup.eu
Polgar ACRO	□	■		■	■	□											□	□	□		□		■										polgar-acro.eu
Pöyry Finland Oy (now AFRY)	■	□		■	□												■	□	■	□		□											afry.com/en
Prefusion LLP	■	■	■	■	■	■	■	□	■		□	■	■	■	■	■	■	■	■	□	■	■	■	□	■	□	■		■				prefusion.co.uk
Primetra Global Regulatory Consultants	■	■	□	□	■	□		■	■	■		■	■	□	■	■		■	■	■				■							■		primetra.com
Proactima AS	■	■			■	■											■	□	■	□		■											proactima.com

Key: Icons above represent the percentage breakdown of services provided by each company 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)
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	◗	◗							◗
Qualisys GmbH		Germany		10-25	10-25			◗		◗	●			◗
Quality Technical Services LLC		China	US	10-25	10-25	●								◗
Ramboll	**126**	**Denmark**	**35 countries**	**5,000 plus**	**100-500**	●	◗		◗					
Randis ChemWise (Shanghai) Co., Ltd.		China	Taiwan	10-25	5-10	●	◗	◗	◗		◗	◗		
REACH Advice GmbH		Germany		1	1	◗	◗	◗				◗		
REACh ChemConsult GmbH		Germany		2-5	2-5	●	◗					◗		
Reach Chemical BV		The Netherlands		1	1	●	◗							
REACH Global Services S.A.	**128**	**Belgium**	**Turkey**	**10-25**	**10-25**	◗	●			◗	◗	◗		◗
REACH Monitor		Spain		10-25	2-5	●	◗					◗		
REACH n Roll Oy		Finland		2-5	2-5	◗	◗	◗		◗				
Reach Only Representative Ltd		UK	Republic of Ireland			●	◗			◗	◗	◗		
REACH Orphan Substances Consortium bvba ROSC		Belgium		2-5	2-5	◗	◗	◗			◗			
REACH24H		China		50-100	50-100	◗	●		◗	◗		◗		◗
REACH24H Consulting Group		China	Ireland, US	100-500	50-100	●	◗		◗	◗	◗	◗		
ReachCentrum SA		Belgium	EU, Taiwan, Vietnam, S.Korea, China, US	10-25	10-25	◗	●	◗		◗		◗		
REACHECK Solutions GmbH		Germany		5-10	2-5	◗		◗			◗	◗		◗
REACHLaw	**130**	**Finland**	**Belgium, UK, Turkey, India, South Korea**	**50-100**	**50-100**	◗	◗	◗	◗	◗	◗	◗		
REACHLINKED		China		5-10	5-10	◗	◗				◗			
REACHReady	**132**	**UK**		**2-5**	**2-5**	◗	◗	◗	◗	◗	◗	◗	◗	
REACHsuite		UK	The Netherlands, Belgium	5-10	5-10	◗				●		◗		
REACHwise		UK	The Netherlands	2-5	2-5	●	◗					◗		
Redebel Regulatory Affairs S.C.R.L.		Belgium		50-100	50-100	●				◗		◗		
Redeker Sellner Dahs Rechtsanwälte		Germany	Belgium	100-500	5-10	◗	●							
REGARTIS		Czech Republic	Serbia	10-25	10-25	◗	◗			◗	◗	◗		
RegScan Inc.		US								◗	◗			
RegTox Solutions Inc.		Canada	Canada, US	1	1	●					◗	◗		
Renfrey Regulatory and Compliance Consultancy Ltd		UK		1	1	●						◗		
RimaOne		Germany		25-50	25-50					●				
Risk & Policy Analysts Ltd (RPA)	**134**	**UK**	**UK, Italy, Czechia**	**25-50**	**10-25**	●						◗		
Riskchem		South Africa		2-5	1	◗	◗						●	
RNI SRL		Italia	ONLY ITALY PREMISE (MILAN, COMO, ROME)	5-10	5-10	●	◗					◗		
ROSConsortium BVBA		Belgium		1	1	◗	◗							
Rovaltain Research Staphyt		France		25-50	10-25	◗		●				◗		◗
Royal HaskoningDHV		The Netherlands	1 offices worldwide	5,000 plus	50-100	◗	◗	◗	◗	◗	◗	◗		
SAFENANO		UK	Singapore	100-500	25-50	●			◗			◗		
Safety Assessment Solution Co Ltd	**164**	**South Korea**		**25-50**	**10-25**	◗	◗		◗	◗	◗	◗		
