# Global Service Providers Guide 2023

The guide to global chemicals management and control services

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# Foreword

**Welcome to the thirteenth edition of the Chemical Watch Service Providers Guide.**

For more than 15 years Chemical Watch 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.

Our annual Service Providers Guide provides the opportunity to analyse the regulatory and non-regulatory issues that are driving work for businesses and to identify key emerging trends from the results of our annual survey of regulatory professionals from around the globe.

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 two special reports, on the transport and storage of dangerous goods and international chemicals management. These were first published as part of the Chemical Watch 2023 Global Outlook series in January and February. A research brief, based on data from Scivera and Chemical Watch and first published in February 2023 by Enhesa, identifies the five chemical families facing the greatest level of regulatory activity across the globe and and shows, as a consequence, why producers of everyday products need to be aware of the chemical risks in their supply chains

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 Guide remains testament to the diversity and strength of this shared marketplace – with more than 70 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**

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# Key trends in chemicals management and control

**The 13th annual Chemical Watch Chemicals Management and Control Survey finds REACH strengthening its grip even further as the lead driver of market activity, and professionals anticipating strong growth in their use of external services over the next 12 months.**

Between November 2022 and January 2023, Chemical Watch surveyed its global chemicals management community to uncover the key factors driving activity in the market, as well as track changes in employment and spot emerging trends.

Some 553 professionals took part in the survey. Of those taking part 37% work in the chemicals and life sciences sector, 12% in the consumer products (home and personal care) sector, 11% in the electrical and electronics, and engineering, automotive and aerospace sectors, and 11% in general manufacturing. A further 11% are employed by service providers including consultants, laboratories and law firms.

Regulatory affairs professionals make up the largest group of respondents at 29%. A further 18% are product stewards, 17% compliance managers, 10% consultants and 7% toxicologists or other scientists.

## Market drivers

The EU's REACH Regulation continues to dominate the regulatory agenda. This year, 93% of survey respondents cited "any aspect of REACH" as a leading factor in regulatory activity – up from 91% in 2022, 87% in 2021 and 84% in 2020.

Front of mind for respondents will be the much-anticipated publication of proposals to revise the Regulation. European Commissioner Virginijus Sinkevičius said in March that the EU executive is "working at full speed" on the revision and hopes to deliver the proposal in the summer.

How chemicals are regulated in the EU will be dictated by the revision, which is expected to usher in new concepts and requirements such as essential use, mixtures assessment factors, reform of the authorisation and restriction processes, additional information requirements for endocrine disruptors and the possible registering of certain polymers.

The EU's Regulation for classification, labelling and packaging (CLP) of substances and mixtures came second in the survey to REACH and was cited by 66% of respondents as a leading driver of regulatory activity – up from 61% in last year's survey.

Like REACH, CLP is undergoing significant revision. In December the European Commission published its final proposal to revise the Regulation, as well as a Delegated Regulation and Annex to add new hazard classes for endocrine disruptors and other harmful substances.

The revision of CLP, alongside the planned revision of REACH, is a major part of the EU's chemicals strategy for sustainability (CSS) – itself a key building block of the European Green Deal. Hence it is no surprise to find the CSS in third place in this year's survey, cited by 62% of respondents as a leading factor driving their work.

Other important elements of the CSS include the framework, adopted by the Commission in December,

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on the safe and sustainable by design (SSbD) concept, and an EU REACH restriction proposal, published in February, that aims to place limits on all uses of more than 10,000 PFASs.

In fourth place is "any aspect of US regulation" cited by 56% of respondents as a leading driver of regulatory activity – down slightly from 59% in 2022.

In fifth place is the circular economy, which saw a big jump in respondents citing it as a key driver of activity – up from 41% in last year's survey to 55% in 2023 – reflecting the growing importance of all aspects of sustainability in corporate goals across the globe.

Among non-regulatory drivers in this year's survey, customer and supply chain demands are cited by a rapidly increasing number of respondents as a key driver of activity – up from 58% last year to 67% in 2003. Next comes consumer concerns, cited by 55%, followed by government policies/spending cited by 36%.

## 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 participants continue to anticipate strong growth in their use of external services over the next 12 months, with some 61% of respondents saying they expect this will continue to increase over the next five years.

A closer look at the different types of services survey respondents are looking for reveals the biggest need is for information with 72% of respondents saying this will grow over the next 12 months, and 82% saying it will grow over the next five years.

Two thirds (66%) of respondents anticipate greater use of external IT and software services over the next year, while 62% anticipate greater use of external training services over the same period.

Meanwhile, almost three-quarters (74%) of respondents anticipate their company's need for advisory and consultancy services will grow over the next five years. A further 62% expect their use of training services to grow over the same period.

Turning to employment within the chemicals management sector, 38% of respondents expect the number of chemicals management and control staff employed in their organisation to increase over the next 12 months, while 57% expect numbers to remain static.

Respondents were positive about job prospects globally, with 56% saying they are good – up from 50% in 2022 and 45% in 2020. A further 46% said the opportunity to progress in their career within their own organisation was good – up from 36% in the last two years.

Meanwhile job satisfaction remains positive with 58% saying they are satisfied with their current roles.

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 2023?

**The EU's REACH and CLP Regulations continue to dominate chemicals management activity, but sector specific legislation, sustainability initiatives and consumer and supply chain demands are making their mark. Freelance writer Elaine Burridge reports on the 13th Chemical Watch Chemicals Management and Control Survey.**

Europe's REACH Regulation once again maintains its position as the top driver of chemicals management activity.

Indeed, the number of product safety and regulatory professionals citing it as a key regulatory driver in the 13th annual Chemical Watch Chemicals Management and Control Survey has grown to 93% from 90% last year, and from 85% in 2018, illustrating the dominance and continuing importance of this particular piece of legislation.

Specific components of REACH – namely registration, SVHC obligations and Annex XVII restrictions – also feature highly, taking fourth, fifth and sixth positions in this year's poll with 48%, 47% and 42% of respondents respectively citing them as key regulatory drivers for their work.

Meanwhile, the European Commission's plans to revise REACH look likely to keep this legislation in all its forms at the top of industry professionals' workloads for many more years to come.

## Chemical strategy for sustainability

The proposed REACH revision is intended to align EU chemical rules with the Commission's ambitions under its chemicals strategy for sustainability (CSS), which itself is in third place in the Chemical Watch poll this year with 51% of industry professionals citing it as a key regulatory driver.

The intent behind the CSS is to have a clearer and harmonised system of how a chemical is regulated – in other words, one substance, one approach – moving away from a substance having differing compliance requirements under different pieces of legislation.

This change could also see chemicals with similar classifications grouped together. Indeed, this approach is included in plans for the revision of the EU's classification, labelling and packaging (CLP) Regulation which, after EU REACH, was cited by the second largest number of respondents as a key regulatory driver in this year's survey – up from 61% in 2022 to 66% in 2023.

The Commission has 85 actions to perform under the CSS, including the revisions to the REACH and CLP Regulations, as well as certain product legislation. But the REACH revision itself has been delayed until the fourth quarter of 2023 – although European Commissioner Virginijus Sinkevičius said in March that the Commission is doing its "utmost" to deliver the REACH revision earlier, potentially this summer.

Under REACH, the revision proposes to reform the authorisation and restriction processes, ask for more information on endocrine disruptors and possibly require certain polymers to be registered, among other plans. Complying with these proposals will no doubt continue to maintain chemicals management professionals' attention on REACH in future.

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## Figure 1: Leading regulatory drivers for survey participants

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## Focus on UK REACH softens

By contrast, work on UK REACH has become less important in the past year and this is highlighted by a drop of 10% in the number of respondents citing this legislation as a key part of their workload – 40% versus 50% last year. UK REACH took effect on 1 January 2021, effectively bringing EU REACH into UK law.

It is very likely that a key factor behind the legislation's lower level of importance is that, following industry feedback to a public consultation in 2022, the UK's Department for Environment, Food and Rural Affairs (Defra) extended the deadlines for registration by three years. The first deadline is in October 2026, then October 2028 and October 2030, depending on the tonnage band. This has given companies a bit more breathing space.

Additionally, Defra plans to extend the timelines for completing its compliance checks on registration dossiers. The agency had not proposed any dates by mid-March; however, it has previously said that the new dates would align with the revised registration timeline.

Defra also announced on 31 January that it intends to publish its chemicals strategy sometime in 2023, mapping out the path to a complete transition to UK REACH and providing some clarity for companies and service providers.

> Outside of Europe, the US is once again the second most important driver for survey respondents' workloads with 56% citing US regulation as a key driver of chemicals management activity

## TSCA key US focus

Outside of Europe, the US is once again the second most important driver for survey respondents' workloads with 56% citing US regulation as a key driver of chemicals management activity. This is down by 3% from 2022.

Work in the US continues to be heavily driven by changes to TSCA, which it is anticipated will be complemented soon by demands to comply with the Occupational Safety and Health Administration (Osha) Hazardous Communication Rule to be published this year.

However California's Proposition 65 took the top spot for the US, with 32% of respondents citing the state law as a key driver of their work in 2023, down a fraction from 2022's survey when 34% of respondents cited it as a key driver.

**Figure 2: Leading regulatory drivers by sector**

| Chemicals, life sciences and similar | Consumer Products |
|---|---|
| EU CLP regulation | Cosmetics regulations |
| EU chemicals strategy for sustainability | EU CLP regulation |
| EU REACH registration | EU REACH registration |
| EU REACH dossier updates | EU REACH dossier updates |
| EU chemicals strategy for sustainability (CSS) | EU REACH Annex XVII Restrictions |
| Circular economy | EU chemicals strategy for sustainability (CSS) |
| Food contact material regulations | UK REACH |
| EU REACH evaluation related activities | Packaging regulations |
| EU REACH SVHC obligations | EU chemicals strategy for sustainability |
| EU Green Deal | European strategy for plastics |
| **All manufacturing** | **Service provider, including consultants, laboratories, lawyers etc** |
| EU CLP regulation | EU CLP regulation |
| Circular economy | EU chemicals strategy for sustainability |
| EU chemicals strategy for sustainability | Circular economy |
| EU REACH SVHC obligations | European strategy for plastics |
| Packaging regulations | EU REACH dossier updates |
| EU REACH Annex XVII Restrictions | EU REACH SVHC obligations |
| EU chemicals strategy for sustainability (CSS) | EU chemicals strategy for sustainability (CSS) |
| US: California Proposition 65 | UK REACH |
| RoHS regulations | EU Biocidal product regulation (BPR) |
| EU REACH registration | EU Waste Framework Directive and Scip Database |

Cosmetics too are another key focus in the US with the passing last December of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). The Act introduces new requirements for product listing, safety substantiation, fragrance allergen labelling and good manufacturing practices (GMP).

## Asia developments

Regulatory compliance in South Korea (K-REACH), Turkey (KKDIK), China and India also accounts for a significant slice of our survey respondents' attention, with 26% citing K-REACH as a key driver of their work, 25% Turkey generally, 21% management of existing chemicals in China and 21% India generally.

Last October, South Korea's Ministry of Environment (MoE) published proposed reforms to K-REACH and the Chemical Control Act (CCA), with the intention of implementing a system based on hazard types and toxicity levels.

China meanwhile continues to tighten its chemicals legislation and the control of new toxic chemicals looks likely to feature strongly this year. In May 2022, the country's State Council published its final action plan for new toxic chemicals, outlining its framework for chemical management policies – including new regulations, guidelines, restrictions and bans on priority substances for the next three years.

> 55% of respondents cited the circular economy as a key driver of activity

Cosmetics too remain an area of attention. China's Cosmetics Supervision and Administration Regulation (CSAR) – introduced in January 2021 – continues to evolve with new data requirements for raw materials, revised technical standards and additional labelling rules, among others.

In India, new e-waste rules were due to enter into force in April and the government has also pledged to develop a national plan to reduce production and consumption of hydrofluorocarbons (HFC).

## Sector specific regulations and sustainability

Looking at the results for sector specific regulations, this year's respondents placed packaging regulations in first place with 42% citing them as a key regulatory driver of activity – up from 38% last year.

By contrast, the EU biocidal products Regulation (BPR) which came top last year, slid to third place in this year's survey with 31% citing it as a key regulatory driver – down from 43%.

Food contact materials (FCMs) remained in second place with 37% of respondents citing them as a key regulatory driver, while the EU Directive on the restriction of hazardous substances (RoHS) in electrical and electronic equipment remained in fourth position.

Cosmetics regulations were cited by 22% of respondents as a key driver of their work – while 21% cited transport of dangerous goods (TDG) regulations as an important factor driving their activities.

Reflecting the growing impact of broader sustainability considerations on their work, 55% of respondents cited the circular economy as a key driver of activity, while 42% cited the European strategy for plastics as a major factor impacting their work.

Environmental, social and governance (ESG) initiatives were cited by 40% as a major driver of activity, while microplastics were cited by 37% as a feature driving their work.

### Figure 3: Leading non-regulatory drivers for survey participants

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> Reflecting the growing impact of broader sustainability considerations on their work, 55% of respondents cited the circular economy as a key driver of activity

Meanwhile at an international level 37% cited implementation of the Stockholm Convention on persistent organic pollutants (POPs) as a key regulatory driver.

## Non-regulatory drivers

The past couple of years have seen huge disruption to global supply chains thanks to a combination of factors. These include port closures, labour shortages, the Covid-19 pandemic and the conflict in Ukraine. These have driven costs up to record levels and led to significant delays in shipments.

While the situation has improved with congestion levels easing and freight rates falling, a slowdown in the global economy and rising inflation have dampened demand along supply chains.

These ongoing negative impacts have helped to ensure that customer and supply chain demands remain the top non-regulatory driver of activity in this year's survey cited by more than two-thirds of respondents (67%). This is followed by consumer concerns regarding products/services – cited by55% of respondents as a key non-regulatory driver – and then governmental policies/spending, cited by 36%.

The main difference between this year's poll and last, is that economic performance has fallen from second position to fourth, effectively swapping places with consumer concerns on product/services.

Also noteworthy is that NGO pressure has become a much more important driver – 27% of respondents cited this as a key non-regulatory driver versus 19% in 2022 – and political issues in certain regions has entered the list as a key non-regulatory driver, reflecting the current geopolitical climate that includes not only the Russia-Ukraine war, but rising tensions between the US and China – and between the West and Iran.

Looking back further, to see what, if anything, has changed in the past five years, reveals that in 2018, the top three non-regulatory drivers were standards, downsizing of in-house teams and government policies/spending.

While the latter driver retained its position as the third most frequently cited non-regulatory driver in Chemical Watch surveys in 2021, 2022 and 2023, standards no longer feature as a non-regulatory driver in the latest poll – and downsizing has seen a significant fall in importance, cited by just 11% of survey participants.

**Figure 4: What is your primary job function?**

## Who answered the survey?

This year, 553 people took part in the Chemical Watch Chemicals Management and Control Survey. More than half (55%) are located in Europe, a quarter are in North America and 16% in Asia. The remainder were divided between Latin America, Africa and the Middle East. The US had the largest number of survey participants, followed by the UK and Germany. About half of the respondents took a global perspective, while just over a quarter concentrated on Europe, with a much smaller number focused on North America and Asia-Pacific.

Breaking down respondents by industry, 37% work in chemicals and life sciences, 11% in other manufacturing 7% in consumer products, personal care and cosmetics, 6% in electrical and electronics, 5% in engineering, automotive, aerospace and similar. Respondents from service providers, including consultants, laboratories and lawyers make up 11%, while 5% hold government roles and 3% are from trade associations.

Most – 41% – come from enterprises (more than 5,000 employees) and 29% are from large companies (250-5,000 staff). As for job functions, 29% work in regulatory affairs, 18% work in product safety/stewardship and 17% are compliance managers.

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# What is the outlook for chemicals regulatory and management services in 2023?

**While helping clients with aspects of REACH continues to dominate workloads for many service providers, the ongoing shift to digital tools is keeping IT and software solutions at the top of the list of services retained by respondents on a permanent basis. Elaine Burridge reports.**

In an uncertain world, dominated by an energy crisis, war in Ukraine and rising inflation, the only certainty for providers of chemicals regulatory and management services is the increasing volume and complexity of global chemical regulations.

With companies reducing costs and restructuring, the need for outsourcing of functions such as chemical regulatory compliance has increased, says Rose Passarella, associate director, chemicals group at Intertek Assuris.

Areas of work that are frequently referenced by service providers include EU REACH, UK REACH, South Korea's K-REACH and Turkey's KKDIK. Also, the European Commission's chemicals strategy for sustainability (CSS) contains proposed updates to the classification, labelling and packaging (CLP) Regulation. Cosmetics, food and food-contact materials, evolving regulations in Latin America and rapidly growing global regulatory requirements around per- and polyfluoroalkyl substances (PFASs) are other major areas of focus.

In Europe, Jan Oltmans, general manager at chemical evaluation and risk assessment specialist FoBiG, says demand for updating REACH registration dossiers has been very strong, with customers needing support to comment on Echa draft decisions and for exposure and risk assessments, as well as monitoring studies where the agency has requested tests.

Requests have also been very high for supporting REACH authorisation applications along with reviews for substances that have been initially authorised. Oltmans expects similar needs from customers this year, which he anticipates will be "very high" particularly for REACH registration and authorisation.

> Service providers mention growing demand for assistance with developing chemical management regulations in countries such as Chile, Colombia, Brazil, Argentina, Costa Rica and Peru.

Michael Cleuvers, managing director of Germany's knoell, says Europe's Green Deal, the establishment of a framework for developing "inherently safe and sustainable" chemicals and materials, the REACH revision and ongoing updates to the Regulation's candidate list, as well as possible changes to the Restriction on Hazardous Substances (RoHS) in electrical and electronic equipment, are the areas where he sees the greatest demand for services.

Dr Cleuvers also mentions the draft European Supply Chain Act that requires companies to manage social

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and environmental impacts along the value chain. The European Parliament is expected to agree the legislation by mid-2023, with member states having two years to transpose the Directive into national law.

For Alan Ritchie, technical director, REACH and product stewardship at consultancy WSP, work in the early part of 2022 was very much focused on Brexit and UK REACH, but he says this has eased now that the UK government intends to consult on a new registration model this year, with a view to introducing legislation in 2024. In the meantime, regulatory work in Europe has taken off "like crazy" this year, with the company needing to hire several people.

David Carlander, chemical director at Risk & Policy Analysts (RPA), says he is also seeing regular and strong demand for services across both EU and UK REACH – especially on authorisations under the former. "We also see strong demand for socio-economic analysis to support input to regulatory changes," he says, adding that the divergence of UK REACH and EU Reach is "a challenge that needs to be managed by industries present in both markets".

**Figure 5: Anticipated changes in need for inhouse staff to support chemicals management work over the next 12 months and five years**

**Figure 6: Anticipated changes in need for external services to support chemicals management work over the next 12 months and five years**

Global regulatory consulting firm The Acta Group has experienced brisk business in 2022 and its president Lynn Bergeson says many jurisdictions are playing catch-up post the Covid-19 pandemic and redoubling efforts to get back on track with REACH-like registration programmes. She adds that the EU is "moving aggressively" with implementing parts of the CSS, and PFAS law and policy are "emerging everywhere". "We are experiencing significant growth in all service areas and growth in the chemicals sector shows no sign of abating. The US, Europe, and Latin America appear especially primed for growth in all areas," Bergeson says.

## US focus

Bergeson, who is also managing partner of US law firm Bergeson & Campbell, notes services around the UN's globally harmonized system (GHS) of classification and labelling of chemicals, safety data sheets (SDSs), the Occupational Safety and Health Act (Osha) and TSCA are strong areas of demand in the US.

Bergeson adds that the Food and Drug Administration's expressed interest in chemicals entering the food supply, and its newly announced "enhanced approach" to food chemical safety, could "evolve in an unpredictable and impactful way making engagement essential".

Cosmetics too are increasingly demanding attention. The passage late last December of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) "signalled renewed regulatory attention on cosmetic ingredients" and Bergeson sees similar attention playing out in the EU.

In addition, the electronics sector is experiencing "disproportionate" review. Bergeson says the EPA's reprisal of the persistent, bioaccumulative and toxic (PBT) rule due later this year is expected to be especially impactful on the US industry. And as electric vehicle technology continues to expand, this will also put pressure on EPA's review of TSCA's Section 5 new chemical review.

Latin America is emerging as a developing region in terms of regulation. Monica Locatelli, managing director of TEAM Mastery, says she has seen more development in this region during the past two years than in Asia, notably in the agrochemicals and food sectors. Service providers mention growing demand for assistance with developing chemical management regulations in countries such as Chile, Colombia, Brazil, Argentina, Costa Rica and Peru.

## Growth in Asia

Turning to Asia, legislation continues to expand, especially in countries such as South Korea, China and India and particularly in the chemicals, cosmetics and food sectors. David Wan, head of strategy operation at CIRS Group, says demand in 2022 for services relating to K-REACH grew significantly and requests for testing services were also very high, especially for cosmetics and food. Indeed, requests for cosmetics testing jumped by 25%, which he believes is partly due to the changes under China's Cosmetics Supervision Administration Regulation (CSAR).

CIRS continues to work on several lead registrant projects under K-REACH ahead of the second full registration deadline (for substances between 100 and 1000 tpa) which falls in 2024. Additionally, while Wan says the timeline for implementing India's chemicals regulations is still unclear, "we expect to see more requests for the region as companies strive to remain compliant with the changing regulatory landscape".

Overall, Wan expects to see the greatest demand for its services in Asia, especially China. One area to watch in the near term in China, he says, is the need for carbon footprint calculations, a field that CIRS expects to expand further into. "The Chinese authorities continue to develop their regulations and we will closely monitor them and see how we are able to best serve our clients accordingly," he says.

Dan Bastien, associate director, chemicals group at Intertek Assuris is also predicting that the impending deadline for K-REACH will spur high demand from companies looking to prepare for changes to the Act. In addition, the consultancy anticipates that in an open, post-pandemic China, regulators there will spend more time pursuing global producers to ensure their compliance with the country's cosmetic regulations.

Other areas of focus for service providers in Asia include updates to South Korea's biocidal products Regulation (BPR), Japan's Poisonous and Deleterious Substances Control Law (PDSCL), Australia's inventory of industrial chemicals (AIIC), and Thailand's new criteria for complying with Annex 5.6 – its hazardous substances list under the Hazardous Substances Act. Vietnam too is planning to revise its overarching chemicals law with the National Assembly expected to pass legislation for the Law on Chemicals in May 2025.

The Middle East is another developing region. Here Wesley Chen, vice president, sustainability, quality and safety, at Intertek Assuris says new electrical restricted substance requirements continue to emerge. For example, on 4 July 2022, Saudi Arabia introduced a requirement for conformity assessments on substances in electrical and electronic equipment under its RoHS-like regulation.

## Ongoing challenges

PFASs too are a major and expanding area of work as jurisdictions around the world look to impose restrictions or bans on these 'forever chemicals'. In February, Echa announced it was evaluating a proposal submitted by Germany, the Netherlands, Sweden, Denmark and Norway, to restrict about 10,000 PFASs. The move is regarded as a first step towards a European ban on the substances.

"The recent PFAS restriction proposal with its potentially large impacts on society will be high on the agenda for many sectors this year, including the construction, hydrogen, automotive and semiconductor industries," says RPA's Carlander.

PFASs will also be high on the agenda for WSP, which acquired the Environment & Infrastructure business of John Wood Group in September 2022. The business has a focus on managing PFASs across customer operations, as well as treatment technologies and techniques to mitigate and eliminate the substances and other contaminants.

**Figure 7: Changes in proportion of spend on external chemicals management and control services**

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Another important challenge ahead, says Ritchie at WSP, is the move towards controlling chemicals by groups, essentially following the same approach as for PFASs. "We will see more regulations worldwide – and certainly in Europe – where chemicals will be grouped. That will be a double-edged sword," he says, referring to Echa's focus on grouping substances based on tonnage, intrinsic hazard and end-use rather than the actual chemistry involved.

Meanwhile, recruitment problems persist as service providers highlight difficulties around hiring suitably qualified and experienced staff. Ritchie says it is a major challenge getting the right skillset to cover all the bases when you do not know what the next "regulatory Whac-A-Mole" will be. Knoell's Dr Cleuvers agrees that the "war for talent" continues while Lynn Bergeson adds that ensuring sufficient staffing and workload allocation is a "constant work in progress".

Dieter Drohmann, CEO of German consultancy Chemservice says small service providers of less than ten people will find it difficult to address the increasing complexity of regulations and he expects more consolidation of the sector through acquisition in the future. He believes that firms employing more than 25 staff will be more able to offer a 'one-stop shop' and grow their businesses globally, adding that Chemservice has managed to hire ten new people so far this year.

**Figure 8: Services retained by participants on a permanent basis**

Both Francoise Saint-Romain and Magaly Courtois, managing partner and regulatory affairs manager respectively with Lisam Telegis, echo Dr Drohmann's comments. They say while every new regulation or update is an opportunity for service providers, many are often SMEs and therefore face a major challenge in needing to understand and solve all kinds of legal uncertainties on foreign regulations for customers and – more importantly – also for themselves.

"Diversification is key to prevent ups and downs in regulatory activities to affect service providing companies. But diversification means that we need to remain knowledgeable in our current areas of expertise and we need to explore new areas permanently. This is both particularly challenging and incredibly motivating," says Saint-Romain.

Looking ahead, Lisam Telegis believes customers will increasingly need more filtered and customised information. TEAM Mastery's Locatelli adds that service providers have an essential role as a bridge between chemical companies and regulatory authorities. She says: "European authorities have requests that are often economically unaffordable and scientifically inapplicable, and it is of utmost importance that service providers can act as translators and intermediaries between the reality of industry and production and theoretical authority requests."

## Industry trends

The ongoing shift to digital tools remains a key trend for the chemicals management and control industry, as companies seek to enhance their communication processes and data analysis. Digitisation also offers further opportunities to service providers for deploying their software processes. Chen at Intertek Assuris says there are growing prospects for software-as-a-service and artificial intelligence technologies.

> 46% of respondents expect use of external services (generally) to increase over the next 12 months – while 61% expect their use of external services to increase over the next five years, with 6% saying that increase will be significant.

Other major trends that are top of the agenda are the energy transition and sustainability/the circular economy. The pace of technological innovation in these two areas "vastly outstrips the [US] government's ability to regulate, which sets up a chronic tension of obtaining approvals in the absence of a coherent regulatory framework," says Bergeson & Campbell's Lynn Bergeson. She adds ". This requires all our assets – legal, regulatory, economic and scientific – to deploy effectively to problem solve.",

Service providers believe that customers will become increasingly reliant on external support for managing chemicals and chemical products, and that support will need to be high quality. As Dr Cleuvers at knoell puts it: "Quick and dirty solutions are not sustainable", adding that now is a "good environment for consultants – if you know your stuff."

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## Figure 9: Anticipated change of services required over the next five years

## Chemical Watch survey results

According to the results of the 13th annual Chemical Watch Chemicals Management and Control Survey, IT and software solutions are at the top of the list of services retained by respondents on a permanent basis followed by Information and consultancy/advisory. But when looking at services retained frequently, consultancy/advisory is in first place, followed by training and laboratory services. Looking at services retained on an occasional basis, consultancy slips to third place behind legal and training services.

Satisfaction levels are high with less than 3% citing dissatisfaction with services provided. Where there is dissatisfaction, price is most frequently cited as the cause. And while 41% of respondents said they would not change their service provider, more than half said they possibly would.

There are some significant changes regarding where respondents anticipate their departments will spend their budget this year. Nearly twice as many respondents cited laboratory work as one of the services where they expect to spend their budget this year – up from 12.6% in 2022 to 22.8%. More respondents also anticipate spending on representation and management in 2023 up from just 2.5% in 2022 to 15.8%. Conversely, 15.9% said they expected to spend on consultancy services in 2023 – down from 32.7% in 2022. Legal services are cited by 5.5% – down from 13.5% in 2022.

Survey respondents expect 71% of their chemicals management work to be completed by their in-house team in 2023 – a small increase on 2022 (68%). At the same time, 46% of respondents expect use of external services (generally) to increase over the next 12 months – while 61% expect their use of external services to increase over the next five years, with 6% saying that increase will be significant.

Breaking this down by function, demand for information will be the primary reason this year for using external service providers, followed by IT/software solutions. When looking at the situation five years from now, information remains the key driver, but general consultancy/advisory follows.

Looking at changing needs over the next five years in the consultancy and advisory services category, 63% expect to need more help on compliance matters and 60% on environmental risk assessments. Within the information category, demand for regulatory/policy, as well as regulatory and chemical hazard databases is predicted to increase, and in the IT solutions segment, a significant rise is also expected for training services.

**Figure 10: Anticipated changes in need for external services by sector to support chemicals management work over the next 12 months**

**Figure 11: Anticipated changes in need for external services by sector to support chemicals management work over next 5 years**

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# What are the prospects for professionals working in chemicals management and control in 2023?

**This year's Chemicals Management and Control Survey finds job security, satisfaction and opportunities high at a global level, while the drive for sustainability is creating a need for 'problem solvers'. Chemical Watch reporter Emma Davies takes a look at the figures.**

This year's Chemicals Management and Control Survey found that regulatory professionals continue to have a strong sense of job security. However, a growing percentage – 57% compared with 48% in 2022 – predict that the number of people working in this area within their own organisation will remain static in the coming year. Almost 60% of professionals surveyed said they get satisfaction from their work, a figure that has remained remarkably similar for the past decade.

Chemical Watch's 13th annual survey highlights the EU chemicals strategy for sustainability (CSS) as a strong regulatory driver, bringing changes to both REACH and the CLP. South Korea's K-REACH and Turkey's KKDIK also have a high weighting in responses. The KKDIK has a registration deadline of 31 December 2023 and the K-REACH deadline for registering substances exceeding 100 tonnes a year is 31 December 2024.

When it comes to EU REACH, Bryan Zhou, deputy general manager, Europe, at product safety and regulatory consulting firm CIRS says that while some larger companies acting as lead registrants under the Regulation are dealing with registrations in other regions, many smaller companies are holding off.

CIRS – the Chemical Inspection & Regulation Service – has headquarters in China, with subsidiaries in Ireland, South Korea, the US and the UK. Until significant new regulations appear, it does not foresee increasing the number of chemical regulatory consultants that it employs, says David Wan, director of the organisation's overseas division.

Instead, relative stability in the global chemical regulatory scene is "increasing the service standard for many consulting firms", according to Zhou. For example, CIRS is "digging deeper" with its services, looking for different ways to support customers, he says.

The EU's focus on sustainability is also changing the way that industry operates and consultancies "need to think about how to support their clients better", including with more digital services, he adds. "We are focusing on how to offer more designer services to our customers. It is an opportunity and also a challenge."

CIRS is recruiting staff for a new IT team to develop apps for its services, to help clients both to understand regulations and to work out which actions they need to take. "They can check information using software rather than through our consultants," says Wan. As a result, the focus on IT is likely to reduce regulatory staffing levels, he predicts.

## Strategic roles

A drive for sustainability is also changing the way that in-house regulatory teams function. Jim Kildea heads a regulatory team at US technology company HP, which includes regulatory managers, toxicologists, and people working in "hazard communications". Most of its focus

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Increasingly, the regulatory team is "shifting to more of a strategic role", helping to guide HP as a business, he says. "We are doing a lot more assessments and evaluations, not only of the chemicals but also of the regulations. Where is a regulation heading? What does it mean for the business?" His team advises on business risks linked to regulatory changes, as well as recommending actions.

**Figure 12: Job security felt by respondents in their own roles and across all roles within organisations**

**Figure 13: Staffing trends over the next 12 months within respondent organisations**

Kildea's comments fit with the survey finding that 62% strongly agree that their organisation's strategy embraces chemicals management, up from 53% in 2022.

**Figure 14: Average salary by location**

In the past several years, "engagement has also really increased" with formulation teams at HP," Kildea says. This includes discussions on chemical substitutions and the suitability of possible alternatives.

As a result, he needs staff to be "very good problem solvers". "The business partners want a black and white answer, and we are dealing in shades of grey all of the time. Dealing with ambiguity is a real skill that we need to look at."

Kildea expects staff not only to have expertise in regulatory compliance, but also to be able to work with regulators, trade associations and internal departments. Many of the skills are learned on the job, he says, but he likes to recruit people who already have several years of experience.

Demand is going up for almost every skill in regulatory roles, says Michael Cleuvers, managing director at consultancy knoell. The increase in demand is perhaps highest for experts able to deal with "regulatory intricacies", such as in silico solutions for (eco-) toxicological data and in complex fields such as endocrine disruption, he says. With the upcoming REACH revision and proposed polymer registration, there might also be a higher need for polymer chemists, he predicts.

## Regional variations

Some global regions are easier to recruit in than others. Kildea is currently recruiting in Mexico, which is proving challenging. "It seems that when you talk about regulatory compliance, a lot is focused on pharmaceuticals and healthcare," he says.

Dr Cleuvers agrees that staff challenges around the globe differ. For example, finding the "right people" for regulatory roles in the US is relatively straightforward but staff are "very expensive to hire". Meanwhile, in other areas there are simply not enough skilled people, especially in parts of the Asia-Pacific region, he says.

The survey results back this up, with the average salary in North America being equivalent to €89,000, significantly higher than a European average of €67,000. The average salary for the rest of the world (outside Europe and North America) is much lower, but has seen the largest increase year on year, from €43,000 in 2022 to €65,000 in 2023.

## Survey data

The SPG survey received more than 500 responses, with 55% of respondents based in Europe and 25% in North America. Around one tenth work for service providers, including consultants, laboratories and lawyers.

### Figure 15: Job prospects in respondents' country vs globally in 2022

### Figure 16: Opportunities to progress in a chosen career within respondent's organisation and the wider jobs market

More than 55% of respondents say that global prospects for chemicals management and control professionals are good, up from 49.5% in 2022 and 44.6% in 2021 when much of the world remained in the grip of the Covid-19 pandemic.

When questioned, 44% of respondents predicted that the use of external services will increase over the next 12 months, but this number goes up to 55% when asked about the next five years.

### Figure 17: Average salary by job title

The "increased complexity" of regulatory requirements means that a variety of experts is needed, says Dr Cleuvers. "Many companies cannot hire somebody for each and every requirement. Hence, they either try to train the existing staff or they decide to outsource work."

Despite good global prospects, 57% of respondents predict that the number of people working in chemicals management and control within their companies will

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remain the same, with 38% predicting an increase. In last year's survey, around 50% of respondents predicted an increase in numbers in their companies.

The sense of job security compared with the previous year remains stable. The figure of around 70% is consistent with survey results going back to 2013. This leaves just 6% feeling there is less job security than last year, which compares with figures of over 12% at the peak of the pandemic.

### Figure 18: Average salary by industry sector

Despite the increasing number of professionals predicting that the number of people working in chemicals management and control within their own organisation will remain static, almost 46% see good opportunities to progress in their current companies – up from 36% in 2022. Meanwhile the number seeing "good" opportunities to advance in their chosen careers in the "wider jobs market", has slipped from almost 75% in 2022, to around 66% in 2023.

### Figure 19: Average salary by gender

The survey data suggests that salaries in most areas are staying the same or increasing slightly compared with last year, including for regulatory affairs management, product safety, EHS management and compliance management. The exception is for toxicologists and other scientists, who have seen a modest drop in pay compared with 2022.

Reflecting other sectors, female employees are on lower salaries than men, despite recent pay increases.

On average the highest salaries reported in this year's survey are in business development and management, with an average salary of €107,000. Then, reflecting an increasing focus on sustainability across the board, come those working in sustainability management, with average pay of over €80,000.

## Training needs

Every survey since 2019 has shown that half of respondents consider that training needs are increasing, with more than 40% seeing them as staying the same. Less than 5% of those surveyed think that training needs are decreasing.

