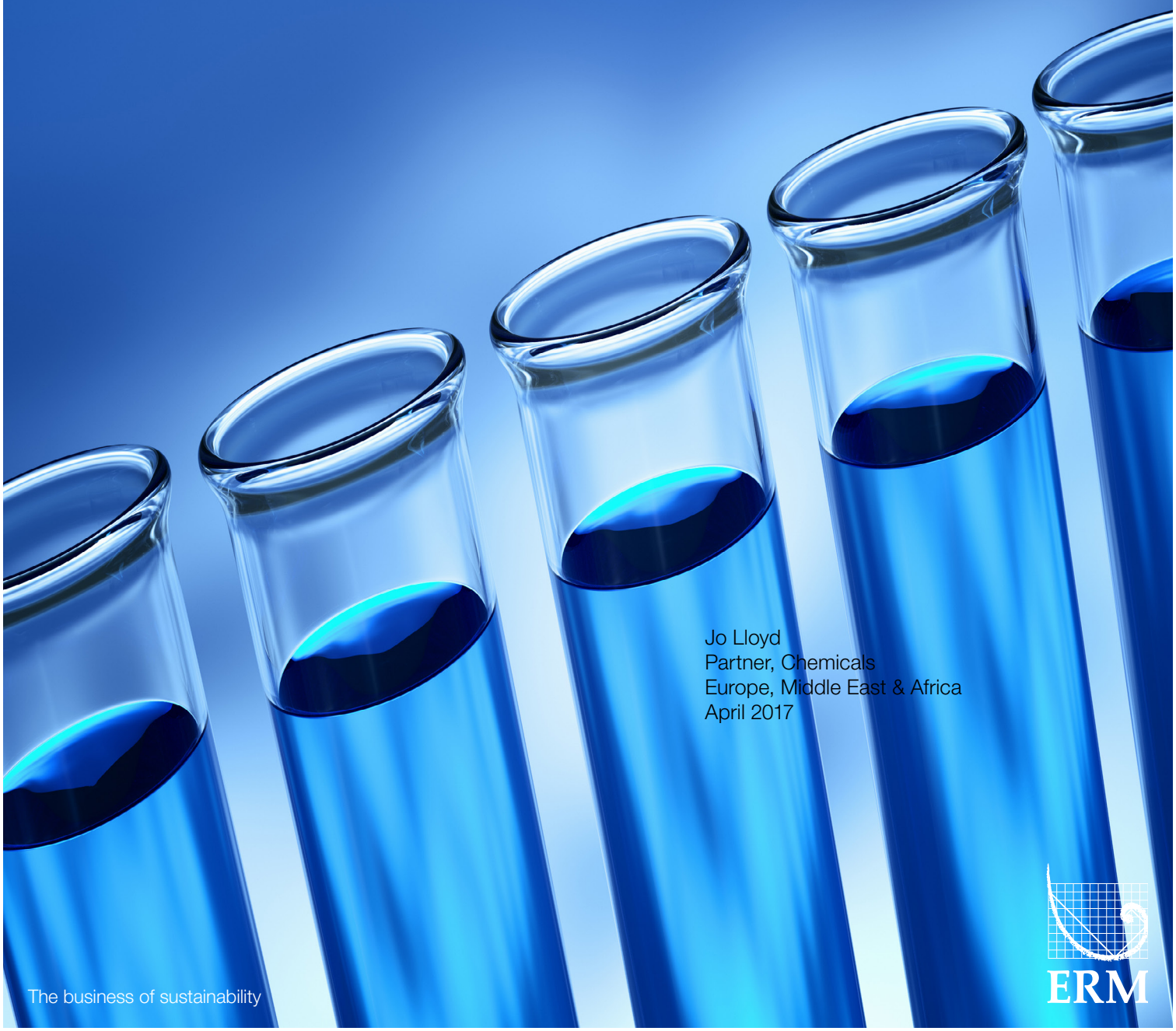
Keeping Up with Global Chemical Regulatory Changes

An EU Perspective



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The business of sustainability

ERM

Overview

Regulation is an essential part of modern society and ethical governance. In regards to product stewardship, societal norms are driving the demand for safer, more environmentally sound products, and this trend is reflected in evolving global policies.

Within the European Union (EU), regulation adds value in areas such as competition, trade, and the internal market to build an equal playing field that creates opportunities for business, workers, and consumers. EU regulation also protects the health and safety of all stakeholders, and creates a common framework by replacing or aligning the laws of the 28 Member States.[1]

1. Soon to be 27 post Brexit: http://www.bbc.com/news/uk-politics-32810887

The Paradox of Chemicals

Chemicals are an integral part of society and present in almost every consumer product. They are key in virtually every production process, be it food, electronics, toys, clothes, or cars. However, by their very nature, chemicals are often reactive and many possess inherent physiochemical, environmental, or human health hazards that require management throughout their life cycle.