Santec		San Francisco, CA, US		100-500	100-500	◗					●	◗		◗
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	**165**	**Japan**	**China, Singapore, South Korea, Taiwan**	**1,000-2,000**	**25-50**	●								
SCC	**136**	**Germany**	**Japan, United Kingdom**	**100-500**	**50-100**	●	◗	◗	◗					
Scitegrity		UK				◗				●	◗			
Scymaris Ltd	**138**	**United Kingdom**	**United States**						◗					
Selerant		Italy	US, India, China, Germany, France, Serbia, Ukraine, Australia, Spain	100-500	50-100	◗	◗			◗	◗	◗		◗
SenzaGen		Sweden	Sweden, US	10-25	5-10	◗			◗					◗
ServiREACH, S.A.		Spain		10-25	10-25	◗			◗		◗			◗
SFS Chemical Safety		US		25-50	25-50	◗	◗				◗			
SGS		Switzerland	China, France, Germany, Hong Kong, UK, US	5,000 plus					◗					◗
ShawCor		Canada		2,000-5,000	2-5		●							
Siam S.L.	**165**	**Spain**	**Spain, U.S.A., Denmark, Switzerland, Norway, Island, Estonia, Latvia, Lithuania, Finland, Greece, Cyprus, Holland, Belgium, India, Israel, Italy, Czech Republic, Potugal, UK, Ireland, Romania, Serbia**	**25-50**	**25-50**	◗				●		◗		
SIEF-IT		Poland		5-10	5-10	◗	◗			◗				◗
SLR Consulting		UK		25-50	2-5	●						◗		
Smithers		US	UK	100-500					◗					
SOCOTEC Environment		France	France	5,000 plus	5-10	●	◗							
spectra Consult GmbH		Germany		2-5	2-5	●						◗		
Sphera Solutions	**140**	**US**	**Worldwide**	**1,000-2,000**	**100-500**	◗				◗	◗	◗		
Spinnaker Coating, LLC		US		2-5	2-5	)	●	◗	)	◗	)	)		
Staphyt	**142**	**France**	**Europe, Brazil**	**100-500**	**100-500**	●	◗					◗		
Stefanie Merenyi		Germany		1	1	●		◗				◗		
Steptoe & Johnson LLP		US	Belgium	100-500	25-50	◗	◗	●			◗			
Stewardship Solutions Ltd		UK		5-10	5-10	●								
Subvise (Chemycal)		Germany		2-5	2-5						●			
Surface Science Western		Canada		10-25	10-25	◗			◗			◗		
Sustainability Consult		Belgium		5-10	1	●								
SustChem Engineering Ltd		Greece		5-10	5-10	●	◗		◗			◗		

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◖ 40-60% ◗ 20-40% ◗ 5-20%) <5%

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
ProductIP					■	■											■		■	■		■	■										productip.com
Prosacon GmbH	■	■			■			□	□	□	□	□		□		□	■		■	■		■		■	□		□						prosacon.eu
PwC	■																■																pwc.nl/en
Qualisys GmbH	■	□	■	□	■	■	□										■	□	■	■		■	■										qualisys.eu
Quality Technical Services LLC	■	□													■																		qtsinspect.com
Ramboll	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	ramboll.com
Randis ChemWise (Shanghai) Co., Ltd.	■	□			□	■										□	■		■	■	□	□	□	□									randis.cn
REACH Advice GmbH	■	□															■	■	■														reach-advice.com
REACh ChemConsult GmbH	■	□	□		■	■	□								■	□	■		■	■		■	■	□	□	□	□	□					reach-chemconsult.com
Reach Chemical BV	■																■		■	■		□		□									reacheu.nl
REACH Global Services S.A.	■				■	■			□	□	□	□	□	□	□		■	■	■	■	□	■	■				□	□					reach-gs.eu
REACH Monitor	■	■	■	□	■	■	□										■	■	■	■	□	■	■	□									reachmonitor.org