While almost half (46%) of respondents consider their training needs to be fully met, the survey also reveals an increase in the percentage whose training needs are only "partially identified and met", up to 47%, compared with 42% in 2022.

Around a third of people say that the company that they work for doesn't have a big enough training budget to cover their, and their team's, training needs.

"As a service provider for a variety of training in the area of chemical compliance, we hear quite often from participants that it was not easy for them to get the budget for the training," says Dr Cleuvers. "In a world with continuous challenges and developments, training opportunities are essential to be up to date and to be able to cope with the work," he adds.

# What should we expect for transport and storage regulations in 2023?

**In this special report, first published in January 2023 as part of the Chemical Watch Global Outlook series, transport and storage editor Peter Mackay and senior reporter Dr Amanda Doyle look at the major developments to expect across the world in the storage and transport of dangerous goods**

For those involved in the transport of dangerous goods, 2023 started right on time. As ever, the international regulations covering the transport of dangerous goods by air – the ICAO Technical Instructions 2023-2024 and the International Air Transport Association's (Iata) Dangerous Goods Regulations 64th edition – took effect promptly on 1 January.

This was also the case for the end of the transitional period for consignor-only (also referred to as 'office-only') operators to appoint a safety adviser (DGSA) under the ADR. That requirement was introduced in the 2019 edition but the arrival of the deadline appeared to take many in the industry by surprise.

There are other international regulations that have been updated as from 1 January 2023, but will not become mandatory until later. The ADR has a six-month transitional period and will become mandatory from 1 July; the same goes for the more European-based RID and ADN.

Amendment 41-22 to the International Maritime Dangerous Goods (IMDG) Code has a 12-month transitional period and, while it may be used now, it does not become mandatory until 1 January 2024. So during 2023 shippers and carriers can choose whether to use the existing Amendment 40-20 or the new Amendment 41-22.

All of these amendments derive at least in part from the 22nd revised edition of the UN Recommendations on the Transport of Dangerous Goods (widely referred to as the 'Model Regulations'); this was adopted by the UN Committee of Experts in December 2020 and published in March 2021.

## Key developments

- UN regulatory agencies will give more weight to the UN sustainable development goals (SDGs) in their discussions this year, which is expected to deliver regulations on the transport of electric vehicles and their use to carry dangerous goods, and the wider use of recycled plastics in dangerous goods packaging
- Regulators throughout the supply chain are also following developments in energy storage technology, with new provisions for sodium ion batteries already accepted
- The 2023 editions of the international regulations for transport of dangerous goods by road (ADR), rail (RID) and inland waters (ADN) will become mandatory in signatory states from 1 July
- Transport Canada is consulting on a major revision of its TDG Regulations, with a final rule likely to be issued later this year
- Australia's updated Dangerous Goods Code ADG 7.8 will be available for use from 1 April in those states and territories that have adopted it in their legislation; it will become mandatory on 1 April 2024

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## Emerging topics

In December, the UN Committee of Experts adopted the next round of amendments. These are found in the 23rd revised edition of the Model Regulations. The various modal, regional and national authorities will be working through them this year and next, and incorporating into their regulations for entry into force from 2025.

The changes include the adoption of a relatively large number of new entries in the dangerous goods list:

- fire suppressant dispersing devices (UN 0514 for Division 1.4S, UN 3559 for non-explosive);
- tetramethylammonium hydroxide aqueous (TMAH) solution (UN 1835);
- sodium ion batteries (UN 3551 and 3552);
- disilane (UN 3553);
- gallium contained in manufactured articles (UN 3554);
- trifluoromethyltetrazole, sodium salt in acetone (UN 3555);
- vehicle, lithium ion battery powered (UN 3556);
- vehicle, lithium metal battery powered (UN 3557); and
- vehicle, sodium ion battery powered (UN 3558).

These have brought with them a lot of other necessary changes including a new 2.9.5 dealing with sodium ion batteries, and the inclusion of the batteries in several paragraphs relating to lithium cells and batteries. The proper shipping name of UN 3292 is changed from 'SODIUM' to 'METALLIC SODIUM or SODIUM ALLOY' to clarify its applicability.

There are also some new special provisions applicable to the new entries, as well as very many amendments to existing special provisions. The more significant include:

- SP 252, relating to ammonium nitrate hot concentrated solutions;
- SP 310, covering pre-production and small production run cells and batteries; and
- SP 388, to include the new entries for battery-powered vehicles.

The new special provisions are:

- SP 399, giving a transition period for electronic detonators;
- SP 400 and 401, covering sodium ion cells and batteries;
- SP 403 on nitrocellulose membrane filters;
- SP 404 and 405 for battery-powered vehicles;
- SP 406 on the use of pressure receptacles under limited quantity provisions;
- SP 407 on the classification of fire suppressant dispersant devices;
- SP 408 on the classification of aqueous solutions of TMAH; and
- SP 409 to provide a transitional period for TMAH classification.

New packing instructions have been developed for some of the new UN entries. And there are many other amendments throughout Part 4 of the Model Regulations.

## Sustainability and decarbonisation

Most of the regulatory bodies – with the exception of Iata (the International Air Transport Association) and OTIF (the Intergovernmental Organisation for International Carriage by Rail, which is responsible for RID) – are agencies of the UN. As such, they have been charged with acting in accordance with the organisation's sustainable development goals. This is having an impact on new regulation in the transport of dangerous goods; for instance, the December meeting of the UN Committee of Experts agreed a change to the definition of 'recycled plastics material' designed to recognise and promote greater use of recyclate in packagings for the transport of dangerous goods.

Industry is keen to play its part in this process and is pushing against the boundaries of what is permitted under the transport regulations, in terms of the use of recycled plastics and alternative fuels in vehicle power trains.

The UN ECE Working Party on the Transport of Dangerous Goods (WP15), which is responsible for maintaining the technical annexes to the ADR Agreement, worked quickly last year to bring in a provision to allow the use of battery-electric and hybrid vehicles for the transport of dangerous goods (other than flammables and explosives). That was clearly an interim solution and WP15 will be working during this year and next on developing provisions to cover FL and EX vehicles, through an informal working group on electrified vehicles. That group has already identified some issues relating to ISO standards and regulations developed by the World Forum for the Harmonisation of Vehicle Regulations (WP29) and will be working with those bodies to ensure that any ADR provisions fit in with broader transport regulations. The informal working group has also noted that WP29 is looking at autonomous vehicles, and this may be something that WP15 will have to take cognisance of before very long.

WP15 will be pursuing these topics at its four scheduled meetings for the 2023/24 regulatory biennium, with the aim of finalising the 2025 text of the ADR at its session in spring 2024. They will all follow a session of the joint meeting of RID/ADR/ADN experts, which is designed to ensure continued harmonisation between those three sets of regulations, insofar as is possible and desirable, with the standing working group of OTIF's RID Safety Committee handling the incorporation of amendments into the rail regulations.

## Air and sea plans

The ICAO, through its Dangerous Goods Panel (DGP), and the International Maritime Organisation (IMO), through its Sub-committee on Carriage of Cargoes

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and Containers (CCC) and Editorial & Technical (E&T) Group, have both already started work on transposing the amendments contained in the 23rd revised edition of the UN Model Regulations into the ICAO Technical Instructions and IMDG Code; however, work so far has not taken account of the final changes adopted by the UN Committee of Experts in December. For instance, the DGP working group met last November and adopted a very lengthy list of changes, though not always in line with the UN provisions because of the specific risks posed by dangerous goods in air transport. There will, for example, be variations in the provisions for the transport of aerosols and pressure receptacles.

DGP's working group is due to meet in the spring to continue work on the revision of the Technical Instructions, when it will be able to address those amendments recently adopted by the UN Committee of Experts.

All sessions of DGP and its working group are followed by a meeting of Iata's Dangerous Goods Board (DGB), which this year will be preparing the text of the 65th edition of its Dangerous Goods Regulations for entry into force on 1 January 2024. This will not include any of the amendments in the 23rd revised edition of the UN Model Regulations, unless they are deemed to be an urgent safety issue; Iata publishes a new edition of its DGR every year, but it does not want to introduce modal disharmony by being out of step with the biennial updates to the other modal regulations.

IMO's CCC is due to convene late September, where it will aim to complete work on the incorporation of the changes in the 23rd revised edition of the UN Model Regulations into the IMDG Code, Amendment 42-24. This amendment will also include mode-specific changes. All will need to be ratified and formally adopted by the IMO Maritime Safety Committee (MSC) in 2024.

## Domestic arrangements

Almost all UN member states follow the ICAO Technical Instructions and IMDG Code for the international transport of dangerous goods by air and sea, respectively. However, the regulation of domestic surface transport is often a national affair – though an increasing number of countries are adopting the ADR as a model for their own regulations. Some nations strive to keep up with the biennial revision of international provisions, though they do not always meet that target.

In the US, for example, the Pipeline and Hazardous Materials Safety Administration, an agency of the Department of Transportation (DoT), has not been able to get its proposals to update the Hazardous Materials Regulations (HMR) found in Title 49 of the Code of Federal Regulations (49 CFR) ready in time to enter into force at the start of 2023; the PHMSA fell behind during the Trump administration, when it had to work harder to justify regulatory changes.

Last November, recognising that US HMR will be out of step with international regulations, the PHMSA issued a notice of enforcement discretion: this means it will not penalise those who ship hazardous materials under updated international provisions, pending the anticipated revision.

Canada is further behind the international provisions than the US, but Transport Canada has been consulting with industry and communities since 2019 on a major revision to its Transportation of Dangerous Goods Regulations. It published detailed proposals in the *Canada Gazette* Part I on 26 November, which aim to bring TDGR into line with international provisions and to recognise certain aspects of the US HMR to facilitate cross-border transport. Transport Canada asked for comments by 9 February, after which it will work on finalising the amendment for publication in the *Canada Gazette* Part II and entry into force later this year.

Another important change coming this year in Canada is the establishment of a registration database for all facilities involved in the import, offering for transport, handling or transport of dangerous goods. This follows concerns raised by the Office of the Commissioner of the Environment and Sustainable Development as far back as 2011, noting that Transport Canada lacked sufficient information to fully understand the risks involved in the transport of dangerous goods in the country. Following consultation with industry, Transport Canada published its proposals for the database last June. And a final ruling is expected to be published in the Canada Gazette Part II later this year.

Australia has finalised the adoption of the provisions in the 22nd revised edition of the UN Model Regulations, with the updated version of the Australian Dangerous Goods Code (ADG) version 7.8 available for use from 1 April; it will become mandatory on 1 April 2024. It should be noted that the code must be incorporated into the legislation of each state and territory. And it is by no means certain that all will have completed the necessary action by April this year. ADG 7.8 is more closely aligned with the UN Model Regulations in various areas, which improves harmonisation with the international air and sea regulations.

Elsewhere, Mexico has been working on updating its Normas (NOMs) in the area of dangerous goods transport to align more closely with the UN provisions. Some have already been published and more activity is likely this year, but no firm dates for this yet. Similarly, China has continued with its long-running process of harmonising more closely with UN (and ADR) provisions and further announcements should be forthcoming during the year.

More generally, broader adoption of the ADR, either directly into domestic legislation or as a model for compliance and enforcement, is bringing nations around the world closer into alignment. Countries in Latin America and Africa, in particular, are showing interest not only in adopting it in some form but even taking part in discussions at WP15, a move that has been welcomed by the working party.

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# What does 2023 hold for international chemicals management?

**In this second special report, published in February 2023 as part of the Chemical Watch Global Outlook series, managing editor for Europe, Leigh Stringer, takes a look at what is expected to be an important year for international work on chemicals management**

### Key developments

- Beyond 2020 global chemicals framework to be agreed in September
- Second meeting to establish a science policy panel on chemicals to be held this year
- Second meeting in May to establish a global plastics pollution treaty
- Conference of the parties of the Basel, Rotterdam and Stockholm Conventions in May

As countries and regions around the world propose, consider and adopt more and more national legislation on chemicals, international level work can often fall under the radar. However, keeping a close eye on developments this year will be key, with several major international instruments in the works that could change the course of how chemicals are produced and used globally.

## Post-2020 global chemicals framework

An international framework for chemicals and waste was supposed to be adopted in 2020 to supersede the current one – the Strategic Approach to International Chemicals Managements (Saicm). When adopted in 2007, 2020 was set as Saicm's mandated deadline. However, negotiations for its successor were delayed because of the Covid-19 pandemic.

Negotiations have now resumed, and this year will see stakeholders gather for the fifth International Conference on Chemicals Management (ICCM5) where a new framework will be agreed and adopted. The meeting could be the beginning of a more ambitious, action-oriented global framework, after it was generally agreed that Saicm had failed to achieve its goal by the deadline date.

Ahead of this, the fourth meeting of the Intersessional Process (IP4) – discussions and negotiations to inform the post 2020 framework agreement – will be held in Nairobi, Kenya from 27 February–2 March.

Draft Intersessional Process texts for the framework propose an annex that sets out specific targets for industry, something that has not been explicit in Saicm.

## Industry-related targets

**Proposed annex setting industry-related targets under a new international framework:**

"The involvement of industry and the private sector throughout the value chain needs to be significantly enhanced under this instrument at all levels," – extract from the post-2020 co-chairs draft text.

## Draft target on industry sector strategies:

**Target D6** – by 20XX, sustainable chemical and waste management strategies have b een developed and implemented for XY major economic sectors with intense chemical use, which identify priority chemicals of concern, standards and measures to reduce chemical

input and footprint along the value chains (such as textiles, electronics, building, agriculture etc).

## Related draft targets:

**Target B2** – by 20XX, stakeholders in the value chain ensure that reliable information on chemicals in [materials and] articles is available throughout their lifecycle [including at the waste stage], to enable informed decisions and safe management of chemicals in a clean circular economy.

**Target D1** – that companies consistently invest in and achieve innovations toward advancing green and sustainable chemistry, cleaner production, and the deployment of lifecycle management approaches for chemicals.

**Target D3** – by 20XX, companies, including from the investment sector, incorporate strategies and policies to implement the sound management of chemicals [and waste] in their investment approaches and business models and apply internationally-recognised reporting standards.

**Target D8** – by 20XX minimum requirements for third-party/private/non-governmental standards, labels and certification schemes are defined and reviewed on an ongoing basis; potential for harmonisation is explored, adherence increased and applied by the private sector, and monitored by governments and other stakeholders.

If included, countries around the world could use these targets as a base for policies and legislation, as well as to guide companies in their own work to manage chemicals and waste.

### Key dates

- Intersessional process meeting (IP4.2): 27 February–2 March
- Fifth meeting of the International Conference on Chemicals Management (ICCM5): 25–29 September

## Science policy panel

UN member states agreed to establish an intergovernmental science-policy panel on chemicals, waste and pollution at a United Nations Environment Assembly (Unea) meeting in Nairobi in 2021 – a move that was welcomed by stakeholders across the board.

Pollution is one of Unep's three strategic pillars, alongside climate change and biodiversity. The panel will aim to address concerns that pollution, chemicals and waste continue to receive less attention and resources, and are not adequately addressed by science policy panels, like those of the International Panel on Climate Change (IPCC) and the Intergovernmental Platform on Biodiversity and Ecosystem Services (Ipbes).

The "principal functions" set out for the panel to undertake include:

- horizon scanning, that is a systematic examination of information to identify potential threats, risks, emerging issues and opportunities, and identify issues of concern and propose evidence-based options for solutions to address them, where possible;
- making assessments on the character and scale of particular issues, and where appropriate and possible, providing potential solutions, and generating outputs that inform all stakeholders, to support them in addressing the issue; and
- provide up-to-date and relevant information, catalyse scientific research, facilitate communication between scientists and policymakers, explain and disseminate findings for different audiences and raise public awareness.

Unea organised a working group (OEWG) in 2022 to prepare proposals for the panel. Following an initial meeting (OEWG 1) in Nairobi in October last year, the group met in Bangkok, Thailand on 30 January–3 February to address procedural matters, including how it will elect its chair and bureau, as well as the rules of procedure for the conduct of its work (OEWG 1.2).

OEWG 2 will take place later this year to further define these elements, while a third is planned for 2024. Adoption of the science policy panel is scheduled for the end of 2024, early 2025.

### Key dates

- OEWG 2: 2023
- OEWG 3: 2024
- Panel adoption: late 2024/early 2025

## Global treaty on plastics pollution

During last year's Unea, environment ministers from 175 countries adopted the resolution *End plastic pollution: Towards an international legally binding instrument*. This sets out plans to develop a global treaty by 2024. The agreement has been hailed as the most significant since the 2015 Paris Agreement on climate change.

Countries and regions involved in negotiating the treaty have called for the inclusion of measures that eliminate the use of some plastic products and chemical additives.

Their interventions came during the first meeting of the Intergovernmental Negotiating Committee (INC), which took place in Punta del Este, Uruguay, between 28 November and 2 December last year.

The INC's second meeting will take place in May in Paris, while the third will be held in December at Unep's headquarters in Nairobi, Kenya.

While the aim of the treaty is to address plastic pollution, particularly in the marine environment, negotiators are considering plastics production and chemical additives to make and provide function to plastics. If these discussions progress, and negotiators include any related

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targets in the final text, companies producing and using plastics and plastic additives could be affected.

### Key dates

- Second Intergovernmental Negotiating Committee meeting: 22–26 May
- Third Intergovernmental Negotiating Committee meeting: 11–15 December
- Adoption of treaty planned for 2024

## Stockholm Convention

The Stockholm Convention on Persistent Organic Pollutants was adopted on 22 May 2001 and entered into force on 17 May 2004.

It is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have harmful impacts on human health or on the environment.

The 11th Conference of the Parties of the Stockholm Convention will be held in May, alongside those of fellow treaties, the Basel and Rotterdam Conventions. Signatories to the Stockholm Convention will consider the recommendations by its Persistent Organic Pollutants Review Committee (POPRC) to list methoxychlor, dechlorane plus and UV-328, as well as the recommendations related to decaBDE, SCCPs and PFOS, its salts and PFOSF.

Following this, the nineteenth meeting of the POPRC is scheduled to take place in October in Rome.

The committee will consider draft risk management evaluations on:

- chlorinated paraffins with carbon chain lengths in the range C14–17 and chlorination levels at or exceeding 45% chlorine by weight; and
- long-chain perfluorocarboxylic acids (PFCAs), their salts and related compounds.

It will decide whether to recommend them for listing under the convention for either elimination, restriction or reduction.

### Key dates

- Basel, Rotterdam, Stockholm 11th Conference of the Parties: 1–12 May
- Stockholm POPRC's 19th meeting: 9–13 October
- IOMC – register for information request

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# Product-level ESG risk looms large for multinationals

**This research brief, based on data from Scivera and Chemical Watch, identifies the five chemical families facing the greatest level of regulatory activity across the globe – and shows as a consequence, why producers of everyday products need to be aware of the chemical risks in their supply chains.**

## Key findings

**'Forever chemicals' in the spotlight:** A surge in new regulatory proposals and investor initiatives have taken aim at so-called "forever chemicals", which are manmade compounds that do not degrade naturally in the environment. Traces of these chemicals, such as PFASs, have been found to leach into soil, air and water, and significant exposure has been linked to health risks for humans.

**Five widely used chemicals subject to more than 1,600 regulatory developments:** Five commonly used chemical groups – per- and polyfluoroalkyl substances (PFASs), bisphenol A (BPA), ortho-phthalates, medium-chain chlorinated paraffins (MCCPs) and polyvinyl chloride (PVC) – are the subject of more than 1,600 current and pending regulatory developments globally.

**Ortho-phthalates underscore hidden risks in supply chain:** Less well-known chemicals, such as ortho-phthalates, which are used in everything from food production materials and packaging to medical devices, are currently in the crosshairs of more than 400 different regulatory initiatives. Three hundred of these were introduced in 2019 alone.

## Executive summary

A perfect storm of environmental crises, pandemic and economic uncertainty has spurred a global reckoning on public health, sustainability, worker safety, wellness and corporate responsibility. As a result, regulators around the world are sharpening their pencils to launch new environmental, social and governance (ESG) and environmental, health and safety (EHS) requirements and the world's largest corporations, institutional investors and government leaders have all put their voices and big dollars behind headline-grabbing sustainability initiatives.

> Based on this analysis, we found a total of more than 1,600 global regulatory initiatives currently pending that will create serious challenges for industries including: packaging, cosmetics, children's products and toys, electronics, textiles and furniture.

While most of these initiatives have focused on topline environmental and sustainability targets, such as achieving net zero status by 2025 or participating in the UN Global Compact, few have gone deep enough to address the ESG risks enmeshed in their supply chains.

The individual products we use every day – from footwear and apparel to cosmetics and housewares – are loaded with compounds and chemicals that are starting to come into the crosshairs of ESG regulations

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worldwide. Few companies that produce these products are ready for the looming financial, reputational and operational risks that will come along with product-level ESG regulation.

To help put this growing constellation of risks in perspective, we have scoured our Scivera library of chemical hazard assessments and our Chemical Watch database of global chemicals regulation to identify the top five chemical families widely used in products ranging from clothing to cosmetics to home goods to packaging that are currently facing the greatest regulatory scrutiny on a global basis. Based on this analysis, we found a total of more than 1,600 global regulatory initiatives currently pending that will create serious challenges for industries including: packaging, cosmetics, children's products and toys, electronics, textiles and furniture.

## Analysis methodology

To conduct this analysis, Scivera toxicologists reviewed the Restriction Roadmap issued by the European Union and other global regulators to identify chemical groups that are likely to be subjected to the largest number of new regulations, along with the product families and industries in which they are used most frequently. These chemical groups were then cross-referenced against the Chemical Watch database of global chemicals regulation to determine the total number of current and pending regulations affecting each chemical group globally, and analysed by Chemical Watch and Enhesa's team of regional chemicals management experts.

The analysis included global, national and regional laws, regulations, proposals and policy recommendations that have either been proposed or come into force over the past 10 years.

## Results

Regulatory authorities around the world have increasingly trained their focus on putting strict controls on the use of chemicals that have been found to pose human health risk. Within that broad universe of chemical management regulation, a handful of widely used chemicals and chemical groups continue to claim the lion's share of attention.

## PFASs in the spotlight

Based on our analysis, per- and polyfluoroalkyl substances, commonly referred to as PFASs, are currently leading the way in global regulatory scrutiny. This well-known chemical group has been used since the 1950s in everything from nonstick cookware, water-repellent clothing, stain-resistant fabrics, packaging, flame retardants, cosmetics and more. Colloquially known as "forever chemicals", PFASs do not degrade naturally in the environment, so traces have been found to leach into soil, air and water and significant exposure has been linked to a host of health risks for humans.

**Global regulatory developments on some hazardous chemicals**

| Chemical group | Total regulatory developments | Common applications | Affected industries |
|---|---|---|---|
| Per- and polyfluoroalkyl substances (PFASs) | 1,200+ | Textiles (including furniture), paper coatings, food packaging, pots and pans, floor polishes, window cleaners, car care products, ski waxes, lubricants and fire foam, cosmetics | Chemical and product manufacturing, consumer-packaged goods (which includes cosmetics), personal care, home care, textiles, food and beverages |
| Ortho-phthalates | 400 | Personal care, cleaning products, PVC | Household goods, cosmetics, manufacturing |
| Bisphenol A (BPA) | 201 | Flame retardants, UV stabilisers, pH indicators or as a developer in thermal printing, CDs, DVDs and dental materials, plastic bottles, lunch boxes, electronics, building materials, food packaging | Food and beverage, manufacturing, consumer-packaged goods, electronics |
| Medium-chain chlorinated paraffins (MCCPs) | 1 | Textile auxiliaries, plasticisers, flame retardants, children's products, lubricants, metal working fluids, fillers, coating materials; PVC plastics, paints | Manufacturing, toys, household goods |
| Polyvinyl chloride (PVC) | 14 | PVC can be used in a broad range of applications, from car seals and flexible roof membranes to pipes and window frames and plastic packaging | Building and construction products, manufacturing, household goods |

To-date, roughly 1,200 global regulatory initiatives have been launched to regulate PFASs, with 800 of these emerging over the past three years. In the US, in 2022 alone, a total of 145 new bills governing the use of PFASs were proposed, resulting in one federal law and 16 new laws in 11 US states. Between 2020 and 2021, 38 pieces of new legislation were passed.

Recent legislation has been focused primarily on the use of PFASs in firefighting foams, children's products, furniture and textiles. Recently, US state legislatures and state agencies have been preparing to expand that scope to include the use of PFASs in more applications, including cosmetics and personal care products, food packaging materials, ski wax and other consumer products. While California, Maine, New York, Washington and Vermont are leading the charge, at least 15 other states have some form of laws or regulations restricting the use of the chemicals in various products. Colorado and Maine have banned several categories of products containing PFASs altogether.

> Now is the time to start asking the tough questions and digging deep into the detailed chemical composition of everything from apparel to packaging to make sure ESG goals are not derailed by hidden risks.

Internationally, perfluorooctanoic acid (PFOA) – a "branch" of chemical groups under PFASs, has been named as a persistent organic pollutant (POP) under the Stockholm Convention, which has been ratified by 186 and 31 EU-member states and jurisdictions that adopt EU regulations. For many of these countries, any restrictions required by the Convention will automatically or will soon become part of their national law. In addition, Denmark, Germany, the Netherlands, Norway and Sweden – with the support of France – have initiated their own studies on PFASs and were expected to propose new restrictions to Echa in February 2023.

## One word: plastics

While PFASs have received a great deal of media attention recently, the remaining chemical groups included in this analysis have not received the same level of public scrutiny. Yet these chemicals – bisphenol A (BPA), ortho-phthalates, medium-chain chlorinated paraffins (MCCPs) and polyvinyl chloride (PVC) – which are ubiquitous in consumer-packaged goods, electronics and children's products, are currently the subject of more than 600 different regulatory initiatives around the world.

With applications ranging from the manufacturing of plastics to the development of lubricants and coolants to building and construction, these are some of the most widely produced chemicals in the world. Ortho-phthalates, for example, which are plasticisers used in everything from food production materials and packaging to medical devices, are currently in the crosshairs of more than 400 different regulatory initiatives. Three hundred of these were introduced in 2019 alone as a number of European countries introduced restrictions on the use of the chemical in electrical and electronic products and food contact materials. This year, the US introduced 37 different bills addressing the use of ortho-phthalates and 10 states introduced potential restrictions or bans on the substances. Maryland and California have already banned the substances' use in cosmetics.

Similarly, some 201 new regulatory initiatives have been introduced to address the use of BPA in products across the Americas, Europe and Asia. MCCPs and PVC have seen lower volumes of legislative activity, but they remain in the spotlight. The EU is currently evaluating whether to restrict the use of MCCPs in electronics in a proposal slated to go into effect after 2024. PVC has been banned in certain packaging materials in South Korea, New Zealand and Taiwan, and the US is currently considering designating the material as hazardous waste under the Resource Conservation and Recovery Act, which will introduce a host of new requirements for manufacturers.

## Discussion

As the world starts to get serious about sustainability and the impact that these chemicals have on our health and the health of our planet, thousands of everyday products are coming under greater regulatory scrutiny. And that is going to pose big challenges for the corporations that produce and distribute these products globally.

Not only will they need to retool and reengineer decades-old manufacturing processes, but they will need to navigate a labyrinthine global network of national and regional regulations that are rolling out at breakneck pace with each passing day. Simply keeping pace with new requirements and managing supply chains accordingly is poised to become the operations management challenge of our time.

The first step for many companies in navigating this transformation will be awareness. While the major chemical manufacturers and distributors at the centre of these issues are likely aware of many of these pending regulations, the producers of the end products that use them are often completely ignorant to the chemical risks hiding in their supply chains. Now is the time to start asking the tough questions and digging deep into the detailed chemical composition of everything from apparel to packaging to make sure ESG goals are not derailed by hidden risks.

## Authors

This Enhesa Research Brief was authored by Lori Bestervelt, PhD, Global Operations Lead, Scivera, part of Enhesa; Colleen McLoughlin, PhD, Director, Toxicology, Scivera, part of Enhesa; and Nhat Nguyen, Chief Analyst, Chemical Watch, part of Enhesa.

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# The cosmetics milestones you need to know about in 2023 and beyond

In this infographic, first published in March 2023, get a view of some of the most important dates for the sector

## 2023

### 1 January

China: The Cosmetics Supervision and Administration Regulation (CSAR) requires all safety-related information on raw materials in a cosmetic product to be submitted for new registrations

### 1 January

New York: Maximum allowable concentration for 1,4 dioxane must be at or below 2 ppm for personal care products, and at 10 ppm for cosmetic products

### 1 May

China: Multiple CSAR submission deadlines for information and data on cosmetic products including ingredients, source of raw materials and printed label claims; and for adding special mark to previously registered children's cosmetics

### 11 May

Asean: A ban on using skin-lightening agent deoxyarbutin as a cosmetic ingredient in force in all member countries, except Myanmar

### 31 May

New Zealand: Submission deadline for the Environmental Protection Authority's public consultation on its proposal to phase out PFAS in all cosmetics by 2025

### 21 August

South Korea: Hair dye products may not contain the following substances: o-Aminophenol, Catechol (pyrocatechol), m-phenylenediamine, m-Phenylenediamine HCl, Pyrogallol

### 1 November

Brazil: Mandatory requirements on labelling language for personal hygiene products, cosmetics and fragrances takes effect

### 1 November

Asean: Permission required to use preservative climbazole in cosmetics

## December

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

## 21 November

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

## 2024

## 31 December

New York: Maximum concentration of 1,4 dioxane in household and personal care products must be 1 ppm or less

## December

US federal: Under the Modernization of Cosmetics Regulation Act, manufacturers of cosmetic products must register their facilities and submit product listings to the FDA

## 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

## 2030

## 1 January

Maine: A person may not offer or distribute for sale any product containing intentionally added PFASs, unless the product has been exempted

# Food contact materials key dates in 2023 and beyond

## Keep your compliance goals on track

Increased regulatory scrutiny of entire product lifecycles in the food and drinks industry is transforming the compliance landscape for the sector.

Get a view of some of the most important dates affecting food contact materials (FCMs) in this Chemical Watch infographic.

**2023**

### 1 January

**California:** Online disclosure requirements in effect for cookware of any PFASs in cookware handles or food-contact surfaces. On-product labelling requirements come into force on 1 July 2023

### 3 January

**Brazil:** National-level adoption of Mercosur Resolutions amending positive list of substances and other provisions, aimed at food contact plastics

### 3 January

**Thailand:** Mandatory standards in force affecting plastic utensils and containers for food for microwave use

### February

**Washington:** State restrictions on PFASs in plates, food boats, pizza boxes and wraps and liners begins

### 1 February

**Victoria, Australia:** State ban begins on single-use plastic items including (among others) drinking straws, cutlery, plates, drink stirrers, expanded polystyrene food and drink service containers and any cover lid made from conventional, degradable and compostable materials. Exemption on some items that have been machine-packaged in place until 31 December 2025

### 3 April

**Thailand:** Mandatory standard in force affecting fluoro-polymer coated utensils in contact with food

### 14 May

**Croatia:** Producers of food contact articles must report their activity to the Ministry of Health

### 14 June

**EU:** Latest date for industry to apply for authorisation under REACH for phthalate (inc DEHP) use in food contact materials

### 30 June

**China:** Revised food contact standard for paper and cardboard enters into force

### Q2

**EU:** Revision of EU Rules on Food Contact Materials and Commission adoption anticipated

### 1 July

**Vermont:** State to prohibit manufacture, sale or distribution of food packaging containing intentionally added PFAS and bisphenols; and its components containing intentionally added ortho-phthalates

### 10 July

**EU:** From this date, only plastics containing recycled material manufactured with a suitable recycling technology may be placed on the market

### 1 July

**Western Australia:** State ban on supply of barrier/produce bags; microbeads; polystyrene packaging; polystyrene cups; coffee cups and lids; cotton buds with plastic shafts; lids for cups, bowls and containers; and oxo-degradable plastics (plastics designed to break up more rapidly into fragments under certain conditions); and provision of false or misleading information about a banned plastic item

## Year end

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

## 2025

## 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

## 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

## 1 January

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

## 2024

## 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

## 31 December

**Connecticut:** State ban on the sale of food packaging containing intentionally added PFAS

# PFAS key dates in 2023 and beyond

## Keep up with the latest restrictions

Use this Chemical Watch infographic, first published in April 2023, for a view of some key dates affecting the use of PFASs in products such as cookware, personal care and firefighting foams..

**2023**

### 1 January

**California:** Manufacturers required to disclose online any PFASs in cookware handles or food-contact surfaces online. On-product labelling requirements also required from 1 July

### 1 January

**Maine:** State restrictions on PFASs in carpets, rugs and textile treatments enter into force

### 7 February

**EU:** Publication of EU countries' PFAS restriction dossier

### 1 February

**Washington:** State restrictions begin on PFASs in plates, food boats, pizza boxes and wraps and liners

### 22 March

**EU:** Start of the public consultation on the PFAS restriction dossier

### March

**EU:** Adoption of Echa's Rac opinion

### June

**EU:** Seac's final opinion for the PFAS firefighting foams restriction to be adopted

### 1 July

**California:** State to adopt first-ever prohibition on PFAS-containing juvenile products

## 2024

### 1 January

**Colorado, Connecticut, Maryland, Minnesota and Rhode Island:** PFAS-containing food packaging bans start

### 31 December

**China:** Exemptions for the ban on production, processing and use of perfluorooctanesulfonic acid and its salts, and perfluorooctanesulfonyl fluoride (PFOS group) expire

### Q2

**US:** EPA plans to publish final TSCA PFAS reporting rule (exact timing uncertain)

### Q2

**Canada:** Expected release of Health Canada and the ECCC's 'State of PFAS report'

### 1 July

**Vermont:** State restrictions on PFASs in food packaging, carpets, rugs and textile treatments begin

## 2025

### January

**California:** State to prohibit textile articles that contain regulated PFASs

**California:** State expands existing law to prohibit intentionally added PFASs in cosmetic products

**Colorado:** State requires manufacturers of impacted products to provide written notification due 30 days before 1 January 2025 for existing products

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

**Illinois:** State to ban class B firefighting foam containing intentionally added PFASs and requires manufacturers of these products to register with the state EPA

## CONTACTS

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|---|---|
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| Ownership | New Mountain Capital and Endicott Capital |
| Locations | US, Canada, Europe, Asia |
| Founded | 1988 |

## OVERVIEW

3E™ delivers intelligent compliance solutions that empower companies around the globe to reduce risk, drive continuous improvement and create new growth opportunities. 3E has set the standard for combining regulatory expertise and enriched global compliance content, transforming it into actionable intelligence to enhance chemical and workplace safety, product safety and stewardship supply chain transparency and sustainability.

| VITAL STATISTICS | 2021/22 |
|---|---|
| No of offices | 13 |
| No of countries represented | Global |
| Staff, group | 525 |
| Staff, chemical service provision | 80% |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Carlsbad, CA, US: 3E's headquarters

Bethesda, MD, US; Canton, OH, US; Fort Collins, CO, US; Montreal, QC, Canada; Copenhagen, Denmark; Frankfurt, Germany; Markdorf, Germany; Siegen, Germany; Sofia, Bulgaria; Krakow, Poland; Beijing, China; Tokyo, Japan

## SERVICES PROVIDED

**Product safety and stewardship tools and decision support**

**Regulatory research and monitoring** – subscription-based online reference tools for researching and tracking how chemicals and substances are regulated around the globe. Tools for scanning the horizon for emerging regulations. Content coverage is global in scope and includes chemicals, cosmetics, personal care, food contact and food, flavours and beverages. Users can run compliance checks for formulations and quickly determine how changing regulations impact products and markets.

**Notification, registration and reporting**

**Global chemical registration, notification and reporting** – consulting support for new chemical notification, chemical registration and reporting, including REACH and REACH-like requirements.

**EU poison centre notifications** – solutions and services to help companies meet both current and upcoming notification obligations.

