REACH and its Impact on the United States

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Introduction

REACH stands for Registration, Evaluation and Authorization of Chemicals, and is the chemicals regulation of the European Union (EU). REACH affects manufacturing and distribution companies that have a supply chain that runs through the EU in any way; that import or source from the EU; or that manufacture, sell or plan to sell in Europe. Depending upon your view point, it is either a complicated and costly new chemicals management program, or it is an innovative system of chemical regulation that will provide crucial information on the safety of chemicals used in industry.

Pittsburgh Plastics Mfg. (PPM) is a contract manufacturer of products for medical, foot care, safety and other industrial markets with a focus on polymeric cushioning solutions. PPM has customers located in Europe, and these customers require information regarding REACH compliance. PPM in turn requests information from our raw material suppliers. One purpose of this technical paper is to help our U.S. suppliers understand REACH; another purpose is to look at how REACH impacts U.S. chemical producers and manufacturers of finished goods.

Discussion

Why REACH

From the EU's perspective, there were many problems with their former chemical legislation. The former legislation was a patchwork of many different directives and regulations. There were different rules for "existing" and "new" chemicals. New chemicals (those introduced to market after 1981) had to be tested before being marketed, but there was no such provision for existing chemicals (those introduced to market before 1982). Therefore, the effects of the majority of existing chemicals on health and environment were not sufficiently determined. On the other hand, notification and testing for new chemicals was required for volumes as low as 10 kg per year, and this served as a barrier to innovation. Before REACH, the majority of the responsibility of managing the risks of chemicals was with public authorities rather than industry. Pre-REACH Regulation EEC 793/93 concerned the evaluation and control of existing chemicals. Under this regulation, only 141 chemicals were identified as priority substances for risk assessment, and recommendations for risk reduction were developed for only a portion of these (the total number of marketed chemicals by the start of REACH was over 100,000).

Basics of REACH

The EU published a new chemical regulation called REACH (Regulation EC 1907/2006) in late 2006 and the regulation was implemented on June 1, 2007. The following are some of the goals of REACH:

- To provide a high level of protection to human health and the environment
- To ensure transparency throughout the whole chemical supply chain
- To provide a single EU chemicals regulatory system
- To transfer the burden of proof on how a chemical can be used safely from public authorities to the whole chemical industry (manufacturers, importers and downstream users)
- To substitute hazardous substances, that is, to remove certain chemicals from the marketplace
- To minimize testing on animals

The European Chemicals Agency (ECHA) is based in Helsinki, Finland, and was established to implement REACH. In brief, industry registers chemicals, and the ECHA evaluates and authorizes chemicals. Under REACH, ECHA or a member state of the EU may propose a chemical to be identified as a Substance of Very High Concern (SVHC) due to its hazardous properties regarding health and environment. Some basic elements of REACH are listed below:

- Registration requires manufacturers and importers of chemicals to obtain information on their products and to use that data to manage them safely.

- Safety information is passed up and down the supply chain.
- REACH requires information on the classification and labeling of substances, but specifics are found in a separate regulation titled Regulation on Classification, Labeling and Packaging of Substances and Mixtures (CLP). This regulation incorporates rules agreed to at the UN level, the so-called Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- ECHA evaluates the chemical registrations to determine whether use of the substance poses a risk to human health or the environment.
- ECHA has the authority to require authorization of chemicals with properties of high concern and to subject to conditions or prohibit chemicals deemed dangerous.

The following defines four important REACH terms regarding object classifications:

- Substance means a chemical element and its compounds. The term includes both substances obtained by a manufacturing process and substances in their natural state.
- Mixture or preparation means a blend or solution composed of two or more substances. Typical examples of mixtures are paints, inks, detergents, wax crayons, and polyurethane systems.
- Article means a manufactured good which, during production, is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. Examples of articles are cups, furniture and most toys.
- Article with intended release of a substance means the article contains a substance intended to be released under normal and reasonably foreseeable conditions of use. Furthermore, release of the substance is not the primary function of the article. Examples of articles with intended release are fragranced clothing or toys. Products such as toner cartridges, candles and aerosols are better described as substances or mixtures within a container. See the following link for more guidance: http://echa.europa.eu/documents/10162/13632/articles_en.pdf

REACH Registration

Registration is a critical obligation within REACH. Registration applies to chemical substances produced within, imported into, or placed on the EU market, where they are further used and sold. Manufacturers and importers may have to register their chemicals when volumes reach the threshold of one tonne (metric ton) annually. This applies to a chemical substance on its own, in a preparation (mixture of substances), or intentionally released from articles. Registration is made by submitting a technical dossier to ECHA containing information about the substance's properties, labeling, manufacture and use, guidance on safe use, and exposure risks. Information requirements increase with increasing tonnage.

