



Is the Coatings Industry Heading Towards Increased Chemical Regulation in the Wake of the EU's REACH Regulation?

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Clearly, the coatings industry has made great progress since the early cave paintings of over 30,000 years ago, but much of that progress has been focused on quality. That is not to say that we have not reached major milestones in terms of improving the safety of coatings products. In the 1950s, industry began voluntarily limiting the use of lead-based pigments in consumer paints long before it was banned by EPA. Similarly, in the 1980s, the coatings industry found safer alternatives for the mercury biocides used in interior and exterior latex paints. In the 1990s, a strong push began to reduce VOC emissions from architectural coatings and consumer products. However, this article is not about the past—it is about the future. The future success of coating companies will, to a great extent, depend on their ability to know and understand the regulatory landscape in which they must operate. To accomplish this, we will take a brief look at how Europe's REACH regulation has forever changed the regulatory landscape, followed by a historical perspective to illustrate that, in North America, things are heading in a similar direction.

EUROPE LEADS THE WAY

Europe's REACH regulation was entered into force in June of 2007. The essence of REACH can be summed up as follows: "The chemical industry must demonstrate substances can be used safely or stop doing business in Europe." In effect, REACH has shifted the burden of proof away from the regulatory agencies and placed it directly in the laps of the companies that manufacture and import the substances currently used in products and any substances that may be used in the future. In the U.S., the EPA must go to great lengths to ban a substance from the marketplace. The burden of proof is on them to demonstrate that substances cannot be produced or used safely and only then can they take regulatory action to ban it. Under REACH, however, the regulation defines the conditions under which sub-

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stances can be used safely and it is up to manufacturers, including importers, to show that their substances meet those conditions or they will be restricted from the marketplace.

REACH stands for the Registration, Evaluation, and Authorization of Chemicals. REACH applies to individual chemical substances whether they are manufactured or imported alone, as part of a preparation (e.g., a coating), as part of an article where the substance is intended to be released (e.g., a paint pen), or as part of an article where the substance is not intended to be released (e.g., a substance in the paint covering a vehicle). REACH "Registration" is the process followed by chemical manufacturers and importers to submit their data and information to demonstrate that, for each substance and each use being registered, the substance can be used without significant risk to human health or the environment. By forcing companies through this process, substances that clearly pose an unacceptable risk in certain end uses will likely not be registered for that use and, hence, will be voluntarily restricted. For so-called "Substances of Very High Concern," manufacturers and importers will be faced with the possibility that their substance will be subject to "Authorization" procedures, whereby the manufacturers and importers will be required to seek approval for continued use of the substance in the EU marketplace. Here lies the hidden "R" in REACH that stands for Restriction. Substances will either not be registered for particular uses (a type of voluntary restriction) or will not be Authorized (a type of mandatory restriction). As more and more substances are restricted in the marketplace, it will become increasingly difficult for companies to track which substances can be used in which applications in which parts of the world.

WHAT ABOUT THE U.S. AND CANADA?

My prediction is that REACH sets the stage for two dynamics to emerge in North America. First, and most importantly, the information to be developed and made available under REACH will be used to seek new restrictions on substances in North America. At the same time, the 1 metric tonne registration threshold and the Product and Process Oriented Research and Development (PPORD) provisions of the REACH regulation have the potential to open the door for new innovative substances to enter the EU marketplace. If successful, they can then be further commercialized in the U.S. and in Canada. We will examine both of these predictions in a bit more detail.

A HISTORICAL PERSPECTIVE

My first prediction is an easy one to make, since we have been heading in that direction since 1976, when the Toxic Substances and Control Act (TSCA) was first enacted in the United States. Section 2b of TSCA requires that:

"Adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."

However, in meeting this requirement, regulations must not "unduly impede commerce or place economic barriers." Clearly, in 1976, a REACH-type regulation would have impeded commerce. However, in a post-REACH environment, requiring more information from manufacturers will be increasingly viewed as less burdensome and may even eventually become standard practice.

Since regulators in North America will have access to the "hazard" data produced for REACH (e.g., the mammalian toxicology, environmental fate, and ecotoxicology data), agencies will likely focus on gathering relevant "exposure" information from manufacturers and downstream users so that the "risk" can be properly characterized. This will mean providing information on product volumes and end-use applications and, in some cases, may even require more detailed information on the nature and extent of exposures and releases throughout a product's entire life-cycle.