REACH n Roll Oy	■	□	□	□	■	■	□	□	□	□	□	□	□	□	□	□	■	□	■	■	□	■	■	□	□	□	□	□	□	□	□	□	reachnroll.com
Reach Only Representative Ltd	■				■	■									■		■	□	■	■		■											rorltd.com
REACH Orphan Substances Consortium bvba ROSC	■	■	□	□	□	□	□	■	□	■	□	■	□	□	□	□	■	□	□	□	□	□	□	□	□	■	□	■	□				ROSconsortium.eu
REACH24H	■	□			■	□											■	□	■	□	■	□	■										reach24h.com
REACH24H Consulting Group	■	■			■	■	■										■	■	■	□	■	■	■										reach24h.com/en-us
ReachCentrum SA	■	□	□	□	■		□	□	□	□	□	□	□	□	□	□	■	■	■	■	□	■		■		□	□	□			□	□	reachcentrum.eu
REACHECK Solutions GmbH	■				□	□		■	■	□				□		□	■	■	■	■		□	□		□	■	■						reacheck.eu
REACHLaw	■	■	□		□	□		■	□	■	□	□	□			□	■	■	■	■	□	□	□	□	□	■							reachlaw.fi
REACHLINKED	■	□															■		■	■													reachlinked.com
REACHReady	■	□	□	■	■	□	□										■		■	■	□	■	□										reachready.co.uk
REACHsuite	□	□	□			□											■	□	□	□	□	□	□										REACHsuite.com
REACHwise	■	□	□	□	■	■	□					□	■	■		□	■		■	■		■	■				■						reachwise.com
Redebel Regulatory Affairs S.C.R.L.	■	■			■	□		□					■	■	■		■	■	■	■		■	■	■									redebel.be
Redeker Sellner Dahs Rechtsanwälte	■	□	□	□	■	■	□										■		■	■		■	■	■									redeker.de
REGARTIS	■				■	□		□	□	□		□	□		□	□	■	□	■	□		■	□		□	■							regartis.com
RegScan Inc.																																	regscan.com
RegTox Solutions Inc.	□	□		□		□		□	■			■	■		□				■	□		□	□	□			□					□	regtoxsolutions.com
Renfrey Regulatory and Compliance Consultancy Ltd	□				□	□							■				■	■	■	□		□											rrandcc.com
RimaOne	■	■	□	■	■	□	□										■	□	■	■	□	□	□										rimaone.com
Risk & Policy Analysts Ltd (RPA)	■	□	■	□	■	■		□	□	■	□	■	■	■	□	■	■		■	□		■	■		■	■	■	■	■	□	■	□	rpaltd.co.uk
Riskchem																	■	■	■														riskchem.co.za
RNI SRL	■	■	■	□	■	■	□	□	□	□	□	■	■	■	□	■	□		□	□	■	■	■	■	□	■	■	■	□	■	■	□	reachup.it
ROSConsortium BVBA	■	□					■	■	■	■	■	■		□			■	□	■	□					■	■	■						kvconsultings.com
Rovaltain Research Staphyt	■	■	■	■	■	■	□				□	■	□	■	□	■	■	□	■	□	■	□	■	□		□		□	■	□	■	□	rovaltainresearch.com
Royal HaskoningDHV	■	□	■	□	■	■	■	□	□	□	■	■	■	■	■	■	■	□	■	□	■	□	■	□	□	■		■					royalhaskoningdhv.com
SAFENANO	■	□	□		□												■	□	■	□	■	□	□	□									safenano.org
Safety Assessment Solution Co Ltd	■				■						■							□	□	■	□	■											safety-as.com
Santec	■	□	□	□	□	■	□	■	□	■	□	■	■	■	□	■	■	□	□	■	□	□	■	□	■		■				□	■	stantec.com/en
SAP AG	■	■	■		■	■											■	■	■	■	■	■	■										sap.com
SAP Japan Co, Ltd	■				□												■	■	■	■	□												sap.com
SATRA Technology																	■		□		□												satra.co.uk
SCAS Europe	■			■	□									□			■	■	■	□	□	□		□									scas-eu.be
SCC	■	■	■	■	■	■	□	□	□	□	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	scc-gmbh.de
Scitegrity	■	■	■			■											■															■	scitegrity.com
Scymaris Ltd	■	■	□	■	■	■				□				□	□	□	□		□	□		□	□	□				□				□	scymaris.com
Selerant	■	■	□	□	□	■	□		□	□	□	■		□	■	■	■	■	■	■	■	■	□	■	□							■	selerant.com
SenzaGen	■	□	■	□	■	■			■		□	■	□	■	■																		senzagen.com