REACH requires chemical manufacturers to submit a Chemical Safety Report (CSR) for chemicals that are imported or produced in quantities ≥ 10 metric tons per year per registrant. The CSR includes a human health and environmental hazard assessment and a determination of whether a chemical has persistent, bioaccumulative or toxic properties. The goal of the CSR is to understand the exposure scenario(s) for each use and demonstrate that these risks can be adequately controlled. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends to be implemented by downstream users. To facilitate this, REACH requires downstream users to give the chemical manufacturer enough information to allow it to assess the substance's safety in the context of each use, or the user may perform its own CSR.

There is a fee to register and the cost varies (e.g. tonnage, data submitted, company size). Registration is phased-in over 11 years according to the following timetable:

- June 1, 2008 – registration begins for "new" substances supplied at ≥ 1 tonne per annum (tpa)
- December 1, 2010 – registration deadline for substances supplied at ≥ 1000 tpa and certain substances of high concern
- June 1, 2013 – registration deadline for substances supplied at ≥ 100 tpa
- June 1, 2018 - registration deadline for substances supplied at ≥ 1 tpa

Registration is based on the principal of one registration for one substance. Hence, registrants are required to jointly submit information on the substance's intrinsic properties (hazardous properties, study summaries), classification and labeling, and testing proposals (where appropriate). Also, registrants have

the option of jointly submitting the CSR and guidance on safe use. However, manufacturers and importers are allowed to opt out of the joint submission of registration dossiers if this would result in excessive cost, if they disagree with the lead registrant on the interpretation of information, or if disclosure of confidential information would cause substantial commercial damage. The right to opt out does not apply to participation in the SIEF (Substance Information Exchange Forum) or to data sharing obligations. Registrants wanting to opt out from joint submission must document and justify their reasons.

Some substances are exempt from all or certain aspects of REACH because they are regulated by other legislation. The following are completely exempt from REACH:

- Radioactive substances
- Substances under customs supervision
- Substances used in the interest of defense and covered by national exemptions
- Non-isolated intermediates
- Dangerous substances in transit
- Waste

The following are some substances that are partially exempt from REACH:

- Substances that represent minimum risk because of their inherent properties (e.g. water, certain gases, cellulose pulp, and minerals and ores if not chemically modified)
- Polymers (however, monomers [or other substances] are registered by manufacturers or importers if monomer [or other substance] is present at ≥ 2 % of polymer weight and total annual quantity ≥ one tonne)
- Medicinal products
- Food and foodstuff additives
- Plant protection products and biocides
- On-site and transported isolated intermediates
- Substances used in product and process-oriented R&D

EU manufacturers and importers are authorized to register, but non-EU companies may not directly register. There are three options for non-EU companies:

- Appoint an Only Representative (OR), a legal entity in the EU that is hired as an independent partner. With an OR, the non-EU company maintains control of the entire registration process and maintains control of its market.
- Maintain a legal business entity within Europe (parent or wholly owned subsidiary). This option may be costly and requires careful management.
- Work through an importer(s) inside the EU. May need to disclose confidential information to each importer. Also, may restrict development of future distribution channels in the EU.

See the following link for information on registration:
http://echa.europa.eu/documents/10162/13632/registration_en.pdf
See the following link to check if a substance is registered and to view registrations:
http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Core REACH Responsibilities for Industry
The following is a non-exhaustive overview of industries' main responsibilities regarding REACH. Mentioned below are the terms Annex XIV and Annex XVII. Annex XVII sets out the list of restrictions on the manufacture, placing on the market and use of certain dangerous chemical substances, mixtures and articles. Substances listed in Annex XIV require special authorization in order to be used.