**Scip reporting** – 3E™ provides an end-to-end solution for Scip notification, streamlining supplier data acquisition, dossier creation and validation, notification submission and ongoing change management.

**System-integrated data, rules, phrases and templates** – integrated chemical, regulatory, toxicity and ecotoxicity data, dangerous goods content and vendor SDS data for authoring SDSs and labels and managing EHS compliance activities. Integrates with any third party platform including advanced/specialised integration with SAP EHS and S/4HANA for product compliance.

**SDS authoring and distribution**

**SDS and label authoring software** – an enterprise software solution suite designed for companies' in-house EHS staff to produce SDSs, labels, exposure scenarios and other hazard communication documentation using value-added, up-to-date regulatory content.

**SDS authoring services** – on demand and subscription-based assistance with authoring SDSs, labels and exposure scenarios via 3E's own fully dedicated, inhouse staff of highly qualified and multilingual authors.

**SDS distribution** – facilitates the dissemination of SDSs to all stakeholders to fulfil hazard communication requirements.

**Chemical and workplace safety compliance**

**SDS and chemical management** – powerful suite of products and services for the management of vendor supplier SDSs.

**Risk assessment** – analyse the toxicity of chemicals used in the workplace to determine risk profile. Fulfil hazard communication requirements with instant access to SDSs and chemical inventory information.

**Dangerous goods transportation** – around-the-clock global hotline access for guidance and classification of shipping hazardous materials for any mode.

**Emergency response** – emergency response for spills, ingestions or exposures and for dispatching emergency responders to an incident.

**Disclosures, permits and reports** – outsourced services for researching, identifying, analysing, tracking, completing and submitting required disclosures, permits and reports.

**Hazardous waste management and classification services** – supports customers' hazardous waste management obligations, including proper storage and disposal.

**Supply chain stewardship**

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

**Consulting services**

**Product compliance** – a full spectrum of services that address the challenges of bringing a product to market and managing compliance from a global perspective.

**TSCA** – services range from fully outsourcing TSCA compliance to project based, function-specific areas.

**Safer chemical analytics** – intelligent hazard and risk assessment and management services that assess the relative hazards of chemicals or products, including predictive toxicology and interim techniques such as read across and Qsar.

## CORPORATE DEVELOPMENTS AND ACHIEVEMENTS

| | |
|---|---|
| **1998** | Company founded |
| **2004** | Acquisition: Ariel Research Corporation; international expansion |
| **2007** | Acquisitions: HSE Systems and MSDS Solutions |
| **2010** | Acquired by Verisk Analytics |
| **2014** | Expanded global presence with office in Tokyo |
| **2018** | Expanded global presence with office in Beijing |
| **2019** | Acquisition and Strategic Software Development Alliance: SAP's Content as a Service (CaaS) business, which included the Environmental Health and Safety Regulatory Content (ERC) and Environmental Health and Safety Regulatory Documentation (ERD) teams and data assets |
| **2022** | Acquired by New Mountain Capital |
| **2022** | Acquired Toxnot |

## PARTNERS

Airsweb, ASD, BIOVIA, Cority, Dotmatics, ERM, Enablon, Flashpoint, Gensuite, Intelex, ISO Metrix, Jaggaer, Kelaroo, Links-AS, Reliance Label Solutions, SAI Global, SAP, SI PRO, The Chemical Daily, and more.

## CLIENTS

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

## TESTIMONIALS

"3E allows us to make the world a safer place by giving us clarity and the ability to be compliant in the regions of the world where Valvoline decides to serve. SAP is our core platform that we are using for financials and supply chain, but we also use it as a key portion of our regulatory compliance programme. The content that 3E provides matches very nicely with the functionality that SAP provides and allows us to stay current with the regulations that are coming along as well as allowing Valvoline to expand almost seamlessly into the regions that we wish to do business in."

*Global ERP Services Manager, Valvoline*

## CASE STUDY 1: CHS cultivates chemical and workplace safety with 3E Solutions

Industry: agronomy, agriculture, energy, food, food ingredients, oil and gas, lubricants

**Challenges:**

- Lack of access to updated, compliant SDSs in all locations
- Inefficient chemical management and inventory tracking
- Highly manual processes for meeting Service Availability and Readiness Assessment (SARA) reporting requirements

**Results:**

- Saving 15 minutes per SDS by eliminating manual review and data extraction processes
- Elimination of manual processes including SDS obtainment and SDS filtering and indexing
- Streamlined SARA reporting
- Standardisation of processes resulting in cost savings
- Ease of integration with third party applications

## CASE STUDY 2: Global food and flavours manufacturer feeds SAP EHS with integrated content from 3E

**Industry: Food and flavours**

**Challenge:**

The global food and flavouring manufacturer did not have an efficient method for fulfilling its SDS and labelling requirements.

**Solution:**

3E Integrated Content for SAP EHS and an array of services.

**Results:**

The popular manufacturer leverages 3E North American and European product safety data, physical chemical, toxicological and ecotoxicological content (PCTEC), expert rules, templates and phrases to fuel its SAP EHS platform for SDS authoring. It also relies on 3E to obtain and integrate its vendor raw material SDS data for use in the authoring process. The solution has significantly streamlined the manufacturer's compliance processes as well as increased its level of compliance.

## STAFF SELECTION

**Chanyanis Utiskul, Regulatory Research Analyst, Asia Pacific**

As 3E's Asia Pacific regulatory expert, Chanyanis Utiskul is responsible for assessing regulatory statutes and regulations for the Asia-Pacific region. She closely monitors and provides in-depth analysis of regulatory compliance information and translates this into accurate regulatory content for 3E's propriety products including 3E Insight for Chemicals, 3E Insight for Food and 3E Monitor.

Prior to joining 3E, Ms Utiskul gained more than 11 years of governmental and industrial expertise in the field of regulatory compliance and international trade affairs. She was a trade expert at the Royal Thai Embassy Washington, DC and the attorney-at-law at Pepsi Co. in Bangkok, Thailand.

**Erin Adams**

Erin Adams has more than a decade of domestic and international regulatory experience. She is a global SDS and label author, managing projects for clients from a variety of industries. Ms Adams also works with the software development team to interpret regulations and provide guidance on implementation, ensuring ultimate regulatory compliance. Her work in household, industrial and institutional chemicals and experience in areas of formulation, Quality Management Systems (ISO9001), transportation compliance and product management gives Ms Adams a unique perspective on the daily regulatory challenges facing all levels of the chemical industry.

**Isaac Powell, Principal Product Manager**

Isaac Powell has nearly two decades of EHS experience with implementing compliance management programmess including regulatory reporting, emergency response, hazardous waste and dangerous goods management. In his current role, he oversees the product development of 3E's supply chain compliance solution. Prior to this position, he was the Product Manager for 3E Technical Services including emergency response, hazardous waste management, transportation, classification and regulatory reporting services.

Mr Powell is a member of the AWMA, AHMP, SCHC, and National Fire Protection Association & International Code Council.

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| Directors | Lynn L Bergeson and Lisa M Campbell |
| Ownership | Private company, affiliated with: Bergeson & Campbell, PC B&C® Consortia Management, LLC |
| Locations | US, UK, EU, and China |
| 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, Europe and China, 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

| VITAL STATISTICS | 2021/22 |
|---|---|
| No of offices | 4 |
| No of countries represented | >25 |
| Staff, group | 35+ |
| Staff, chemical service provision | 35+ |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

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

China: 1009 Tongguang Tower, No 12 Nongzhanguan Nanli, Beijing, China 100125, Tel: +86 108 453 4538

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 (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 (i.e. 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 (**www.tscatutor.com**), and Fifra Tutor (**www.fifratutor.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 – Senior Regulatory Consultant**

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.

**Emma Louise Jackson, CBIOL, MSB – Regulatory Consultant**

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.

**Edith G Nagy – Regulatory Consultant**

Ms Nagy assists clients with EHS compliance, with a focus on pesticides, biocides and product stewardship. Ms Nagy's international experience and extensive language skills (English, Romanian, Hungarian, German, Spanish, French and Italian) are valuable assets to clients pursuing and maintaining commercialisation in multiple global markets.

**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.

apeiron

## CONTACTS

| | |
|---|---|
| Web site | www.apeiron-team.eu |
| E-mail | info@apeiron-team.eu |
| Head office | Berten Pilstraat 4, 2640 Mortsel, Belgium |
| Tel | +32 3 808 20 67 |
| Contact | Elke Van Asbroeck |
| Directors | Elke Van Asbroeck, 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 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 | 2021/22 |
|---|---|
| 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 nanomaterials 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**

- 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 identificaton, hazard assessment, study monitoring, exposure and risk assessment, evaluation of PBT and endocrine disrupting (ED) properties, integration of nanomaterials 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.

**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!

## CORPORATE DEVELOPMENTS & 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<br>Submission of various Union authorisations under the BPR<br>Successful conclusion of a BoA case on additional persistence testing<br>Development of an inhouse RMOA methodology.<br>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<br>Managing outsourced REACH registrations for more than 400 substances. Development of more than five authorisation dossiers |
| **2022** | 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.

## CLIENTS

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

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

## TESTIMONIALS

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

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

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

"During the 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*

## 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 persistence 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 luclid 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
- Due diligence

**Hiram Moerman – Chemical Engineer**

- Previously in polymer industry
- REACH authorisation
- Alternative assessment
- Risk management option analysis
- Sustainable chemicals management
- 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 | www.arcadis.com |
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| Contact | Europe: maaike.bilau@arcadis.com<br>+32 492 73 0489<br>North America: andy.newcombe@arcadis.com<br>+1 302 584 5999 |
| Directors | Peter Oosterveer, CEO<br>Alan Brookes COO |
| 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 and safety and sustainability into the design and delivery of solutions across the globe.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €4bn |
| Turnover, chemical service provision | €10m |
| No of offices | 350+ |
| No of countries represented | 70 |
| Staff, group | 36,000+ |
| Staff, chemical service provision | 70+ |

## SERVICE AREA BREAKDOWN

## 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 programmes and audit services**

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

**Worldwide regulatory monitoring**

Includes continuous regulatory tracking of changes for emerging and existing chemical (eg REACH, GHS, BPR) and product regulations (eg PPWR, WEEE, RoHS, MDR, batteries, waste).

Continuous tracking of changes driven by the European Green Deal and the European Commission's chemicals strategy for sustainability evaluating the potential risks and opportunities this creates for your business.

**Data management for product compliance**

Includes 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**

Includes chemical (plus nanomaterials) 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**

Includes financial management, third party communication and representation (Siefs, MS CA, Echa), role as trustee, as well as technical consultant for dossier preparation (eg product family, union versus national authorisation, testing strategy, read-across justification, etc).

**Agrochemical fate and exposure**

Includes 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 & ACHIEVEMENTS

| | |
|---|---|
| **1888** | Parent company, Heidemij, formed in the Netherlands |
| **1998** | Global company becomes Arcadis |
| **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 |
| **2022** | 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 |
| **2022** | 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, socio-economic analysis and the chemical safety report. Arcadis provided support in the identification of exemptions and overall strategy development.

Arcadis has supported companies in answering questions from the committees and in communication with Echa. For all dossiers reviewed by Echa and the committees, feedback was very positive.

## CASE STUDY 2: Authorisation dossiers for biocidal products

Arcadis has supported the preparation of multiple applications for authorisation of biocidal products. The support included developing a testing strategy, human health and environmental risk assessment as well as definition of claims. Support also includes all communication with the competent authorities as well as adaptation of the dossier.

## 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 analytical 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 California regulatory authorities and tracks Prop 65 trends, such as those related to bisphenol A (BPA), phthalates, lead, and per- and polyalkyl substances (eg PFOA, PFOS).

## CASE STUDY 4: Product stewardship organisational redesign and supporting tool selection

Arcadis has supported multiple global companies with defining or redefining 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 to support plant protection product re-authorisation in Europe

To support the re-registration of a plant protection product (PPP) in the EU, a search for publicly available groundwater monitoring data was conducted across 17 countries by performing online database searches and contacting regulatory agencies, authorities and organisations. The data collected were cleaned, processed, and compiled into a single data structure to facilitate detailed statistical analysis.

At approximately 100 sites with low-level PPP concentrations located in Belgium, the Czech Republic, France, Slovakia, Slovenia, and Portugal, field surveys were conducted to better understand the agricultural setting and environmental factors that might have contributed to the groundwater detections observed. Surveys across all countries were conducted using an Arcadis developed mobile application that captured pertinent data.

## CASE STUDY 6: Life cycle impact assessment and cost benefit analysis to study the feasibility of industrial symbiosis opportunities

The International Copper Alliance (ICA) aimed to identify possible opportunities for its members for industrial symbiosis and to quantify them.

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 by means of a Life Cycle Assessment (LCA), which analysed the environmental feasibility of the industrial symbiosis solutions, 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 – Toxicology and Product Stewardship**

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.

**Andy Newcombe – Agrochemical Product Stewardship**

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 environmental fate issues associated with their products and has considerable experience in providing clients with litigation support services.

**Chrystelle Verhoest – Senior Product Sustainability Consultant**

Chrystelle has more than ten years' experience in bio- and circular economy as well as operational experience in environmental and social governance in the energy sector. She is responsible for designing and providing solutions that support customers in their journey towards more sustainable production.

**Christina Clements – Senior Product Stewardship Consultant**

Christina has more than 25 years' of 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 CLP, TSCA, Fifra and import/export of chemicals and consumer products.

**Nele Deleebeeck, PhD – Senior Environmental Risk Assessor**

Nele has more15 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 plays a key role in the preparation of applications for authorisation: she has been involved in the development of case- and site-specific chemical safety assessments/risk reduction plans, the comparison of intrinsic hazards of potential alternatives with those of the SVHC, and in the assessment of social, economic and environmental impacts of the different scenarios included in the SEA.

arcerion
REACH | CLP | Seveso | Biocides

## CONTACTS

| | |
|---|---|
| Website | www.arcerion.com |
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| Head office | Arcerion GmbH, Gabrielenstr. 15 80636 München, Germany |
| Tel | +49 89 38899797 |
| Fax | +49 89 38899798 |
| Contact | Anne Feldhaus |
| Directors | Dr Michael Piber, Executive Director<br>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 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 | 2021/22 |
|---|---|
| No of offices | 3 |
| No of countries represented | Global |
| Staff, group | 18 |
| Staff, chemical service provision | 11 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

München, Germany

Hamburg, Germany

## 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 & 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 prove 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 of experience in 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 of 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.

ARCHE CONSULTING

## CONTACTS

| | |
|---|---|
| Website | www.arche-consulting.be |
| E-mail | info@arche-consulting.be |
| Head office | Liefkensstraat 35d, 9032 Gent-Wondelgem, Belgium |
| Tel | +32 9 216 70 38 |
| Contact | Marnix Vangheluwe |
| Directors | Marnix Vangheluwe<br>Patrick Van Sprang |
| 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 | 2021/22 |
|---|---|
| No of offices | 2 |
| No of countries represented | 1 |
| Staff, group | 41 |
| Staff, chemical service provision | 32 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Tiensevest 132, 3000 Leuven, Belgium. Tel: +32 16 28 49 01

## 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 & 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
- Fieldfisher
- Fertiliser Consultants Network
- 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, etc;
- 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 **www.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 – Managing Director ARCHE Consulting**

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 – Managing Director ARCHE Consulting**

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 – Senior Science Project Manager**

Frederik obtained his PhD degree in bio-engineering 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 – Expert Science Manager**

An graduated in 2004 as master in bio-engineering (gene technology) from the Catholic University of Leuven. She obtained her PhD in medical sciences in 2009. From 2010 till 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 | www.arrowregulatory.com |
| E-mail | info@arrowregulatory.com |
| Head office | 6th Floor East West Building<br>2 Tollhouse Hill<br>Nottingham, NG1 5FS, UK |
| Tel | +44 1159 352 243 |
| Contact | Dr Sara Kirkham/Dr Carlo Poncipe |
| Directors | Dr Sara Kirkham<br>Dr Carlo Poncipe<br>Elicia Hodgson<br>Dr Joanna Ganatsiou (Austria) |
| Ownership | Limited Company |
| Locations | UK, Ireland, Austria |
| Founded | May 2016 (UK), Oct 2017 (IE), Mar 2020 (AT) |

## OVERVIEW

Arrow Regulatory has extensive knowledge of chemical legislation, particularly in the EU biocidal products Regulation, REACH and CLP, as well as the equivalent GB regulations. The company has considerable experience in the development of regulatory strategies, designing test programmes and providing tailored advice, in addition to the preparation of dossiers and risk assessments. Working with both international consortia and global partners Arrow Regulatory has experience in obtaining worldwide registrations for chemicals and biocides.

Collectively the Arrow Regulatory team has prepared in excess of 65 REACH lead dossiers and worked on 38 different biocide active substance inclusion dossiers, more than 95 active substance PT combinations and close to 50 single product/product family authorisations.

Arrow Regulatory is able to offer an integrated and tailored service with our experts adding value by applying their thorough understanding of separate pieces of legislation to each company-specific enquiry. Our aim is to provide a high level of service to all clients, irrespective of their size.

| VITAL STATISTICS | 2021/22 |
|---|---|
| No of offices | 3 |
| No of countries represented | 3 |
| Staff, group | 11 |
| Staff, chemical service provision | 11 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Nottingham, UK

Dublin, Ireland

Innsbruck, Austria

## 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– 2023** | Team expands to eleven consultants |
| **2017** | Formation of Arrow Regulatory (Ireland) Limited in Dublin, Ireland |
| **2020** | Formation of Arrow Regulatory GmbH in Innsbruck, Austria |

## PARTNERS

Available on request.

## 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 of 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 of 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 12 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 16 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 16 years' experience in the preparation of active substance dossiers and biocidal product authorisations under the BPD and BPR. Working on consortium management, devising product families' regulatory strategies, 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.

**Michael Werner, Dr rer. nat.**

Michael is an expert regulatory toxicologist at Arrow Regulatory. He is a chemist as well as certified (DGPT) and Eurotox registered toxicologist, with almost 30 years of experience in human health hazard, exposure and risk assessments for PPPs, biocides and industrial chemicals. Within the field of biocides, Michael has focused primarily on human health, efficacy and regulatory aspects, across the majority of product types.

He provides regulatory as well as scientific/technical advice to clients with a view to the development of tailor-made dossier strategies for the approval of bioicidal active substances and authorisation of biocidal products/biocidal product families including their discussion and defence before regulatory authorities at national and EU level. Over the last 20 years of working in the field of biocides, Michael has prepared more than 30 biocidal active substance and product dossiers.

ARTEMISA

| CONTACTS | |
|---|---|
| Website | www.artemisa.si |
| E-mail | registrations@artemisa.si |
| Head office | Artemisa d.o.o., Cvetlična ulica 20, 2270 Ormož, Slovenia |
| Tel | +386 8 181 00 20 |
| Contact | Ms Bojana Zgonec |
| Directors | Ms Bojana Zgonec |
| Ownership | Private company |
| Locations | Slovenia, Slovakia, Poland, Hungary, Croatia |
| 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 | 2021/22 |
|---|---|
| No of offices | 4 |
| No of countries represented | 27 |
| Staff, group | 18 |
| Staff, chemical service provision | 13 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

**Plant protection services in eastern EU, Ukraine, Georgia, CIS countries (Russia, 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-need 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; and
- biopesticides.

**Regulatory services for registration of fertilisers, biostimulants and supplementary soil substances in the eastern EU, Ukraine, Georgia, CIS countries (Russia, 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 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 language;
- 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 (Russia, 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, reformating 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 different countries of the region 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 & ACHIEVEMENTS

| | |
|---|---|
| **2018** | Company established |
| **2018** | Branch offices established in Poland and Slovakia |
| **2020** | Services extended to CIS countries and Turkey |
| **2021** | Branch office in Croatia |

## 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 the 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.

## 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 | www.auxilife.com |
| E-mail | info@auxilife.com<br>info@eu.auxilife.com |
| Head office | Auxilife Scientific Services Pvt. Ltd.– India, A-503, Speciality Business Centre, Balewadi Road, Balewadi, Pune-411045, Maharashtra, India |
| Tel | +91 7757024864<br>+46 101022289 |
| Contact | Pooja Vishnoi and Nisar Shaikh |
| Directors | Shisher Kumra<br>Niraj Kumra |
| Ownership | Private company |
| Locations | India |
| Founded | 2011 |

## OVERVIEW

Auxilife Scientific Services Pvt Ltd is a regulatory consulting company and a subsidiary fully owned by GPC Group, Sweden. For the past 12 years, Auxilife has been supporting agrochemical companies in successfully registering products in Europe, India and other key countries and regions. Auxilife's aim is to remove regulatory barriers and to assist clients in achieving their market growth aspirations.

Over the years, EU and India's regulatory projects have successfully corroborated Auxilife's strategy of supporting the agrochemical industry with solutions in the most economical way.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €0.5m |
| Turnover, Agrochemical and Biocide service provision | €0.5m |
| No of offices | 1 |
| No of countries represented | 15 |
| Staff, group | >20 |
| Staff, chemical service provision | >15 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

India

## SERVICES PROVIDED

**Regulatory dossier and submission services**

Regulatory strategy, dossier preparation, data gap analysis, study monitoring, study placement, conducting efficacy studies, data waiver, query justification, literature search, QSAR, preliminary risk assessments, preparation of higher-tier risk assessments, submission and post-submission follow-ups. We provide global pesticide and biocide services that is to say in the EU, UK, India, Africa, and other regions and countries.

**Plant protection product registration in the EU**

Our team of regulatory experts and scientists have worked on a variety of projects, regarding plant protection products (PPP), and our extensive work experience empowers us to register your product in the EU. We have supported our clients forin multiple regulatory projects involving active substances and PPPs.

**Plant protection product registration in India**

Auxilife is a leading company in the industry, with strong knowledge of the pesticide registration process. India's Central Insecticide Board and Registration Committee (CIBRC) listed wide categories of PPP registrations such as pesticides, insecticides, biopesticides, seed treatment and plant growth regulators. The CIBRC also regulates vector control, LLIN (long-lasting insecticidal nets) and household pesticide registrations in India.

**Regulatory support in South America, Asean countries and African regions**

Auxilife can support companies with the registration of pesticides, biostimulants, and fertilisers, and can also help in placing products on the market in those regions.

**Biocide registration in Europe**

Auxilife provides regulatory and scientific support regarding the approval of active substances and biocide products in the EU, as per the biocidal products Regulation (BPR) EU 528/2012. Our service portfolio includes approval/renewal services for any active substances and biocide products, development of regulatory strategies and identification of compliance requirements under the BPR, in all the four main groups:

- national authorisation with the option to apply for mutual recognition in other member states;
- union authorisation;
- simplified authorisation; and
- authorisation for same product.

**Biostimulant registration in India**

Auxilife offers scientific services to register biostimulants, which are being regulated under the new Gazette Notification guidelines in India. On the 23 February 2021, The Ministry of Agriculture and Farmers' Welfare issued the Fertilizer (Inorganic, Organic or Mixed) (Control) Amendment Order, 2021 to further amend the Fertilizer (Inorganic, Organic or Mixed) (Control) Order, 1985. Auxilife provides complete support to register biostimulants, data generation, liaison with regulatory authority, submission, and post-submission.

**Efficacy field trial support in India (exploratory and regulatory)**

Auxilife provides efficacy field trials support in all Indian agro-climatic conditions at multiple locations with varied seasons.

**Disinfectant registration in India**

In India, disinfectants (including surface disinfectants, wipes, sanitisers etc) are currently regulated under the Drug and Cosmetics Act by the Central Drugs Standard Control Organisation (CDSCO) and all regulations applicable to drugs need to be followed for registering disinfectants.

**Classification labelling (C&L) and safety data sheet (SDS) services in more than 30 countries:**

- CLP notification of substances;
- CLP notification of the mixtures;
- poison centre notification;
- safety data sheets for substance (local language);
- safety data sheets for mixtures (local language); and
- extended safety data sheets (local language).

**Technical and regulatory support in endocrine disruptors (ED) assessments:**

Endocrine disruptors assessments are a mandatory requirement for putting pesticides and biocides on the EU market. Auxilife provides different supporting services regarding these assessments, such as systemic literature reviews for any active substance and co-formulant, as well as for the toxicity or hazard identification of any chemical.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2012** | Established and registered as a private limited company. |
| **2013** | Auxilife successfully delivered the company's first product registration in India. |
| **2014** | Auxilife supported it clients with application renewal. |
| **2016** | Auxilife started supporting clients with their biocide registrations. |
| **2017-2018** | Auxilife strives for a complete compliance mechanism with its in-house resources of registering pesticides in India and Europe. |
| **2019** | Auxilife started supporting clients with agricultural field trials in India. |
| **2020** | Auxilife merged with the Global Product Compliance Group. |
| **2021** | Auxilife initiated a global regulatory support mechanism to support clients with global regulatory requirements, including South America, Asean countries and African regions. |
| **2022** | Auxilife conducted a series of webinars on agrochemicals to help companies understand the relevant regulatory requirements in key global regions. |

## CLIENTS

Auxilife has clients in Europe, the US, Japan, India, China, and other major regions. It has successfully registered novel products for its clients in India and the EU. Product categories include plant protection, biostimulants, biopesticides, fertilisers, biocides, household insecticides and medical devices.

## TESTIMONIALS

On service quality criteria, 98% of client companies have rated the agrochemical compliance assistance services being offered by Auxilife as very good.

## CASE STUDY 1: PPP registration support for active substance renewal in the EU

Auxilife has been supporting clients that are participating in new and renewal processes for active substances, and PPP in the EU. We have expertise and experience dealing with several member states across the EU.

On behalf of clients, we are participating in a renewal programme. For this project, we have overcome all the challenges related to the different risk assessments and constant updates in the guidelines including endocrine disruptor assessment.

## CASE STUDY 2: Biopesticide product registration in the EU

Auxilife supports clients in their first-time registration of approval of new active substances in the microbial category. Auxilife initiates a meeting with the authorities and ensures the evaluation process is carried out.

## CASE STUDY 3: Plant protection product registration in India

Auxilife is the only agrochemical consultant in India with technical expertise and resources to support global agrochemical companies with their product registration in India. We have provided support to companies in the registration of new active substances in India.

We had discussions with the Indian authorities and agreed how to proceed with evaluation. First the active substance was included in the schedule list and then we sought the research test and trial (RTT) permit to bring the product sample to India to conduct India specific studies. The RTT permit is a mandatory requirement for importing a product sample to generate India specific data/studies.

Our experts generated and monitored the relevant studies from reputed contact research organisations (CROs) and bio-efficacy trials from India's state agriculture universities (SAUs).

After applying for the registration under section 9(3) of the 'Technical import of new molecule of Insecticide Rule' and submitting the dossier, we successfully handled questions raised by the authorities based on the scientific justifications.

## STAFF SELECTION

**Dr Jayachandran Nair – CEO**

Dr Jayachandran Nair has been a leading professional in the areas of environment and global chemical regulations since 1998. His focus areas involve global regulatory compliance, capacity building, strategic planning, and strengthening in-house resources for industries. At Auxilife, he specialises in planning and business expansion.

**Shisher Kumra – Executive Director**

Shisher Kumra is an environmental law and policy expert with 28 years' experience in the areas of cleaner production, cleaner technology, sustainability management, chemical policy and regulation, circular economy and regulatory representation. He specialises in regulatory affairs, legal expertise, chemical assessment and toxicology.

**Dr Rajiv Paul – Senior Regulatory Ecotoxicologist**

Dr Rajiv Paul has more than six years' experience in pesticide registration and consulting work and has a PhD in ecotoxicology, which involved fish toxicity and biochemical assessment of heavy metals. He has been working in ecotoxicology with pesticides registration requirements in various countries and assessing the endocrine disruptors properties of active substances.

**Pooja Vishnoi – General Manager and Regulatory Head**

Pooja Vishnoi is an expert with more than eight years' regulatory experience in plant protection products, biocides, and other chemicals. She holds a master's degree in environmental engineering and, in her career has worked in environmental impact assessment, environmental fate and behaviour, and with EU and India regulatory and technical assessment.

**Pritee Panicker – Manager Regulatory Affairs**

Pritee Panicker is an environmentalist, with more than ten years' experience working as a regulatory expert and ecotoxicologist. She possesses a keen understanding of plant protection products regulatory compliance in India and other countries.

**Nisar Shaikh – Business Development Manager**

Nisar Shaikh holds an MBA in marketing from the London School of Business and Finance, London and has more than ten years' business development and marketing strategy experience. He helps steer renowned agrochemical companies wanting to successfully place their products in key global markets.

## CONTACTS

| | |
|---|---|
| Website | www.biogenius.de |
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| Tel | + 49 2204 83077 0 |
| Fax | + 49 2204 83077 11 |
| Contact | Alexander Brux |
| Directors | Mike Bublitz, Alexander Brux |
| Ownership | Private company |
| Locations | Germany |
| Founded | 2004 |

## OVERVIEW

Since 2005, BioGenus has been supporting its customers with an indepth 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 | 2021/22 |
|---|---|
| No of offices | 1 |
| No of countries represented | 1 |
| Staff, group | 26 |
| Staff, chemical service provision | 17 |

## 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 (e.g. 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 fulfills all requirements of national and international product authorisations according to the BPR:

- 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".

## 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®

# 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 | www.chemdox.com |
| E-mail | office@chemdox.com |
| Head office | Salztorgasse 1/2A<br>1010 Vienna<br>Austria |
| Tel | Europe: +43 1 5321489 0<br>Americas: +1 888 8369462 |
| Contact | Anton Zrzavy |
| Directors | Anton Zrzavy |
| Ownership | UCS - unique computing solutions gmbh |
| Locations | Austria, USA |
| 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 our clients like about us?

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

Good software adapts to the needs of their 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

| VITAL STATISTICS | 2021/22 |
|---|---|
| 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), USA

## 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 (e.g. GHS, transport, national regulations). 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 current and 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 & 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 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 or on the phone.

**Training**

To get the most out of CHEMDOX®, we offer introductory, individual, and open trainings for users, as well as technical trainings (e.g. 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 programs
- Implementation of interfaces to other systems
- Development of special software modules
- Document template configuration

## CORPORATE DEVELOPMENTS & 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; and
- 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 due to 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 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 (e.g. 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 through-put 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.

Chemleg
Chemical Legislation

## CONTACTS

| | |
|---|---|
| Website | www.chemleg.com |
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| Tel | +90 (216) 706 1307 |
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| Contact | Ms Elif Koç (elif@chemleg.com)<br>Mr Gökhan Ardıç (gokhan@chemleg.com)<br>Mr Mehmet Yolcu (mehmet@chemleg.com) |
| Ownership | Limited company |
| Locations | Turkey |
| Founded | 2017 |

## OVERVIEW

Chemleg is a consultancy company in Turkey providing chemical regulatory compliance services to firms working in the chemical industry. Our staff have many years of professional experience working with technical chemicals information and legislation. Our experienced consultants provide chemical regulatory support for companies, to help give them a competitive advantage in the global market, by providing accurate, efficient and high-quality services.

Chemleg staff includes more than 60 chemical regulatory experts and more than 35 of the chemical assessment experts necessary for KKDIK– Turkey REACH– experts that are mandatory for KKDIK dossier registration and drawing up chemical safety reports. Chemleg provides services globally and locally, working with trade and university associations, technical universities and laboratories.

**Our core service areas are:**

- only representative services for KKDIK (Turkey REACH), Turkey CLP Regulation and Turkey BPR;
- KKDIK (Turkey REACH) compliance services;
- letter of Access (LoA) sharing process management for KKDIK (Turkey REACH);
- KKDIKPro service for lead registrant to manage LoA sharing among co registrants;
- KKDIKPro service for data sales process behalf of data owners;
- Turkey BPR compliance service;
- SDS authoring services;
- SDS certification services for Turkish SDS;
- preparation of label and technical information forms for general chemicals;
- CLP compliance (Turkey CLP-SEA and EU CLP) and GHS compliance services;
- Turkey detergent regulation compliance services;
- training and consultancy services;
- Chemleg is partnered with Telematic for providing EPY SDS authoring software;
- technical translation services; and
- an accredited training institution for chemical assessment experts authorised by the MoEU.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | >€1,500,000 |
| Turnover, chemical service provision | >€1,500,000 |
| No of offices | 2 |
| Staff, group | >70 |
| Staff, chemical service provision | >60 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

**Only representative (OR) service**

- KKDIK (Turkey REACH) Regulation
- Turkey BPR Regulation
- Turkey CLP Regulation

**KKDIK compliance services**

Chemleg supports companies, located in or outside Turkey with KKDIK registration. This will be realised in two steps: pre-registration and registration respectively.

CHEMLEG services:

- to be done late pre-registration;
- joining and following up all activities in KKDIK Sief;
- KKDIK registration dossier preparation/translation/submission (for lead and member (co) registrants);
- Sief communication management (lead and member registrant);
- LoA sharing model management through KKDIKPro internally developed software;
- managing LoA sharing cost calculation/reimbursement process through KKDIKPro software;
- translation of EU REACH dossiers into Turkish and compilation for KKDIK, including uses, robust study summaries, chemical safety report (CSR), chemical safety analytics (CSA), risk assessment report etc;
- submission of translated KKDIK registration dossiers and CSRs to KKS by chemical assessment experts;
- providing administrative management for the data owner;
- following up consortium activities;
- determining chemical characterisation of substances;
- data management and data-gap analysis for KKDIK (Turkey REACH);
- establishing of the substance inventory list under Annex-17;
- training institution for chemical assessment experts; and
- developing software for managing of KKDIKPro process.

**Turkish biocidal product Regulation compliance services**

Biocidal products can be sold in Turkey after fulfilling the requirements of the country's biocidal products Regulation. Biocidal products can be on market in Turkey after getting a licence. Chemleg supports companies within the scope of the Turkey BPR requirements. Chemleg services include:CHEMLEG services:

- determination of a product's scope;
- preparation of Annex-IIA and Annex-IIB and risk assessment reports for license dossier of biocidal products during application for all product types; management of the licensing process;
- technical evaluation and suitability assessment for the physico-chemical analysis and efficacy test methods;
- management of the analyses/efficacy test procedures; and
- assessment and translation of toxicologic, eco-toxicologic tests.

**Turkish CLP Regulation compliance services**

- Classification of substances/mixtures supplied to the market
- Labelling and packaging of harmful substances/mixtures
- Notification to C&L (SEA) inventory through KKS
- Determination of label and packaging dimensions of hazardous substances and mixtures.

**KKDIK Annex-II SDS compliance services**

- Preparation of safety data sheets
- Checking the safety data sheets availability
- Certification of safety data sheets after review

Safety data sheets should be prepared in accordance with Turkey SDS regulation/KKDIK Annex-II by certified persons. Chemleg authorises SDSs using its own certificated experts. Chemleg is a distributor of EPY SDS authoring software including technical and regulatory support.

**KKDIKPro software**

KKDIKPro software has been developed for the organised and effective management of KKDIK (Turkey REACH) registration processes. It is aimed at providing a fair and transparent process for joint registration members. With KKDIKPro, the LoA sharing, all documentation related to this process, and payment transactions can be managed.

It can be distinguished from similar software, thanks to its many facilitating features such as current LoA fee calculation, automatic e-mail notifications, being a common platform that can be used by different lead registrants and being a system that is always open to updating and improvement. The accurate operation provided by automatic processes is timesaving.

**SDS software**

Chemleg has a partnership with Telematic providing safety data sheet and label software to the Turkish market. EPY is a modular, integrated software suite developed specifically to help chemical companies comply with the regulations governing chemical products.

