

REACH – A Far-reaching Approach to Chemical Risk Management

Six years and counting

In 2007, the European Union (EU) put a transformational stake in the ground towards protecting human health and the environment by implementing REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)—the most comprehensive and far-reaching process for registration requirement, REACH mandates that companies assess the potential risks of chemicals they manufacture in or import into the EU at or above one ton per year, whether the chemicals are individual substances or substances included in a mixture or article (a manufactured good). By taking this precautionary stance, REACH has completely upended the traditional world of chemical regulation and hazard management.

In 2013, REACH met a significant milestone, as the long awaited registration deadline for substances measuring 100-1000 tons per year came and went. By the end of May 2013, more than three thousand companies had submitted just over 9,000 registration dossiers. By the end of August, the European Chemicals Agency (ECHA) had completed its review of the dossiers, approving almost all of them and registering close to 3,000 substances—most of which were registered in joint submissions by companies working together, validating that particular program goal. The next major milestone for the program will be the May 31, 2018 deadline for registering substances in the quantity of 1-100 tons. Given that the total number of chemicals to be registered through REACH is estimated at approximately 30,000, the next wave of registration could prove to be challenging.

Consequences and Controversy

The registration results to date seem to spell success—on the surface. But the reality is that achieving these results has not come without controversy. REACH has had both intended and unintended consequences—some good and some not so good. Further, REACH's influence is extending beyond the EU and its chemical concerns, and is proving to have global relevance.

Understanding REACH's consequences and influences will be a driving force for REACH in the future and is likely to shape other similar initiatives, as nations around the world strive to protect people and the planet.

REACH's impacts have been most keenly felt in the areas of:

- Shifting responsibility for chemical risk assessment from government to industry
- Focusing on the reduction of chemical risk, rather than simply identifying hazards
- Addressing chemical risk throughout the supply chain
- Testing chemicals on animals
- Globalizing the REACH model

A Shift in Responsibility

One of the most fundamental ways in which REACH has broken the mold in chemical hazard management is by shifting the responsibility for identifying risks from government to industry. A guiding principal behind this requirement is that when it comes to chemicals, industries—not governments—are the experts, so who better to provide the most accurate and timely information about chemical properties and related risks? Also, unlike a public entity, companies are working with and managing chemicals on a daily basis through established chemical hazard management processes. Thus, the most efficient source for providing this information is the manufacturer. In addition, in cases where a substance is manufactured or imported by more than one company, REACH requires companies to submit certain information together and, in some cases, to share data. Industries are communities. Therefore, the doors to critical information-sharing are likely to be open among industry peers, regardless of governing body or national affiliation.

As it turns out, the amount of publicly available chemical risk and hazard-related data that now exists within the REACH system is providing a wealth of information for companies both inside and outside the EU—eliminating redundancies as these companies look to upgrade their chemical reporting processes. With REACH’s expectation of registering approximately 30,000 chemicals by 2018, the future impact from information-sharing has the potential to be huge. Further, the chemicals currently registered are well known, high production volume chemicals about which a good deal of information has already been made available. The next phase of registration is likely to reveal information that has not been available thus far. Companies that are proactive in making use of this information by identifying, assessing, publishing, and mitigating chemical risk have a competitive edge in the marketplace—appealing to customers while staying ahead of the curve on possible chemical regulation requirements that could come down the line, as concern about environmental sustainability escalates.

However, while making industry the responsible party might seem like the perfect solution, considerable logistical and financial difficulties can ensue when applying the industry-based approach. As beneficial a program as it is, REACH has proven over the years to be very complicated and costly—by its own admission. And while REACH itself is neutral in how it treats the companies required to comply, the small and medium-sized enterprise (SME) sector—which typically does not have the resources in place to manage a highly administrative process—has felt the impact more heavily. The European Commission’s latest report specifically addresses and makes a commitment to alleviating this inequity—which is likely to increase in the next phase of compliance, when substances in quantities from 1-100 tons will need to be registered. The Commission also acknowledges that even for large companies, especially those in highly competitive markets where profit margins are low, the extra expense of compliance has sometimes had a negative impact (Davis, 2013). In addition, there is always the risk that information-sharing between companies will not be as forthcoming as hoped, due to privacy and competitive concerns.