1. Manufacturers and importers of substances in quantities < 1 tpa:

- Prepare and supply safety data sheets (SDS) for substances and mixtures
- Comply with restrictions on manufacture and use of substances and mixtures as defined in Annex XVII.
- Apply for authorization for use of substances listed in Annex XIV

2. Manufacturers and importers of substances in quantities ≥ 1 tpa:

- Implement Risk Management Measures (RMM) for their own manufacture and use
- Submit registration. Mixtures (preparations) are not registered
- Keep current the information submitted in the registration
- Prepare and supply safety data sheets (SDS) for substances and mixtures
- Comply with restrictions on manufacture and use of substances and mixtures as defined in Annex XVII.
- Apply for authorization for use of substances listed in Annex XIV

3. Producer of articles:

- Under some circumstances register substances in articles if > 1 tpa
- Keep current the information submitted in the registration
- Under some circumstances notify ECHA regarding substances in articles if > 1 tpa
- If the article contains a substance from the SVHC candidate list (defined below) in a concentration > 0.1 % w/w, provide the recipient of the article with sufficient information for safe use.
- Implement RMMs as described in SDS
- Comply with any restrictions on manufacture and use of substances and mixtures as defined in Annex XVII.
- Apply for authorization for use of substances listed in Annex XIV, and then comply with the authorization

4. Importers of articles:

- Under some circumstances register substances in articles if > 1 tpa
- Keep current the information submitted in the registration
- Under some circumstances notify substances in articles if > 1 tpa
- Comply with any restrictions on manufacture and use of substances and mixtures as defined in Annex XVII
- Apply for authorization for use of substances listed in Annex XIV

Substances in articles may require registration or notification to ECHA, or may require communication of information to downstream users, distributors and consumers. The following table summarizes the requirements for each. An article producer makes or assemblies an article, and an article supplier places an article on the market. An article supplier may be an article producer or importer, distributor, or other actor in the supply chain.

Table 1. Primary of obligations for substances in articles

Obligation	Registration	Notification	Communication of Information
Legal basis in REACH	Article 7(1)	Article 7(2)	Article 33
Actors concerned	Article producers and importers	Article producers and importers	Article suppliers
Substances concerned	Substance intended to be released from article	Substance included in candidate list of SVHC	Substance included in candidate list of SVHC
Tonnage threshold	1 tpa	1 tpa	--
Concentration in article threshold	--	0.1 % (w/w)	0.1 % (w/w)
Exemption from obligation possible on the basis of:			
Substance already registered for same use	yes	yes	no
Exposure can be excluded	no	yes	no

Substances of Very High Concern
Substances of Very High Concern (SVHC) are chemicals that have hazards with serious consequences. The criteria in REACH, Article 57 for SVHC are:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR)
- Substances that are persistent, bio-accumulative and toxic (PBT)
- Substances which are very persistent and very bio-accumulative (vPvB)
- Substances for which there is scientific evidence of probable serious effects to human health and the environment. Such substances do not meet the above criteria, but give rise to an equivalent level of concern. This equivalent concern criterion allows substances with unanticipated health or environmental risks to be regulated under REACH. Such substances are identified on a case-by-case basis.

Once a substance is added to the candidate list, REACH imposes immediate obligations on manufacturers and importers to declare the substances, if present, as described below:

- SVHC notification: Submit notification to ECHA if any SVHC on the candidate list is present in an article at a concentration above 0.1% (w/w) and the total amount of the SVHC exceeds 1 tpa per producer or importer and the substance has not yet been registered for that specific use.
- Communication requirement regarding articles: Suppliers of an article containing a substance on the Candidate List at a concentration above 0.1 % (w/w) are obliged to inform the recipients of the article along the supply chain about the chemical name(s) and how the article can be safely used.
- Communication requirement regarding substances and mixtures: Suppliers of a substance that appears on the Candidate list must provide their customers a safety data sheet. Suppliers of a preparation not classified as dangerous (according to Directive 1999/45/EEC) must provide the recipients on request, with a safety data sheet if the preparation contains a substance on the Candidate List at a concentration of at least 0.1% (w/w) for non-gaseous preparations or 0.2% for gaseous preparations.
- Restriction: Any substance with an unacceptable risk may be on Annex XVII (restricted substances list). Substances, mixtures or articles may not be manufactured, placed on the market or used unless compliant with conditions of any restrictions in Annex XVII. Restrictions may apply to all or specific uses.
- Authorization: Priority SVHCs on the candidate list will be included in Annex XIV (authorization list). Those SVHCs will not be allowed to be used, placed on the market, or imported into the EU after a date to be set, unless the company is granted an authorization. Specified uses may not require authorization.