In addition to full compliance with the Turkish and European regulations, the possibility of creating SDSs and hazard labels has now been added for the Chinese, US and Canadian markets. We as Chemleg also provide training, regulatory and technical support on EPY.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2019-2022** | Chemleg managed more than 8,000 substances pre-registration as an only representative |
| | Chemleg translated more than 600 dossiers and CSRs between 2019 and 2022 |
| | Chemleg submitted more than 5,000 substances C&L notifications |
| | Chemleg prepared more than 5,000 SDSs |
| | Chemleg registered more than 50 biocidal products |

## ACCREDITATIONS

- Member of Istanbul Chamber of Commerce
- Chemical Assessment Expert (Trainer) Certificate
- Training institution for "chemical assessment expert" authorised by the MoEU

## PARTNERS

Telematic (Italy) for EPY SDS authoring software

## CLIENTS

Chemleg's clients are companies working in the chemical and associated industries around the world, such as the UK, US, Norway, Italy, Germany, France, Bulgaria, Belgium, Netherlands, Japan, China, Russia, and more. Our clients span manufacturers, importers and downstream users in raw materials, biocides, paints and coatings, cosmetics, cleaning products, the petrochemicals industry, etc.

Chemleg also works with consultancy companies to help clients comply with Turkish chemical control regulations in the UK, Italy, China, US and Germany.

CHEMLEG does not disclose client names but they may be revealed upon request, if clients consent.

## STAFF SELECTION

**Elif Koç**

KKDIK technical and training Manager Elif is a chemist with a master's degree. A chemical assessment expert, she has more than 15 years of experience in the chemical industry as a researcher and regulatory specialist. Elif is responsible for helping companies manage the OR process of regulatory compliance for KKDIK. Additionally she manages the data/ LoA sharing process and models with the data owners and or consortia.

Elif previously worked on projects for the Scientific and Technological Research Council of Turkey, in its R&D departments as an analytical method development and validation specialist for active substance and impurities, and for a consultancy company as biocide department team leader. Here she managed lots of international companies' biocidal product requirements for Turkey.

She carried out the first submission in Turkey for a biocidal product to be used for the purpose of R&D and managed the entire process.

**Gökhan ARDIÇ**

SDS solution manager Gökhan is a chemist and health and safety expert, with a master's degree from Marmara University. He has more than eight years of experience in chemical regulatory services, especially safety data sheet authoring. He has a CAE certificate and has compiled almost 10,000 SDSs in many different languages. He is also authorised to author Turkish safety data sheets, and is an expert on the classification, labelling and packaging (Turkey SEA/EU CLP) regulation.

He gives training on safe usage and storage of chemicals, is the responsible person for Chemleg's SDS authoring software and provides technical and regulatory support for companies using this software. His specialities include: SDS authoring (including e-SDS with exposure scenarios); product safety; chemicals management; assessing toxicological and ecotoxicological test results from CSR; chemical labelling; technical and regulatory support.

**Mehmet Yolcu**

KKDIK sales and marketing manager Mehmet is a chemist with a master's degree. A health and safety expert, he has more than eight years of experience as a chemical regulatory consultant, especially with Turkish CLP/CICR and the EU REACH regulation for Turkish exporters. He has carried out thousands of C&L, CICR and SDS notifications for companies. In addition, he has delivered group and individual training on the KKDIK, CLP, SDS and EU REACH regulations.

He managed the project scope and processes for the EU REACH, Turkish CLP, CICR and Turkish SDS regulations for companies. He provides support for Turkish-based companies on their responsibilities under EU CLP and EU REACH when exporting products to EU member states.

He can also interpret the provisions of new or updated chemical regulations.

**Haydar Hazer**

Chemical assessment expert Haydar worked for the chemicals management department of the MoEU for 23 years. He helped establish the Chemicals Inventory System and Chemicals Registration System (KKS) and worked on harmonising the CLP and REACH Regulations for Turkey. He has been working on the KKDIK and Turkey's CLP Regulation since their harmonisation process began in Turkey. He has attended many national Caracal and REACH meetings, as well as seminars and trainings as the representative of the MoEU.

**Chemleg's other members of staff**

As of the beginning of 2023, Chemleg has 70 members of staff and regularly expands its team. Chemleg's's staff are chemists and chemical engineers. Chemleg staff members have chemical assessment expert certificates.

They have experience ranging from three to seven years within the field of chemical regulatory consultancy, including EU REACH, the KKDIK, SDS authoring and biocidal products.

## CONTACTS

| | |
|---|---|
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| 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 | 2021/22 |
|---|---|
| Turnover, group | €3.5m |
| Turnover, chemical service provision | €1.8m |
| No of offices | 2 |
| No of countries represented | 1 |
| Staff, group | 32 |
| Staff, chemical service provision | 12 |

## 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 ranging from the legal side to all the technical matters to complying with international and national chemical and medical control legislation. For almost 20 years Chemsafe has developed a unique expertise in regulatory toxicology provided to customers of different fields: ranging from chemicals including biocides and agro, 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 company 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)
- *In silico* with DEREK, SARAH, METEOR, ZENETH
- 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 documentation for the dossier 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
- study monitoring (toxicological, clinical).

**BU Training**

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

## CORPORATE DEVELOPMENTS & 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<br>Staff increased to 12 people<br>First biocides product dossier for two actives submitted and authorised |
| **2012** | Pharma business service created<br>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<br>Acquisition of ILC Srl, a company active in GMP activities for pharma companies worldwide |
| **2020** | New operative offices open in Quagliuzzo (TO), Italy<br>New partnership with China, Brazil. 26 employees |
| **2022** | Creation of the BU training, staff up to 32, GLP like archive started |

## ACCREDITATIONS

Chemsafe is a full member of ORO, the EU Only Representatives Organisation and the Industrial Union of Turin and Federchimica, Italy

## 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 of experience as a toxicologist

**Dr Paolo Rossi, BDM Chemical Area**

Biotechnologist. Twelve years of experience in business development management activities at an international level

**Dr Iavello Alessandra – Head of BU Medical Devices**

Medical biotechnologist, ten years of experience

**Dr Francesca Fasano – Head of BU Chemical**

Industrial chemist and chemist, 14 years of experience.

**Dr Marco Rodda – Head of BU Pharma**

Biologist, European registered toxicologist (ERT), 11 years of experience

**Dr Federica Carra, Head 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)

**Dr Emanuela Fino, CFO**

Thirty years of experience

# CHEMSERVICE

## CONTACTS

| | |
|---|---|
| Website | www.chemservice-group.com |
| E-mail | contact@chemservice-group.com |
| Head office | Chemservice GmbH<br>Herrnsheimer Hauptstr. 1b, 67550 Worms, Germany<br>Chemservice SA<br>13, Fausermillen, 6689 Mertert, Luxembourg<br>Chemservice Asia Co Ltd<br>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 |
| Fax | +49 6241 95480 25 / +352 270776 75 / +82 52 223 6230 |
| Contact | Karl-Heinz Reis (Germany)<br>Dr Dominik Kirf (Luxembourg)<br>Jae-Seong Choi (Korea) |
| Directors | Dr Dieter Drohmann, CEO, Managing Director Americas<br>Karl-Heinz Reis, Director Global Regulatory Affairs<br>Christopher Cohrs, Director Supply Chain Compliance<br>Dr Dominik Kirf, Director Toxicology & Risk Assessment<br>Thomas Schaefer, Director Data & System Services<br>Doris Peters, Managing Director Consortia, Managing Director Switzerland<br>Jae-Seong Choi, Director Korea<br>Dr Jaime Sales, Managing Director Iberia<br>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 | 2021/22 |
|---|---|
| Turnover, group (w/o non-integrated affiliated companies) | €10m |
| Turnover, chemical service provision | €10m |
| No of offices (w/o non-integrated affiliated companies) | 10 |
| No of countries represented | 8 |
| Staff, group (w/o non-integrated affiliated companies) | ca. 80 |
| Staff, chemical service provision | ca. 70 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Chemservice GmbH, Worms, Germany
Chemservice SA, Mertert, Luxembourg
Chemservice Asia Co Ltd, Ulsan, South Korea
Chemservice Schweiz GmbH, Morschach, Switzerland
Chemservice Iberia, Castellón, Spain
Chemservice UK Ltd, Maidstone, UK
Chemservice Americas LLC, Chicago (IL), US
Consortia Management GmbH, Worms, Germany
Consortia Asia Co Ltd, Seoul, Korea
ChemAdvocacy Turkey, Istanbul, Turkey

## SERVICES PROVIDED

**Global regulatory affairs consulting**

We provide a wide range of services to help you comply with national and international chemical control legislation. The scope of chemicals is very wide. Therefore, chemical legislation is comprehensive 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 you in complying with international chemical regulations such as REACH, K-REACH, UK REACH and KKDIK. Our various legal entities offer regulatory consultancy for the Swiss, South American and US markets.

**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 the 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 (especially REACH) 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.

With our online letter of access (LoA) portal (www.reach-loa.com) we offer 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 also 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 & ACHIEVEMENTS

| | |
|---|---|
| **2007** | Start-up in Luxembourg |
| **2008** | Opening of Chemservice office in Germany<br>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<br>Launch of Joint Venture 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<br>Launch of Consortia Asia Co Ltd in Korea<br>Acquisition and merger of REACh ChemAdvice GmbH into Chemservice GmbH |
| **2019** | Establishment of three new Chemservice entities:<br>Chemservice Iberia, Spain<br>Chemservice UK<br>Chemservice Americas, US |
| **2020** | Extension of Chemservice offices in Germany and Luxembourg<br>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.<br>Launch of ChemAdvocacy Turkey |
| **2022** | 15 years of Chemservice<br>Opening of new US office in Chicago |

## 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, we ensure that you receive the best chemical compliance support around the world. Our partners are located in Argentina, Brazil, Canada, China, Colombia, India, Japan, Mexico and Taiwan, among others.

## 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

In recent years, 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 about 20 consortia and 12 lead registrants under REACH, K-REACH and KKDIK. The services range from the general set-up of a new consortium including the set-up of the consortium documentation and opening a trustee account on behalf of the consortium members, to taking over the LoA management and LoA calculation for a lead registrant in case further registrants join a joint submission.

Over the course of a project, each of our clients benefits 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 **https://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 1,600 REACH member and lead dossiers to 1,350 small volume substance registrations in South Korea and about 4,500 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 | www.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 along with L1 and L3 emergency response, including 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

| | 2021/22 |
|---|---|
| No of offices | 2 |
| Staff, group | 78 |
| Staff, chemical service provision | 35 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

US

UK

## SERVICES PROVIDED

**Emergency Response**
- L1 emergency response phone number
- Hazmat response and clean-up

**Incident Reporting**
- 5800 form
- Incident report distribution

**Consulting Solutions**
- Crisis management
- Business continuity

**Training**
- Online hazmat training

**Safety Data Sheet Solutions**
- Authoring
- Access
- Distribution

**Battery Compliance**
- L1 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 National 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 CHEMTREC summit |
| **2023** | CHEMTREC develops an online HAZWOPER 8-hour refresher training course |

## 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 center partner and provided them with the SDS. The poison center 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 liters 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

**Bruce Samuelsen, Chief Executive**

Bruce Samuelsen has more than 35 years' experience in the professional services and engineering fields, with a focus on engineering and management across a diverse set of US and global clients. Bruce came to CHEMTREC from SERCO North America, where he held dual roles as Chief Growth Officer for the Americas division and Senior Vice President, International Maritime Programs reporting to the Group CEO based in the UK.

Prior to Serco, He worked at Alion Science and Technology, where he held multiple executive roles including Chief Operating Officer and President of the Naval Systems Business Unit.

**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 organizations who have complex risk and compliance challenges, Rich is responsible for forming strategic partnerships with international accounts that interface into and out of the U.S. 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 minimize operational risks and help with compliance whilst protecting their bottom line.

**Joe Milazzo, Operations Center Director**

Joe Milazzo has been with CHEMTREC since 1988 and serves as the Director of the Operations Center, where his responsibilities encompass complete operational overview and oversight of CHEMTREC emergency services. He has attended several industry HAZMAT training sessions with various chemical manufacturer response teams, including one of the few that trained with live chemicals. He previously served as the CHEMTREC Training Coordinator where he designed operational and company-specific training. He is a graduate of the International Academies of Emergency Dispatch Communication Center manager course.

# CIRS

## CONTACTS

| | |
|---|---|
| Website | www.cirs-group.com |
| E-mail | service@cirs-group.com |
| Head office | 11/F, Bldg 1, Dongguan Hi-Tech Park, 288 Qiuyi Rd, Binjiang District, Hangzhou, China |
| Tel | +353 (1) 477 3710 (Ireland) +86 571 8720 6574 (China) |
| Fax | +86 8720 6533 |
| Contact | David Wan |
| Directors | Lucy Li, President of CIRS Group<br>Walt Lin, Vice President of CIRS Group<br>Hangsik Yim, Managing Director of CIRS Group Korea<br>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 | 2021/22 |
|---|---|
| Turnover, group | approx €30m |
| Turnover, chemical service provision | approx €15m |
| No of offices | 8 |
| No of countries represented | 5 |
| Staff, group | 400 |
| 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; and
- 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; and
- 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 GMP.

**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, and other local regulations and international rules;
- product information file (PIF): provide a cosmetic product safety report (CPSR) and ensure the completeness of PIF; and
- 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);and
- cosmetics efficacy testing.

## CORPORATE DEVELOPMENTS & 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<br>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<br>Partnership with Chemsafe |
| **2019** | Authored 100,000th global SDS<br>Completed 3,000th K-REACH pre-registration<br>Completed 10,000th China Cosmetics Registration<br>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 |

## 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 18,000 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 many years of 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, Toxicologist, 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 200 REACH LR projects and has prepared more than 500 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 was involved in the translation of the book Risk assessment of chemicals–an introduction, which introduced the concept of risk assessment to China.

He is proficient in various chemical risk assessment software and models such as EPA-SUIT, Euses, ECE-TRA, Iuclid 6, and Chesar.

**Queenier Yang – Team Leader, Toxicologist, CIRS HQ**

Queenier has more than 13 years' of experience in regulations including EU REACH, K-REACH, US TSCA, Canada DSL/NDSL, and Australia's AICIS. Her team has completed more than 2,000 registration dossiers, including 100+ LR dossiers under EU REACH. Her expert use of Qsar and read-across instead of testing, successfully gains compliance with K-REACH, KKDIK, and DSL/NDSL.

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

April has more than ten years' of 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, 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.

She is often invited to advise foreign food and food supplement companies at international regulatory conferences.

**Eric Xiong – Director of Industrial Chemicals Sector, CIRS HQ**

Eric has twelve years' of 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 thirteen years' of 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.

Each year, his team completes more than 100 medical device registrations and 20 clinical research projects 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 of 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 16 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.

## CONTACTS

| | |
|---|---|
| Website | www.chemhse.com<br>www.cncic.cn |
| E-mail | qiaojing@cncic.cn |
| Head office | No. 53 Xiaoguan St, Anding Menwai, Beijing, China |
| Tel | +86 10 64415355 |
| Contact | Jane Qiao |
| Directors | Victor Lu |
| 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 well-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, environmental and energy management, safety management, and chemical and material standards formulation for value enhancement.

| VITAL STATISTICS | 2021/22 |
|---|---|
| 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 64421139. regulation@hse.cncic.cn

## SERVICES PROVIDED

### Regulatory compliance consulting

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

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

Services include:

- industrial chemical registration in China, South Korea and Japan;
- ccosmetics 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.

### Market consulting

CNCIC provides clients with a full range of tailored market consulting services, such as in-depth analysis of market opportunities and risks from various angles of the industrial chain to assist clients in investment decision-making, market development and strategic planning.

### Strategy consulting

Based on its comprehensive market consulting experience to get in-depth insight into the market environment, competitive environment, policy environment and technological environment, CNCIC Consulting can provide businesses with the most viable strategic consulting services, help them enhance their core competitiveness, and become winners in the increasingly complex domestic and international competition.

CNCIC Consulting has long worked with national and provincial chemical parks, and provided them with a tailored 'one-stop' consulting service based on their development environment and current situation, as well as their existing problems and development goals.

### Investment consulting

CNCIC upholds the concept of professionalism, authority, objectivity and foresight, explores investment opportunities, evaluates investment risks and formulates investment plans for enterprises, thus supporting their investment decisions.

### Healthcare consulting

With rich and professional experience in pharmaceutical industry, CNCIC is committed to research in pharmaceutical, medical instrument and other important biomedical sectors and has a thorough understanding of relevant policies and regulations in China, trends of international medical technology, professional physicians and the pharmaceutical market dynamics.

### Environmental and energy management consulting

By using innovative and scientific technologies to provide integrated solutions, CNCIC is committed to helping chemical enterprises improve the efficiency of their energy use and management.

### Safety 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.

**Establishment of chemical standards**

CNCIC has been involved in the management and operation of the Secretariat of the Chemical Standardisation Branch of the China Standardisation Association, the Secretariat of the CSTM/FC05 (Chinese Standards for Testing and Materials Group Committee /Field Committee 05), the safety production management work group of the Standardisation Working Committee of China Petroleum and Chemical Industry Association, the Standardisation Working Committee of China Chemical Industry Information Association and other chemical standardisation organisations.

## CORPORATE DEVELOPMENTS & 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

During the regular registration of new chemicals we submitted accounts for almost 20% of the total number of submissions according to the statistical data from the authorities.

Until now, 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.

CNCIC has successfully received the filing number for cosmetics new ingredients under the new regulation.

As for the marketing consulting service, for a long time, we have been involved in a wide range of professional fields in the process of customer service, covering the whole industrial chain of 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 book 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 various 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

**Peter Huang**

CNCIC Consulting CEO, previously worked in the bio-pharmaceutical teams of well-known management consulting companies and held the post of Asia Pacific Vice President in a foreign chemical consulting company. He has more than 15 years' experience in the chemical consulting business, has sponsored hundreds of chemical consulting projects and assumed the position of project manager in major consulting projects.

Peter Huang has rich experience in project management and execution. He has profound knowledge of various sectors in the chemical industry and can accurately perceive market dynamics and development trends of chemical sectors and propose unique insights.

**Victor Lu**

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

Mr Lu has led relevant teams in CNCIC Consulting to complete several hundred consulting projects regarding market analysis, industrial research and industrial planning. He also established the CNCIC Research Institute of Industrial Economics.

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.

## CONTACTS

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

## OVERVIEW

EBRC is a privately owned consulting organisation based in Hannover, Germany, providing consulting services with a focus on 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 | 2021/22 |
|---|---|
| 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 & ACHIEVEMENTS

| | |
|---|---|
| **1993** | Foundation of EBRC (initial staffing: six people) |
| **2022** | 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 2005–07 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 (2005–07), 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 |
| Head office | ERBC Group – Chemin de Montifault, 18800 Baugy, France |
| Tel | +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 | 2021/22 |
|---|---|
| No of offices | 5 |
| Staff, group | >350 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

ERBC SAS – Chemin de Montifault, 18800 Baugy, France

ERBC SrL – via Tito Speri 12/14, 00071 Pomezia (Rome), Italy

Laboratoire Novaxia SAS – 6 Rue des Champs Godin, 41220 Saint-Laurent-Nouan, France

Oncofactory SAS – 43 Boulevard Du 11 Novembre 1918 L'Atrium, 69100 Villeurbanne, France

## SERVICES PROVIDED

- Genetic, *in chemico* 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, pathology)

**Infrastructure and team include:**

- 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; and
- a multi-disciplinary team of experts – toxicologists, pathologists, pharmacologists, biologists, pharmacists, chemists, veterinarians and engineers.

To maintain its leadership, 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 industry.

## CORPORATE DEVELOPMENTS & 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 |
| **2022** | ERBC acquires Laboratoires Novaxia |
| **2022** | ERBC acquires Oncofactory |

## ACCREDITATIONS

- AAALAC
- GLP
- FDA approved
- ISO 14001:2004
- BS OHSAS 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.

## TESTIMONALS

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 GLP (Good Laboratory Practice).

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 animal 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

**Alexandre Bidaut**

Test Facility Manager, ERBC France

**Fabrice Nesslany**

Associate Scientific Director, Genetic and In Vitro Toxicology

**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**

Director of Client Services– Expert, General Toxicology

**Daniela Gallo**

Head of Toxicology

**Pascal Clayette**

Immunologist, Virologist

# eurofins

## CONTACTS

| | |
|---|---|
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| Tel | +49 89 899 650 0 |
| Contact | Iris Pfisterer |
| Directors | Gilles Martin, Chief Executive Officer |
| Ownership | listed at French Stock Exchange |
| Locations | 940 locations worldwide |
| Founded | 1987 |

## OVERVIEW

With more than €6.72bn annual revenues in 2021 and over 61,000 staff in more than 900 laboratories across 59 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, agro-chemical, 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 2022

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €6.72bn |
| No of offices | 940 |
| No of countries represented | 59 |
| Staff, group | >61,000 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Eurofins, a global network of companies, has a presence in 59 countries. Our main testing facilities for chemical/REACH services are located 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 & ACHIEVEMENTS

| | |
|---|---|
| **1987** | Foundation of Eurofins Scientific<br>Continuous growth and acquisitions |
| **1997** | IPO on the French Stock Exchange |
| **2008/09** | 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 of experience working in scientific institutes and the contract research industry and drives the development of new *in vitro* assays within Eurofins.

**Kevin Clark – General Manager, Columbia, US**

Kevin has worked out of our Columbia laboratory since 1985, drawing on his experience to continually improve processes, methods and technologies and master the new challenges we face in the analytical world.

**David Carver – Synthesis, London, UK**

David has more than 25 years of 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

| | |
|---|---|
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| Tel | +32 2 742 70 00 |
| Fax | +32 2 742 71 00 |
| Contact | Claudio Mereu |
| Directors | Claudio Mereu, Joint Managing Partner<br>Koen Van Maldegem, Partner<br>Peter Sellar, Partner<br>Gerard McElwee, Partner |
| Ownership | Limited liability partnership |
| Locations | 25 |
| Founded | 1835 |

## OVERVIEW

Fieldfisher is a full service European law firm with a network that spans more than 1,700 people across 25 international offices (in 11 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 ecodesign 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 | 2021/22 |
|---|---|
| No of offices | 25 |
| No of countries represented | 11 |
| Staff, group | 1700 |
| Staff, chemical service provision | 24 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Amsterdam, Barcelona, Beijing, Belfast (x2), Berlin, Birmingham, Bologna, Brussels, Dublin, Düsseldorf, Frankfurt, Guangzhou, Hamburg, London, Luxembourg, Madrid, Manchester, Milan, Munich, Paris, Rome, Turin, Venice, Shanghai, Silicon Valley.

## SERVICES PROVIDED

**Chemicals**

We have more than 20 years of 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 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**

We advise international pesticides companies on the European 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 taskforces, initial 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 indepth knowledge of the free-rider and EU competition law issues at stake. We guide a number of active substance/product type combinations through the EU review programme for existing active substances. We lobby 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.

## CORPORATE DEVELOPMENTS & 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** |

## TESTIMONIALS

"Fieldfisher provides clear responses written in such a way that people who are not legal-based can understand."

"They are always at the forefront of anticipating change in regulatory frameworks." *Chambers Europe-wide, 2023, Regulatory: Environment– Band 1*

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*

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*

A team of experts with an excellent knowledge of environmental and chemical law. *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*

## 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 or not 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 studies on vertebrate animals 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 the Echa's BoA (A-007-2016). The BoA had ordered Echa to grant access to the studies property of another company to our client. However, Echa decided to reassess again the efforts made by the parties in the data sharing negotiations, and concluded that Sharda should not be granted access to studies because it did not make "every effort" in the negotiations.

As the conclusion and the reasons of Echa in this new decision was diametrically opposite to the first decision, our department represented Sharda in a second appeal before the BoA. The case is unprecedented as this is the first appeal lodged against a decision issued by Echa upon remission from the BoA.

On 17 November 2020, the BoA annulled the Echa decision thereby allowing Sharda Europe B.V.B.A., to refer to studies concerning the active substance alpha-cypermethrin, owned by BASF Agro BV.

## CASE STUDY 3: Solvay Solutions UK Limited vs. Dow Benelux BV– Case A-009-2019

Fieldfisher successfully represented Solvay Solutions UK Ltd in an appeal before the Echa's BoA, in relation to an Echa decision granting Dow Benelux B.V. permission to refer to studies concerning the active substance tetrakis(hydroxymethyl)phosphonium sulphate (2:1) (THPS) owned by the Appellant, Solvay Solutions UK Limited.

On 7 March 2018, the BoA accepted a first appeal by the applicant against Echa's decision (Case A-014-2016) on the grounds that Echa had failed to consider Dow Benelux B.V.'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 for re-examination.

On 6 May 2019, Echa again granted Dow Benelux B.V. 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 decided that none of the criteria had been fulfilled and annulled Echa's decision granting Dow Benelux B.V. permission to refer to the studies.

## STAFF SELECTION

**Claudio Mereu**

Joint Managing Partner, EU Regulatory partner

**Koen Van Maldegem**

EU Regulatory Partner

**Peter Sellar**

EU Regulatory Partner

**Gerard McElwee**

EU Regulatory Partner

## CONTACTS

| | |
|---|---|
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| Fax | +49 761 3860820 |
| 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 30 years of experience in exposure assessment and risk characterisation. FoBiG's REACH experience dates back to 2001, participating in Cefic- and VCI-sponsored projects. FoBiG successfully prepared numerous registration dossiers for phase-in and new substances and is currently engaged in updates of registration dossiers for several clients.

Furthermore, we have extensive experience in authorisation under REACH. FoBiG successfully prepared many authorisation dossiers for threshold and non-threshold Annex XIV substances and is involved in further authorisation projects at various stages of the application, including review reports. Further projects deal with providing support for Corap-listed substances (substance evaluation) and for substances targeted by Echa dossier evaluations.

| VITAL STATISTICS | 2022 |
|---|---|
| Turnover, group | €1m |
| Turnover, chemical service provision | €1m |
| No of offices | 1 |
| No of countries represented | Europe-wide |
| Staff, group | 13 |
| Staff, chemical service provision | 10 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

### REACH registration

FoBiG provides full-scale scientific support to meet industry's REACH obligations:

- Iuclid 6 files (including literature searches, data gap analysis, evaluation of 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).

Up to now, FoBiG was/is involved in preparing registration dossiers for hundreds of substances/categories for small and large companies.

### REACH authorisation

Together with our partner RPA Ltd, FoBiG prepares complete dossiers (Iuclid 6) 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;
- 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).

Up to now FoBiG was/is involved in preparing initial applications for authorisations as well as review reports for about 20 substances and numerous uses for single companies, small and large consortia.

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 (based on very substantial monitoring data) 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 competent authorities/Echa.

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 evaluations with regard to occupational safety and health. 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 & ACHIEVEMENTS

| | |
|---|---|
| **1986** | Founded as personal company by Fritz Kalberlah |
| **1992** | Reorganised as private company (GmbH) with company partners F Kalberlah, K Schneider, M Hassauer |
| **2009** | New company partner Jan Oltmanns |
| **2018** | F Kalberlah and M Hassauer retired, long-term staff members 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 Directorates General (DG) of the European Commission)
- (German) federal and other authorities (eg BfR, Baua, UBA)
- Stakeholder organisations (eg VCI, trade unions)

## CASE STUDY 1: Read-across for filling data-gaps

Application of read-across and category approaches for filling data gaps in registration dossiers: read-across proved to be the most successful strategy during the first two REACH registration phases for filling data gaps. Cases, where FoBiG successfully applied read-across in registration dossiers include:

- category formation/grouping based on structural relationship;
- read-across from metabolites to parent compounds or vice versa; and
- read-across along homologous structural changes.

At the same time, Echa (see Echa's RAAF – Read-across assessment framework) asks for detailed justifications for applying read-across approaches, which require in-depth analyses of toxicokinetic and other available data. Read-across hypotheses and justifications need to be carefully documented as part of the registration dossiers. Approaches used for read-across are one of Echa's focuses in dossier evaluation.

## CASE STUDY 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 from registration dossiers need to be improved. Detailed descriptions of the technical processes, RMMs and conditions of use as well as availability of measured data (eg air and/or bio-monitoring measurements), which may be supported by higher tier modelling (eg by ART and RISKOFDERM), are key to a successful application. In addition to workers exposure characterisation, assessment of human exposure via the environment is an essential part of the authorisation CSR. 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 substances will be targeted by such evaluations. Consequently, updating various parts of registration dossiers (regarding data requirements, exposure assessment, risk characterisation) might 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 the requirements of the agency's RAAF (see above).

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

## CONTACTS

| | |
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| Contact | Ulrich Mann |
| Directors | Björn Noll<br>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 | 2021/22 |
|---|---|
| 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
- Fulfilment 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 & ACHIEVEMENTS

| | |
|---|---|
| **1986** | Foundation, Ingelheim, Germany |
| **2008** | Acquisition of GBK by Björn 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 STUDY

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

**Björn Noll – Owner and Managing Director**

Since May 2008, managing director and owner of GBK GmbH in Ingelheim. He has been engaged in dangerous goods logistics and international chemicals law for more than 25 years. As EU hazardous goods officer, he has all the necessary qualifications for all modes of transport.

**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.

## CONTACTS

| | |
|---|---|
| Website | https://gpcregulatory.com<br>https://gpcgateway.com |
| E-mail | info@gpcregulatory.com<br>compliance@gpcregulatory.com |
| Head office | IDEON Science Park, Beta 5, Scheelevägen 17, 223 63 Lund Sweden |
| Tel | +46 46 2114615 |
| Contact | Shisher Kumra |
| Directors | Shisher Kumra, Mukta Kumra, Ulrika Lindstedt |
| Ownership | GPC Holding, Sweden |
| Locations | Sweden, India, South Korea, UK, Turkey, Russia, Australia and China |
| Founded | 2008 |

## OVERVIEW

The Global Product Compliance (GPC) Group is a company incorporated in 2008, in Lund Sweden. GPC provides global support and end-to-end solutions for chemical regulatory compliance management. We operate globally with offices in eight countries and thanks to more than 60 collaborations with regional and national partners offering local regulatory compliance-related services, we cover the global regulatory landscape in more than 40 countries worldwide.

Demands from our large clients for intelligence on new regulations encouraged us to widen our horizons towards new locations and new sectors.

Starting with EU REACH, we have now ventured into most of the regulations that have emerged over the past few years.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | >€75m |
| Turnover, chemical service provision | >€75m |
| No of offices | 9 |
| No of countries represented | >50 |
| Staff, group | 120 |
| Staff, chemical service provision | 100 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Sweden, India (Pune and Nagpur), South Korea, UK, Turkey, Russia, Australia, Taiwan and China

## SERVICES PROVIDED

**Our specialist regulatory areas are:**

- India REACH (ICMSR)/BIS;
- EU REACH;
- UK REACH;
- Eurasia REACH;
- KKDIK (Turkey REACH);
- Korea REACH;
- Taiwan TCCSCA;
- agrochemicals (India, EU, Turkey, South America); and
- cosmetics regulations (EU, India, US).

**Compliance services within the above regulations:**

- registrations and notifications (pre and late pre-registration/pre-notification);
- global regulatory compliance and status assessment;
- substance/dossier evaluation process management;
- lead registration activity, technical dossier preparation;
- toxicological assessment and dossier updates;
- contract study management and monitoring;
- compliance verification and certificates;
- REACH and CLP compliant SDS and extended SDS (e-SDS) and SDS translations;
- BIS, India compulsory certification for chemicals;
- plant protection product registration;
- biocide and bio-stimulant registration; and
- portal of compliance certificate management systems.

**Global chemical regulation service accomplishments:**

- 1,500+ happy clients with 99% client retention;
- managed portfolio of 15,000+ substances;
- registered 1,200+ substances and lead registration and consortia management of 600+ substances;
- 14,000+ pre-registrations and notifications, globally;
- authoring of 4,500+ REACH and CLP-compliant SDSs and 350+ e-SDSs. Translated SDS in 30+ languages;
- extensive network of OECD-GLP-certified CROs managing toxicological, ecotoxicological, environmental and physico-chemical studies; and
- 5,000+ users of the compliance certificate management systems portal.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2015/16** | The company group is accredited as a certified inspection body; business affiliate in South Korea; research collaborator of Lund University, Sweden |
| **2018** | Completed all EU REACH final and first deadline Korea REACH registrations; business affiliates in the UK and Ireland |
| **2019** | Initiated Eurasia and Turkey REACH services |
| **2019** | Signed MOU with Chemtopia, South Korea |
| **2020** | Business affiliate in Turkey, Taiwan, and Russia |
| **2020** | Knowledge partner, outreach collaboration with Cosmed Cosmetics Association, France |
| **2020** | Contributed to the draft of the 'Indian Chemicals Management and Safety Rules' |
| **2020** | Started Bureau of Indian Standards (BIS) Certification Service |
| **2021** | Launched the 'International Regulatory Internship Program' with the Regulatory Representatives and Managers Association (RRMA) |
| **2022** | GPC became the co-organiser of the Asian Chemicals Forum ACF – HCF with HCF<br>GPC hosted approximately 80 webinars with 5,500+ attendees |

## ACCREDITATIONS

**Accreditation:** AAA, Bisnode, Highest Credit Worthiness

**Memberships (Regulatory advisory):**

- member of CII National Chemicals Committee;
- IKEM: Innovations and The Chemical Industries in Sweden;
- SIBC – Sweden India Business Council, Sweden;
- Confederation of Swedish Enterprise, Sweden;
- Sustainable Business Hub, Sweden;
- Indian Chemical Council, India; and
- Regulatory Representatives and Managers Association (RRMA), India.

## PARTNERS

**Recognitions as a regulatory knowledge partner:**

- Confederation of Indian Industry (CII)
- Indian Chemical Council (ICC)
- Indian Chemicals and Management and Safety Rules – technical committee member; Ministry of Chemicals and Petrochemicals, India
- Basic Chemicals, Cosmetics and Dyes Export Promotion Council (Chemexcil), India; and
- Regulatory Representatives and Managers Association (RRMA).

**Other organisations:**

- osmed, Cosmetics Association, France;
- China National Chemical Information Center, China;
- All India Printing Ink Manufacturer's Association, India; and
- Gujarat Dyestuffs Manufacturers Association, India.

**Research partners:**

- Technical University of Denmark, Denmark;
- Lund University, Sweden;
- Jadavpur University, India;
- Centre for Cellular and Molecular Biology (CSIR), India;
- National Institute of Industrial Engineering (NITIE), India; and
- ESSEM, India.

## CLIENTS

GPC provides compliance services to a wide range of clients from more than 40 countries.

Our clients mostly come from chemical and petrochemical industries but are also in agrochemicals, food additives, cosmetics, electrical and electronics, automotives, the leather, garments and apparel sector, the plastic and rubber and, steel industries, writing instruments, polymers, paint, and dyes etc.

## TESTIMONIALS

Our more than 1,500 happy clients and 99% retention rate are a testimony to the great rapport we share with them and the fine quality that we offer in our services.

On the service quality criteria, 92% of the client companies have rated the compliance assistance services provided by GPC as very good.

## CASE STUDY 1: Mutual reliance and sustainable growth

Our clients' needs have played an important role in GPC's growth. Their expansion plans have directly influenced and encouraged us to diversify our services toward new and upcoming regulations. Today, thanks to offices in eight countries and an extensive network of more than 60 global collaborators, GPC can cover a wide range of regulations with a global overview across regions and sectors.

## CASE STUDY 2: Automation of compliance process management

GPC has developed and created a free end-to-end solution to streamline the compliance management processes of our clients. The portal has three main components:

- **Compliance initiation:** clients can maintain, manage, and update their compliance-related information as well as request services such as pre-registrations, registrations and notifications;
- **Consortia management:** clients can request and manage information related to the lead registration process including, but not limited to, syndication, LoA, administration of agreements, archiving of documents, etc; and
- **Supply chain communication:** communication and due diligence between supplier, buyer and OR are simplified thanks to the certificate management system.

## CASE STUDY 3: DEHA

We have collaborated with experienced CROs worldwide to support our clients with a wide range of regulatory testing requirements. Recently, we helped one of our clients decide on a capable and cost-effective CRO to comply with a study request from Echa. The entire process included several rounds of discussion with the CROs in our network, registrants (including the client) and our technical experts. It started with discussions regarding study requirements with various labs, followed by proposing a suitable CRO based on study experience and timeline.