As previously stated, we have been heading in this direction for the last 30 years. Some of the major highlights that have brought us to where we are today are as follows. In the early 1980s, the U.S. EPA formalized its Pre-manufacture Notification (PMN) process, which is still in place today and requires manufacturers to submit hazard, exposure, and release information prior to manufacturing any "new" substances. Around that same time, the EU issued directives for Member States to establish similar procedures for new substance notification. In 1993, the U.S., Canada, and Mexico agreed to work cooperatively on environmental issues, which set the stage for Canada to adopt policies similar to the U.S. for regulating chemicals in commerce. In 1998, the EPA put forth a "challenge" to the U.S. chemicals industry to, in essence, either put up or shut up with respect to the hazards of "existing" chemicals in commerce. As a result, the HPV Challenge Program was born and industry has spent the last 10 years studying the toxicity and fate of high production volume chemicals produced in the U.S. In 1999, the Canadian Environmental Protection Act (CEPA) was enacted, which included provisions for assessing the risk of new and existing substances. In 2001, the REACH White Paper

was published offering what the EU believed was a better way to control the risk of new and existing substances by transferring the burden directly on the producers themselves. In 2002, the EPA began its Sustainable Futures program with the aim of making its risk assessment tools available to industry so that they could use them to develop more sustainable chemicals in the future (i.e., chemicals with less impact on human health and the environment). In 2003, the EPA required "exposure" information to be included with Inventory Update submissions that are required to be made by chemical manufacturers and importers every five years. The EPA is currently using this exposure information to set regulatory priorities and assess risk. In 2005, the EPA extended the HPV Challenge Program to include "exposure" information, which is also being used in setting priorities and assessing risk. In 2006, the United Nations adopted a Strategic Approach to International Chemicals Management (SAICM), which is a policy framework to ensure chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health through international cooperation. While no "one size fits all" approach has been adopted in the SAICM framework, the data and information being developed under REACH will likely play a key role in the regulation of chemicals around the world. In December of 2006, the final REACH text was adopted and, as a result, Europe is to mandate that chemical manufacturers characterize the hazards, exposures, and risks of the substances they produce. In the U.S. and Canada, this work has been done by the reg-



ulators and progress has been steady but slow relative to the total number of substances in commerce. In addition, the results of these agency-derived assessments have been criticized by industry as overly conservative.

WHAT'S THE CURRENT STATE OF PLAY?

In 2007, California announced its Green Chemistry Initiative to look for a better way to regulate chemicals in California commerce. Also in 2007, the U.S., Canada, and Mexico signed the Trilateral Agreement to cooperate specifically on chemicals management, which arguably opens the door for a North American version of REACH in the future. In April of this year, the U.S. Senate held hearings, led by Senator Barbara Boxer of California, to discuss the U.S.'s current chemicals management policies under TSCA and offered stark criticism of our current system contrasted against Europe's new REACH system. In May of this year, U.S. Senator Frank Lautenberg of New Jersey introduced legislation known as the "Kid Safe Chemicals Act" that would, similar to REACH, regulate chemicals that go into consumer products. And finally, a bill that has been negotiated by California legislators, the Schwarzenegger administration, and environmental and

chemical industry groups, known as AB1879, appears ready to pass the California state legislature. This bill would require the Department of Toxic Substances Control, in the California Environmental Protection Agency, to adopt regulations by January 1, 2011, to establish a process by which

chemicals or chemical ingredients in products can be identified and prioritized for consideration as being chemicals of concern. The department would also be required to adopt regulations to establish a process by which chemicals of concern in products, and their potential alternatives, are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.

BACK TO THE PREDICTIONS

So, now we have arrived back to my first prediction: "The information to be developed and made available under REACH will be used to seek new restrictions on substances here in North America."

If anyone can look back to 1976, as we just have, and conclude that we are unlikely to face more restrictions, I would certainly welcome the debate. What is not clear, however, is exactly how the data will be used in the U.S. and Canada. Will it be used within the existing chemicals management framework or will it be used by legislators to justify a new framework? In either case, industry will have to defend the safety of some substances and will have to seek more sustainable alternatives for others. While much of this burden will likely fall upon the chemical manufacturers, coatings formulators will also need to understand

the risk profile of each ingredient being used and will need to closely monitor the regulatory status of any substances that might face restrictions. In addition, formulators will need to be willing to contribute information to help defend the safety of substances and be willing to work with manufacturers to test more sustainable ones. In addition, they will need to be ready to quickly reformulate when appropriate.