Over the past 50 years, balancing the need of society to continue to use chemicals and thereby contributing to prosperity whilst safeguarding society against the potential human health and environment risks arising from that very use has been the backbone of the EU's now comprehensive chemical management framework. This framework comprises over 100 pieces of primary chemical legislation.

The EU Chemical Management Framework

Development of the EU Chemical Management Framework started in 1967 with the adoption of a directive that harmonised the Member State rules for classification, packaging, and labelling of chemical substances across what was then called the European Economic Community. This directive enabled the free circulation of chemicals without the need to re-classify, re-package, and re-label the chemical product when being traded across national borders; it also established a community-wide harmonised system of communicating chemical hazards, thus enabling users to take appropriate safety measures.

As part of the EU's 2002 commitment delivered at the World Summit on Sustainable Development, the EU agreed that by 2020, chemicals would be produced and used in ways that minimise significant adverse impacts on human health and the environment.[2] This was the beginning for the implementation of the now infamous REACH regulation and the Globally Harmonized System (GHS) of Classification and Labelling for Packaging and Supply of Chemicals in the EU, commonly known as the CLP regulation.

Crucially, the advent of REACH reversed the burden of proof from one where authorities had to prove that the use of a chemical is unsafe to one where industry had to prove that the use of a chemical is safe. This accelerated the number of "substance information datasets" or "dossiers" compiled each year to rise from tens to the thousands. Today, 9,500 substances have been registered by industry under REACH as part of the 2010 to 2018 phase-in process; this has created the largest publicly available substance database in the world, which is managed by the European Chemicals Agency (ECHA) based in Helsinki. It is widely expected that the REACH database will contain information on more than 30,000 substances by the end of 2018.

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The legislative framework for chemicals now comprises both chemicals legislation in the strict sense of the word (directly regulating chemical substances and mixtures such as REACH and CLP) and related legislation. Related legislation includes regulating the conditions under which chemicals are manufactured, treated, or used (e.g., occupational health and safety or environmental legislation) and regulating the products in which chemicals are used (e.g., biocides, pesticides, pharmaceuticals, veterinary product, or consumer goods). However, the use and presence of hazardous chemicals in many finished articles and consumer goods is still not regulated systematically.

2. http://www.unmillenniumproject.org/documents/131302_wssd_report_reissued.pdf

Reaching Forward

With the final June 2018 phase-in deadline fast approaching for REACH registration, we are now well into the final lap of what has been a marathon event. And, as with marathon races rather than sprints, we need to be wary of hitting the wall after a promising start and an exemplary tactical race thus far. Whilst many businesses now will be well-practiced and efficient in preparing dossiers of substance hazard and risk characterisation in order to complete registrations, we are finding that many of our clients are turning to us at this late stage when they unexpectedly find themselves resource-constrained, as a larger number of substances in the 1- to 100-tonne range – some of which are potentially more exotic – need to be addressed. The final stretch towards the 2018 deadline will also see many EU importers and manufacturers specialising in chemicals used in smaller tonnages dealing with the process for the first time, including those businesses that would not consider themselves to be a chemicals company.

Until recently, high-level communication about REACH focussed solely on registration. However, as all parts of the master plan swing into action, the plan brings with it an increasing, rather than diminishing, workload. These resource-intensive and less-predictive requirements include:

- Addressing dossier quality questions raised by the authorities as part of their evaluation of substances registered in 2010 and 2013;
- Managing the implications of an increasing number of entries in Annex XVII restricting the uses of certain substances of concern;
- Keeping up-to-date with Substance of Very High Concern (SVHC) communication obligations as more substances are added to the REACH Candidate list for Authorisation; and
- Navigating through the newly chartered waters of Authorisation as authorities agree that an increasing number of SVHCs on the Candidate List require an Authorisation (such as a permit) for those manufacturing or using it in the EU to continue to do so.

Following a commitment made by the European Commission to include “all relevant known” SVHCs in the Candidate List by 2020, ECHA published an ambitious implementation plan, which is now starting to challenge the industry. Companies need to be vigilant of not only what substances are on the list today, but also of which substances within their product or use portfolio may end up on the list in the future.

ERM's product stewardship teams have worked with many global companies to implement product stewardship programmes that contain a warning system for identifying where a product may contain an SVHC that could present a risk to business continuity, providing valuable time to evaluate the company's response. This could mean a requirement to embark on a plan to look for suitable alternative "greener" chemistry or prepare to apply for a time-limited authorisation if there is no viable alternative in the pipeline. For many businesses, the need to prepare authorisation dossiers, demonstrate adequate control, analyse alternatives, and explain the socioeconomic case for the continued use of its chemistries is just the beginning.