ServiREACH, S.A.	■	■	■	□	■	■	□								■	■	■		■	□	■	■	■										servireach.com
SFS Chemical Safety				□	□	□		■							■	■			■	■	□	■	□	□		□			□	□		■	chemicalsafety.com
SGS	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■					sgs.com/en/services/reach
ShawCor	■														□		■			■	■												shawcor.com
Siam S.L.	■	□	□	□	■	■	□				■	■	■				■	■	■	■	■	■	■									■	siam-it.com
SIEF-IT																																	sief-it.com
SLR Consulting	■	■	■	■	□	□	□									□	■		□	■	□												slrconsulting.com/en/services/safety-advisory
Smithers	■	■	■	□	■	■	□					□	□	□	■	■	■	■	■	■	■	■	■	■									smithers.com
SOCOTEC Environment	■		□	□	□	□		□	■	■	□		□	□	□	□	■		□	□	□	□			□	□	□	□	■	□	■	□	socotec.fr/nos-solutions/environnement/mesures-environnementales
spectra Consult GmbH	■	□	□		■	□	□					□		□	□	■		■	■		■	□	□	□									spectra-consult.de
Sphera Solutions	■	■	■	■	■		■			■	■		■		■		■		■	■	■	■						■	■	■	■		sphera.com
Spinnaker Coating, LLC	■		■												□	□					□												spinps.com
Staphyt	■	■		□	■						■				■	■	■		■			■	■	■							□		staphyt.com
Stefanie Merenyi																																	merenyi.de
Steptoe & Johnson LLP	■	■	□	■	■	■	□	■	□	■	□	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■						steptoe.com
Stewardship Solutions Ltd	■	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	■	□	■	□	□	□	□	□	□	□	□						stewardshipsolutions.co.uk
Subvise (Chemycal)																	■		□														chemycal.com
Surface Science Western	□		□																														surfacesciencewestern.com
Sustainability Consult				■																													sustainabilityconsult.com
SustChem Engineering Ltd	■	□			■	□											■		■	□	■	□	■	□									sustchem.gr

Key: Icons above represent the percentage breakdown of services provided by each company 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)
SustChem Technical Consulting SA		Greece	Cyprus	25-50	25-50	●	◗		)		◗	)		
Sweco Finland Ltd	**165**	**Finland**	**Finland**	**2,000-5,000**	**25-50**	●	◗							
Syska Voskian Consulting		US	Denmark	2-5	2-5	●						◗		
▶ **TEAM mastery S.r.l.**	**144**	**Italy**		**25-50**	**10-25**	●	◗	)		)	◗	◗		)
Ted Simon LLC		US		1	1	●								
TEI Analytical, Inc		US		5-10	5-10	◗			●					
Telematic srl		Italy		10-25	5-10	◗				●		◗		
Tenviro		Sweden	The Netherlands	1	1	◗	◗	◗			◗	◗		
TERRA-The Electronics Reuse & Recycling Alliance		US	US	2-5	2-5		●							
Tetra Tech		US	Germany, Canada, UK	5,000 plus	25-50	◗	◗			◗	◗	◗		
The Chemical Compliance Coach		The Netherlands	Spain	2-5	2-5	●	◗				◗	◗		
The Compliance Map Ltd.		UK	US, Australia	25-50	10-25	◗	◗		◗	●	◗	◗		
The Isosceles Group		US		10-25	10-25	◗	◗			◗	◗	◗		
The Martec Group		US	Germany, China, Japan, Brazil, Chile	50-100	1	●								
The Redstone Group		US	The Netherlands	10-25	10-25	●								
the SDS factory | de ViB fabriek		The Netherlands	UK, Germany, Belgium	2-5	2-5	●				◗		◗		
TJS Technical Services Inc.		Canada		2-5	1	●								
TO21 Co. Ltd.		South Korea		50-100	25-50	◗				◗	◗			◗