The 0.1% (w/w) criterion refers to the weight of the article manufactured in or imported to the EU. So it may refer to the weight of a finished good (automobile) or a component weight (bumper).

The SVHC candidate list is updated regularly. There are 138 substances on the candidate list, which was last updated 12/19/12. ECHA has recommended 42 substances for inclusion on Annex XIV (the authorization list). As of March 2013, there are 14 substances on the authorization list. Presently, there are more than 1000 substances in REACH Annex XVII, grouped in 59 categories. See the following links:
http://echa.europa.eu/web/guest/candidate-list-table
http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions

Impacts of REACH on U.S. Chemical Producers
REACH is providing U.S. customers, workers and consumers with new safety information. But the cost is steep; the total cost of registering a single substance reaches 2 million dollars if tonnage is high. The impact of REACH on small and medium enterprises is considerable; some choose to withdraw products form the EU market. On the other hand, REACH encourages data sharing through joint submission, in which case the lead registrant and consortium will do most of the work such as GLP testing, preparation of

technical dossier and Chemical Safety Report. Member registrants only need to pay the lead registrant a fee and prepare their individual part of the registration dossier.
S. Houlton reports that the number of substances pre-registered for REACH hugely exceeded expectations, with 2.7 million pre-registrations for more than 140,000 substances logged by the 2008 deadline, instead of the predicted 180,000 registrations for 29,000 substances. In an opinion piece in Nature, toxicologist Thomas Hartung and consultant chemist Costanza Rovida called for a review of REACH because of its enormous cost both in terms of capital and animals. Hartung and Rovida estimated that full compliance could use 52 million animals and cost $12.5 billion. The most expensive test is the two-generation test to evaluate reproductive toxicology, in which toxic effects are studied in the offspring of exposed rats and then in a second generation According to Hartung, two generation reproductive toxicity testing typically takes two years to complete, requires 3200 animals and costs $780,000 per chemical.[1]

A report from Tufts University (Ackerman et al [2]) makes the argument that U.S. producers are far better off paying the costs related to REACH to retain access to European markets. In 2006, U.S. REACH compliance costs were estimated at $14 million per year; sales revenue from chemical exports subject to REACH was estimated at $14 billion per year.

The Tufts paper sites two examples of lost export markets due to failure to respond to concerns of foreign consumers. One cautionary tale was provided by genetically modified corn. U.S. growers were not able to reliably separate conventional from genetically modified corn. Since European consumers rejected genetically modified food, corn exports dropped from $100 million to $8 million or less. A similar but larger loss occurred in meatpacking, when U.S. producers and USDA regulators failed to respond appropriately to foreign consumers' fears of mad cow disease. Creekstone Farms, a U.S. beef producer, serves as an illustration. Creekstone Farms negotiated an agreement with the Japanese government to resume sales in Japan if Creekstone adopted Japanese testing standards. However, the USDA invoked old food safety laws to prohibit any American producer from exceeding U.S. government testing standards for percentage of animals tested. U.S. annual beef exports dropped from $3 billion in 2003 to $550 million in 2004.

Ackerman et al describe how the U.S. government actively worked to generate opposition to REACH within Europe. A revised REACH proposal, published in October 2003, reflected many of the specific changes which the U.S. had advocated, including exclusion of polymers, reduced regulation of intermediates, and looser requirements regarding chemicals found in products.

Chemical producers have a number of concerns beyond cost. ECHA groups companies together who have preregistered similar substances. Those companies, many of which are competitors, need to work together to provide much of the detailed information required for registration. This process forces companies to share confidential business information. Furthermore, one registration for one substance may make it difficult to differentiate a chemical product Also, REACH allows the EU to share information with other national governments. The U.S. EPA can gain access to confidential business information submitted under REACH.[3]

Impacts of REACH on U.S. Article Manufacturers
REACH restricts the use of certain chemicals and provides significant financial incentive for chemical companies to eliminate chemicals. When a substance is banned in Europe or placed on the SVHC candidate list, it affects production and use decisions around the world. For manufacturers of finished goods, the cost of chemical substitution and reformulation is incalculable.