Following that, the client approved the CRO after it provided satisfactory answers to all technical questions raised by various registrants on CRO capability, study handling and outline. This led to a significant reduction of around 50%, of the testing cost in comparison to the costs from CROs proposed by other registrants.

## CASE STUDY 4: Contribution to Indian chemical policy

As India's largest regulatory compliance service provider, GPC has acquired extensive knowledge of the chemical industry's needs and the trends in the country. GPC was commissioned by the Indian Ministry of Commerce for several studies and reports contributing toward the draft and finalisation of India's chemical regulation, the Indian Chemicals Management and Safety Rules (ICMSR).

GPC is proud to be the only non-governmental organisation that is part of the technical committee responsible for drafting and finalising the ICMSR.

## CASE STUDY 5: International regulatory internship programme

To promote an understanding of chemical compliance and to nurture compliance talents, GPC initiated a regulatory internship programme in India and Sweden in 2020 and received positive feedback from the students. In 2021, GPC partnered with the Regulatory Representatives and Managers Association (RRMA) and a number of academic institutes such as the Vellore Institute of Technology (VIT), Harcourt Butler Technical University (HBTU), the National Institute of Pharmaceutical Education and Research (NIPER), the Institute of Chemical Technology (ICT), Manipal Institute of Technology (MIT), and the Indian Institute of Management (IIM) Jammu, Sirmaur, and Lucknow.

More than 55 students have participated since the start of the programme.

## STAFF SELECTION

**Business:** Shisher Kumra, executive director; Mukta Kumra,director administration and finance; Dr Jayachandran Nair, CEO, GPC India; Dr Vaibhav Diwan, global business development manager; Keith Yongho Jung, digital marketing manager; Floriane Bérain, business development executive; Lotta Larsson, administrative executive; Mirac Mert Pelister, head of Turkey business operations; Kerstin Uebele, junior marketing; Doménica Bustillos Barrezueta, junior marketing.

**Chemical Safety Management:** Dr Anders Bergqvist, head, toxicology; Dr Zsuzsanna Szepesi, senior toxicologist; Mangesh Barbate, GM (dossier management); Dr Shweta Deoskar, senior expert substance sameness; Dr Akshita Bajaj, senior toxicologist; Priyanka Manapure, senior manager, toxicology; Dr Komal Telreja, eco-toxicology; Dr Sashikumar Nair, toxicological adviser; Alexia Pelloux, regulatory ecotoxicologist; Dr Hao Fan, regulatory chemist.

**Regulatory:** Ketki Kulkarni, senior regulatory and account manager; Dr Chia-Sui Hsu (Jess), regulatory manager; Gyeong Jeong Min (Ashley), South Korea business coordinator; Zhengmin Li, regulatory manager (China); Elena Kondryukona, regulatory adviser (Eurasia); Cansel Hacıoğlu, marketing executive and regulatory adviser (Turkey).

# Landbell H2 Compliance

## CONTACTS

| | |
|---|---|
| Website | www.h2compliance.com |
| E-mail | info@h2compliance.com |
| Head office | Unit 14D Nutgrove Office<br>Park Rathfarnham<br>Ireland |
| Tel | 01 2989136 |
| Contact | Kevin Hoban |
| Directors | Kevin Hoban, John Hayes, Grant Kinsman |
| Ownership | Part of the Landbell group of companies |
| Locations | 8 (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 of topics including REACH, UK REACH and REACH-like programmes, GHS implementation worldwide (SDS and labelling), PCN and 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.

Being part of the Landbell Group expands our services into the environmental arena and the circular economy – covering WEEE, batteries, packaging, take back programmes as well as software offerings.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | > €250m |
| 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); USA (Washington, DC and Michigan); Poland (Warsaw and Lodz); UK (London and Belfast); Finland (Helsinki)

## SERVICES PROVIDED

### REACH registration and dossier management

H2 Compliance provides 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 provide full project management to completion.

At present, the emphasis is on keeping registrations up to date with the requirements for dossier updates within the set timelines, following up evaluation decisions, and managing contractual engagement with co-registrants.

### Only representative service

H2 Compliance supports numerous non-EU producers by acting as OR and taking over duties of their importers. Since 2021, we provide an OR service into the UK, and through our partners, into Turkey and South Korea.

We provide a comprehensive service relying on deep knowledge and appreciation of complex supply chains, technical execution, financial management and communication with clients and their customers.

### Stewardship support and substances of concern

H2 Compliance assists companies with their stewardship needs, building sustainable chemical management programs that proactively address the growing list of requirements. Stewardship can help gain or maintain access to key markets or supply chains with early alert on regulatory challenges, allowing companies to plan accordingly.

Substances of concern, SVHCs, and chemicals under restriction and authorisation are a potential business risk requiring early assessment and appropriate action. In the EU, the authorisation process involves gaining permission to remain on the EU market while progressively replacing the authorised substance. Restrictions for groups of chemicals as an approach to manage risks is challenging for industry.

H2 Compliance helps clients with their chemical management programmes by reviewing substances on their inventory and analysing which are, or may be, subject to regulatory measures through a proprietary element1™ substance tracking platform tailored to the client's needs.

### UK REACH

With the UK's withdrawal from the EU, companies are faced with 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.

We help clients understand the requirements, clarify future data needs, and determine the impact of the Northern Ireland Protocol on their business

### Notifications: PCN, C&L, Scip

H2 Compliance helps companies determine and meet their EU notification obligations that are central to the safe management of chemical products:

- poison centre notifications (PCN) for hazardous mixtures placed on the EU market;
- C&L notifications for hazardous substances imported or manufactured in the EU; and
- substances of concern in products (Scip) notifications for SVHCs present in articles placed on the EU market.

Using our customisable software platform, we submit and enable ongoing maintenance of notifications over time.

### SDSs and label services

We author safety data sheets (SDS) for the EU and any other jurisdiction.

Development of SDS and labels remains a core obligation for those placing hazardous products onto the global marketplace. With our toxicological, industrial hygiene and regulatory knowledge and an international partner network, we build and maintain hazard communication programmes for our clients and their specific product portfolios.

### Regulatory and EPR tracking services

H2 Compliance tracks chemicals management regulations in over 45 countries providing regular overviews and expert analysis to the Clients via our element1™ platform. Additionally, we prepare targeted assessments on how various regulations and their changes affect Client's specific portfolios and supply chains.

Being part of the Landbell Group, we also have just about the most comprehensive set of data on extended producer responsibility (EPR) in the form of a regulatory tracking service for WEEE, batteries and packaging obligations for global markets.

**Global chemical regulatory support**

The chemical regulatory arena is changing rapidly and companies shipping worldwide need to keep up to date with regional or national regulations to maintain compliance. Some countries have live requirements in place, such as South Korea, China, Japan, Switzerland and Turkey, while many emerging regulations, such as India and Israel require careful monitoring and preparation work.

We determine where obligations exist within clients' supply chains and ensure their timely execution. Our experts help companies comply with requirements for placing on the market of new and existing chemicals in Asia, Australia, Europe and North America. We facilitate reusing clients' REACH assets and investments in non-EU jurisdictions.

With offices in the US, we provide complete support with North American obligations. Our network of trusted partners also assist us in supporting our customers globally.

**element1™ software**

One of the leading platforms for chemical regulatory management, element1™ supports the delivery of REACH & REACH-like compliance services, global supply chain compliance, tracking substances of concern, and meeting classification and labelling obligations.

Launched at the outset of REACH for only representative services, dossier authoring, hazcom and project management, element1™ has expanded to support tonnage management, supplier compliance, dossier updates, PCN and Scip notifications, and similar duties in other jurisdictions.

Provided as a SAAS model, element1™ features secure private cloud platform, direct submission to regulators, advanced user management and fully configurable workflows to suit compliance needs of organisations managing chemical portfolios at substance and product levels. Coupled with support by the team of chemical stewardship experts, element1™ is your one-stop-shop for executing chemical and product compliance programmes globally.

## CORPORATE DEVELOPMENTS & 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 |

## ACCREDITATIONS

Approved REACH Ready Gold Member

Director acting Vice President of Only Representative Organisation

Co-sponsor of the Green Alley Circular Economy Awards

Sponsor of the Irish Pharma Awards

## PARTNERS

We have a network of trusted partners in geographically diverse locations who assist us in providing global support to our customers.

## CLIENTS

H2 Compliance has more than 300 customers across a diverse range of industries. Core clients are from the pharmaceutical industry, medical devices, petroleum, fragrances, polymers and metals sectors. We support over 3,500 downstream users within the clients' supply chains, and in excess of 30,000 global customers 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-Co 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: 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 H2 Compliance 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™, which has recently been upgraded into the next generation of chemical management software, element1™ plus. 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 2: 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 SDSs for products 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.

## CASE STUDY 3: Global compliance

H2 Compliance developed a service, assisting clients to meet their chemical regulatory requirements around the globe. One such example is for a global US-based polymer producer that designs and manufactures additives for rubber and plastics. While the client concentrates on their core business, H2 provides support to ensure chemical regulatory compliance firstly in Europe and more recently, due to a widening of their market, in South Korea, China, and Turkey via local trusted partners in these regions. H2 Compliance effectively acts as a one-stop-shop for chemical regulatory compliance.

## STAFF SELECTION

**Kevin Hoban – Chief Operations Officer**

Co-founder of H2 Compliance. More than 30 years of experience in industry, heads up business development, commercials, software activities as well as the only representative practice. Qualified MSc industrial chemist and environmental engineer.

**Grant Kinsman – CEO**

A mechanical engineer with over 35 years of experience in the IT and consulting industry. Extensive global technology, scale-up, finance, business and marketing experience.

**Dr John Hayes– Director**

With over 30 years of experience in the IT and Pharmaceutical space, John is a qualified biotechnologist and doctor of physical chemistry. Deep experience in regulatory affairs has characterised his career which is now applied to leadership of the environmental consulting activities within the group.

RÉPUBLIQUE FRANÇAISE
*Liberté Égalité Fraternité*

INERIS
*maîtriser le risque pour un développement durable*

## CONTACTS

| | |
|---|---|
| Website | www.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) |
| Fax | +33 (0)3 44 55 66 55 |
| 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, in order to guide them in their actions with regard to health, safety and environmental protection.

INERIS combines experimental approaches with expertise in modelling and risk methodology. It is equipped with physical/chemical analysis laboratories, GLP-compliant toxicology and ecotoxicology facilities, large-scale fire gallery and explosion platform, and test facilities that are among the best in France, both for studying accidental phenomena and effects on living beings.

INERIS offers multi-disciplinary approaches with the capacity to conduct complex studies in many areas, including chemistry, *in vivo* 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, ATEX, etc), or in response to research and development needs.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €74.8m |
| No of offices | 4 |
| No of countries represented | Global |
| Staff, group | 505 |
| 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 REACH regulation and its implementation. The testing capabilities and expertise permit a complete offer for the registration of substances in accordance with the requirements of REACH.

It includes the development of luclid dossier and the chemical safety report according to the exposure scenario and management measures to ensure a high level of protection for workers, general population and environment. In the context of 3R strategy, INERIS can also provide advice on the selection of the best alternative in integrated approaches for testing and assessment of your substance (Qsar, PBPK modelling and read-across, testing strategies).

INERIS can help industry with the selection of the best substitution option (substitution.ineris.fr/fr). It can provide an analysis of chemical solutions by searching existing regulatory constraints and performing a screening assessment in order to avoid regrettable substitution by substances of concern (SVHC).

**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).

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 1,600°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 and regulatory GLP toxicology studies for chemicals (including nanoparticles, explosive substances and fumes) and physical agents. The 1,000m² *in vivo* facility is composed of mice and rat housing areas and innovative installations allowing exposure 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 (OECD 431, 439 and 492);
- acute tests (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.

In the context of experimental toxicology, INERIS focuses on alternative methods to animal testing by the development of *in vitro* assays (using an air-liquid interface Vitrocell system for the exposure of cell cultures and tissues to air compounds) combined with *in silico* tools (Iata, AOP).

In addition, INERIS provides the service of host a team project, by supplying animal housing and equipment.

### Ecotoxicological testing

INERIS provides 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), fish lethality test (OECD 203) 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 and drugs residues.

### Nanoparticles hazard assessment

INERIS has a complete *in vivo* (rat models) nose-only inhalation system (HCT) to expose animals to nanoparticle aerosols, with associated metrology, TEM and physico-chemical characterisation of nanoparticles. It 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 of 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. (**www.cofrac.fr**), under n°1-0157, 2-1251, 1-2291, 5-0045.

## CLIENTS

INERIS works with more than 2,000 clients around the world from various industry sectors and disciplines, including chemistry, paints and coatings, cosmetics, food, oil, gas and petrochemicals, automotive and heavy equipment manufacturers, construction, marine, consumer electronics, nanotechnology, etc.

## CASE STUDY: 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 tonne/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

| | |
|---|---|
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| Contact | Rose Passarella |
| Directors | André Lacroix, Chief Executive Officer;<br>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 | 2021/22 |
|---|---|
| No of offices | 1,000+ |
| No of countries represented | 100+ |
| Staff, group | 46,000+ |
| Staff, chemical service provision | 5,000+ |

## SERVICES PROVIDED

## 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, Türkiye, 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

**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)

### 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)
- 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

## CORPORATE DEVELOPMENTS & 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

Ms Joyce Borkhoff – Active member of the Industry Co-ordinating Group (ICG) for the Canadian Environmental Protection Act (CEPA), Responsible Distribution Canada (RDC), the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), Cosmetics Alliance Canada, Colour Pigments Manufactures Association (CPMA), and Canadian Paints and Coatings Association (CPCA).

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.

## 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 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

**Joyce Borkhoff, Vice President, Chemicals & Food/Nutrition, North America**
Focus: chemicals, agri, biocides, pesticides – 25 years' plus experience

**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 & 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

**Ozlem Keles, Regulatory Expert, Türkiye**
Focus: chemicals, biocides, global restricted substances, cosmetics and personal care, sustainability – seven years' plus experience

**Naeem Mady, Vice President, Regulatory Market Access, US**
Focus: chemicals, food contact, sustainability – 50 years' plus experience

**Michael Brorsson, Business Developer, Sweden**
Focus: chemicals, biocides, food contact, restricted substances – 10 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, Business Unit Manager, India**
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

## CONTACTS

| | |
|---|---|
| Website | www.kahlbergconsulting.com |
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| Tel | +39 02 6700319 |
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| Contact | Vanessa Alberti |
| Directors | Michela Kahlberg, CEO |
| Ownership | Private company |
| Locations | Italy, UK |
| Founded | 2008 |

## OVERVIEW

Kahlberg Consulting is a leading chemical consulting company based in Milan, Italy, and an expert in REACH, 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.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | >€1,000,000 |
| Turnover, chemical service provision | >€1,000,000 |
| No of offices | 2 |
| No of countries represented | >30 (globally) |
| Staff, group | 21 |
| Staff, chemical service provision | 14 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Italy, UK

## 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 whole regulatory course of the REACH update proposal, including and focusing on polymers and REACH registration. We are already assisting companies in preparing for the new challenge with the following activities:

- 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 center 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 approval
- 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

**UK biocides**
- Request of inclusion in Article 95 UK
- Request for authorisation for biocidal products and active substances in UK

**UK Pic – Prior informed consent**

**UK PPP – Pesticides or plant protection products**

**Worldwide services**
- Korea REACH
- Eurasia REACH
- Albania, Kosovo, Montenegro, North Macedonia, Serbia

## CORPORATE DEVELOPMENTS & 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

## CLIENTS

Biggest players in the global market as well as small, medium-sized clients.

## CASE STUDY 1: REACH polymers

Currently the REACH Regulation does not require registration or evaluation of polymers, but during the last two years the competent authorities and Echa have been working hard to help the Commission in presenting a proposal for updating REACH by the end of 2023, including for the registration of polymers.

Since the number and the type of polymers on the European market are considerable, it is easy to understand that this new registration obligation will be a great challenge for the industry. Physico-chemical properties, toxicological and eco-toxicological data are not available on polymers; identity and grouping will require big effort in time and resources. With this in mind, Kahlberg Consulting had started to work on polymers since the beginning of the discussion. Two webinars were held with more than 300 participants, in order to keep companies involved in this task updated.

Dedicated software has been developed with the aim of helping companies to have information stored and well organised, making calculations based on different criteria, creating polymers groups with similar characteristics and having a tool for the notification without re-entering the requested information in other systems (eg 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 angles. 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 the technical concerns, as well as the commercial ones. 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 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 50 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 the chemical industry in Czechoslovakia (now Czech Republic) 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 in industrial chemistry from the Università degli Studi of Milano. Product safety expert, more than a decade of work with the REACH Regulation.

**Dr Elif Dereli Eke – Regulatory Affairs Specialist**

She has a bachelor's and master's degree in chemical engineering from Yıldız Technical University and Bogazici University. PhD in chemical engineering from Bogazici University. Previously a post-doctoral research fellow. Regulatory affairs officer for KKDIK.

**Janna Hamdar – Regulatory Affairs Officer**

She has a bachelor's degree in industrial chemistry. Product safety and REACH consultant junior.

**Giada Marchetti – Regulatory Affairs Officer**

She has a bachelor's degree in chemical toxicological environmental science and safety and a master's degree in safety assessment of xenobiotics and biotechnological products, REACH consultant junior.

KFT
The CHEMICAL COMPLIANCE Company

## CONTACTS

| | |
|---|---|
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| Tel | +49 6155 8981– 400 |
| Fax | +49 6155 8981– 500 |
| Contact | Marcus Rosenberger, Stefan Palla, Mario Andric |
| Directors | Marcus Rosenberger, Managing Director<br>Stefan Palla, Managing Director |
| Ownership | Wholly owned subsidiary of Infraserv GmbH & Co. Höchst KG |
| Locations | Griesheim, Headquarter, Germany<br>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 | 2021/22 |
|---|---|
| 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 the monitoring of the implementation and the 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. 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 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 requisition 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 CLP, the German detergents and cleaning agents act (WRMG), and product notifications in all European countries, Turkey, the US and many other countries.

**Remote data management**

For more than 20 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 a broad spectrum of seminars around the compliance aspects of REACH, SDS, GHS/CLP, and international chemical regulations.

The available selection can be found at **www.kft-academy.com**. In-house training and customised coaching are available on demand at **academy@kft.de**.

A monthly web seminar "KFT chemical compliance live" can be accessed free of charge.

## CORPORATE DEVELOPMENTS & 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** |
| **2010** | > 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 9001:2015 |
| **2020** | Wholly owned subsidiary of Infraserv GmbH & Co. Höchst 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 include everything 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 preregistered 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;
- 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 | www.knoell.com/en |
| E-mail | info@knoell.com |
| Head office | Konrad-Zuse-Ring 25, Eastsite XII, 68163 Mannheim, Germany |
| Tel | +49 (0)621-718858-0 |
| 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, 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 products, food contact materials and additives, novel food, cosmetics, medical devices as well as animal health-related products, including sustainability aspects and their associated special services triggered by the EU chemicals strategy for sustainability.

knoell: your go-to partner for registration, 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 | 2021/22 |
|---|---|
| Turnover, group | ~ €60m |
| Turnover, chemical service provision | ~ €20m |
| No of offices | 24 |
| No of countries represented | 15 |
| Staff, group | ~ 600 |
| Staff, chemical service provision | >180 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

**Europe**
**Germany** – Mannheim, Leverkusen, Berlin, Münster; **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– 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 your product portfolio, 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
- Preparation of dossiers and electronic submission (eg Iuclid, R4BP, 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 silico*) 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
- Thorough 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 under GHS, CLP, 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 products 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 for you 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 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** on topics from all regulatory areas covered by us via our knoell academy

**Workshops and seminars**

- Wide range of training programmes offered as seminars, training, web-seminars, e-learning and workshops by our knoell academy

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **1996** | Foundation, Mannheim, Germany |
| **2002** | Office in Leverkusen, Germany |
| **2007– to date** | Continuous global growth by founding new entities (Switzerland, 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 provide training courses and bespoke in-house seminars, covering all our areas of expertise<br>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)<br>Expand our portfolio to animal health consulting services – acquisition of Cyton Biosciences Ltd, Bristol, UK<br>Extend regulatory affair services from Europe to Japan and the Asia-Pacific region<br>Successful preparation of more than 400 REACH dossiers and more than 100 chemical safety reports<br>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** | Name change: Dr Knoell Consult GmbH becomes knoell Germany GmbH<br>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 |
| **2019** | Successful submission of more than 1.000 pre-registrations for K-REACH |
| **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).<br>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<br>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. |

## ACCREDITATIONS

Qualified Cefic – partner

## PARTNERS

SCAS Japan, SCAS Europe, Domo Salute, Cekindo, Mourão Henrique Consultores Associados, CRAD, AgriThority, Chemical Watch

## CLIENTS

We deliver flexible services to globally acting companies as well as to small- and medium-sized enterprises. We also take care of big consortia and taskforces. We work on- and off-site to support our customers' specific local needs.

## TESTIMONIALS

The Spanish Ministry of Environment described our dossier for a wood preservative as, "the best organised and well-done dossier in comparison with the rest of dossiers received from other companies".

Additional testimonials can be provided on request.

## 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

LISAM SYSTEMS
Enabling full compliance.

## CONTACTS

| | |
|---|---|
| Website | Global: www.lisam.com<br>Regulatory advisory: www.lisam-telegis.fr |
| 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<br>Thierry Levintoff, Owner and CFO Lisam Global<br>Françoise Saint-Romain, Managing Partner (Regulatory) |
| Ownership | Private company |
| Locations | Belgium, France, Germany, UK, Romania, Lithuania, US, Canada, India, Turkey, Brazil, China, Japan, Luxembourg, Singapore, South Africa, Italy, the Netherlands, Mexico, South Korea, Australia, Argentina, Spain |
| Founded | 1999 |

## OVERVIEW

Founded in 1999, Lisam Systems is a global provider of environmental, health and safety (EH&S) compliance management software solutions and services, operating from offices worldwide. By combining an easy- to-use, flexible technology built on the Microsoft .NET platform, with the latest regulatory content, Lisam brings innovative, affordable and timely solutions to solve EH&S challenges faced by manufacturers, distributors and users of chemical products.

Working with industry associations and partners, Lisam has developed, proprietary, vertical EH&S solutions for the chemical, 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 52 languages. With the opening of offices in Australia, Lisam can provide support and regulatory services for all five continents.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €49m |
| Turnover, chemical service provision | €24m |
| No of offices | 20 |
| No of countries represented | 25 |
| Staff, group | 400 |
| Staff, chemical service provision | 230 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Belgium, France, Germany, UK, Romania, US, Canada, India, Turkey, Brazil, Lithuania, Singapore, Luxembourg (WikiChemia), China, South Africa, Italy, the Netherlands (CHESSOL), Australia, Spain

## SERVICES PROVIDED

**Regulatory advisory services**

Lisam Telegis is the main department of regulatory expertise of Lisam Systems, partner of the chemical industry in regulations on health, safety and environment for more than 20 years.

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, CLP, (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 Telegis 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 Systems' EH&S modules, train your teams, and support you with change requests and incidents.

**ExESS® EH&S packages**

ExESS EH&S applications are easy to use and flexible to configure. The system provides a powerful, open strategy for integrating with customer and third-party content.

It allows for real-time API integration with a broad range of enterprise systems, and batch integration with built-in integration tools:

- **SDS and 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 OEL 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 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, CLP, 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 & ACHIEVEMENTS

| | |
|---|---|
| **1999** | Creation of Lisam Systems in Belgium |
| **2002** | Acquisition of Belgian company ESI (Protheus Software) |
| **2006** | Acquisition of Telegis, France, to offer support and regulatory consultancy services |
| **2007** | Lisam India opens in association with Kalosoft Systems Technologies |
| **2009** | Acquisition of Hemmis, reinforcing development team and integrates ExESS software<br>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<br>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 Singapore, China and Lithuania, Netherlands (CHESSOL) |
| **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

## CLIENTS

With premises and partners around the globe, Lisam applications and regulatory advisory services are adopted by more than 2000 medium and large clients worldwide, in all industry sectors.

## TESTIMONIALS

"Lisam's ExESS® software centralises all our needs regarding REACH and GHS, and this on a worldwide scale. Employees from 28 offices around the world are connecting to the ExESS software to generate compliant SDS, labels or other documents.

We chose the Lisam solution for their worldwide compliance and support, and for their commitment to keep track of legislation changes and implement future GHS whenever released," *Vice President, Corporate QSHE of a multinational consumer goods manufacturer*

"After a comprehensive selection process, we chose to work with Lisam Systems and 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 Systems fully understood our needs and our process flow. We didn't need to adapt our way of working to the new system, for it's so flexible that it adapted itself to our way of working," *Senior Director HSEQ of a global actor in the petrochemical Industry*

For confidential reasons, testimonials on our regulatory services will gladly be provided on request.

## CASE STUDY 1: Gas industry centralised SDS/label software

Context:

- multiple tools used for SDS and labels authoring;
- some subsidiaries using the same tool, but with different approach;
- some subsidiaries share a centralised database, while others use their own, lack of synergy; and
- 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; and
- one corporate standard for all compliance documents.

## CASE STUDY 2: Global regulatory success stories

Lisam Telegis 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 Systems. He took over the CEO position in June 2012, managing the global expansion of the company. Michel obtained a civil engineer degree in 1986 and has worked for 25 years as IBM mainframe consultant in the financial market.

**Magaly Courtois, Regulatory Services Manager Lisam Telegis**

After graduating as a chemical engineer specialising in environment, Magaly acquired broad skills in regulatory affairs in more than her 20 years at Lisam Telegis. Keen to stay at the forefront of knowledge and customer needs, she manages and develops the department in charge of SDS and eSDS authoring, REACH registration dossiers, biocidal products authorisation dossiers, regulatory monitoring and many other missions.

# 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 |
| Locations | Stuttgart |
| Founded | 2018 |

## OVERVIEW

Makersite is a software-as-a-service company based in Stuttgart, Germany. We work with AI, data, and apps to enable our customers to make informed decisions about products and their supply chains.

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, 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

| | 2021/22 |
|---|---|
| No of offices | 4 |
| No of countries represented | Global |
| Staff, group | 50+ |

## 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.

**One subscription includes over 140 data integrations**

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.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2018** | Founded in Munich<br>Launched the platform with product sustainability and costing applications |
| **2019** | Top ten startups in Europe by Innovation Radar<br>Launched compliance applications and integrated more than 100 data providers |
| **2022** | €18m Series A investment<br>Partnership with Autodesk, leader in product design software<br>One of five finalists for the German Sustainability Award<br>Partnership with Beroe to build more resilient supply chains |

## 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, Bayer, Vestas, Schaeffler, and ca. 30 more

## CASE STUDY 1: Detecting restricted chemicals and analysing potential alternatives

Makersite worked with a major US chemical association to fully automate the process of assessing health risks from chemical products based on the REACH methodology. Further to that, a multi-criteria decision analysis (MCDA) approach was used to find safer substitutes and analyse them across financial and non-financial criteria.

Stewardship teams can perform these analyses in seconds instead of hours with improved accuracy because of the standardised, automated process. Engineering teams can understand the chemical risks associated with their choices and assess what could be a better alternative with visual reports and reliable data.

## CASE STUDY 2: Powering supplier collaboration for the HPDC

Makersite powers the supply chain data collection functionality for the Health Product Declaration Collaborative's platform – the HPD Builder. Manufacturers can request material declarations from their suppliers, which can use their bills of materials to generate HPD-compliant reports and submit them to their customers. This allows manufacturers to improve supplier collaboration and provide better information to their stakeholders while protecting the intellectual property of suppliers.

The automated checking against live data sources detects irregularities and restricted substances as they enter the system to accelerate the verification process. Manufacturers can now automatically assess compliance in minutes and pinpoint problematic components and substances that need to be discussed with suppliers.

## CASE STUDY 3: Complete compliance and sustainability analyses in minutes

Makersite is helping a leading electronic manufacturer to drive more sustainable, compliant and cost-effective decisions. The platform accepts full material declarations (FMD). Using an AI-supported engine together with the manufacturer's product's bill of materials, it generates complete supply chain models including supplier and manufacturing data.

This fully automated process allows our customer to assess compliance against multiple regulations and internal standards, perform complete and in-depth lifecycle assessments with unprecedented accuracy, and estimate the cost of design changes in minutes instead of months.

## 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 modeling 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 13+ years of 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 applied to the natural sciences. He has a PhD in physical organic chemistry and has worked as a researcher in the fields of nanotechnology, biotechnology and food chemistry, where he made several discoveries of new materials, unknown natural products, and new cocoabased consumer products (ruby cacao).

He currently works for Makersite as a data science lead who builds data models for sustainability, compliance, and risk in the manufacturing industry.

NEXREG

## CONTACTS

| | |
|---|---|
| Website | www.nexreg.com |
| E-mail | info@nexreg.com |
| Head office | 380 Wellington Street – Tower B<br>Suite 610<br>London ON,<br>N6A 5B5<br>Canada |
| Locations | Canada |
| Tel | +1 519-488-5126 |
| Contact | info@nexreg.com |
| Ownership | Private |
| Founded | 2005 |

## OVERVIEW

Nexreg Compliance Inc. is a full-Service chemical product MSDS/SDS authoring, and consumer/industrial label review company. The Nexreg team of consultants and partners are experts on chemical product-related regulations in key jurisdictions, and facilitators of chemical product management worldwide. Founded in 2005 with a mission to provide world-class, comprehensive regulatory compliance services.

Nexreg invests to guarantee that our consultants and clients have access to quality EH&S regulatory information and technology. We have access to multiple regulatory databases, authoring software and the ability to monitor and track industry and government source data. We use these resources to access chemical data, scientific studies, product transport information, official regulatory text, governmental guidance and more.

The regulatory needs of our clients have firm deadlines that need to be met; often arising with little notice. We seek to ensure a transparent process from project start to finish, encouraging open and timely communication with our clients. Our turnaround times are the fastest in the industry, and we offer RUSH services to respond to our clients unexpected regulatory needs.

We stand behind our work and guarantee its accuracy and compliance with government standards and regulations. All of our service offerings use quality information that can be verified through several sources. Additionally, we employ an extensive review process at each critical stage in a project. If an issue arises, swift and immediate action is taken to achieve resolution. Clients can rest assured knowing that all of our work is fully insured against errors and omissions; reducing or eliminating liability risk.

| VITAL STATISTICS | 2021/22 |
|---|---|
| No of offices | 1 |
| Staff, group | 15-25 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

- MSDS authoring
- MSDS translation
- MSDS updating
- MSDS compliance
- MSDS hosting and management
- Label services
- GHS compliance
- REACH compliance
- Properties testing
- Prop 65 compliance
- Health Canada compliance

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

**2005** Founded

## ACCREDITATIONS

- The Better Business Bureau (BBB)
- American Industrial Hygiene Association (AIHA)
- Southern Aerosol Technical Association (SATA)
- Canadian Federation of Independent Business (CFIB)
- Society of Chemical Hazard Communication (SCHC)
- International Sanitary Supply Association (ISSA)

## CLIENTS

- Aerosol products
- Agriculture
- Automotive
- Aerospace
- Energy
- Oil and gas
- Construction
- Cosmetics
- Pulp and paper
- Retail and consumer products
- Food and beverage

# NEXREG

Nexreg Compliance Inc. is a chemical regulatory compliance company with over 15 years of global regulatory experience in (M)SDS authoring. Nexreg maintains a rigorous quality assurance system to ensure products consistently meet required regulatory standards. Nexreg offers a wide variety of services for industrial and commercial regulatory needs.

## CORE SERVICES

### (M)SDS Authoring

Specializing in Material Safety Data Sheet and industrial label authoring for over 120 countries including North American GHS, European CLP, and Asian GHS. Additional services include (M)SDS updating, review, classification, reformulation, periodic renewal, and technical translations.

### Consumer Product Compliance

Retail label validation, formula review, and certification for consumer product compliance in Canada, USA, Mexico, Europe, Australia, New Zealand, Japan, and Russia. Nexreg also offers California Proposition 65 product review and State Right-to-Know Assessments.

### Cosmetic Product Compliance

Formulation review and label validation for Canada, USA, and Europe. Additional services include Health Canada Notification, US FDA label validation and Safety Assessment, EU Product Information File authoring, EU Responsible Person Services and EU/UK CPNP submission.

## ADDITIONAL SERVICES

- Canada Drug and Natural Health Product & USA FDA Registration
- California SB258 Right To Know Assessment
- Hand Sanitizer and Disinfectant Registration and Guidance
- Emergency Response Services
- Online SDS Management Services
- Active Chemical Monitoring
- Transportation Classification and Label Authoring
- EU Poison Centre Notification
- EU REACH Registration
- Prop 65 Review


**Contact Us**

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Local: (519)-488-5126
Fax: (519)-488-5217
www.nexreg.com

RAMBOLL

## CONTACTS

| | |
|---|---|
| Website | www.ramboll.com |
| E-mail | rudolf.wilden@ramboll.com |
| Head office | Copenhagen, Denmark |
| Tel | +49 152 2258 1047 |
| Contact | Dr Rudolf Wilden, Global Key Account Program Lead |
| Directors | Dr Martina Vosteen, Dr Benedikt Fischer (Germany)<br>Dr Meera Cush, Thomas Griffiths (UK)<br>Erin Tesch, Dr Lisa Navarro (US)<br>Anna Holst (Sweden)<br>Dr Andrea Pegoli (Italy)<br>Dr Rosa Cirera (Spain)<br>Willi Muenninghoff (Asia Pacific)<br>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 | 2021/22 |
|---|---|
| Turnover, group | €1,910m (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

## GLOBAL OFFICES

We support our clients globally, having 300 offices worldwide.

## 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 device;
- 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.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2014** | Ramboll acquires ENVIRON |
| **2016** | Ramboll acquires specialist consultancy BiPRO |
| **2019** | Ramboll acquires OBG |
| **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 strategy and opens new offices in Japan and South Korea |

## 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.

## 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.

Ramboll have submitted, and their customers have been granted, many REACH authorisations for this and other substances. Also, due to Ramboll's international footprint and size, they are well suited to assist customers with multijurisdictional projects." *Ursula Schliessner, Jones Day, consortium manager of the CTACSub 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*

## 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: Application for authorisation under REACH

A cross-sector consortium asked us to prepare an upstream application to support the authorisation of chromium trioxide in various critical surface treatments under REACH. It is regarded as the most complex application to date. We continue to support the applicants to implement the authorisation.

## 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 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)**

A 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, Global Key Account Program Lead (focus Europe)**

Twenty years' experience in supporting clients maximising the value of product-related HSE compliance and stewardship programmes.

**Dr Robert DeMott – Principal, product safety and 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 Rücker – Principal, Regulatory Toxicology**

A board certified toxicologist (ERT/DABT) with more than 15 years expertise in assessing hazards and risks from chemical exposures.

RGS REACH Global Services

## CONTACTS

| | |
|---|---|
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| Tel | +32 (2) 234 77 78/ +32 (2) 234 79 11 |
| Contact | Anna Figlarek |
| Directors | Global Offices CEO A. Ecmel Yorganci<br>Chairman of the Board Adil Pelister |
| Ownership | Private company owned by Chemicals and Chemical Products Exporters' Association (IKMIB) |
| Locations | Headquarters: Brussels, Belgium<br>Subsidiary: Istanbul, Turkey |
| Founded | 2008 |

## OVERVIEW

Brussels-based REACH Global Services SA (RGS) and its Turkish subsidiary RGS Danışmanlık AŞ are professional regulatory consulting companies advising clients in the chemicals and allied industries to comply with EU, Turkey 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 OR 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, as well as on relevant Turkish chemical by-laws.

| VITAL STATISTICS | 2021/22 |
|---|---|
| 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, Turkey

REACH Global Danışmanlık AŞ Istanbul, Turkey

## 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 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 services cover:

- submissions for inquiry & registration dossiers;
- Sief/consortia representation;
- tailor-made tonnage tracking IT system and certification for compliance of the downstream user (DU)/importer;
- general consultancy services for EU-based companies on substance registration, and interactions regarding authorities' requests/inspections; and
- assessment and certification services assisting non-EU manufacturers to prove final product compliance.