The Focus on Risk

REACH's admirable focus on identifying serious risks and restricting use of the most hazardous chemicals is resulting in the development of new chemicals that are friendlier to humans and the environment. REACH is also driving healthy competition. For example, in the tire industry the need to curtail or eliminate certain chemicals has spurred the introduction of several more environmentally-friendly oils and polymers into the market—resulting in increased choice, increased competition, and a spirit of innovation. An article in the *European Rubber Journal* titled "Oil Supply Business Radically Changed by Legislation" (Shaw, 2012) claims REACH has had a "global impact on the supply of raw materials" for the tire industry and "completely changed the oil supply industry" for the better. The article states 80% of the oil now used in the tire industry is "clean oil" and the regulations have given rise to both a specialty supply chain and technological advancement.

But, the article also acknowledges these more advanced technologies could pose barriers to market entry for some who want to join the tire industry. Innovative solutions can come at considerable cost—adding an additional financial burden on top of the administrative burden already created by REACH requirements.

Making industry directly responsible for hazard reporting and risk mitigation makes sense in terms of managing the issue at the source. However, there are concerns it could prompt an overly conservative approach to chemical hazard management—resulting in "over the top" exposure scenarios that are not well-grounded in reality, but are presented because manufacturers are excessively concerned about liabilities or are simply required to comply with REACH directives. There are also concerns that the focus on risk could unnecessarily reduce cost-effectiveness.

Industrial hygienist Dan Markiewicz addresses both these issues in his article, "Dilemmas Posed by EU's REACH Legislation" (*Industrial Safety and Hygiene News*, 2011), based on his personal experience when encountering a REACH "code of good practice" during chemical monitoring for one of his clients. While he acknowledged the code was well written, he felt it went to a precautionary extreme. Markiewicz believes REACH carries the risk of being "excessively safe" through unrealistic exposure code, and that excessive safety measures could "come at an unnecessary cost and concern."

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Supply Chain

REACH's insistence on addressing the entire supply chain for any chemical—both upstream and downstream—has benefits in terms of bringing to light the many areas where chemicals are used and could pose risk. It also opens up the opportunity for companies and their partners to work together more closely. As previously described, in certain industries—such as the tire and oil industries—involving the supply chain has had the positive affect of driving technical advancement.

However, involving the entire supply chain can also add logistical and administrative complexities—which often translate into additional costs, draining of resources, and a slew of other issues that hinder business productivity. In addition, some industries are affected more deeply than others. Requirements to communicate downstream have been a real challenge for the coating industry—which is doubly impacted because REACH does not easily accommodate mixtures, a large component of the coating business.

The Coatings World article, “REACH Requirements for Downstream Communication of Safety Information Challenges Coatings Sector” (Milmo, 2013), documents a host of issues, including:

- The lack of definition around how to share exposure scenario information for mixed substances
- The risk of passing along inconsistent safety information due to little to no understanding of how mixtures are being used downstream or what the on-site conditions are
- Differing needs between various downstream users
- The proliferation of unnecessary information on safety data sheets, making them too complex for the intended audience and therefore unusable

Animal Testing

Testing the effects of certain chemicals on animals has been a longstanding method for determining the risks of those chemicals to humans. Ironically, though risk assessment is foundational to the REACH program, one of its key objectives is to reduce chemical testing on animals to identify those risks. REACH instructs companies to assess risk through alternative means—such as sharing testing information to avoid duplicating tests, grouping and categorizing substances to extrapolate risks based on similarities, and using computer technology.

The REACH program insists testing chemicals on live animals should only be used as a last resort. In the foreword to the ECHA report, “The Use of Alternatives to Testing on Animals for the REACH Regulation” (2011), ECHA Executive Director Geert Dancet makes the case that based on REACH data collected up through 2010, REACH has done well at achieving its animal testing objective—and applauds companies for sharing information, stating that “companies have shared data or made extensive use of the alternative methods available so as to avoid the need to test chemicals on animals, which is positive” (p. 2). However, Dancet also admits unearthing alternative methods is a “work in progress” and that the early data might not be the ultimate data.