Tox Focus LLC		US		1	1	●						)	)	
toXcel		UK	US	25-50	10-25	◗	◗		◗		◗	)	)	)
▶ **Toxicon srl**	**146**	**Italy**		**5-10**	**5-10**	◗	◗	◗	◗	)	◗	◗	)	)
Toxi-Coop Toxicological Research Centre Ltd.		Hungary	Switzerland, US	50-100	25-50	◗			●					
Toxikon (Labcorp)		US	Belgium	100-500	5-10	◗			●					
TOXIT & S-IN Soluzioni Informatiche Srl		Italy		10-25	2-5	◗				◗	◗	◗		
ToxMinds		Belgium	India, Germany	10-25	10-25	●	◗				◗	◗		
ToxServices LLC		US	United Kingdom	25-50	10-25	◗		◗		◗	◗	◗		
ToxStrategies		US		25-50	5-10	●	)				)	)		
TraceGains		US		25-50	25-50					●				
Trade Wind B.V.		The Netherlands	Uited States of America	5-10	5-10	●				◗				
Tradebe UK		UK	Spain, US, France	1,000-2,000	500-1000	◗	●		◗					
TRASYS		Belgium	Europe	500-1000	50-100	◗	◗			●		◗		
Triskelion		The Netherlands	Japan, US, Canada (sales offices)	100-500	100-500	◗	◗		◗					
▶ **TSG Consulting**	**148**	**England**	**France, Germany, Spain, US, Canada**	**100-500**	**100-500**	●								
▶ **TÜV SÜD Industrie Service GmbH**	**150**	**Germany**	**Japan, Singapore, China, United Kingdom, EU**	**5,000 plus**	**50-100**	◗	◗		◗	◗	◗	◗		
UetlibergPartners GmbH		Switerland		2-5	2-5	●								
▶ **UL Solutions**	**152**	**US**	**UK, Germany, France, Belgium, China, Japan**	**5,000 plus**	**1,000-2,000**	◗				●	◗	◗		
▶ **UMCO GmbH**	**154**	**Germany**		**50-100**	**25-50**	●	◗	◗			◗	◗		◗
Universit Bordeaux Segalen		France		500-1,000	100-500	◗	◗	◗	◗	◗	◗	◗		◗
Vanta Bioscience		India		25-50	10-25				●					
Veeva Systems		United States	Canada, France, United Kingdom, Germany, Spain, Hungary, China, South Korea, Japan, India, Singapore, Brasil, Australia	5,000 plus	100-500					●				
▶ **VelocityEHS**	**156**	**US**				◗		)		●	◗	◗		
Verdant Law, PLLC		US		5-10	5-10	◗	◗	●				◗	◗	◗
▶ **Vitis Regulatory**	**158**	**UK**	**Belgium, Germany**	**25-50**	**10-25**	●	◗			◗	◗	)		)
VITO NV team EHS Toxicology Services		Belgium		10-25	10-25	◗	◗	◗	●		◗			
Vivotecnia Research		Spain		50-100	25-50				●					
Von Roll REACH GmbH		Germany		2-5	2-5	●	◗					◗		
VRS Regulatory		UK		5-10	2-5	●								
W.E. Train Consulting		US		2-5	1	◗						●		◗
wca environment		UK	Scotland, Italy	10-25	10-25	●	◗							
Wercs Professional Services		US	Belgium, Germany, China, Japan	100-500	10-25	●				◗				
WIL Research		US	The Netherlands	1,000-2,000	100-500	◗	)		●					
Wildlife International, a Division of EAG, Inc		US	The Netherlands	100-500	50-100	◗			●			)		)
Wiley		US		100-500	10-25	◗	◗	◗			◗	◗		
WILLIAM WILSON Wyeside Consulting Ltd		UK		2-5	1	◗		◗						
Womble Bond Dickinson (UK) LLP		UK	United States	1,000-2,000	50-100	◗		●						
WRc plc		UK		100-500	10-25	●	◗				◗	◗		
WSP UK Ltd	**165**	**UK**	**Wordwide**	**5,000 plus**	**25-50**	●	◗				◗	◗		
WTConsulting		Switzerland		5-10	5-10	●	◗				◗	◗		
XCellR8		UK		10-25	10-25	◗			●					
YASH Technologies		US	Europe, Asia, Australia	2,000-5,000	50-100	◗				●	◗	)	)	)