**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's 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) only representative services**

Turkish-REACH (KKDIK), is published as of 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 Turkey to successfully comply with the Turkish national legislation. SIEF (MBDF) communications increased for exchange of information between potential registrants. Registration deadline: 31 December 2023

**Turkish chemical regulations representative (trustee) services**

RGS represents international companies putting chemical substances and mixtures into the Turkish market under the Ministry of Environment Urbanisation and Climate Change (MoEUCC) database since 2010. According to the bylaw on the classification, labelling and packaging of substances and mixtures, hazardous substances and hazardous polymers placed on the Turkish market should also be notified to the MoEUCC regardless of their volume.

RGS, through its Turkish operations, acts as a representative (trustee) alleviating companies of this regulatory compliance labyrinth. Many companies located outside of Turkey placing substances and preparations on the market choose to work with RGS to protect their confidential business information with professional consultancy services for compliance. RGS also provides SDS authoring services under the SDS Regulation in Turkey, which should be provided to the companies in Turkish and submitted to the MoEUCC.

**General consultancy services**

RGS offers tailored-made training sessions on REACH, EU cosmetics and Turkish chemical Regulations (KKDIK and SEA) compliance. Should your company require expertise in regulatory compliance or related industry legislation then please do not hesitate to contact us.

Auditing and certification services are also offered to companies having difficulty proving compliance during exports into the EU.

**Other global chemicals legislation**

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.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2008** | REACH Global Services SA. established in Brussels, BelgiumIstanbul Liaison Office established in Turkey |
| **2010** | Appointed as an OR for over 220 companies by the end of the year, representing 80% of the Turkish chemicals exportation 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<br>Started providing product information file (PIF) 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, Turkey.<br>Successfully notified 2000+ cosmetics products into the cosmetics products notification portal (CPNP) by 2016. |
| **2017** | Based on 12-year-long 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 2000+ pre/registration for over 450 manufacturers |
| **2019** | Pre-registered and notified 4250+ substances under KKDIK as OR/TPR, and SEA as Trustee<br>Preliminary preparations of Sief/consortia establishment for Turkey in direct communication with the EU REACH Consortia<br>Extending activities in UK, and Eurasia. |
| **2020** | Pre-registered more than 10.000 substances under KKDIK as OR/TPR for over 350 manufacturers and notified 4000+ substances for SEA. Leads Sief/consortia activities within Turkey.<br>Representing companies under UK REACH through strategic partners. |
| **2021** | Commenced working on Sief/consortium management, 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 over 6000+ co-registrants |

## ACCREDIATIONS

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 M 2,5 € and M 2 USD.

## CLIENTS

RGS' client portfolio (1000+ 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.

## STAFF SELECTION

RGS Board Members and management have more than 30 years of chemical industry experience and international regulatory affairs practice. The RGS technical team consists of chemists, chemical engineers, and environmental engineers with masters degrees from five to 15 years of experience. Our consultants are experienced within the areas of regulatory management of chemicals both in the EU and Turkey, with extensive practices 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

| | |
|---|---|
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| Tel/Fax | +358 9 412 3055 / +358 9 412 3049 |
| Contact | Frederik Johanson, Partner, Sales |
| Directors | Jouni Honkavaara, CEO, Partner<br>Frederik Johanson, Partner, Sales |
| Ownership | Private company |
| Locations | Finland, Belgium, UK, Turkey, India |
| 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 product safety 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, SEA and GBF, UK REACH and GB CLP, K-REACH and GHS, 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 help companies understand the impacts on their businesses of the ongoing developments regarding the EU REACH Revision and the EU Chemicals Strategy for Sustainability.

REACHLaw services its clients in the following languages: English, Finnish, French, German, Hindi, Hungarian, Italian, Russian, Spanish, Swedish, Turkish and Ukrainian.

## VITAL STATISTICS

| VITAL STATISTICS | 2021/22 |
|---|---|
| No of offices | 5 |
| No of countries represented | 60+ |
| Staff, group | 50+ |
| Staff, chemical service provision | 40+ |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Helsinki, Brussels, Manchester, Istanbul and New Delhi

## SERVICES PROVIDED

**REACH authorisation support services and advocacy**

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, and are working on, more than 30 applications for more than 40 uses that include individual and joint applications, and consortia for upstream and downstream applicants.

**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, and New Delhi, and our global partner network.

**Our support covers** EU REACH and CLP, UK REACH and GB CLP, Turkey KKDIK, SEA and GBF, K-REACH and GHS, and many more.

To date, REACHLaw has prepared 3,000+ registrations, including updates, 200+ lead registrations, 30+ authorisation applications, 5,000+ Turkey KKDIK pre-registrations, 500+ UK REACH downstream user import notifications, 500+ K-REACH pre-registration, and many more.

**REACH Revision Strategy and Consulting Services**

Companies placing substances, mixtures and articles containing SVHCs on the EU market are advised to assess the REACH Revision's possible impacts on their products, monitor the adoption of new legislation and prepare for the upcoming regulatory changes.

REACHLaw support: Our services bring together our regulatory expertise and your product know-how, guiding you through the various elements of the REACH Revision and helping you take the appropriate actions. REACHLaw can support your preparations for the REACH Revision in various ways. Our services include:

- REACH Revision impact / change analysis and monitoring;
- position development for Commission calls for feedback and ECHA public consultations;
- training/awareness raising for industry associations and upstream suppliers; and
- consultancy (Regulatory, Technical, Legal)

## CORPORATE DEVELOPMENTS & 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<br>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** | Supported several companies with advocacy projects. Working on different authorisation cases and registrations |
| **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<br>Supported several companies with their 2019 applications for authorisation and KKDIK pre-registrations |
| **2019** | Prepared several large-scale joint applications for authorisation<br>Supported EU 27 and UK companies to maintain access to the EU/EEA market as well as to the UK market<br>Prepared large number of KKDIK pre-registrations<br>REACHLaw Moscow office was established<br>REACHLaw London office was established<br>Prepared thousands of notifications in Russia |
| **2020** | Prepared and submitted thousands of KKDIK pre-registrations<br>Helped article suppliers with their Scip notification obligations<br>Helped UK and EU companies to address Brexit related impacts<br>Helped industry with India BIS applications<br>REACHLaw YouTube channel – REACHLAW TALKS – launched |
| **2021** | Supported industry with UK REACH registration requirements and provisional measures: downstream user import notifications, grandfathering and more.<br>Helping companies with their KKDIK lead registrations.<br>Supported companies to comply with Scip notification obligations and prepared companies to deal with the upcoming India REACH Regulation. |
| **2022** | Supported companies with the preparation and submission of late DUINs, UK REACH lead and co-registrations, and the NRES process<br>Continue helping companies with their KKDIK lead and co-registration-related processes<br>Provided support with data sharing regarding REACH-like regulations<br>Helping companies understand the requirements of upcoming India REACH and Eurasia REACH regulations |
| **2023** | Continue to help companies with Turkey KKDIK lead registrations and co-registrations<br>Providing support with data sharing and REACH-like regulations<br>Helping companies understand the obligations under the proposed REACH Revision and the Chemicals Strategy for Sustainability |

## ACCREDITATIONS

Internationalisation award from the president of Finland in 2009. Innovative-Growth sustainable company by Europe Innova in 2011. Among 200 fastest growing companies in Finland by Kauppalehti in 2011. Young Innovative Growth Company Programme by TEKES completed in 2012.

## PARTNERS

REACHLaw collaborates with several industry associations and has partners in all of the key areas globally.

## 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.

## 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 end result for data sharing and related cost sharing is as optimal and cost efficient as possible.

REACHLaw leverages 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: REACH authorisation

REACHLaw is currently assisting many of its clients with Turkey KKDIK lead registration for the 31 December 2023 registration deadline, both as a service provider and as an only representative as the KKDIK lead registrant. Compared with EU REACH, KKDIK lead registration is for the most part an exercise in administrative and technical work. Therefore, the lead registration process has been relatively quick to complete to the point of submission of the lead dossier, provided there are no significant issues in obtaining legitimate data access and sub-licensing rights for co-registrants wishing to join the joint submission.

In some cases, sub-licensing is not granted and therefore, each registrant, lead registrant included, have had/will have to obtain the data use rights directly from the data holder residing outside of Turkey, typically the EU REACH lead registrant or consortium. After submission, when the total cost of work and data has been fixed, at least to that point, the letter of access sales start for the purpose of admitting other companies aiming to register the same substance into the joint submission. Although, no data sharing regulation as such is yet in force in Turkey, REACHLaw has advised its clients to work with the lead registration as if such a regulation would be in place.

REACHLaw continues its work with the KKDIK lead registrations with the aim of submitting these to the Turkish Ministry of Environment, Urbanization and Climate Change in good time, ahead of the registration deadline, thus allowing KKDIK co-registrants ample time to purchase the letter of access and join the joint submission.

## STAFF SELECTION

**Tim Becker, MA (law)** – Senior Legal Advisor

**Sini Suomela MSc (organic chemistry)** – Head of OR and Registration Practice

**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

## CONTACTS

| | |
|---|---|
| Website | rpaltd.co.uk |
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| Tel | +44 1603 558442 |
| Fax | +44 1508 520758 |
| Contact | David Carlander |
| Directors | Matthew Lambert<br>Teresa Fenn<br>David Carlander<br>Eliza Kritikos |
| Ownership | Employee owned |
| Locations | UK, Italy |
| Founded | 1990 |

## OVERVIEW

Risk & Policy Analysts Ltd (RPA), established in 1990, is an independent 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 development and application of socio-economic analysis (SEA) to chemical risk management and is particularly proud of its reputation for preparing applications for authorisation of SVHCs under REACH for industry clients.

RPA 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.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €3m |
| No of offices | 3 |
| No of countries represented | Focus on EU-27, EEA, UK and candidate countries |
| Staff, group | 38 |
| Staff, chemical service provision | 21 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

RPA: UK; RPA Europe: Italy, RPA-Prague, Czech Republic

## 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 and their alternatives and the preparation of SEAs, which may be used to inform the development of a restriction dossier or support industry in defending substances for which harmonised hazard classifications are proposed.

**Regulations and impact assessment**

RPA advises industry clients and regulators on the (potential) impacts of regulations and regulatory change. Recent examples include work on REACH, PFAS, nanomaterials, OELs, WEEE/RoHS, CMRs at work, toy safety, cosmetics, biocides, drinking water and WFD.

## CORPORATE DEVELOPMENTS & 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 |

## PARTNERS

RPA works with FoBiG, Ökopol, Field Fisher, Bureau Veritas, Triskelion, Milieu, DHI, RIVM, Arche Consulting, IEH Consulting, ReachCentrum 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, Titanium Dioxide Industry Consortium and UKWIR).

A range of companies (from multinationals to SMEs) and consortia, including Bayer Pharma AG, DEZA a.s., Dow Chemicals, Eli Lilly, Grupa Azoty, Grupa Lotos, H&R Group, Lanxess, Rolls-Royce, Nouryon, Spolana and more.

## 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." *Industry client*

"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."

"[Company] 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." *UK Government Official*

## 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 on from this RPA has supported several private clients with socio-economic analyses of PFAS in 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' of 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 – Principal Consultant**

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. He is currently working with an industry consortium developing an Authorisation Review Report and in RPA's recent PFAS work.

**Richard Roy – Principal Consultant, Chemicals**

Richard has held a number of positions across industry, consultancies and trade associations and has extensive experience in the tracking of regulatory activity, the interpretation of legislative requirements, project management, and the delivery of training courses. Richard has strong knowledge of global chemical management legislation and more than 15 years' experience in the support of compliance activities relating to REACH, CLP and the BPR. At RPA Richard is working on a number of projects, including the preparation of applications for re-authorisation of several substances under EU and UK REACH.

**David Fleet – Principal Consultant**

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.

**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.

**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.

## CONTACTS

| | |
|---|---|
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| Tel | +49 671 298 46-0 |
| Fax | +49 671 298 46-100 |
| Contact | Dr Thomas Roth (Head of Chemicals) |
| Directors | Florian Pistel<br>Dr Monika Hofer |
| Ownership | Private company |
| Locations | 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, agrochemicals and biorationals, biocides, medical devices and pharmaceuticals, feed additives, food contact materials and GLP archiving

| VITAL STATISTICS | 2021/22 |
|---|---|
| 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 700 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, Turkey, 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 and biorationals**

In the field of plant protection and plant 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, including biostimulants, fertilisers, plant strengtheners and soil conditioners 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); and
- MRL/import tolerances and Codex MRLs.

**Registration of biocides**

Our biocides experts have successfully submitted and defended dossiers for more than 20 biocidal active substances in nearly all product types (more than 70 active substance dossiers) as well as numerous dossiers for biocidal products and product families in line with BPD 98/8/EC or BPR (Regulation (EU) No 528/2012). We provide regulatory support in the EU, UK and Asia-Pacific.

**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 over 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 are also your partner for 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 and maintain this status.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **1989** | SCC GmbH founded |
| | Agrochemicals, Biorationals and Regulatory Science business units established |
| **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 |

## ACCREDITATIONS

- GLP archive since 2004
- Full Member of the Only Representative Organisation (ORO)
- Member of the "Helix Team" (Fieldfisher, Risk & 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.

## CLIENTS

Small to large (global) companies in the areas of chemicals, agrochemicals and biorationals, 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 ten years, and head of Chemicals since 2017. He previously worked for a large chemical multinational, having gained considerable professional experience in the evaluation and registration of consumer products and chemicals worldwide.

**Isabel Kirbach**

Ms Kirbach has a master's degree in chemical engineering. She has been with SCC since 2004. Her focus is on joint submissions, Iuclid and consortia management.

**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 |
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| Head office | Brixham Laboratories, Freshwater Quarry, Brixham, Devon, TQ5 8BA, UK |
| Tel | +44 (0)1803 659170 |
| Directors | Stephen Derrington |
| Ownership | Private limited company |
| Locations | UK |
| Founded | 2016 |

## OVERVIEW

Scymaris offers high quality aquatic ecotoxicology, environmental fate and analytical chemistry services to the global agrochemical, human pharmaceutical, industrial chemicals, biocides 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.

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.

We offer non-GLP and GLP testing services supporting in-house research and regulatory compliant studies for data submission in all geographic regions. 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 | 2021/22 |
|---|---|
| No of offices | 1 |
| Staff, group | 60 |

## SERVICE AREA BREAKDOWN

Laboratory
100%

## GLOBAL OFFICES

UK and US

## SERVICES PROVIDED

**Ecotoxicology – Aquatic – Freshwater and Marine**

**Analytical Chemistry**

**Environmental Fate**

**Biodegradation**

**Radiolabelling**

## 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)

(Short) **Project Description:** (of the challenge).

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.

**Outcome:**

Project is currently ongoing.

## CASE STUDY 2: Identification of unlabelled transformation products in environmental fate studies

(Short) **Project Description:** (of the challenge).

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 ± 10 mmu (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 ± 5 ppm. 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

(Short) **Project Description:** (of the challenge).

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.

# SGS

## CONTACTS

| | |
|---|---|
| Website | www.sgs.com/cp |
| E-mail | consumer.products@sgs.com |
| Head office | 1 Place des Alpes<br>P.O. Box 2152 1211<br>Geneva<br>Switzerland |
| Directors | Charles Ly Wa Hoi, Executive Vice President |
| Founded | 1878 |

## OVERVIEW

SGS's Connectivity & Products (C&P) division is part of SGS, the world's leading testing, inspection and certification company. With more than 130 years of experience and a global network of over 97,000 employees and working in 2,650 offices and laboratories, we support businesses with our comprehensive portfolio of innovative and trusted solutions covering the complete supply chain – from raw ingredients to finished products.

Whether you operate in the clothing, textiles, footwear, furniture, food contact materials, toys, juvenile products, automotive or electrical and electronic goods sectors, our value-adding services will enable you to design, source and manufacture products that conform to and exceed target market chemical regulations.

In a changing, more interconnected world, our solutions help you mitigate risk while optimising financial outcomes.

| VITAL STATISTICS | 2021/22 |
|---|---|
| No of offices | 2,650 |
| Staff, group | 97,000 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

SGS's Connectivity & Products division provides high-quality chemical testing and certification services for a comprehensive range of consumer goods. With our global network of industry-recognised scientific, engineering and regulatory experts, we will support your business throughout your product's lifecycle – helping you to mitigate risks while ensuring market compliance.

**Services include:**

All consumer products

- Analytical chemistry – covering restricted and prohibited substances, contaminants and active ingredients
- Efficacy testing
- Stability testing
- Migration testing
- Label verification
- Exposure assessments
- Compliance testing against a wide variety of national and international standards and regulations, including RoHS, REACH, WEEE, the waste framework Directive (WFD), California Prop 65, POPs legislation and GPSD
- Impact analysis
- Dossier creation and registration
- VOCs testing
- Product risk assessment
- SVHC screening
- Green inspections/environmental safety tests
- Global testing strategies
- Auditing, training and consultancy
- Technical assistance

**Specialist sector-specific services include:**

**Automotive**

- Interior emissions
- Engine and vehicle testing
- Regulatory compliance testing
- Battery testing

**Electrical and electronics (Connectivity)**

- Chemical compliance testing to applicable restricted substance regulations (RoHS, REACH, California Prop 65, WEEE, etc)

**Food contact materials**

- Compliance testing and certification against global market regulations that apply in Asia Pacific, Mercosur countries, the EU, Canada, US, China, Japan, etc

**Furniture, home furnishings and houseware**

- Compliance testing against global standards (BIFMA, ANSI, ASTM, EN, BS, GB, JIS, SASO, AUS/NZ, etc)
- SGS CARB ATCM certification

**Paper, nonwovens and packaging**

- Odour analysis
- ISTA certification
- ASTM, NWSP, AATCC and TAPPI test methods for:
  - baby hygiene products;
  - paper, pulp and print materials;
  - medical use;
  - personal care and absorbent products;
  - nonwovens; and
  - packaging.

**Textiles and footwear**

- Chemical compliance testing against global market regulations and market standards (EU REACH, California Prop 65, US CPSIA, GB, ZDHC MRSL, bluesign®SYSTEM)
- Preferred material verification service including Vegan, rPET, doped dye, vegetable dyes, etc
- Chromium VI solution
- Root cause analysis and solutions on chemical performance

**Toys and juvenile products**

Compliance testing against market requirements, including:

- EU toy safety Directive;
- US CPSIA; and
- South Korea KC certification.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **1878** | SGS is founded in Rouen, France, by Henri Goldstuck. |
| **1879** | Business takes off and SGS open new offices in France's three largest ports: Le Havre, Dunkirk and Marseille. |
| **1915** | The headquarters moves from Paris to Geneva, Switzerland. |
| **1919** | The name Société Générale de Surveillance (SGS) is adopted. |
| **1955** | SGS begin the industrial services business inspecting industrial machines. |
| **1962** | SGS establish services for the oil, gas and chemical sector, minerals industries, and governments and institutions. |
| **1970** | In the 70's SGS begin providing environmental consultancy and remediation services in the oil and gas sector. |
| **1981** | SGS goes public. Less than four years later, sales reach CHF 1.5bn (Swiss francs). |
| **1991** | Booming economies in Asia fuel SGS's growth and the company expands its business. |
| **Today** | Today, SGS operates across a wide variety of industry sectors with more than 97,000 employees across 2,650 offices and laboratories, and is active in nearly every country in the world. |

## ACCREDITATIONS

ISO/IEC 17025 for laboratories

## CASE STUDY 1: Avoiding PFAS in food contact materials and other consumer products

Per- and polyfluoroalkyl substances (PFAS), also known as 'forever chemicals', are increasingly being regulated in global food contact material markets and other consumer products due to the risk of reprotoxicity, carcinogenicity, bio- and environmental accumulation.

SGS C&P provides comprehensive testing and certification solutions to help operators in the food contact materials and articles industry ensure compliance with target market regulations. We support manufacturers and suppliers as they navigate the complex regulatory landscapes relating to PFAS, in areas such as the US (state regulations, including California Prop 65) and Europe (REACH, POPs and the food contact materials Regulation).

Key to achieving and maintaining compliance is identifying the presence of substances belonging to the vast PFAS family. We provide tailor made solutions for our clients to determine the presence of PFAS chemicals in their products by using state-of-the-art screening and/or target analysis methodologies.

## CASE STUDY 2: Building trust in sustainability claims

Ecolabelling is now common in all consumer product markets. However, while making claims is easy, substantiating them is not. Fragmented markets are contaminated by 'greenwashing', creating confusion and potentially reducing consumer trust in your products.

SGS C&P provide an independent certification and verification scheme for environmental claims. Using globally recognised standards and processes, including ISO 17065 and ISO 14021, US Federal Trade Commission Green Guides, etc. We assess your product against hazardous substance criteria and a wide variety of environmental claims, including compostable, biodegradable and biobased.

Certified products can then carry the SGS Green Mark, allowing you to differentiate your product in the marketplace, while enhancing consumer trust through increased transparency.

## CASE STUDY 3: Helping textile manufacturers meet the European Green Deal

In 2019 the EU announced its intention to become the first climate-neutral continent, meaning all 27 member states must commit to the European Green Deal (EGD). This contains a specific strategy for chemicals that includes nearly 100 actions, and prioritises a range of substances: CMR, endocrine disruptors, PBT, vPvB, immunotoxicants, neurotoxicants, etc.

Bluesign, a member of the SGS Group, is helping the textile supply chain to be fully prepared to meet the demands of the EGD, with a holistic system that provides solutions in sustainable processing and manufacturing. With the bluesign FINDER, textile manufacturers have access to a search engine with more than 20,000 bluesign APPROVED textile auxiliaries and colorants, which makes chemical change management following the EGD philosophy much easier.

Bluesign also supports players in the textile supply chain, with tailor made services, from product stewardship, sustainability reporting, carbon foot printing and knowledge transfer, to installing and maintaining an appropriate supply chain due diligence management system.

## STAFF SELECTION

**Richie Chang – a member of global RSTS electrical and electronic competence centre**

Richie has a master's degree in chemical engineering and more than 18 years' experience in consumer product chemical safety and quality. He supports RSTS-EE on the SGS global platform, including regulatory and standard developments to provide quality product solutions for international markets.

**Tammy Cheng – global RSTS, hardlines and softlines director and global softlines technical development head**

Tammy is a chemist and has more than 25 years' experience in consumer product chemical safety and quality testing. She leads technical and services development, individual affiliates chemical laboratory capabilities development and technical governance for the relevant services.

**Dr Awa He – chair of global RSTS electrical and electronic competence centre**

Awa He has a PhD in chemistry and more than15 years' experience in consumer product chemical safety and quality. He is leading the Global RSTS-EE Competence Center on the technical and service development, and supporting the affiliates' capability development and technical alignment.

**Dr Udo Krischke – global technical manager RSTS and food contact material business development manager**

Udo has a PhD in analytical chemistry and more than 20 years' experience in the fields of consumer product testing and certification. He has a broad background in analytical testing and the respective regulatory framework. While his focus is currently on food contact materials he also contributes to the standardisation work of international committees to determine certain substances in electrical and electronic equipment.

**Dr Hing Wo Tsang – global information and innovation manager**

Hing Wo Tsang has a PhD in chemistry and more than 18 years' experience in consumer product chemical safety and quality. He supports hardlines on the global platform, including regulatory and standard developments to provide quality product solutions for international markets. He also participates in SGS's committee on food contact materials and articles.

Staphyt
empower science together

## CONTACTS

| | |
|---|---|
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| Tel | +33 (0)3 21 21 45 21<br>+33 (0)7 88 35 5211 |
| Contact | Aurély Beghin |
| Directors | Regulatory Business Director: Aurély Beghin |
| Ownership | Staphyt |
| Locations | France, UK, Austria, Poland, Czech Republic, Italy, Spain, Hungary, Brazil |

## OVERVIEW

Our large 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/Latin America and in many other countries.

Our mission is to help our clients to meet all aspects of their chemical and biological regulatory obligations, to achieve authorisation for the production, marketing and sale 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.

We offer complete management of your registration projects, from understanding data requirements, managing contract research organisations (CROs) to generate the data, production of the relevant dossiers and post submission support. If you wish, we can also work in close collaboration with our extensive Staphyt Agrosciences group, laboratory and glasshouse teams, to meet many of your needs, further reducing the number of parties you have to interact with.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €44.7m (2021) |
| No of offices | 10 |
| No of countries represented | >40 |
| Staff, group | >700 |
| Staff, chemical service provision | >120 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

**Areas of expertise**

Sectors covered: plant protection products, fertilisers, biostimulants, biocides, chemical substances (REACH & CLP).

**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;
- expert statements and Efsa compliant literature searches;
- regulatory support in all European countries, Brazil, Australia and many others;
- technical and regulatory training;
- update service Regulatory Watch (newsletter by subscription); and
- support with issues resulting from the UK's withdrawal from the EU (Brexit), including UK REACH.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **1989** | Creation of Staphyt |
| **2015** | Acquisition of Ambrosi Scientific Consulting by Staphyt Group |
| **2018** | Acquisition of TB Agrartechnik (Austria) by Staphyt Group |
| **2018** | Acquisition of APC by Staphyt Group |
| **2020** | Setting Regulatory Affairs office in Brazil |

## ACCREDITATIONS

GLP, GEP, Research Tax Credit accreditation and training.

## 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 start-ups. They specialise in one or more of the following types of business: biocides, industrial chemicals, plant protection products, adjuvants, fertilisers and biostimulants.

## 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."

"I would choose Staphyt for the good relationship with the dossier managers in the different projects and follow-up, the experts also try to tackle problems pragmatically and try to think together with the client for the best solution."

"The assistance we received on the endocrine disruption 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."

**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 modelling. 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 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: Combined field and regulatory services for crops

Our regulatory and agroscience teams worked together to organise out of season field trials in South Africa, Australia and New Zealand, in order to speed up the generation of data needed in the EU to confirm the performance of a new formulation. We were able to justify the inclusion of this data as supporting evidence, showing comparability with EU conditions where appropriate. This initiative resulted in a registration being obtained for the client one year earlier than first anticipated.

## CASE STUDY 5: 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. 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 team has expertise in all areas.

Our experts are drawn from regulatory authorities, industry, grower organisations or testing facilities and from other consultancies, providing Staphyt Regulatory Affairs with a varied and comprehensive offering to our clients.

**Aurély Béghin – Deputy 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.

Previously, Aurély spent seven years in the chemicals industry, where she led product development, from R&D to commercial availability, managed regulatory matters and the relationships with marketing and commercial departments, as well as supporting the group merger processes.

**Garth Drury – Principal Consultant**

Garth Drury joined our team in 2021. With more than 30 years of 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.

Know the rules, play your market.

## CONTACTS

| | |
|---|---|
| Website | www.team-mastery.eu |
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| Head office | Via 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 leading service provider in the area of chemical regulatory affairs, covering all aspects of REACH, BPR, plant protection products (PPP), medical devices (MD), and other regulations. Our staff are highly motivated with specific expertise in chemistry, toxicology, environmental toxicology and risk assessment. We are committed to assisting customers along the supply chain using our industrial experience, helping with the cost-efficient implementation of European and global regulations on chemicals. Our approach is focused on the most advanced and innovative solutions, that combine a scientific approach with regulatory needs to gain the highest benefit for industry and the downstream users.

| VITAL STATISTICS | 2021/22 |
|---|---|
| Turnover, group | €2m |
| Turnover, chemical service provision | €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 long experience in the preparation of REACH registration dossiers, both as lead registrant and joiner. This activity includes any type of update of existing dossiers: tonnage band increase/downgrade, response to specific requests from Echa, etc. Noteworthy is the activity of updating a dossier to make it compliant with the latest requests from Echa.

**READ across justification**

TEAM mastery is leader in read-across justifications, in compliance with the latest Echa standard requests. We have submitted many successful dossiers containing read-across justifications to waive demanding in vivo tests. Read-across is performed in combination with Qsar modelling and in vitro testing, when necessary.

**Testing and in vitro strategy development, Qsar modelling**

An integrated testing strategy is the first step for cost optimisation and building rationale for waiving. Expertise in Qsar modelling has often been successful in discussion with national authorities and scientific working groups.

**Assessment and characterisation of nanomaterials**

TEAM mastery offers assistance in the registration of nanomaterials following an analytical evaluation and (eco)toxicological assessment.

**Authorisation dossiers**

TEAM mastery has gained in depth expertise in the development of complete authorisation dossiers with analysis of alternatives and socio-economic analysis.

**Consortia management**

Experience in consortia management. We can provide legal advice, agreement documents, meeting location, cost calculation, managing of letters of access (LoAs).

**Test monitoring**

In case new tests are required, TEAM mastery will take care of selecting the most appropriate lab, review the protocol, audit the lab and check the results.

**Risk Assessment**

TEAM mastery can offer the possibility of preparing CSRs, adding new uses or preparing a downstream user dedicated CSR. Exposure modelling is performed with most of the recognised official tools like Euses, Ecetoc TRA, EASY TRA, ART, CONS EXPO, RISKofDERM.

**Evaluation process**

Echa is now evaluating all substances. In some cases, there are pending decisions to include a substance as a candidate SVHC. TEAM mastery can support registrants in their discussions with Echa during this process.

**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

**BPR services**

- Full dossier preparation for active substance and products
- Technical equivalence
- Testing strategy development
- Management of biocidal product family (BPF)
- Management of biocidal product family (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

**PPP services**

- Full dossier preparation for active substance and products
- Testing strategy development
- Study monitoring
- Risk assessment
- Finalisation and discussion with national and EU authorities
- Post-submission support

**MD services**

- Medical devices
- Human health risk assessment
- Environmental risk assessment
- Determination of the PDE (permitted daily exposure)
- Assessment of mutagenic impurities

**Feed and Food registration**

- Dossier preparation
- Risk assessment
- Test monitoring
- Assistance to customers for Efsa calls for data

**EU cosmetics Directive**

- Regulatory compliance support
- Product notification
- Cosmetics ingredient profiles
- Product information files
- Cosmetic product safety reports
- Product labelling review and support

**World services**

- UK, Turkey, Korea, Eurasia, China and Japan, US, Canada and Brasil

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2008** | Foundation of REACH mastery |
| **2010** | About 120 successful registrations for the first REACH deadline |
| **2012** | Implementation of the BPR division |
| **2014** | Preparation and submission of the first application for REACH authorisation |
| **2015** | Implementation of the group to comply with the needs of the biocidal products Regulation and pharma industry. Presentation of the first accepted CLH dossier and of the first family dossiers for biocidal products to the Italian member state |
| **2016** | Implementation of the group to comply with the needs of the plant protection products Regulation. Presentation of two dossiers after Article 95 disputes on biocides and two authorisation dossiers |
| **2018** | Technical management and dossiers implementation of the biggest Italian taskforce for the national authorisation of sodium hypochlorite |
| **2018** | New company name as TEAM mastery |
| **2021** | The new division "WORLD mastery" is born |
| **2022** | New Quaternary Salts task force for Biocidal Product National Authorisation and REACH Registration of Polymers implementation. |
| **2023** | 11 REACH Applications for Authorisation<br>The new division "TEAM academy" is born |

## PARTNERS

- Centro REACH S.r.l.
- Kahlberg Consulting S.r.l.
- Isemed S.r.l.
- Research projects in collaboration with: Department of Pharmacological and Biomolecular Sciences, University of Milan; Department of Earth and Environmental Sciences, University of Milano-Bicocca, Milan; Department of Science and High Technology, University of Insubria
- Strong partnership with CAAT Europe (Centre of Alternatives to Animal Testing)
- Partner of SaferWorldbyDesign platform **saferworldbydesign.com/**

## CLIENTS

We are working with about 500 customers around Europe; they are manufacturers, distributors, downstream users, from SMEs to international chemical companies involved in many different industrial fields including fertilisers, leather, textile, paper, pharmaceuticals, galvanic, food, cosmetic, polymers and many others.

## CASE STUDY 1: REACH compliance check

The group has proved itself one of the most professionally prepared in the European scenario to manage all different aspects of a REACH dossier. TEAM mastery has prepared hundreds of lead dossiers, many of them with a full study plan ordered and monitored. UVCBs and difficult substances are our main specialisation area.

With the increased number of Echa compliance checks, many dossiers need to be reevaluated, discussed and improved from the first submission of 2010. TEAM mastery was able to improve the exposure scenarios, read across justifications and the overall quality of the existing dossiers.

## CASE STUDY 2: Application for Authorisation

After the incertitude of the chromium trioxide Authorisation for decorative use 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, thanks to the solid experience of the many applications presented in recent years.

## CASE STUDY 3: Quaternary salts Biocides consortium

TEAM mastery is working together 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 for the first deadline in 2022. Hundreds of products have been studied and organised for applications for the next few years.

## CASE STUDY 4: Nanomaterials

TEAM mastery provides assistance in the identification and characterisation of nanoforms as well as on the definition of eco(toxicological) testing strategies, including grouping of nanoforms for read-across approaches. TEAM mastery supported several clients in their compliance to the Commission Regulation (EU) 2018/1881 (amending the REACH regulation) on new information requirements for nanoforms of substances.

## CASE STUDY 5: New approach methodologies

Companies are more and more interested in new approach methodologies (NAMs) for the toxicological assessment of chemicals without the use of in vivo experiments. This is driven by compliance with the EU cosmetic Regulation or for ethical reasons, but also after acknowledging the limitations of the traditional approach based on animal testing. TEAM mastery, in collaboration with different universities or specialised CROs, can provide advanced strategies based on NAMs, following the setup of the best protocol, the interpretations of the results and the preparation of the dossiers for the authorities.

## 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, when it was only a minor proposal. The cooperation with many specialists within international companies and universities allowed her to specialise in consortia management and dossier preparation.

**Dr Costanza Rovida – ERT REACH Regulatory Specialist**

Graduated in chemistry, after 15 years of experience in the field of analytical chemistry, she is now responsible for the management of individual projects and global customer assistance. She is also part of CAAT-Europe team and participant in an integrated EU project, EU-ToxRisk, focused on integrated development of alternative toxicological methods to animal testing.

**Dr Stefano Tortelli – Biocides Regulatory Specialist**

Graduated in chemistry, Stefano developed experience in project management and human resources, before dedicating himself to the regulatory field.

**Dr. Giovanna Attardi – PPP Regulatory Specialist**

Graduated in communication science, she developed experience in the regulatory area, initially as GLP Quality Assurance manager, then going through the registration offices of several companies. She joined TEAM mastery as regulatory specialist for the PPP and Agro regulatory Division.

tsg

## CONTACTS

| | |
|---|---|
| Website | www.tsgconsulting.com |
| E-mail | info@tsgconsulting.com |
| Head office | TSG Consulting, Concordia House, St James Business Park<br>Grimbald Crag Court, Knaresborough, North Yorkshire HG5 8QB, UK |
| Tel | +44 (0) 1423 799 633 |
| Contact | Vicky Atkinson |
| Directors | Daryl Thomas (Europe), Ryan Gaunt (North America) |
| Ownership | Science Group plc |
| Locations | Global, with offices in France, Germany, Spain, UK, US, 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 | 2021/22 |
|---|---|
| Turnover, group | >£80m |
| Turnover, chemical service provision | >£30m |
| No of offices | 12 |
| No of countries represented | Worldwide regulatory support |
| Staff, group | 400 |
| Staff, chemical service provision | >100 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

UK (Cambridge, Epsom, Knaresborough, London)

Continental Europe (Paris, France; Goslar, Germany; Oviedo, Spain)

North America (Sacramento, US; Washington DC, US; London, Ontario, Canada)

Asia (Hong Kong, Shenzhen, Taiwan)

## 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 luclid 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
- EPA, 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, it 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**

More than 30 years' experience in human health and environmental 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 more than ten years' experience providing scientific and regulatory support across the plant protection, biocides and cosmetics industries and 20 years in total managing multi-disciplinary scientific projects.