Mike Kirschner, in a Forbes report by A. Westervelt, states that companies must be careful when substituting a known toxic substance with an alternative. "Regrettable substitutions happen all the time, he says. Replacing lead in gas with MTBE, for example, was just replacing an airborne carcinogen with an aquatic toxin. The pesticide industry is full of these sorts of stories. And in the electronics industry, Europe made the industry get rid of lead in solder, but the replacement used [typically tin-silver-copper solder] is environmentally no better. It's no worse, but it's no better. If you don't make checking alternatives part of the regulation then that's what happens." [4]

Manufacturers of finished goods in the U.S. are required to address not only various U.S. regulation requirements, but also European requirements. "If an article is imported into the EU, some customers may require that the article is compliant with REACH. To respond to such a request and hence maintain confidence in the customer base, producers or importers will need to know the composition of their articles. This might be a reasonable task under some circumstances or highly challenging under others. Take the example of a US firm manufacturing an electronic toy for import to the EU. The firm may receive components from companies located in many regions such as the Far East. The chemical composition of the component may be unknown or the component supplier may be unwilling to reveal the composition for commercial reasons. This leaves the article producer the choice to cease exports to the EU or alter the sourcing of the component. This example becomes more complex with multiple suppliers (e.g. automobile industry)." [5]

"How does a European chemical regulation (REACH) impact a local North American automobile part manufacturer?" is the title of an article by Aditya E. Sharma. The answer stems from customer demands cascading across the supply chain. "Suppliers, whose operations are exclusively outside of the EU, say in North America (NA), are being asked to demonstrate due-diligence by some of their customers who have a global footprint. The rationale given is that customers who may choose to have products within EU and to mitigate risk are looking to their suppliers for conformance irrespective of regulatory obligations or jurisdictional boundaries. In such a scenario, although technically EU REACH may not be applicable, NA suppliers are being forced to evaluate REACH to support their clients' REACH initiatives (or else they may lose favorable standing with their customers).

You would think manufacturers/suppliers with primarily non-chemical operations would not be concerned as products would be classified as "Articles" (limited registration obligations). However, the need for manufacturers and suppliers to identify and communicate the ever growing list of SVHC, more than 0.1% by weight in an Article, to their customers and consumers on request has made sure that all type of products need to be considered. Suppliers need to provide adequate information on the safe use and disposal of the article, including the name of the SVHC(s) concerned. Furthermore, manufacturers and importers of articles have to notify the European Chemicals Agency on the quantities of SVHCs used in their articles. This intensifies the need for certain information to be shared across the global supply chain." [6]

REACH Help

Companies have an immediate legal obligation when a substance is added to the SVHC candidate list. Therefore, planning for substances that are likely to make the list is prudent. The SIN (substitute it now) list is a project of ChemSec, a non-governmental organization founded in 2002 by four environmental organizations. Substances on the SIN list are likely to make the candidate list. The SIN list and database are found at the following links:
http://www.chemsec.org/images/stories/2011/chemsec/SIN_List_2.0_all_378.pdf
http://w3.chemsec.org/

The U.S. Department of Commerce may be very helpful to individual U.S. firms regarding REACH; see the following link:
http://export.gov/europeanunion/reachclp/index.asp

The ANSI (American National Standards Institute) website states that their Network on Chemical Regulation (Network) is a forum for U.S. manufacturers to jointly address domestic, regional, foreign and global chemical regulations. The Network was established in response to business concerns about the impact of REACH and other global chemical controls. Companies affected by REACH and other foreign chemical regulations are urged to join the network. See the following link:
http://www.ansi.org/standards_activities/standards_boards_panels/chemical_regulation.aspx?menuid=3#.UMizy6yWQoY

The websites of the European Chemical Industry Council, ECHA and European Commission are helpful sources of information:
http://www.cefic.org/Regulatory-Framework/Governmental-Initiatives-and-Regulations1/REACH/

http://www.cefic.org/Industry-support/Implementing-reach/

http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation
http://echa.europa.eu/web/guest/regulations/reach/understanding-reach

http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

Free email alerts may be requested from REACH Ready, a REACH and CLP consulting company:
http://www.reachready.co.uk/

Companies need to use REACH specific software systems such as IUCLID5, REACH IT, SIEFs and CSA Tool for registration and creating SDS. Software companies such as SAP and ACTIO have developed software for integrating these specific systems with an organization's existing IT system for SDS authoring and distribution, procurement and sales. This type of software automates the process of collecting and managing information required from suppliers and customers to comply with REACH directives. The software can help ensure ongoing compliance with product-related regulations with support for legal, safety, and sustainability obligations along the supply chain.

References

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