This brings us to my second prediction: *"The 1 metric tonne registration threshold and the Product and Process Oriented Research and Development (PPORD) provisions of the REACH regulation have the potential to open the door for new innovative substances to enter the EU marketplace, and, if successful, they can then be further commercialized here in the U.S. and in Canada."*

Under REACH, new substances need not be registered if they are manufactured or imported in quantities of < 1 metric tonne per year per manufacturer or importer. This is similar to the low volume exemption available in the U.S., except that agency approval need not be sought through the notification process. In other words, the exemption under REACH is automatic. Also under REACH, the PPORD provisions permit new substances to be manufactured or imported in quantities exceeding 1 metric tonne per year provided the substance will, for example, in the case of coatings, be produced or imported for the purpose of testing the fields of application of the substance, provided a PPORD notification is filed and all downstream users are identified. This may not be a viable option for consumer applications, but could certainly be of value for customers who are interested in testing large volume specialty formulations. The exemption from registration is good for up to five years and can be extended to as much as 10 years. So, what we can see happening as a result of REACH is that new, more sustainable, substances can be man-

ufactured in commercial quantities in the U.S., for export only, and be placed on the European market in commercial quantities without having to file a new substance notification/registration until it is clear the substance will be accepted in the marketplace.

A LOOK AHEAD

As we move into future, the chemical industry, including the coatings industry, will face increasing regulatory pressures and more and more substances are likely to be restricted. In the near term, substances will be restricted only in certain markets, but the dominoes will start to fall all over the world. It is then only a question of how fast.

To succeed over the long term, manufacturers and formulators will need to understand the risk profile of the substances in their portfolios and will need to stay on top of what is happening in the regulatory arena. Companies will also need to be prepared to either respond in defense of the substances being scrutinized or be able to respond with a more sustainable alternative. To test these alternatives, manufacturers and formulators must not be afraid to use the low volume exemption or PPORD notification provisions of the REACH regulation. After all, they have been put there to encourage innovation.

I suspect that the REACH regulation has given a push to the sustainable development movement and that it has now reached critical momentum. Formulators should stay focused on the science, but it is not only the science that leads to better formulations. Companies should learn what makes chemicals more sustainable and, if they have not already done so, they should get to know their product safety team. If they are good, they can help companies stay on top of the risk and regulatory profiles of products and substances. ☐

NPCA REACH Resources

The European Union (EU) in June 2007 finalized its Registration, Evaluation, and Authorization of Chemicals (REACH) directive. Similar in intent to the Toxic Substances Control Act (TSCA) in the United States, the REACH regulation is different in that it reverses the burden of proof. Instead of the EU government having to demonstrate that the use of a chemical is unsafe, industry now has to show the uses for chemicals it wants to sell in the EU are safe. The regulation is primarily focused on EU-based chemical manufacturers and importers, as well as EU-based coatings companies and their customers in the EU. REACH, however, will also affect U.S. coatings manufacturers who export products to EU customers, since those customers are considered chemical importers under the REACH regulation.

In 2008, the National Paint and Coatings Association created a web page dedicated to REACH information located at www.paint.org/issues/reach.cfm, providing information, compliance resources, and tools to assist industry members in fulfilling their obligations under REACH.

In addition, some general information links on REACH include the following:

REACH Summary Document:

http://echa.europa.eu/doc/timeline_en.pdf. This downloadable brochure provides a brief general overview and timeline.

REACH Regulation:

<http://eur-lex.europa.eu/jOhtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>. This link provides an up-to-date official copy of the actual REACH regulation for download.

REACH Guidance Documents:

http://reach.jrc.it/guidance_en.htm. This link provides entry to a wealth of guidance documents on the later stages of REACH (final registration, evaluation and authorization), as well as general descriptive information.

To help "downstream users"—or companies that purchase chemicals to make products sold in the European Union—understand their obligations under the REACH regulation, the European Chemicals Agency (ECHA) has translated REACH guidance into 22 languages. The information can be found by going to the website above and clicking in the language-selection box in the upper-right corner. According to ECHA, Bulgarian and Romanian versions of the downstream user's guidance will be issued in 2009.

ECHA Website:

<http://echa.europa.eu>. This is a link to the European Chemicals Agency, which lists REACH and other EU chemical regulatory requirements.