

| Product<br>Responsibility<br>Best Practices | SUBJECT   |  | LAST UPDATE |
|---|---|--|-------------|
|   | Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)   |  | July 2018   |
|   | APPLIES TO  | FOCUS ON   |             |
|   | <ul style="list-style-type: none"><li>• Suppliers</li><li>• Distributors</li></ul>  | understanding the burden of proof on companies to identify and manage the risks linked to the substances they manufacture and market in the European union (Eu). |             |
|   | QUICK LINKS   |  |             |
|   | <ul style="list-style-type: none"><li>• PPAI Corporate Responsibility: <a href="http://ppai.org/corporate-responsibility/">ppai.org/corporate-responsibility/</a></li><li>• UL: <a href="http://industries.ul.com/premiums-promotional-and-licensed-goods">industries.ul.com/premiums-promotional-and-licensed-goods</a></li><li>• Consumer Product Safety Commission: <a href="http://www.cpsc.gov">www.cpsc.gov</a></li></ul> |  |             |
|   | Intended for<br>intermediate<br>compliance<br>programs  |  |             |

*Italic grey text indicates a hyperlink listed in the Online Resources section of this document.*

## INTRODUCTION

REACH stands for *Registration, Evaluation, Authorisation, and Restriction of Chemicals*. It is a regulation of the European Union (EU) that was adopted June 1, 2007. The purpose is to “improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.”

### Impact On Business

Almost every company that markets/distributes product in the EU (manufacturer/importer/downstream user) is affected. Similar to regulations in the United States (U.S.) like the *Consumer Product Safety Improvement Act (CPSIA)*, *Toxic Substances Control Act (TSCA)*, *California Proposition 65*, *California Safer Consumer Products (SCP)* program and a host of other state regulations, the REACH has been put in place because the chemical makeup of products has a direct effect on human health and the environment.

Unlike U.S. regulations that differentiate between user applications, REACH applies to all chemical substances regardless of industrial, commercial, or consumer use. Therefore, companies must prove compliance by identifying and managing the risks associated with the products they manufacture and distribute in the EU. For companies located outside the EU it is the responsibility of the importer to fulfill REACH requirements (similar to the U.S. where the importer of record is considered the manufacturer).

## BASIC REQUIREMENTS

The basic requirements of REACH consist of five components:

1. **Substance identification** consists of the chemical name, a number, and the chemical composition. Knowing this information enables registrations to be prepared correctly and efficiently, ensures appropriate and accurate test data, and allows for joint registration and sharing of information to reduce unnecessary testing and costs.

2. **Registration** applies to “substances on their own, substances in mixtures, and certain cases of substances in articles.” A fee is usually charged to register a substance. Thus, the principle for registration is “one substance, one registration,” which essentially means that “manufacturers and importers of the same substance have to submit their registration jointly.” A *registration dossier* has been established, containing the hazard information and assessment of risks, along with how to control such risks. Those that must register are:
  - a. EU manufacturer or importer of substances on their own or in a mixture;
  - b. EU producer or importer of articles meeting the criteria explained in the guidance on requirements for substances in articles; or,
  - c. “Only representative” established in the EU and appointed by a manufacturer, formulator or article producer established outside the EU to fulfill the registration obligations of importers.
3. **Evaluation** refers to information submitted by companies to be evaluated by the *European Chemicals Agency (ECHA)* and member states to assess the accuracy of registration dossiers, testing proposals, and the risk of the substance(s) to human health and the environment. Additional information may be required after the evaluation. Article 54 of the REACH Regulation states, “by 28 February of each year, ECHA has to publish a report on the progress it has made over the previous calendar year on its obligations in relation to evaluation.” The ECHA website provides *guidance on registration and evaluation progress reports*.
4. **Authorisation** is a procedure designed to assure control of risks associated with “*Substances of Very High Concern (SVHCs)*.” Additionally, it seeks to find safer “suitable alternatives” to existing substances. SVHCs require a two-step process and product cannot be placed out in the market unless authorization is given for a

specific use or an exemption for use is granted and the substance is placed on the Authorization List. SVHCs are identified by the following properties:

- a. "Substances meeting the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction category 1A or 1B in accordance with Commission Regulation (EC) No 1272/2008 (CMR substances);
- b. Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH (Annex XIII); and,
- c. Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances."

In order to give advanced information to industry and other stakeholders when an item is identified as a SVHC it is added to the Candidate List for possible inclusion in the Authorization List, which then "creates legal obligations to companies manufacturing, importing or using such substances, whether on their own, in preparations or in articles."

5. **Restriction** is the tool used to manage individual chemicals by themselves or as a mixture. The ECHA or a member state can propose restrictions. REACH imposes bans or limits on the manufacture and sale of specific products containing substances considered to pose unacceptable risks either on its own, in a mixture, or in an article.

## DOWNSTREAM USERS

The EU refers to companies or individuals who use a chemical substance, either on its own or in a mixture, in the course of their industrial or professional activities as "downstream users." These users are responsible for implementing safe use of substances at their own facilities and communicating relevant information to their customers and suppliers. This consists of:

- Providing information regarding their use of the substance(s) or article to suppliers of substances for accurate chemical safety assessment;
- Implementing measures specified by suppliers for safe use;
- Informing suppliers if circumstances of use change or the current risk management advice is not appropriate;
- Taking appropriate action based on whether a substance is included in the Authorization List or the List of Restrictions;
- Providing customers with necessary hazard and use information (formulators only); and,
- Taking action on registration or notification if required and communicating information if required (producers of articles only).

## Communication

U.S. companies exporting product into the EU must work with the importer to notify the ECHA when candidate chemicals are present in their products based on both the following conditions occurring:

1. Chemical content is "above a concentration of 0.1% weight by weight"
2. Chemical presence is "in quantities totaling over one tonne per year"

## Exemptions

Exemptions from notification are possible when the following conditions are met:

1. The producer or importer of an article can exclude the exposure of humans and the environment to the substance during normal or reasonably foreseeable conditions of use of the article, including its disposal. In these cases, the producers and importers will give appropriate instructions to the recipient of the article.
2. The substance has already been registered by a manufacturer or importer in the EU for that use.

Effective communication across the supply chain is critical to maintaining compliance with REACH. In the EU safety data sheets (SDS) are considered the primary tool for communicating chemical information.

## Enforcement

Enforcement of REACH begins with the *Forum for Exchange of Information on Enforcement (Forum)*. "REACH creates a Forum within the ECHA which brings together Member States enforcement authorities in a formal framework." Activities are coordinated and information is shared through the Forum but each member state is responsible for enforcement of REACH and determining penalties for non-compliance.

## Online Resources:

**Candidate List of SVHC** <http://echa.europa.eu/web/guest/candidate-list-table>  
**Authorization List**

<https://echa.europa.eu/identification-of-svhc>

**European Union:** [http://europa.eu/index\\_en.htm](http://europa.eu/index_en.htm)

**European Chemicals Agency (ECHA):** <http://echa.europa.eu/about-us>

**REACH Legislation:** <http://echa.europa.eu/regulations/reach/legislation>

**Forum:** <http://echa.europa.eu/web/guest/about-us/who-we-are/enforcement-forum>

**CPSIA:** <http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/>

**TSCA:** <https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act>

**Prop 65:** <http://oehha.ca.gov/prop65/background/p65plain.html>

**California (SCP):** <https://www.dtscc.ca.gov/scp/>

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