**Iain Watt – Head of Plant Protection**

Thirty four 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**

More than 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**

More than 15 years' experience in international food and beverage regulations, specialising in strategic and compliance projects.

**Abigail Wacek – Head of Federal Affairs**

Specialist in pesticide compliance, with expertise in residual disinfectants, inert ingredient petitions, treated articles, and products that integrate nanoscale materials, especially silver.

**Kelly Rahn – Managing Director, State Affairs**

More than 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.

**Laurie A Clarke, JD, MPP – Vice President and Principal, Medical Device Regulatory**

Former FDA partner at three top-ranked Washington, DC, law firms. Specialises in helping device companies develop and implement regulatory strategies that meet their marketing objectives.

Add value.
Inspire trust.

## CONTACTS

| | |
|---|---|
| Website | www.tuvsud.com/de-reach |
| E-mail | REACH@tuvsud.com |
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| Tel | +49 89 5190-5990 |
| Fax | +49 89 5791-1174 |
| 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 | 2021/22 |
|---|---|
| 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.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **1866** | Established in Mannheim |
| **1926** | Introduction of the TÜV SÜD mark/stamp in Germany |
| **1960** | Establishing chemical services |
| **1990** | Conglomeration of TÜVs from the southern part of Germany to form TÜV SÜD and the expansion of business operations into Asia<br>Best brand of technical services, testing, consulting, training, certification in all industries worldwide – energy producers and providers, nuclear power plants, chemical industry |
| **2006** | Expansion of services in Asean by acquiring Singapore-based PSB Group |
| **2007** | Establishing REACH services. Founder member of the BUSINESSEUROPE REACH Implementation Network |

## ACCREDITATIONS

GLP

## CLIENTS

Due to 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).

## 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 20 years' professional experience.

**Dr Yvonne Fery**

Yvonne Fery is a food chemist, European registered toxicologist and certified REACH multiplicator with more than 12 years' professional experience.

**Dr Bratislav Djordjevic**

Bratislav Djordjevic is a chemist with more than 11 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.

## 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<br>Europe (UK): +44 115 965 1888 |
| Directors | Jill Oakman |
| Ownership | UL Solutions, LLC |
| Locations | Global |
| Founded | 1894 |

## OVERVIEW

At UL Solutions, we help companies manage compliance and sustainability for products through their entire lifecycle and throughout their complex global supply chains. For more than 30 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 management solutions that allow companies to:

- manage their ingredient and product data;
- assess and meet the regulatory compliance obligations required 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 | 2021/22 |
|---|---|
| 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; São 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 hazard communication and chemical data management software allows you to manage your EHS initiatives 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 7,500 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 60+ 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.

**Sustainable product design**

We provide formulators, engineers and R&D experts with the technical and compliance information they need to develop products quicker and with the regulatory insights to successfully enter the marketplace. From selection of the first raw materials, through a complex manufacturing process, to its proper disposal at end of use, UL Solutions provides customers around the globe with the information and resources to make informed and sustainable decisions.

**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.

## CORPORATE DEVELOPMENTS & 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<br>UL Solutions & Johns Hopkins partner to create innovative machine learning software Cheminformatics |
| **2018** | UL Solutions launches search tool UL Product iQ®, for verifying UL certifications of products and components |

| | |
|---|---|
| **2019** | UL Solutions launches Navigator®, an online compliance knowledge base for over 50 countries<br>UL Solutions launches Illuminator®, a first-of-its-kind software tool enabling online access to industry-leading ChemADVISOR data |
| **2020** | UL Solutions integrates regulatory and retailer compliance data into Prospector for early insights in the product development process |
| **2021** | UL Solutions markets chemical footprinting solution for consumable products aiding global retailers and brand owners with their reduction targets |
| **2022** | UL Solutions launches ChemADVISOR® content for SAP® EHS with expert rules, templates, data and phrases for SDS authoring<br>UL Solutions launches industry-specific chemical management and assessment solutions for articles and components |

## ACCREDITATIONS

ISO 27001 (Latham, New York)

## CLIENTS

More than 14,000 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.

## CASE STUDY 1: 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; and
- regulatory expertise and support for handling, transportation, use and disposal of hi-tech electronics.

## 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 product compliance and stewardship needs.

**Benefits:**

- trusted third party to facilitate the secure transfer of product composition data;
- protection of critical CBI;
- automation of GHS compliant safety data sheets (SDS) and labelling documentation; and
- risk mitigation and brand protection.

## CASE STUDY 3: 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; and
- seamless translation of safety data sheets into multiple languages in a matter of minutes.

## STAFF SELECTION

**Darlene Susa-Anderson – 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 they use 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.

**Dr Martina Schneider – Regulatory Affairs Group Leader**

Martina oversees the regulatory advisory services. Building on her background in environmental chemistry, she gained a deep knowledge of European regulations such as REACH, CLP and RoHS, and utilises this expertise to support our customers and critical global content for our ChemADVISOR Regulatory Database.

chemicals compliance consulting UMCO

## CONTACTS

| | |
|---|---|
| Website | www.umco.de |
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| Tel/Fax | +49 (0)40 / 555 546 300 / +49 (0)40 / 555 546 357 |
| Contact | Jan Mönster |
| Directors | Anika Biehl<br>Peter Duschek<br>Ulf Inzelmann |
| Ownership | See directors |
| Locations | Germany |
| Founded | 1982 |

## OVERVIEW

**Chemical Compliance Consulting**

UMCO has been offering compliance solutions for the distribution and handling of chemicals all over the world through its offices in Hamburg and Cologne for the past 40 years.

Our 80 employees look after 1,000 companies in the chemicals, pharmaceuticals, logistics and processing industries worldwide. Through our longstanding consultancy activities, we know exactly what our clients require in their daily operations: 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; and
- professional seminars and training.

## VITAL STATISTICS

| | 2021/22 |
|---|---|
| No of offices | 2 |
| No of countries represented | 1 |
| Staff, group | 80 |
| Staff, chemical service provision | 40 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Germany: Hamburg, Cologne

## 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)
- 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
- 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

**REACH management (REACH Regulation (EU) No 1907/2006)**

**Comprehensive support for lead registrants**

- Preparation of all relevant documents for registration, eg technical dossier in Iuclid 6, risk and exposure assessments and chemical safety reports
- Literature research, data evaluation and data gap analysis
- Study management and monitoring
- 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 letters of access (LoA)
- Compilation of inquiry/registration dossiers and submission to Echa
- REACH registration dossier updates
- Support during Echa compliance checks
- REACH-IT management

**Representative services**

- Only representative (OR) for non-EU manufacturers according to Article 8 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 REACH. compliance, for example restriction (annex XVII), authorisation (annex XIV)
- 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**

- 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
- Study management and monitoring
- Communications with authorities and laboratories
- Preparation of technical dossier in Iuclid 6 and submission
- Preparation of application documents for national notifications (transitional period for actives applicable)

**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)
- GlobalChem24: 24-hour emergency number for chemicals transport and SDS worldwide (together with the NCEC)

**Training**

- Training, workshops and seminars provided across all services
- Inhouse seminars
- Online training and webinars
- Working and process instructions

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2006** | Co-founder of the Global Chemical Consulting Network (GCCN), an entity which provides further services regarding foreign legal regulations |
| **2012** | New development of an independent, proprietary software solution – UMCO Hazard Communication System (UHCS) – for monitoring products and compiling documents for hazard communication |
| **2013** | Customised interfaces for the automatic import and export of data per XML transfer from our UMCO SDS software (UHCS) to 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

- NCEC
- 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

- Assumption of product stewardship and legal chemical products services for paint companies, including determination of classification and labelling for products in all EU regions and languages.
- Compilation of SDS and CLP/GHS labels.

## CASE STUDY 3: REACH consortium management

- Financial management, management of subcontractors, trustees
- Registration management, SIEF and LoA management.

## STAFF SELECTION

We support our customers with an interdisciplinary team of 80 engineers, scientists and legal experts, who are dedicated to ensuring the economic viability, quality, adherence to deadlines and success of our customers' projects.

# VelocityEHS®

## CONTACTS

| | |
|---|---|
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| Tel | +1 866 919 7922 |
| Contact | www.EHS.com \| +1 866 919 7922 |
| Locations | United States, Canada, United Kingdom, Australia, Ireland |
| Founded | 2001 |

## OVERVIEW

Trusted by more than 19,000 customers worldwide, VelocityEHS is the global leader in true SaaS enterprise EHS technology. Through the VelocityEHS Accelerate® Platform, the company helps global enterprises drive operational excellence by delivering best-in-class capabilities for health, 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.

VelocityEHS is headquartered in Chicago, Illinois, with locations in Ann Arbor, Michigan; Tampa, Florida; Oakville, Ontario; Perth, Western Australia; and Cork, Ireland. For more information, visit www.EHS.com.

## VITAL STATISTICS

| | 2022/23 |
|---|---|
| No of offices | 6 |
| No of countries represented | 4 |

## SERVICE AREA BREAKDOWN

## SERVICES PROVIDED

### SDS/chemical management

The award-winning VelocityEHS chemical management solution is the industry gold standard for Cloud and mobile chemical management solutions. Its software is known for delivering the easiest-to-use tools for centralised SDS management and employee right-to-know access (online and offline), as well as container-level product management, secondary workplace labelling (GHS and more), reporting, regulatory list cross-referencing, chemical risk assessments, chemical data archiving and innovative sharing of critical inventory information with first responders.

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.

### 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. Included are the company's certified toxicologists and regulatory experts that are on hand to help companies classify chemicals, as well as author, translate and review chemical-product documents, such as safety data sheets, ingredient disclosure documents, a variety of labels, and more.

Its team is available to assist companies with meeting global chemical management compliance requirements, such as those related to Osha HCS, EU CLP, WHMIS, the other 65+ GHS-aligned hazard communication standards, as well as individual corporate product stewardship and sustainability goals.

The team's work ranges from preparing hybrid SDSs and certified business information (CBI)/trade secret claims to performing ingredient substitution assessments and creating custom container labels. All projects are handled with the greatest attention to detail and in line with industry and regulatory best practices.

### 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:

- hazardous materials shipping papers and manifests, in order to meet DOT, FAA, IMDG, Iata and other global hazmat shipping requirements;
- SDSs, in order 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 from the industry-leading VelocityEHS database; and
- lithium battery shipping support.

### Chemical management services

VelocityEHS offers a range of services to complement its chemical management software that enable customers to further streamline critical safety and chemical management tasks. Whether customers are looking for ways to fast-track a transition from paper to electronic SDS management or confirm an accurate accounting of their physical chemical inventory, the VelocityEHS services team can help.

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 industrial hygiene (IH) solutions – including sample and equipment management, programme management, medical surveillance and respirator fit test – work together or independently to help automate and streamline workflows.

VelocityEHS IH solutions help both certified industrial hygienists and EHS professionals new to the field to succeed through a comprehensive cloud software system that makes it easy to assess and control workplace stressors with tools that simplify sampling and data entry, drive IH programme management and enhance the visibility of workplace risks.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2015** | OH&S new product of the Year – best new SDS management |
| **2016** | Environmental Protection– best new product |
| **2017** | ASSP Safety Attendee Choice Award– best EHS & MSDS software product |
| **2017** | NAEM EHS & Sustainability Software Ratings and Report – most recommended |
| **2016-2020** | ISHN Readers' Choice Award– best SDS management product |
| **2021/22** | OH&S Industrial Hygiene Awards – Industrial Ergonomics and IH Sample & Equipment Management |
| **2017, 2019, 2021-2023** | Verdantix Green Quadrant Report – industry leader |

## 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

NSC, ASSP, AIHA, , Verdantix, EcoVadis, SASB

## CLIENTS

Microsoft Corporation, Toyota, Kraft Heinz, Ashland, 3M, Coca-Cola

## TESTIMONIALS

"VelocityEHS [chemical management] software is so easy to use." *Ikea, North America*

"Very well done, from sales to implementation." *A healthcare customer*

"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*

"Everybody in the company can look something up very quickly and easily. It's become part of our culture of emergency preparedness and response." *Jim Kamon, MAG Automotive*

"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: New Life Chemical & Equipment

VelocityEHS simplified SDS/chemical management for New Life Chemical & Equipment, an industry leader in sustainable chemical recycling with customers around the world. With nearly 1,000 different chemicals at any given time in more than 100,000 square feet of warehouse space, New Life needed an easier way to manage and access a large amount of safety data sheets and chemical inventory information – especially in the face of changes to hazard communication requirements from GHS alignment. Additionally, after a small warehouse fire, the company identified a need for a smoother process to provide critical safety information to first responders.

The company's Cloud-based and mobile SDS/chemical inventory management system was the perfect solution. It gave New Life the ability to easily maintain its library of SDSs and chemical inventory information online, obtain new and updated documents from its industry-leading SDS database, and quickly generate GHS-aligned workplace container labels. Plus, the system's unique, built-in first responder sharing tool provided an efficient way for the company to share its potentially life-saving hazardous chemical inventory information with local emergency responders, making New Life better equipped to handle chemical-related incidents.

## CASE STUDY 2: Primetals Technologies

Primetals Technologies – a joint venture between Mitsubishi and Siemens that provides metals industry processing equipment and solutions – turned to VelocityEHS and its SDS/chemical inventory management solutions to more efficiently manage chemical hazards and ever-evolving compliance requirements. As a manufacturing industry leader with global reach, multiple facilities across locations and nearly 1,000 chemicals on hand that require safety data sheets, Primetals needed a soluti on it could rely on to meet hazard communication requirements and keep its employees safe, all while simplifying day-to-day chemical management tasks.

In addition to the ability to easily access and manage SDSs and chemical inventory details, the company's Cloud-based and mobile system allowed Primetals to more efficiently create secondary workplace container labels and reduce its environmental footprint through the selection of safer chemical substitutions – the latter it achieved by comparing its own product inventory information with that of alternatives from the system's expansive database; an important tool in advancing the company's ongoing commitment to sustainability.

Primetals also found benefit in using VelocityEHS because it offered other easy-to-use EHS solutions, including tools for managing Osha recordkeeping compliance and employee on-demand training on a variety of workplace topics.

## STAFF SELECTION

**John Damgaard, CEO**

In addition to his role at VelocityEHS, John advises CVC Capital on private equity and growth investments across multiple industries. John served as CEO of MatrixCare (acquired by ResMed), growing revenues and EBITDA nearly sixfold in seven years. He served as VP & GM and SVP & COO of Mediware Information Systems (now WellSky). He holds an MBA with Distinction from Bradley University, and a Bachelor of Arts of Computer Science and Mathematics from the University of Northern Iowa as a Presidential Scholar.

## CONTACTS

| | |
|---|---|
| Website | www.vitisregulatory.com |
| E-mail | info@vitisregulatory.com |
| Head office | Saxon House, John Roberts Business Park, Pean Hill, Whitstable, Kent, CT5 3BJ, UK |
| Tel | +44 (0)1227 470901 |
| Contact | Dr Oliver Warwick |
| Directors | Oliver Warwick, Louise, McLaughlin, Rosalind Wildey |
| Ownership | Limited company |
| Locations | UK, Belgium, Germany |
| Founded | Originally formed in 1995 under the name Peter Fisk Associates. Established as a UK limited company in 2006. PFA-Brussels founded as Belgian SRL in 2016. German GmbH established in 2022 |

## OVERVIEW

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 | 2021/22 |
|---|---|
| No of offices | 3 |
| No of countries represented | 3 |
| Staff, group | 35 |
| Staff, chemical service provision | 30 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

Whitstable, Kent, UK

Etterbeek, Brussels, Belgium

Bockenem, Lower Saxony, Germany

## SERVICES PROVIDED

Vitis Regulatory Limited, SRL and GmbH colleagues work together to offer expert advice and support on:

**Regulatory compliance**

- REACH: development of all aspects of technical dossiers, including substance identity and classification and labelling, and response to regulatory evaluation
- Biocidal products: compiling product authorisation dossiers for compliance with 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, and partner with other experts for assessment of efficacy
- Cosmetics: understanding of chemistry, degradation in the environment, toxicology and ecotoxicology to support development of the cosmetic product safety report (CPSR) for notification under the EU cosmetics Regulation
- 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 environmental 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.
- Undertaking 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 including volatiles, poorly soluble or unstable substances and complex mixtures

**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 & ACHIEVEMENTS

| | |
|---|---|
| **1995** | Peter Fisk Associates established |
| **2006** | Incorporated as a private limited company |
| **2008** | PFA Limited gained certification to ISO 9001 |
| **2015** | PFA Limited gained certification to ISO 27001 and ISO 14001 |
| **2016** | PFA-Brussels SRL was established, as a subsidiary of Peter Fisk Associates Limited |
| **2019** | PFA-Brussels SRL gained certification to ISO 9001 |
| **2020** | Internal buyout and change of ownership to Oliver Warwick, Louise McLaughlin, and Ros Wildey |
| **2022** | Change of name to existing company to rebrand as Vitis Regulatory Limited and Vitis Regulatory SRL<br>Vitis Regulatory GmbH was established as a subsidiary of Vitis Regulatory Limited |

## ACCREDITATIONS

**Certifications:**

Vitis Regulatory Limited: ISO 9001 Quality Management System, ISO 14001 Environmental Management System, ISO 27001Information Security Management System

Vitis Regulatory SRL: ISO 9001 Quality Management System

## CLIENTS

Vitis Regulatory has a wide range of clients from both industry and regulatory organisations.

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.

## TESTIMONIALS

Can be provided upon request

## CASE STUDY 1: REACH registrations

Vitis Regulatory has been supporting our clients with EU REACH since the publication of the Regulation back in 2006. Beginning with data gap analysis, strategies for filling endpoints using non-testing methods and developing integrated testing strategies, 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". That work resulted in a report which considers the potential risks to human health and the environment posed by polymers and reviews the need to register them under REACH. The report was made publicly available and was discussed at the 35th Caracal meeting in which it became clear that the prospect of polymers requiring registration under REACH may become a reality in the near future.

The main challenges to bringing polymers into REACH registration are predicted to be around the complexity of substance identity and adapting standard testing regimes to accommodate polymers. The main strategy being to minimise the number of polymers for REACH registration (PRRs) by adequately defining their composition and then grouping and categorising them. This will help to determine when and if testing is appropriate, ultimately reducing the number of animal tests required through the utilisation of read across, Qsars and other regulatory adaptations.

Preparing our clients for the registration of polymers under a revised REACH will allow them to answer important business questions regarding vulnerabilities in their substance portfolios: What data do they have? How can polymers be grouped? How can existing data be used most effectively? What new data may be required? Understanding polymers and how they fit in the current regulatory landscape at an EU or global level will be pivotal for the polymer industry and will allow for long range planning for regulatory compliance and product stewardship. The team at Vitis Regulatory has the expertise and creativity to help businesses of any size develop a strategy for polymers and to be prepared for the implementation of regulations related to polymers.

## 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.

## 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 15 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). Working with directors and team leaders to ensure the delivery of high quality scientific and technical support for clients across industry and government. Input to specific projects and collaborations with partners.

**Louise McLaughlin – Director**

Louise joined the company in 2002. She has a background in analytical chemistry and previously worked in regulatory and analytical departments for a major CRO. She is project leader 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.

**Mike Crookes PhD – Principal Environmental Scientist**

Mike has more than 30 years' experience in the area of environmental risk assessment of chemicals in a regulatory context and is familiar with risk assessment and environmental modelling techniques used under OECD and EU chemicals programmes, including the EU REACH Regulation. Mike is experienced in the environmental exposure assessment of chemicals and in validation and interpretation of information on biodegradation, bioaccumulation and ecotoxicity of chemicals.

**Joanne Massey – Principal Toxicologist**

Joanne has more than 20 years' experience working as a toxicologist, primarily in the field of hazard assessment of industrial chemicals in the regulatory context, but also biocides, food additives, soil contaminants and air pollution. Joanne has taken the lead toxicologist and substance leader roles in the preparation of many, often complex, REACH registration dossiers for numerous clients and consortia, as study monitor for a range of study types, and in planning of targeted testing and read-across strategies.

**Emma Jack PhD, LLM – Principal Consulting Scientist**

Emma has more than 20 years' experience in ecotoxicology and natural resource protection in a regulatory and policy context. Working with both private and public clients and regulatory authorities in both Europe and North America Emma is highly experienced in multi-stakeholder team coordination and management. Regulatory compliance experience includes development and maintenance of datasets, hazard and risk assessment, programme and project management of projects up to US$1m. Emma manages a variety of dossiers under REACH registration.

## CONTACTS

| | |
|---|---|
| Website | www.yordasgroup.com |
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| Tel | +44 (0) 1524 510278 |
| Fax | +44 (0) 1524 510588 |
| Contact | Malcolm Stewart |
| Directors | Jonathan Lutwyche, Dr Sandra Meijer, Adam Rowntree |
| Ownership | Privately owned |
| Locations | UK, Germany, Turkey, Canada. |
| 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

| | 2021/22 |
|---|---|
| No of offices | 5 |
| No of countries represented | Global |
| Staff, group | 97 |
| Staff, chemical service provision | 61 |

## SERVICE AREA BREAKDOWN

## GLOBAL OFFICES

The company has offices and representation in the UK, Germany, Turkey, US, Canada, Japan, China and Brazil.

## 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
- Biocides product regulations (BPR EU, UK, Turkey, South Korea, North and South America) and claim substantiation
- Hazard communication: global safety data sheets (SDS), classification and labelling to GHS, CLP and other global classification systems, exposures scenarios, 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
- 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.

## CORPORATE DEVELOPMENTS & ACHIEVEMENTS

| | |
|---|---|
| **2007** | Founded as The Reach Centre |
| **2017** | Rebranded to Yordas Group and formed a Group of Companies |
| **2018** | Yordas GmbH (Germany) |
| **2018** | Yordas Limited (Canada) established |
| **2020** | Yordas Danışmanlık Limited Şirketi (Türkiye) established |
| **2022** | Yordas K.K (Japan) established |

## 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

## CLIENTS

Our global customer base includes manufacturers, distributors and retailers across a broad variety of industry sectors, along with trade associations and government bodies.

## 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: Materials obsolescence management plan for BAE Systems Maritime

**The client:**

BAE Systems, a leading maritime manufacturer, produces various product ranges for the naval industry as well as developing new technologies across a number of sectors to meet the demand and requirements of the defence industry. Many businesses of this type rely on a number of highly specialised chemical formulations in order to manufacture their finished products. With extremely long and onerous approval cycles for products and components, their supply chains have a high potential of being severely impacted by obsolescence. Yordas Hive's functionality provides our client with the advantage of managing their materials obsolescence company-wide to address both current and upcoming chemicals legislation.

**Yordas Hive helps maintain visibility of high-risk products**

Using Yordas Hive, BAE Systems has been able to take advantage of our information-rich database to determine the obsolescence risk of their substances. The Hive Notifier tool further allows the client to maintain risk status by monitoring changes in relevant regulations.

The Yordas Hive software allows BAE to customise their compliance database and upload their bill of materials and chemical constituent information in order to maintain visibility of high-risk products. In turn, this enables the client to prioritise any required action to mitigate against obsolescence and keep track of the impact of regulatory changes on their products. As a result, BAE Systems saves considerable time and effort, while being reassured that they are getting the most current information about regulatory changes that affect their products, both now and in the future.

yordasgroup.com/case-studies/bae-systems

## 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.

**Benefits for the client**

The client can call on Yordas to help with any issues they encounter related to the chemical compliance of their products, so we can assist as and when required with their needs, as well as keeping in touch regularly with ongoing notifications of the changing regulatory landscape that affects their product portfolio.

yordasgroup.com/case-studies/extension-compliance-team

## STAFF SELECTION

**Sandra Meijer – Principal, Product Stewardship**

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.

**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.

**Rosalinda Gioia – Principal, Science**

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.

**Neil Hunt – Managing Regulatory Scientist, Lead: Nanomaterials Research**

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.

## Anthesis

| CONTACTS | |
|---|---|
| Website | www.anthesisgroup.com |
| E-mail | contact@anthesisgroup.com |
| Head office | Unit J, Taper Studios, 175 Long Lane, London, SE1 4GT |
| Tel/Fax | +44 (0)1865 250 818 |
| Contact | Dawn Allan |
| Ownership | Private company |
| Locations | UK, Europe, US, China, Philippines |
| Founded | 1994 |

### OVERVIEW

Anthesis' Sustainable Chemicals team, formed when Caleb became part of the Anthesis Group in 2014, provides policy and regulatory consultancy in the field of chemical regulation and management. Our clients range from corporate multinationals and worldwide consortia to small companies with a single substance. Proud to be a B Corp, Anthesis seeks to make a significant contribution to a world that is more resilient and productive. With a considerable track record in sustainable chemicals management, we support clients in managing regulatory compliance and beyond.

### SERVICES PROVIDED

- Consortium and Sief management
- EU REACH – dossier development for registration, evaluation and supporting clients through authorisation or restriction
- UK REACH – managing developing requirements and supporting implementation
- Only Representative (OR) and third-party representative services
- Supporting clients through emerging polymer and microplastic regulation
- Classification, labelling and packaging compliance management
- SDS authoring and management, poison centre and C&L notifications
- Product compliance under REACH, RoHS, and Extended Producer Responsibility
- Sustainability strategy development and implementation
- Sustainable procurement
- Chemical management including supply chain mapping, design and implementation
- Lifecycle analysis
- Unique connection with Anthesis Group Services, supporting clients with their approach to the ever-developing sustainability agenda

### CLIENTS

Anthesis supports clients ranging from SMEs to large corporations, European and global industry associations, and global taskforces across a range of industrial sectors and retailers. With a flexible approach, Anthesis consultants act as OR, REACH consortia leads, project managers, and provide ad hoc consultancy support as needed for our clients.

## CEA
CAMBRIDGE ENVIRONMENTAL ASSESSMENTS

| CONTACTS | |
|---|---|
| Website | www.cea.adas.co.uk |
| E-mail | enquiries@cea-res.co.uk |
| Head office | Cambridge Environmental Assessments, Battlegate Road, Boxworth, Cambridge CB23 4NN, UK |
| Tel | +44 (0)7748 932070 |
| Contact | Adrian Terry |
| Ownership | Private |
| Locations | UK (Cambridge, Helsby, Nottingham), Republic of Ireland (Dublin) |
| Founded | 2001 |

### OVERVIEW

Cambridge Environmental Assessments (CEA), part of RSK ADAS, provides technical and strategic expertise and dossier support for chemical registrations. This encompasses agrochemicals, biocides, veterinary and human pharmaceuticals, food additives, fertilisers and general chemicals.

Our team of 27 people is based in the UK and Ireland. It comprises specialists in environmental fate and behaviour; field fate and stewardship; exposure and spatial modelling; aquatic ecotoxicity testing; ecotoxicology and risk assessment; toxicology and human health risk assessment; and regulatory affairs

### SERVICES PROVIDED

Our services include: specialist regulatory support and consultancy across many chemical types; higher tier, non-standard support for challenging products, including design and conduct of higher tier studies; full dossier preparation and support service under the BPR; REACH and chemical regulatory support to clients seeking regulatory compliance for new substances, difficult to identify substances, or those substances where properties or uses require a non-standard approach to toxicology or eco-toxicology testing, alternative testing approaches, non-standard exposure modelling and risk assessment.

### CLIENTS

We work with clients that encompass agrochemical, biocide, veterinary and human pharmaceutical, food, fertiliser and general chemical companies from around the globe. We also provide specialist policy advice and research to government clients and consultancy services to water companies and their associations.

## Chem Academy

| CONTACTS | |
|---|---|
| Website | www.chem-academy.com |
| E-mail | info@chem-academy.com |
| Head office | Bahnhofsplatz 2, D-16321 Bernau bei Berlin, Germany |
| Tel/Fax | +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.

| CONTACTS | |
|---|---|
| Website | https://com4chem.de/en/about/ |
| E-mail | info@com4chem.de |
| Head Office | Chilehaus A, Fischertwiete 2, 20095 Hamburg, Germany |
| Tel | +49 1736176387 |
| Fax | +49 40 320 052 00 |
| 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.

Chemical compliance also means thinking outside the box. New legal challenges must be detected early on in order to incorporate them, and to enable sustainable product development on the market.

European chemicals legislation is not rigid structure. Other developments relate to legal provisions for individual substances, for example classification, restriction and authorisation. New or more stringent general requirements will come with the REACH Revision end of 2023. 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 authorization)
- Strategic REACH consultation, compliance monitoring for substances, PPORD
- Substances in articles, SVHC and SCIP notifications
- Inhouse seminars, webinars and workshops

### CLIENTS

- REACH Selenium & Tellurium Consortium
- Metals producers and distributors including associations
- Paint manufacturers
- Polymer producers
- Producers of medical devices
- Chemicals distributors

| CONTACTS | |
|---|---|
| Website | www.coracle.global |
| E-mail | info@coracle.global |
| Tel/Fax | +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 also have experience in designing 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

| CONTACTS | |
|---|---|
| Website | www.csb-compliance.com |
| E-mail | info@csb-compliance.com |
| Head Office | Dujardinstraße 5, 47829 Krefeld, Germany |
| Tel | +49 2151 652086 0 |
| Fax | +49 2151 652086 9 |
| Contact | Lars Dobbertin |
| Ownership | Privately owned company |
| Locations | Germany, USA & UK |
| Founded | 1996 |

## OVERVIEW

For more than 25 years, CSB Compliance has been a globally active consulting company for chemical compliance solution in family hands with a major focus on competence and reliability.

Complex requirements in the handling of chemical products and their worldwide marketability are our day-to-day business.

Our experienced team of experts with about 25 employees in Germany, UK and USA supports you in all questions concerning chemical compliance.

We make the difficult simple: You Care About Your Business, We Care About Chemical Regulations.

## SERVICES PROVIDED

As an independent service provider, we support you in the planning, implementation and ongoing compliance of solutions for national and international regulatory requirements.

Our portfolio covers the following areas:

**Hazard Communication:** Classification and labelling according to CLP, Safety data sheets and hazard labels. Notifications to poison centres (PCN– Annex VIII CLP), SCIP database & C&L Inventory

**Chemical Regulatory Services:** EU and UK REACH, KKDIK, Biocides

**Dangerous Goods Management:** In this complex subject, we provide our customers with sound advice and are happy to offer support in all matters relating to the classification of dangerous goods in accordance with the UN or the consequences of a classification.

**Toxicological Risk Assessment**: Our toxicologists identify potential hazards for humans and the environment.

## CLIENTS

Our customers – whether they are in the chemical, pharmaceutical, logistics, or processing industries – benefit from the sound technical expertise combined with the many years of experience of our team.

| CONTACTS | |
|---|---|
| Website | www.espheres.com |
| E-mail | Philip.capel@espheres.com |
| Head office | rue des Pères Blancs 4, 1040 Etterbeek, Brussels, Belgium |
| Tel/Fax | + 32 (0)2 740 43 36/ + 32 (0) 473 58 14 73 |
| Contact | Philip Capel |
| Ownership | Private |
| Locations | Belgium, Finland, Germany |
| 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 with REACHLaw help companies to improve their chemical product compliance. We can work 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 softwares, 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 (Verisk 3E, 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

(petro)chemicals, pharmaceuticals, paintings, steel and alloys, pulp and paper, polymers, electronic, semiconductor, cosmetic, automotive industry.

| CONTACTS | |
|---|---|
| Website | www.fera.co.uk/chemical-regulation |
| E-mail | Howard.easterfield@fera.co.uk |
| Head office | Fera Science Ltd |
| Tel | +44 (0)300 100 0321 |
| Contact | Howard.easterfield@fera.co.uk |
| Ownership | Joint Venture between Capita PLC & DEFRA |
| Locations | United Kingdom |
| Founded | 1920 |

## OVERVIEW

Fera Science is a leading national and international centre of excellence for interdisciplinary science, with a focus on environmental, agricultural and food-chain sustainability. GLP testing to support Regulatory Environmental Risk and Safety Assessment is a core capability at Fera. Our expertise covers ecotoxicology, environmental fate, metabolism, physico-chemical properties, analytical chemistry and microbiology. To deliver this work Fera has assembled an impressive range of world class facilities, including temperature-controlled laboratories, state-of-the-art analytical instrumentation, a flow-through aquarium, glasshouses, field plots, animal facilities and a flow-through mesocosm. These facilities allow our expert scientists to deliver a wide range of GLP studies to support the development and registration of plant protection products, feed additives, veterinary medicines, pharmaceuticals, biocides, industrial chemicals (REACH) and biopesticides.

## SERVICES PROVIDED

- Aquatic Ecotoxicology, including fish, invertebrate and plant studies
- Terrestrial Ecotoxicology, including studies on plants, soil organisms and NTAs
- Pollinator Ecotoxicology, including acute, chronic, larval and brood studies
- Expertise in the investigation of endocrine disruption
- Environmental Fate with both radiolabelled and non-labelled test items
- Metabolism studies with plants and animals
- Expertise in aged sorption and plant uptake factor studies
- Analytical Chemistry, including LC-MS/MS, GC-MS/MS, ICP-MS, HRMS & radiochemistry
- Residue depletion studies to support veterinary medicine safety assessment
- Microbiology to support the registration of microbial biopesticides
- QSAR modelling, including mammalian toxicity, ecotoxicity and physiochemical properties
- Mesocosm with static and flow-through test designs to simulate ponds, ditches and streams
- Bespoke studies to support ERA's, for example surface run-off and mopping studies

## Euridea LANGUAGE EXPERTS

| CONTACTS | |
|---|---|
| Website | www.euridea stranslation.com |
| E-mail | translation@euridea stranslation.com |
| Head office | Square de Meeûs 35, 1000 Brussels, Belgium |
| Tel | +32 (0)2 808 4406 / +49 1522 1306186 |
| Fax | +32 (0)2 627 5655 |
| Contact | Kristina Bitvai |
| Ownership | Private company |
| Locations | Belgium, Germany, Hungary |
| Founded | 2007 |

### OVERVIEW

Euridea 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, CPL and BPR Regulations and other related EU, international and local legislation. We have huge 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 translations, certified translations, proofreading and editing services in all European and in many Asian, African and Latin American languages. The translations are always by a native speaker translator and proofread by a second native-speaking translator. We also carry out thorough quality checks on the prepared translation. 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, Ecolab, Hellenic Petroleum, Glencore International, HELM AG, Rio Tinto, Wintershall, International Lead Association, Nickel Institute, Syngenta, DonauChem, Euromines, Tokyo Chemical Industry, Nissan Chemicals, and many more.

## INFOTOX

| CONTACTS | |
|---|---|
| Website | www.infotox.pt |
| E-mail | info@infotox.pt |
| Head office | INFOTOX, Lda, Rua de Moscavide 6D, Parque das Nações, 1990-160, Lisbon, Portugal |
| Tel/Fax | + 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, 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, 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;
- guidance on setting up a post-market surveillance programme;
- 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 centre notifications in the EU/UK;
- 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 (CPSR).

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.

## Kerona Scientific Ltd.

| CONTACTS | |
|---|---|
| Website | www.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 and the UK |
| Founded | 2014 |

### OVERVIEW

With offices in Ireland, Spain 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, fertlisers, chemicals and cosmetics throughout the EU and Middle East.

### SERVICES PROVIDED

Kerona provides a full range of expert 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.

## LKC

| CONTACTS | |
|---|---|
| Website | www.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.