▶ **Yordas Group**	**160**	**UK**	**Germany, Canada, Turkey, Japan, China**	**50-100**	**50-100**	●	◗		◗	◗	◗	◗		◗
Zanos Ltd		UK		5-10	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
SustChem Technical Consulting SA	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	sustchem.gr
Sweco Finland Ltd	■	■	■	■	■	■	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	■	sweco.fi
Syska Voskian Consulting	■	□				■											■		■	■	□												sysvoskconsulting.com
TEAM mastery S.r.l.	■	■	■		■	■		□	■	■	■	■	■	■	■	■	■	□	■	□	□	■	■	■	■	■	■	■	■				team-mastery.eu
Ted Simon LLC	■	■	■	■	■	■	■										■	□	□	□	■	□	□	□									tedsimon-toxicology.com
TEI Analytical, Inc	■	■	■		■	■											■		□		■												teianalytical.com
Telematic srl	■	■	■	■	■	■	■										□	□	■	■	□	□	□	□									epyplus.com
Tenviro	■	■	■	■	■	■											■	□	■	■	■	□	■	□									tenviro.eu
TERRA-The Electronics Reuse & Recycling Alliance								■																									jointerra.org
Tetra Tech	■	□	■	□	■	■											■	■	■	■	■	■	□	□									tetratech.com
The Chemical Compliance Coach	■	■			■	■			■				■				■	□	■	■		■	■	□			■						thechemicalcompliancecoach.com
The Compliance Map Ltd.			■		■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□		■	■	■	■	■	■	■	thecompliancemap.com
The Isosceles Group	■	■		■	■	■		■		■	■	■	■		■	■	■	■	■	■	■	■	□		■	■				■	■		theisogroup.com
The Martec Group	■	■	■	■	■	■	■	■	■	■	■	■	■	■			□				□	□	□	□				■					martecgroup.com
The Redstone Group	■	■	■	□	■	■	■	■	□	□	□	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	□	□	■	redstonegrp.com
the SDS factory | de ViB fabriek	■	■	■		■	□								■		■	□		■	■	□	□	□	□								■	theSDSfactory.com | deViBfabriek.nl
TJS Technical Services Inc.								■	■	■				■			□									■	■	■						tjstechnical.com
TO21 Co. Ltd.	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	□	□	□	to21.co.kr
Tox Focus LLC	■	■		■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■					toxfocus.com
toXcel	■	■	■	■	■	■	■	■	□		■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	toxcel.com
Toxicon srl	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■			toxicon.it
Toxi-Coop Toxicological Research Centre Ltd.	■	■	■		■	■	■						■	■	■		■		■	■		■	■	■			■						toxicoop.com
Toxikon (Labcorp)	■	■	■	■	■	■	■										■	□	□	□	□	□	□	□									medtech.labcorp.com
TOXIT & S-IN Soluzioni Informatiche Srl	■	■	■		■	■	■							■	■		■		■	■		■	■	■			■						toxit.it/en/
ToxMinds	■	■	■	■	■	■							■	■	■	■	■	□	■	□	■	■	■	■									toxminds.com
ToxServices LLC	■	□	■		■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■				■	■		□	■	■		toxservices.com
ToxStrategies	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	□	□	■	■	toxstrategies.com
TraceGains																																	tracegains.com
Trade Wind B.V.	■	□	■	□	■	□		■	□	□	■	■	□	□	□		■	■	■	□	□	□	□	□	■	□	□	□	□	■	□		twnl.nl
Tradebe UK	■	■	■	■	■	■	■																										tradebe.co.uk
TRASYS	■	□	■		■	■	■										■	□	■	□	■	■	□										trasys.be
Triskelion	■	■	■	□	■	□							■		■	■	■	■	■	□	■	□	■	■	■				■	■	■		triskelion.nl