However, according to PETA (People for the Ethical Treatment of Animals), without PETA’s intervention REACH would be ineffective in significantly reducing animal testing, has been responsible for increased animal testing, and early on side-stepped its responsibilities by not heavily enforcing its mandate for manufacturers to find “suitable alternatives” to testing chemicals on animals. With PETA’s heavy involvement in bringing animal testing-related issues to the public eye and advocating amendments to REACH regulations, progress has been made. However, the PETA article, “REACH: the Largest Animal-Testing Programme in the World”, claims that if not closely monitored and lobbied, REACH has the continued potential to increase rather than reduce the amount of chemical tests on animals—and in some cases, this is exactly what has happened. PETA cites the testing of an additional 200,000 animals in order to meet REACH requirements as an example of how REACH’s stated goals on animal testing have not always matched reality (<http://www.peta.org.uk/features/REACH/>).

Globalization

There are those who advocate the globalization of REACH, which could eventually result in a much more consistent and streamlined method for managing chemical risks worldwide. This advocacy is based on the broader concept of “global regulatory harmonization”—which promotes the notion that having consistent regulations of all kinds across the globe will yield better compliance, greater efficiency, and open markets. The benefits to humans and the environment would seem obvious.

However, leveraging a European model is not always a good fit. Environmental lawyer, professor, and editor-in-chief of the Transnational Environmental Law journal Veerle Heyvaert identifies two barriers to effectively globalizing REACH –a difference in priorities and the threat to diversity (Naiki, 2010). Hayvaert points out that developing countries may need to apply their limited resources to more pressing problems than chemical risk assessment, such as sanitation. Additionally, the worldwide enforcement of a European model could stifle the valuable learning and exchange that takes place when divergent cultures are allowed to flourish. There are also cultural considerations. Considerable logistical and financial difficulties could ensue when applying the industry-based approach within a dissimilar governance structure, such as in countries where governmental responsibility is a deeply entrenched cultural value—as is the case in certain Asian countries. While many companies from other nations must comply with REACH requirements because they import into the EU (such as Japan, China, Canada and the US), a remake of existing systems is not necessarily in the cards. Ultimately countries that already have an embedded system for managing chemical hazards are likely to be more resistant to adopting the REACH model, other than leveraging specific relevant aspects that easily integrate into their own process. Those countries that have no such program might be more receptive to adopting the model (Naiki, 2010).

Where Do We Go From Here?

In 2012, the European Commission on Enterprise and Industry conducted a review of the REACH program, concluding that the program was essentially well-functioning and successfully performing to objectives. The Commission determined that no changes to the fundamental requirements were necessary. However, in its official report the Commission also identified key areas that could benefit from adjustment and made the following recommendations:

- Improve the quality of registration documentation
- Alleviate some of the administrative and financial burdens to reporting companies, particularly SMEs, through proposed fee reductions for SMEs and other measures
- Increase support for alternative testing methods so as to continue to reduce animal testing
- Enhance coordination between the Member States in order to improve enforcement
- Provide clarity on how to address nanomaterials

The Commission also expressed its intent to evaluate registration requirements for higher tonnage levels and how REACH is impacting innovation, with a January 2015 report-back deadline. In addition, the Commission, the Member States, and the ECHA together are creating a roadmap for assessing and identifying substances of very high concern (SVHC). The roadmap will define milestones, deliverables and division of work. The end goal is a comprehensive SVHC list, to be completed by 2020.

Clearly REACH has had an impact both within and outside the EU—offering opportunities and benefits as well as bringing to light areas for improvement and issues that are perhaps endemic to an undertaking of such magnitude. While the affected companies certainly have carried a financial and administrative burden, many also are realizing benefits—such as an improved supply chain, innovative technological advancements, and value-adding information-sharing. While it's true REACH has been especially challenging to SMEs, actions such as proposed fee reductions for this group would help alleviate the extra burden. Future developments in REACH may prove to be very interesting and enlightening, as identified issues are addressed and new challenges arise during the next phase of REACH—the registration of substances in the quantity of 1-100 tons.

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