## REACHReady

| CONTACTS | |
|---|---|
| Website | www.reachready.co.uk |
| E-mail | enquiries@reachready.co.uk |
| Head office | Kings Buildings, Smith Square, London SW1P 3JJ |
| Tel/Fax | +44 (0) 20 7901 1444 |
| Contact | Rachel Nabudde |
| Ownership | REACHReady is a wholly owned subsidiary of the Chemical Industries Association |
| Founded | 2006 |

### OVERVIEW

REACHReady offers a confidential 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 programme, gives 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. www.reachready.co.uk

### SERVICES PROVIDED

Helpdesk, Consultancy, Training, Matchmaker

### CLIENTS

Chemical manufacturers, Formulators, Downstream users of chemicals, Article manufacturers, Retailers, Service providers

## REACHwise

| CONTACTS | |
|---|---|
| Website | www.reachwise.com |
| E-mail | info@reachwise.com |
| Head office | 22, St Albans Avenue, London W4 5JP, UK |
| Tel | +44 (0)20 8747 0873 |
| Contact | Peter Douben |
| Ownership | Private company |
| Locations | UK, Netherlands |
| Founded | 2007 |

### OVERVIEW

With extensive REACH, CLP and BPR knowledge, REACHwise provides tailor-made services to producers and users of chemicals throughout the supply chain. Our focus on these areas means our efforts are targeted. We change complex situations into manageable elements, and provide cost-effective solutions.

### SERVICES PROVIDED

**OR and Brexit:** OR services for both the EU27/EEA and UK jurisdictions providing efficient and effective services and maximum flexibility.

**Impact of REACH, CLP and BPR (EU/EEA and UK):** finding comprehensive solutions for companies on the best way to approach the REACH, CLP and BPR "problem" and to remain compliant: stay on the market and grow!

**Sief support:** we provide the whole spectrum of Sief and consortium management.

**REACH registration:** our REACH support covers data evaluation and sharing, preparation of the technical dossier, use and exposure requirements, chemical safety assessment and exposure scenarios.

**Safety data sheets:** we prepare and update SDSs (body and annexed ESs) including translations.

**Exposure scenarios:** for individual substances as well as mixtures ensuring they are comprehensive and communicable: you discharge your obligations; your customers find them easy to understand.

**Downstream uses:** using specialist models we ensure that your conditions are compliant even when they deviate from the registrant's information.

**Biocides:** actives or products, we take care of them: from start to finish, covering all major product types.

### CLIENTS

Our clients receive an efficient service. Hence satisfied customers from the ceramics industry, fertilisers and related industries, fragrance sector, health care sector, home and personal care, lubricants manufacturers and suppliers, metals and minerals sectors, pigments and colorants sector, speciality chemicals industry. Happy retailers include those in the cosmetics sector.

## SCAS Europe

| CONTACTS | |
|---|---|
| Website | www.scas-eu.be |
| E-mail | scaseurope07@scas-eu.be |
| Head office | SCAS Europe (Sumika Chemical Analysis Service), Leonardo da Vincilaan 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 | 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.

## Siam

| CONTACTS | |
|---|---|
| Website | www.siam-it.com |
| E-mail | sales@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 of the 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 | www.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 €2bn. There are more than 30 experts in the compliance team.

### SERVICES PROVIDED

- Chemical 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

| CONTACTS | |
|---|---|
| Website | www.toxicon.it |
| E-mail | info@toxicon.it |
| Head office | Via Robolini 1, 27100 Pavia, Italy |
| Tel/Fax | +39 0382 1938015 / +39 0382 1938026 |
| Contact | Raffaella Butera, MD |
| Directors | Raffaella Butera, MD |
| Ownership | Private company |
| Locations | Italy |
| Founded | 2010 |

### OVERVIEW

Toxicon provides a wide range of expert advice services in regulatory fields and in the areas of toxicology, pharmacology, occupational medicine and consumer safety for companies, institutions and the general public. Our know-how is based on a solid academic background in risk assessment and a deep knowledge of customer needs. Our specialists team consists of physicians, pharmacologists, biologists, chemists, economists and lawyers: complex problems can be solved with success and quality only through teamwork.

### SERVICES PROVIDED

- **Overall services:** guidance on regulatory interpretation, compliance support, auditing
- **REACH:** data sharing, consortia management. Data gap analysis, testing strategy. Dossier preparation including CSA/CSR. Ppord. SDS and e-SDS. Compliance check with ES, scaling, CSR-DU development. ES for mixtures. Authorisations including SEA. Notification to Scip database
- **CLP/GHS:** hazard assessment, C&L, notification to Echa C&L Inventory and to PCN Portal for emergency health response on mixtures
- **BPR Regulation:** data sharing agreements, dossier for active substances approval and biocidal products authorisation at national and EU level
- **Cosmetic products:** safety assessment, product information file, notification
- **Medicines and medical devices:** CTD, genotoxic impurities, PDE assessment, environmental risk assessment. MD chemical and biological characterisation, leachables and extractables assessment
- **Occupational medicine:** risk assessment and management (CAD, CMD). Provisional OELs for APIs and other chemicals
- **Toxicological risk assessment:** documents, expert advice and consultancy
- **Other:** training for companies, universities and institutions

### CLIENTS

Toxicon assists both large companies and SMEs. Moreover, Toxicon works in partnership with institutions, industries and associations for R&D and compliance projects.

## toxfocus

| CONTACTS | |
|---|---|
| Website | www.toxfocus.com |
| E-mail | barbara.vogt@toxfocus.com |
| Head office | 8967 Hunters Way, Highlands Ranch, CO 80129, US |
| Tel/Fax | +1 501 351 4389 |
| Contact | Barbara Vogt, PhD, DABT |
| Ownership | Private company |
| Locations | US |
| Founded | 2008 |

### OVERVIEW

Tox Focus LLC provides toxicologic and scientific content for REACH, cosmetics Regulation, and other regulatory programmes, drawing upon 30 years' experience in corporate and clinical toxicology. The consultancy creates technical Iuclid 6 dossiers for REACH, CLP notifications and harmonisation, weight-of-evidence positions and REACH evaluation responses to Echa/member states. Tox Focus LLC is a qualified risk assessor for the EU cosmetics Regulation and for the US Department of Commerce.

### SERVICES PROVIDED

**REACH:** quality toxicology assessments and strategic planning for compliance with data requirements of regional chemical control legislation, including data gap filling, adaptations to data requirements, identification of analogues and categories, computer modelling and support (QMRF, QPRF), laboratory test commissioning and monitoring, robust study authoring, construction of Iuclid 6 files with validation reports, chemical safety reports, risk assessments, classification, labelling and packaging (CLP), and evaluation support/dossier defence. **Scip:** article and database assessment along with Iuclid 6 data file preparation. **EU cosmetics Regulation:** product risk assessment certificates and cosmetic product safety reports (CPSR) as part of the product information file (PIF).

### CLIENTS

The Redstone Group/SafeBridge Regulatory and Life Sciences Group/Trinity Consultants, Allnex, Cytec Industries Inc, Unilever, Lucite International, Ineos Europe Ltd, The Cyanide Council, Evonik-DeGussa GmbH, Vertellus Specialties Inc, Air Products and Chemicals Inc, Arch Chemicals Inc, Calumet Specialty Products Partners LP, Gulf Bayport Chemicals LP, Gerber Scientific International, AW Chesterton Company, Medi-Ray Inc, GE Healthcare NL, Mayer Brown International LLP, Abercrombie and Fitch, Monat Global Corp, The Nail Consultants, Ltd, US Department of Commerce.

## wsp

| CONTACTS | |
|---|---|
| Website | www.wsp.com |
| E-mail | REACH@wsp.com |
| Head office | 70 Chancery Lane, London, UK |
| Tel/Fax | +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;
- safety data sheet, 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.

# The world looks to you to make it a sustainable place.

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- Changing global EHS regulations
- Best practices in EHS compliance management
- Tips & techniques for multi-national compliance programs

enhesa.

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| 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** | **62** | **US** | **US, Canada, Europe, Asia** | **100-500** | **100-500** | ◗ | | | | ◗ | ◐ | | | |
| 3S-SafelyServingScience | | Greece | | 2-5 | 2-5 | ● | ◗ | | | | | ◗ | | ◗ |
| Accenture | | Belgium | | 5,000 plus | ○ | ◗ | ◗ | | | ◐ | ◗ | ◗ | | |
| **Acta** | **64** | **US** | **UK, Belgium, China** | **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** | **160** | **UK** | **Europe, N. America, China, Philippines** | **100-500** | **5-10** | ● | ◗ | | | ◗ | | | | ◗ |
| **Apeiron-Team NV** | **66** | **Belgium** | | **10-25** | **10-25** | ● | ◗ | | | | ◗ | ◗ | | ◗ |
| **Arcadis** | **68** | **The Netherlands** | **Belgium, Switzerland, North America, China** | **5,000 plus** | **50-100** | ◐ | ◗ | | ◗ | ◗ | ○ | ◗ | | |
| **Arcerion GmbH** | **70** | **Germany** | | **10-25** | **10-25** | ◐ | ◗ | | ◗ | ◗ | ◗ | ◗ | | |
| **ARCHE Consulting** | **72** | **Belgium** | | **25-50** | **25-50** | ● | ◗ | | | ◗ | | ◗ | | |
| **Arrow Regulatory Ltd** | **74** | **UK** | **Ireland, Austria** | **10-25** | **10-25** | ● | ◗ | | | | ○ | ○ | | |
| **Artemisa d.o.o.** | **76** | **Slovenia** | **Slovakia, Poland, Hungary, Croatia** | **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 | ◗ | ◗ | ◗ | | | ◗ | ◗ | | |
| ATOMIUM | | Croatia | | 2-5 | 2-5 | ◐ | ◗ | ◗ | | ◗ | ◗ | ◗ | | |
| ATOUT REACH | | France | | 2-5 | 2-5 | ◐ | ◗ | | | | | ◗ | | |
| **Auxilife Scientific Services Pvt. Ltd** | **78** | **India** | | **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** | **160** | **UK** | **Republic of Ireland** | **5,000 plus** | **25-50** | ● | ◗ | | ◗ | | | ◗ | | |
| 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** | **160** | **Germany** | **Germany** | **10-25** | **5-10** | | | | | | | ● | | |
| ChemAlert (RMT) | | Australia | | | | ◗ | | | | ◐ | ◗ | ◗ | | ◗ |
| **CHEMDOX** | **82** | **Austria** | **US** | **50-100** | **10-25** | | | | | ● | | ◗ | | |
| Chementors Ltd | | Finland | China, Vietnam | 5-10 | 5-10 | ◐ | ◗ | ◗ | ◗ | ◗ | ◗ | ◗ | | |
| Chemex Environmental International Ltd | | UK | | 10-25 | 10-25 | ◗ | | | ● | | | ◗ | | |
| ChemFORWARD | | US | | 5-10 | | ◗ | | ● | | ◗ | | | | |
| ChemHaz Solutions | | Ireland | | 1 | 1 | ● | | | | | | ◗ | | |

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◐ 40-60% ◗ 20-40% ◗ 5-20% ○ <5%

| | Focus of activities | | | | | | | | | | | | | | | Regulatory expertise | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Organisation** | Industrial chemicals | Agrochemicals | Medical & pharmaceuticals | Biotechnology | Biocides | Personal care (inc. cosmetics) | Veterinary medicine | Electrical and electronics | Toys/children's products | Aerospace, automotive & engineering | Construction | Textiles & apparel | Cleaning products | Medical devices | Food (contact) | Occupational | REACH | Global chemical notifications | CLP | GHS-based regulations | New TSCA/LCSA | Biocidal products Regulation | EU cosmetics Regulation | Agrochemical registrations | Food contact | RoHS | Toy Safety Directive | Medical devices Regulation | CMD | CAD | COSHH | US HCS | **Further information** |
| 1cc GmbH | ■ | | | | □ | | | ■ | | □ | | | | □ | | | ■ | ■ | ■ | ■ | □ | □ | | | | ■ | | □ | | | | | www.1cc-consulting.com |
| 24-7 Response | | | | | | | | | | | | | | | | | □ | □ | ■ | ■ | | □ | □ | | | | | | | | | | www.24-7response.org |
| **3E** | ■ | ■ | ■ | □ | □ | ■ | | □ | □ | ■ | ■ | □ | ■ | □ | ■ | □ | ■ | ■ | ■ | ■ | ■ | □ | ■ | | ■ | ■ | □ | □ | | | □ | ■ | www.3Eco.com |
| 3S-SafelyServingScience | ■ | □ | □ | □ | ■ | ■ | | | | | | | ■ | | | ■ | □ | ■ | ■ | ■ | | ■ | ■ | □ | | | | | | | | | www.3s-chem.gr |
| Accenture | ■ | ■ | ■ | ■ | □ | ■ | □ | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | □ | □ | ■ | | | | | | | | | www.accenture.com |
| **Acta** | ■ | ■ | □ | ■ | ■ | ■ | □ | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | □ | □ | ■ | ■ | ■ | ■ | www.actagroup.com |
| Active Steward | ■ | □ | | □ | □ | □ | | | | | | | □ | | □ | | ■ | ■ | ■ | ■ | □ | □ | □ | □ | □ | ■ | | | | | □ | | www.activesteward.com |
| Aegis Regulatory Inc | ■ | | | | □ | □ | | | | | | | | | | | □ | □ | ■ | ■ | □ | | □ | | | | | | | | | | www.aegisreg.com |
| Aequor, Inc. | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | ■ | | ■ | ■ | | | | | | | | ■ | ■ | | ■ | | | | | | | | ■ | www.aequorinc.com |
| AG-HERA | ■ | ■ | ■ | □ | ■ | ■ | ■ | | | | | | | | | | ■ | ■ | ■ | ■ | □ | ■ | ■ | ■ | | | | | | | | | www.ag-hera.com |
| AGREXIS AG | | ■ | | | ■ | | | | | | | | | | | | | | □ | □ | | ■ | | ■ | | | | | | | | | www.agrexis.com |
| Alchemy Compliance Ltd. | ■ | | | | | | | | | | | | | | | | ■ | □ | ■ | ■ | □ | □ | □ | | | | | | | | □ | □ | www.alchemycompliance.com |
| Alemare Solutions Limited | ■ | ■ | | | | ■ | | | | | | | ■ | | | | ■ | □ | ■ | □ | | | □ | | | | | | | | □ | | www.alemare.co.uk |
| ALSTER Consulting > Chemical Compliance | ■ | | | | □ | □ | | | | | | | | | | | ■ | | □ | □ | | □ | □ | | | | | | | | | | www.alster-consulting.eu |
| Altertox Academy | □ | □ | □ | □ | □ | □ | □ | | | | | | □ | □ | | | □ | □ | □ | □ | □ | □ | □ | □ | □ | | | | | | | | www.academy.altertox.be |
| Altox a/s | ■ | | | □ | ■ | ■ | | □ | ■ | ■ | □ | □ | ■ | □ | □ | ■ | ■ | □ | ■ | □ | | ■ | ■ | | □ | □ | ■ | □ | | | | □ | www.altox.dk |
| AMEC (now Wood plc) | ■ | □ | □ | □ | □ | □ | | | | | | | | | | | ■ | □ | □ | □ | ■ | □ | | □ | | | | | | | | | www.woodplc.com |
| Anderson Materials Evaluation, Inc. | ■ | □ | □ | □ | □ | □ | □ | ■ | □ | ■ | ■ | ■ | □ | ■ | □ | □ | | | | | | | | □ | □ | | □ | ■ | | | | | www.andersonmaterials.com |
| Annray Test Co., Ltd. | ■ | | | ■ | | □ | | | | | | | | | | | ■ | □ | | | | | | | | | | | | | | | www.annraytest.com |
| Antea Group | ■ | ■ | ■ | □ | □ | □ | | | | | | | | | | | □ | □ | □ | □ | ■ | | | □ | | | | | | | | | www.anteagroup.com |
| **Anthesis Group** | ■ | □ | | | □ | □ | | ■ | □ | ■ | ■ | ■ | □ | □ | □ | | ■ | ■ | ■ | ■ | ■ | □ | □ | | □ | ■ | | □ | □ | □ | □ | ■ | www.anthesisgroup.com |
| **Apeiron-Team NV** | ■ | □ | □ | | ■ | □ | | □ | □ | □ | □ | □ | □ | | □ | □ | ■ | □ | ■ | □ | □ | ■ | □ | | □ | □ | □ | | □ | □ | | | www.apeiron-team.eu |
| **Arcadis** | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | □ | ■ | ■ | □ | ■ | ■ | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | □ | ■ | □ | □ | ■ | ■ | www.arcadis.com |
| **Arcerion GmbH** | ■ | □ | □ | | ■ | □ | | □ | □ | | | □ | ■ | | | ■ | ■ | ■ | ■ | ■ | □ | ■ | | □ | | ■ | | □ | ■ | ■ | □ | | www.arcerion.com |
| **ARCHE Consulting** | ■ | ■ | ■ | | ■ | ■ | □ | | | □ | | □ | ■ | □ | | | ■ | □ | ■ | ■ | □ | ■ | ■ | ■ | | □ | | □ | | | | | www.arche-consulting.be |
| **Arrow Regulatory Ltd** | ■ | □ | □ | □ | ■ | □ | □ | | | | | | ■ | □ | □ | □ | ■ | ■ | ■ | ■ | □ | ■ | □ | □ | □ | | | □ | | | □ | □ | www.arrowregulatory.com |
| **Artemisa d.o.o.** | □ | ■ | | ■ | ■ | | □ | | | | | | □ | □ | | | □ | □ | ■ | ■ | | ■ | | ■ | | | | □ | | | | | www.artemisa.si |
| Asia Inspection (now QIMA) | □ | □ | | | | □ | | ■ | ■ | | | ■ | □ | | ■ | □ | ■ | | | | | | □ | | ■ | ■ | ■ | | | | | | www.qima.com |
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■ 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) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 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 | ● | | | | | | ◗ | | |
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| ▶ **ChemSafe** | **88** | **Italy** | | **25-50** | **5-10** | ◗ | ◗ | ◗ | ◗ | ◗ | ◗ | ◗ | | |
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| 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 | ◗ | ◗ | ◗ | ◗ | ◗ | | ◗ | ◗ | ◗ |
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| Chemwatch | | Australia | US, Europe, Asia | 100-500 | 100-500 | ◗ | | ◗ | | ◗ | | ◗ | | |
| CHESSOL B.V. | | The Netherlands | Belgium, France, Italy | 5-10 | 2-5 | ● | | | | ◗ | | | | |
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| 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** | ◗ | ◗ | | ◗ | ◗ | ◗ | ◗ | | ◗ |
| CIS Center | | Russia | | 50-100 | 50-100 | ◗ | ◗ | ◗ | | ◗ | ◗ | ◗ | | |
| Citoxlab (part of Charles River) | | France | Hungary | 1,000-2,000 | 100-500 | ◗ | | | ● | | | | | ◗ |
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| ChIR– Chemical Innovation and Regulation | ■ | □ | ■ | □ | □ | | | | | | | | | | | | ■ | | ■ | ■ | □ | □ | □ | □ | | □ | | | | | □ | □ | www.emmcchir.org |
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| CIDP | | | ■ | ■ | | ■ | | | | | | | | | | | □ | | | | | | □ | | | | | | | | | | www.cidp-cro.com |
| Cindax BV | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | www.cindax.com |
| **CIRS** | ■ | ■ | □ | | □ | ■ | □ | ■ | ■ | | | ■ | ■ | ■ | ■ | □ | ■ | ■ | ■ | ■ | □ | □ | □ | ■ | ■ | ■ | ■ | ■ | | | | ■ | www.cirs-group.com |
| CIS Center | ■ | ■ | | | □ | □ | | | | | | | ■ | | | ■ | □ | □ | □ | ■ | | □ | □ | | | □ | | | | | | | www.ciscenter.org |
| Citoxlab (part of Charles River) | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | □ | ■ | □ | | □ | □ | □ | | | □ | | □ | | | | | | | | | www.criver.com |
| CJV Consulting Ltd | ■ | □ | | | ■ | □ | | | | | | | | | | | ■ | □ | ■ | ■ | □ | ■ | □ | | | | | | | | | | www.cjvconsultingltd.wix.com/cjvconsultingltd |
| Clariant | | | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | www.clariant.com |
| **com for chem– Compliance for Chemicals** | ■ | | | | | □ | | □ | | □ | □ | □ | □ | □ | □ | □ | ■ | □ | ■ | □ | □ | | □ | | | □ | | | □ | □ | | | com4chem.de |
| Compliance & Risks | □ | | | □ | ■ | □ | | ■ | ■ | ■ | □ | ■ | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | | | ■ | | www.complianceandrisks.com |
| Compliance Footprint AG | ■ | ■ | | | | | | | | | | | | | | | ■ | □ | ■ | ■ | | | | | | | | | | | | | www.compliance-footprint.com |
| Compliance Services International | ■ | ■ | □ | □ | ■ | ■ | □ | | | | | | | □ | ■ | | ■ | ■ | ■ | ■ | □ | ■ | ■ | ■ | ■ | □ | | □ | | | □ | | www.complianceservices.com |
| Compliance-Footprint AG | ■ | □ | | | □ | | | | | | | | | | □ | | ■ | □ | ■ | □ | □ | □ | □ | | | □ | | | | | | | https://compliance-footprint.com/ |
| Concept Life Sciences | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | www.conceptlifesciences.com |
| Consortia Management GmbH | ■ | □ | | | ■ | □ | | | | | | | | | □ | | ■ | ■ | ■ | ■ | □ | ■ | □ | □ | □ | | | | | | | | www.consortia-management.com |
| CONUSBAT Regulatory Services | | ■ | | ■ | | □ | ■ | | | | | | | | | | | | | | | | | □ | | | | | | | | | www.conusbat.com |
| **Coracle** | ■ | □ | □ | | | ■ | □ | | □ | | | ■ | ■ | | □ | | ■ | ■ | □ | □ | □ | □ | □ | □ | □ | □ | □ | | | | | | www.coracle.global |
| Cosanta | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | ■ | | | | | | □ | | | ■ | ■ | ■ | | www.stoffenmanager.com |
| CRAD | ■ | ■ | □ | □ | ■ | □ | □ | | | □ | | □ | ■ | | □ | □ | ■ | □ | ■ | ■ | □ | ■ | □ | □ | □ | □ | | | | | | | www.crad.com.tr |
| Crowell & Moring | ■ | ■ | ■ | ■ | ■ | | | ■ | | ■ | ■ | ■ | | | | | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | | | | ■ | | | | | www.crowell.com |
| CS Regulatory Ltd | ■ | | | | □ | | | □ | | | | □ | □ | | □ | | ■ | ■ | ■ | ■ | ■ | □ | | | □ | □ | | | | | □ | □ | www.csregulatory.com |
| **CSB Compliance Group** | ■ | | | | ■ | □ | | | | | ■ | | ■ | | □ | | ■ | □ | ■ | ■ | □ | ■ | | | ■ | | | | | | | ■ | www.csb-compliance.com |
| Currenta GmbH & Co. OHG | ■ | ■ | ■ | | □ | □ | □ | | | | | | | | | | ■ | □ | ■ | □ | □ | □ | □ | ■ | | | | | | | | | www.currenta.de |
| Cyprotex | ■ | ■ | ■ | ■ | ■ | ■ | □ | | □ | | | □ | ■ | □ | | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | □ | □ | | | □ | □ | www.cyprotex.com |
| Danger and Safety srl | ■ | | | | ■ | ■ | | | | | | | | | | | ■ | ■ | ■ | ■ | □ | ■ | ■ | | | | | | | | | | www.dangerandsafety.it |
| dangerousgoods.com | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | □ | | | | | | □ | □ | □ | □ | □ | □ | □ | □ | □ | | | | | | | | | www.dangerousgoods.com |
| Danish Technological Institute | □ | ■ | □ | ■ | ■ | □ | □ | | □ | □ | ■ | ■ | ■ | ■ | □ | □ | □ | | □ | | | ■ | □ | □ | □ | □ | □ | □ | | | | | www.dti.dk/biocides |
| Datalab | ■ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | www.datalabsj.com |
| de ViB fabriek | ■ | ■ | □ | □ | □ | □ | □ | | | | | □ | ■ | □ | | ■ | □ | □ | ■ | ■ | □ | □ | □ | □ | □ | □ | □ | | | | | ■ | www.devibfabriek.nl |
| DEKRA Assurance Services GmbH | ■ | □ | □ | □ | □ | □ | □ | | | | | | | | | | ■ | □ | ■ | ■ | □ | □ | □ | □ | | | | | | | | | www.dekra-consulting.de/de/chemikalienverordnung-reach/ |
| DEKRA Consulting GmbH | ■ | □ | □ | | | □ | | | | | | | | | | | ■ | □ | ■ | ■ | □ | □ | □ | □ | | | | | | | | | www.dekra.com/en/consulting |
| DEKRA Process Safety | ■ | ■ | ■ | □ | ■ | ■ | □ | □ | □ | □ | □ | □ | ■ | □ | □ | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | □ | □ | □ | □ | □ | □ | □ | □ | www.dekra-uk.co.uk/en/process-safety-overview/ |
| Dell Tech Laboratories Ltd. | ■ | ■ | □ | □ | ■ | ■ | □ | | | | | | | | | | | □ | □ | ■ | □ | | □ | □ | | | | | | | | | www.delltech.com |
| Delphic HSE | □ | | | | □ | ■ | | | ■ | | | | ■ | □ | □ | | □ | □ | ■ | □ | ■ | □ | ■ | □ | □ | ■ | ■ | | □ | ■ | ■ | ■ | www.delphichse.com |
| Dentons | ■ | □ | ■ | ■ | ■ | ■ | □ | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | www.dentons.com |
| DHI | ■ | □ | ■ | □ | ■ | ■ | ■ | □ | ■ | | | | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | ■ | □ | ■ | □ | □ | ■ | □ | □ | ■ | ■ | www.dhigroup.com |
| DIPHEX Ltd | ■ | ■ | ■ | ■ | | ■ | | | | | | | | | | | | | | | | | | | | | | | | | | | www.diphex.com |
| DORUKSISTEM | ■ | ■ | □ | □ | ■ | ■ | ■ | ■ | ■ | | | ■ | ■ | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | | | ■ | | www.doruksistem.com.tr |
| Dr. Andrea Volpato | ■ | □ | | | □ | | | □ | | □ | | □ | | □ | | | ■ | ■ | ■ | ■ | □ | □ | | □ | | □ | | □ | | | | | www.andreavolpato.it |
| DR-Software | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | www.dr-software.com |
| DXC Technology | | | | | | | | ■ | | ■ | | | | □ | | | ■ | □ | □ | □ | □ | ■ | □ | | □ | ■ | | | ■ | | | | https://public.cdxsystem.com/en/web/cdx/home) |
| Eagle Environmental | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | www.eagleenv.co.za |
| **EBRC Consulting** | ■ | ■ | □ | | ■ | □ | | | □ | | | □ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | □ | ■ | | | □ | | □ | | | | **EBRC Consulting** |
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| Ecolab | ■ | | | | □ | | | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | | | | | | www.ecolab.com |
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| EcoMole Ltd. | ■ | □ | □ | ■ | □ | □ | | | □ | | □ | □ | □ | | □ | □ | ■ | □ | ■ | □ | □ | □ | □ | □ | □ | □ | □ | | | | | | www.ecomole.com |
| EcoMundo | ■ | | | | ■ | ■ | | | | ■ | | | | | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | ■ | | ■ | ■ | | | | | | ■ | www.ecomundo.eu |

**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 | | | | | ● | | | | |
| Enhesa | | Belgium | US, China, Japan, Canada | 100-500 | 1 | ◑ | | ● | | | | ◑ | | |
| Envigo | | US | Offices in 14 countries worldwide | 2,000-5,000 | 500-1,000 | ◑ | | | ● | | | | | |
| 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** | **161** | **Belgium** | **Finland, Germany** | **5-10** | **5-10** | ◑ | | | | ◑ | ◑ | | | |
| ETC | | Slovakia | | 10-25 | 5-10 | ● | ◑ | | | | ◑ | ◑ | | |
| EUPHOR | | US | | 50-100 | 10-25 | ◑ | | | | ● | | | | |
| **Eurideas Language Experts** | **162** | **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** | **161** | **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** | **108** | **Sweden** | **India, South Korea, Ireland, UK, Taiwan, Turkey 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** | **110** | **Ireland** | **US, UK, Poland, Finland** | **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 | | | ● | | | | | | |
| 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** | **112** | **France** | | **1,000-2,000** | **1,000-2,000** | ◑ | ◑ | | ◑ | | ◑ | ◑ | ◑ | ◔ |
| **INFOTOX** | **162** | **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 | | | | | | | | | | | | | | | | Regulatory expertise | | | | | | | | | | | | | | | Further information |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Industrial chemicals | Agrochemicals | Medical & pharmaceuticals | Biotechnology | Biocides | Personal care (inc. cosmetics) | Veterinary medicine | Electrical and electronics | Toys/children's products | Aerospace, automotive & engineering | Construction | Textiles & apparel | Cleaning products | Medical devices | Food (contact) | Occupational | REACH | Global chemical notifications | CLP | GHS-based regulations | New TSCA/LCSA | Biocidal products Regulation | EU cosmetics Regulation | Agrochemical registrations | Food contact | RoHS | Toy Safety Directive | Medical devices Regulation | CMD | CAD | COSHH | US HCS | |
| Economics for the Environment Consultancy Ltd. (eftec) | ■ | □ | □ | □ | ■ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | ■ | ■ | | □ | □ | | ■ | □ | | | | | | ■ | | □ | | www.eftec.co.uk |
| EcoOnline | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | □ | www.ecoonline.com |
| Ecotox Services Australia | ■ | ■ | ■ | ■ | ■ | □ | □ | | | | | | | | | | | | | | | | | | | | | | | | | | www.ecotox.com.au |
| ECT Oekotoxikologie GmbH | ■ | ■ | ■ | | ■ | □ | ■ | | | | | | | | | | ■ | | □ | | | □ | | □ | | | | | | | | | www.ect.de |
| Edif ERA (now Rina) | | | | | | | | ■ | | □ | | | | □ | | | ■ | | □ | | □ | □ | | | | ■ | □ | □ | | | | | www.rina.org/en |
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| elc group | ■ | □ | ■ | □ | □ | ■ | □ | | | | | | | | | | ■ | ■ | ■ | ■ | □ | □ | ■ | □ | | | | | | | | | www.elc-group.com |
| Elements Advisory | □ | □ | □ | | ■ | □ | □ | | | | | | □ | □ | □ | | □ | □ | ■ | □ | | ■ | □ | □ | □ | | | □ | | | | | www.elements-advisory.be |
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| Enhesa | ■ | ■ | □ | □ | ■ | ■ | | ■ | ■ | ■ | □ | □ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | □ | ■ | ■ | ■ | □ | | | ■ | ■ | www.enhesa.com/ |
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**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** | **114** | **UK** | **110+ 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 | | 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 | ● | ◗ | | | ◗ | ◗ | ◗ | | |
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| Keller and Heckman LLP | | US | Belgium, France, China | 100-500 | 25-50 | ◗ | ◗ | ● | | | | | | |
| Kelley Drye & Warren | | US | Brussels | 100-500 | 25-50 | | | | | | ● | | | |
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| 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 | | | | ◗ | ◗ | | | | |
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| Kumi Consulting Ltd | | UK | | 5-10 | 2-5 | ● | | | | | | | | |
| 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 | ● | | | | | | | | |
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| Olon Ricerca Bioscience | | US | | 500-1,000 | 500-1,000 | ◗ | ◗ | | ● | | | | | |
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| SustChem Engineering Ltd | | Greece | | 5-10 | 5-10 | ● | ◗ | | ◗ | | | ◗ | | |
| SustChem Technical Consulting SA | | Greece | Cyprus | 25-50 | 25-50 | ● | ◗ | ◗ | ○ | | | ○ | | |
| **Sweco Finland Ltd** | **164** | **Finland** | **Finland** | **2,000-5,000** | **25-50** | ● | ◗ | | | | | | | |

Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◖ 40-60% ◗ 20-40% ◗ 5-20% ○ <5%

| Organisation | Focus of activities | | | | | | | | | | | | | | | Regulatory expertise | | | | | | | | | | | | | | Further information |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Industrial chemicals | Agrochemicals | Medical & pharmaceuticals | Biotechnology | Biocides | Personal care (inc. cosmetics) | Veterinary medicine | Electrical and electronics | Toys/children's products | Aerospace, automotive & engineering | Construction | Textiles & apparel | Cleaning products | Medical devices | Food (contact) | Occupational | REACH | Global chemical notifications | CLP | GHS-based regulations | New TSCA/LCSA | Biocidal products Regulation | EU cosmetics Regulation | Agrochemical registrations | Food contact | RoHS | Toy Safety Directive | Medical devices Regulation | CMD | CAD | COSHH | US HCS | |
| Qualisys GmbH | ■ | ◘ | ■ | ◘ | ■ | ■ | ◘ | | | | | | | | | | ■ | □ | ■ | ■ | | ■ | ■ | | | | | | | | | | www.qualisys.eu |
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| Randis ChemWise (Shanghai) Co., Ltd. | ■ | □ | | | ◘ | ■ | | | | | | | | | | | □ | ■ | ■ | ■ | □ | ◘ | □ | □ | | | | | | | | | www.randis.cn |
| REACH Advice GmbH | ■ | □ | | | | | | | | | | | | | | | ■ | ■ | ■ | | | | | | | | | | | | | | www.reach-advice.com |
| REACh ChemConsult GmbH | ■ | ◘ | ◘ | | ■ | ■ | ◘ | | | | | | | | ◘ | ◘ | ■ | | ■ | ■ | | ■ | ■ | ◘ | ◘ | ◘ | ◘ | ◘ | | | | | www.reach-chemconsult.com/ |
| Reach Chemical BV | ■ | | | | | | | | | | | | | | | | ■ | | ■ | ■ | | ◘ | | ◘ | | | | | | | | | www.reacheu.nl |
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| REACH Monitor | ■ | ■ | ■ | ◘ | ■ | ■ | ■ | | | | | | | | | | ■ | ■ | ■ | ■ | ◘ | ■ | ■ | ■ | | | | | | | | | www.reachmonitor.org |
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| REACH Orphan Substances Consortium bvba ROSC | ■ | ■ | ◘ | □ | □ | □ | □ | ■ | ◘ | ■ | ■ | ■ | ■ | □ | □ | □ | ■ | □ | ■ | □ | □ | □ | □ | □ | □ | ◘ | ◘ | □ | | | | | www.ROSconsortium.eu |
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| ReachCentrum SA | ■ | ◘ | ◘ | ◘ | ■ | | | □ | □ | □ | □ | □ | ◘ | □ | □ | □ | ■ | ■ | ■ | ■ | ◘ | ■ | | ■ | | ◘ | ◘ | ◘ | | | ◘ | □ | www.reachcentrum.eu |
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**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) |
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| TERRA-The Electronics Reuse & Recycling Alliance | | US | US | 2-5 | 2-5 | | ● | | | | | | | |
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| The Martec Group | | US | Germany, China, Japan, Brazil, Chile | 50-100 | 1 | ● | | | | | | | | |
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| the SDS factory \| de ViB fabriek | | The Netherlands | UK, Germany, Belgium | 2-5 | 2-5 | ● | | | | ◗ | | ◗ | | |
| The Windsor Consulting Group, Inc. | | US | | 5-10 | 2-5 | ◗ | ◗ | ◗ | | | ◗ | ◗ | | ◗ |
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| Toxi-Coop Toxicological Research Centre Ltd. | | Hungary | Switzerland, US | 50-100 | 25-50 | ◗ | | | ● | | | | | |
| Toxikon (Labcorp) | | US | Belgium | 100-500 | 5-10 | ◗ | | | ● | | | | | |
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| Vanta Bioscience | | India | | 25-50 | 10-25 | | | | ● | | | | | |
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Key: Icons above represent the percent breakdown of services provided by each firm as follows:
● >60% ◗ 40-60% ◗ 20-40% ◗ 5-20% ) <5%

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