TSG Consulting	■	■		■	■	■		■	■	■	■	■	■		■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	tsgconsulting.com
TÜV SÜD Industrie Service GmbH	■	□		■	□		□	■	□	■	■	□	□		■	□	■	□	■		■			□	■	□	□						tuvsud.com/de-reach
UetlibergPartners GmbH	■	□			■		■		■	□				■	□	■								■	□								uetlibergpartners.com
UL Solutions	■	■	■	■	■	■	□	■	■	■	■	■	■		■		■	■	■	■	■	■	■	■	■	■	■	■				■	ul.com
UMCO GmbH	■	□	■		■	□		■		□	■		■	□	■	□	■	□	■	□	■		□						■	□	■	■	umco.de
Universit Bordeaux Segalen	■	□	■	□	■	□	■										■	□	■	□	■	□	■										u-bordeaux.com
Vanta Bioscience	■	□	■	□	■	□	■										■			■		□	■										vantabio.com
Veeva Systems	■	■	■	■	■	■	□	■		□		■	■	□	■	□	■	■	■	■	■	■	■	■	■	■			■	■	■	■	industries.veeva.com/chemical
VelocityEHS	■	□	■	□	■	□	■	■	□	■	■	■	■	■	■	□	■	□	■	■	■	□									■	■	ehs.com
Verdant Law, PLLC	■	■	□	□	■	■		■	■	■	□	■	□	■	■	□	■	□	□	■	□		□	■	□			□	□	□	■	verdantlaw.com
Vitis Regulatory	■	□			■	■											■	■	■	□	■	□	■		□								vitisregulatory.com
VITO NV team EHS Toxicology Services	■	□	■	□	■	□	■	□	□	□	□	■	■	■	■		■		■	■		■	□	□	□	□			■	□	■		ehs.vito.be
Vivotecnia Research	■	■	■	■	■	□	■					■	■	■			■	□	□	□		□	■	■				■					vivotecnia.com
Von Roll REACH GmbH	■																■	□	■	□	■												vonroll.com
VRS Regulatory	■	■		■	□	□	□	□	□	□	□	■		■	□	■	■	■	■	■	■	■	■	■	■	■					■		vrs-regulatory.net
W.E. Train Consulting	■	□	■	■	■	□	■										■		■	□													WEtrainConsulting.com
wca environment	■	□	■	□	■	□	■										■	■	■	□	■	□	□										wca-consulting.com
Wercs Professional Services																	□	□	■	■	■	■	□										thewercs.com
WIL Research	■	■	■	■	■	■		■					■	■	■	■	■	■	■	■	■	■		■									wilresearch.com
Wildlife International, a Division of EAG, Inc	■	■	■	■	■	□	■										□	□	□	□	■	□		■									wildlifeinternational.com
Wiley	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■			■	■	■		■		■		■					wiley.law
WILLIAM WILSON Wyeside Consulting Ltd	■	■	■		■		□		■		□	□		■		■		■	■		■		□	■	□		■						wyesideconsulting.com
Womble Bond Dickinson (UK) LLP	■	□	□	□	□	□	□	□	□		■	■	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	womblebonddickinson.com/uk/sectors/manufacturing/chemicals
WRc plc		□	■		□	■	□						■		□	■	■		■		■		■	■	■								wrcgroup.com
WSP UK Ltd	■	□	■		■	■		□	■	■	■	■	■		■	■	■	■	■	■	■	■	□	■	■	■			■	■	■		wsp.com
WTConsulting	■	□	■	□	□	■	□										■	■	■	□	■	□	■	□									wtconsulting.ch
XCellR8	■	■	□	■	■	■	□			■			■	■			■		■	■		■	■				■				■		x-cellr8.com
YASH Technologies	■	■	■		■	■											■	□	■	■	■	■	□										yash.com
Yordas Group	■	■	■		■	■		■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	yordasgroup.com
Zanos Ltd	■				■												□		□														zanos.co.uk

Key: Icons above represent the percentage breakdown of services provided by each company as follows:
■ Core service ■ Service that is occasionally provided □ Service provided by partners and third parties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