Experience tells us from the authorisation applications that ERM has prepared for clients across the chemical, pharmaceutical, automotive, and manufacturing sectors that assessing the business implications of substances subject to authorisation and developing strategies to minimise the impact on business continuity is best done early. There is no substitute for engaging with suppliers and customers as early as possible so that evidence can be assembled in a timely fashion to prepare a scientifically justified and well-argued defence of chemistry.

Another REACH Review

As the 2020 sustainable development goal target date approaches, the European Commission is conducting a review of REACH, and consensus on a number of key issues is emerging that will set the course for the future. The key issues that ERM has identified as important include the following:

Improve the quality of registration dossiers. The poor quality of some dossier information means that not only is it difficult for companies producing or using chemicals to ensure they have the right risk reduction measures in place, but it is also difficult for authorities and ECHA to target the right substances with the right regulatory measures. This may result in ECHA being given the power to reject inadequate dossiers.

Level the playing field on SVHCs in imported articles. Authorities and industry agree that EU-based article producers are at an unfair disadvantage compared to firms importing articles into Europe when it comes to the obligations and restrictions they face. The sunsetting of substances listed in the REACH Annex XIV list of substances subject to the authorisation process applies only to uses that take place in the EU. How this will be resolved is as yet unclear; when REACH was being drafted, the World Trade Organization ruled that authorisation could not apply to imported articles.

Do more to identify SVHCs. As the obligation for identifying SVHCs is given to Member State authorities, the risk management option analyses needs to be made less onerous if the Commission's goal to have all relevant SVHCs on the candidate list by 2020 is to be met.

Nanomaterials, Endocrine Disrupting Chemicals, and combination effects. Although the safe management of all of these is referenced in the Commission's draft 7th Environmental Action Programme (7EAP), which outlines work going forward, it has been criticised severely by some member states, non-governmental organizations (NGOs), and industry. Therefore, we can expect more on this in the near future; a quick win would be updating REACH post 2018 to include additional data requirements for chemicals meeting these definitions.

Do more to encourage substitution and "benign design" of new chemicals. There is broad agreement that some substances on the REACH candidate list are seeing a resultant drop in demand and that users are seeking substitute substances that seem to have a secure future. However, it does not appear that REACH is persuading more downstream users to assess different technologies, new business models, or the development of new, less hazardous substances. There is some recognition that such a shift can only be achieved through economic instruments, research and development, and government-led programmes that bring industry, research institutions, and NGOs together; we can expect more on this in the future.

The Next EU Chemicals Strategy

The development of the EU's chemicals framework over the past 50 years has been continuous, built on the experiences obtained and the approaches developed. Currently, work is going on to assess how to regulate nanomaterials, endocrine disrupters, and hazardous polymers not only within REACH but more widely within product laws such as pesticides, cosmetics, biocides, and more will follow suit. The Commission is also working on a new Circular Economy Action Plan that will assess the interaction between waste, products, and chemicals legislations in order to facilitate the traceability of chemicals in the recycling process and limit unnecessary burden for recyclers and promote more recycling. And finally there is the task of creating an EU strategy for a non-toxic environment, which is front and centre in the 7EAP. This will introduce further instruments to promote the removal of hazardous substances at source, which will ensure that those of us who are product stewards will not be short of things to do and that the marathon has in fact only just started.

How to Learn More

Questions or comments? Email the author at: Jo.Lloyd@erm.com

Jo Lloyd is a Partner in our London office and leads ERM's Northern Europe regulatory product stewardship team. She has extensive experience in European chemical law and was one of the key players in shaping the European chemical legislation, REACH, having led the UK Chemical Industries Association's (CIA) technical input into the debate at the National and European level from 2000 until 2006. Jo supports clients in meeting not only their European chemical obligations, but their global ones as well, utilizing ERM's global product stewardship community.

About ERM

Environmental Resources Management (ERM) is a leading global provider of environmental, health, safety, risk, social consulting services and sustainability related services. We have more than 160 offices in over 40 countries and territories employing more than 4,500 people who work on projects around the world. ERM is committed to providing a service that is consistent, professional and of the highest quality to create value for our clients. We have worked with many of the Global Fortune 500 companies delivering innovative solutions for business and selected government clients helping them understand and manage the sustainability challenges that the world is increasingly facing.

For over 40 years we have been working with clients around the world and in diverse industry sectors to help them to understand and manage their environmental, health, safety, risk and social impacts. The key sectors we serve include Oil & Gas, Mining, Power, and Manufacturing, Chemical and Pharmaceutical. All face critical sustainability challenges and our clients in these and many other areas rely on our ability to assist them operate more sustainably which has a positive impact on our planet.

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