



REACH: the EU Chemical Regulation

This report serves to assist U.S. businesses exporting chemicals, or products using chemicals, by providing information that will improve their knowledge base and understanding of the applicable European Union (EU) legal framework, so they can reliably sell their products in Europe. It provides information about chemicals registration obligations when exporting to the EU; the information requirements for such registrations; how to register; information on chemicals that the EU restricts from being sold or used; information about registration costs; and, sources companies can access for more specialized information.

Introduction

“REACH”, which is an acronym for “Registration, Evaluation, Authorization and Restriction of Chemicals”, is the basic EU regulation applying to chemicals. It has been in force since June 1, 2008 and applies throughout the EU. Iceland, Lichtenstein and Norway also apply the regulation. U.S. based companies should bear in mind that REACH imposes obligations on all companies active in the EU market that use chemical substances. Electronics, automotive, cosmetics and textiles are a few examples of economic sectors that are affected by REACH. As of December 2012, the European Chemicals Agency (ECHA) has received 30,601 registration dossiers for 7,884 unique chemical substances.

1. Registration

REACH is based on the “no data, no market” principle. This means that companies manufacturing or importing chemical substances subject to the regulation may not place products on the EU market without first having registered with ECHA. The following sub-sections address the registration obligation in greater detail.

a. Obligation to register

REACH imposes a general obligation on manufacturers and importers to register with ECHA chemical substances placed on the EU market in volumes above 1 metric ton per year. Registration

applies to substances such as preparations (also called “mixtures”) and, under certain conditions, to articles (finished products) incorporating those substances. Box 1 below highlights the special rules applying to articles.

REACH is both “substance-based” and “company-based”. Substance-based means that every substance present in a preparation or mixture in a quantity greater than or equal to 1 metric ton must be registered with ECHA. Company-based means that each U.S. company exporting 1 metric ton or more of a particular chemical must register.

Companies needing to register must submit a technical dossier providing information on the properties of the chemical substance(s); applicable uses; and, safe ways of handling. In addition, the registrant must submit a chemical safety report for substances manufactured or imported in quantities exceeding 10 metric tons per year. Registration is completed on-line, on the IUCLID database.

The requirements of the technical dossier are specified in the annexes to REACH. Annex VI details the common information to be submitted by all registrants. Annex VII to X apply depending on tonnage: 1 – 10 metric tons (annex VII), 10 – 100 metric tons (annexes VII and VIII), 100 – 1000 tons (annex VII to IX), above 1000 metric tons (annexes VII to X). The yearly tonnage is calculated on the basis of the quantities imported into the EU during the 3 preceding years.

The requirements of the technical dossier are as follows:

- The identity of the manufacturer or importer (Annex VI)
- The identity of the substance (Annex VI)
- Information on the manufacture and uses of the substance (Annex VI)
- The classification and labeling of the substance (Annex VI)
- Guidance on safe use of the substance (Annex VI)
- Study Summaries (Annexes VII to XI)
- Robust study summaries (Annex VII to XI)
- An indication as to what part of the information submitted has been reviewed by an assessor chosen by the manufacturer or importer who has appropriate experience
- Proposals for new testing (Annex IX and X)
- Exposure information for substances 1-10 tons (annex VI)

- A justification for confidential information that should not be published on-line.

The chemical safety report includes a hazard assessment and documentation indicating whether the relevant substance is persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB). It also must identify appropriate risk management measures for all uses identified by the manufacturer or the importer and its downstream users.

For substances classified as dangerous and PBT/vPvB, the chemical safety assessment must also include an exposure assessment and an assessment of risks for health and the environment (risk characterization). Companies need not provide a risk characterization for chemical substances in preparations if they meet the criteria stated in Article 14(2) of REACH.

b. Exemptions from registration

REACH exempts companies from having to register a limited number of chemical substances. These exemptions include:

- Chemical substances imported into the EU or manufactured in quantities below 1 metric ton;
- Chemical substances used for research and development;
- Waste;
- Chemical substances whose uses are covered by other EU legislation such as medicine and food products;
- Pesticides and biocides;
- Polymers (however, monomers included in polymers must be registered); and,
- Companies that had notified chemical substances under previous EU legislation (Directive 67/548/EEC).

Annex IV and V of the REACH regulation lists a number of other chemical substances that are exempt from REACH. These lists include minerals, ores, cement clinkers, crude oil, coal and coke and apply to the extent that they are not chemically modified when placed on the EU market.

c. Submitting a registration dossier

REACH states that only an EU established entity may register; non-EU based companies must rely on the importer or appoint a qualified “Only Representative” (OR).

Many U.S. based companies choose to retain an OR (as opposed to relying on an importer) as it enables them to retain better control over the registration and protect confidential business information. An OR may be a consultant, scientist, a laboratory or any natural/legal person with experience in handling chemicals. In addition to submitting the registration dossier, the OR retains and makes available upon authorized request up-to-date information on quantities imported and customers sold to.

d. Data-sharing and joint submission of registrations

Registrants of the same chemical substance are required to jointly submit information on the hazardous properties of the substance and classification and labeling information. Typically, a single company takes the decision to be the “lead registrant” and coordinate the gathering and submission of data. In some instances, a group of companies will come together to form a consortium to manage a registration or series of registrations. In addition, ECHA will establish a “Substance Information Exchange Forum (SIEF)” to facilitate information sharing. The policy objective of this process is to reduce overall compliance costs and minimize animal testing.

Specific rules are in place to facilitate the data sharing process. In particular, data sharing is always mandatory for animal testing and fair compensation is required. SIEFs are also set up to help companies agree on the classification and labeling of the substance.

The obligation to share data and jointly submit information is limited to technical data and information related to the intrinsic properties of chemical substances being registered. It does not involve exchanging information on market behavior such as production and sales data information about market shares. Where required, ECHA allows a registrant to submit company specific data separately.

Companies considering whether to form a consortium for the purpose of registering under REACH should bear in mind that this must be done in accordance with EU Competition Law. Companies can opt-out from consortia and register on their own if joint submission would be disproportionately

costly, would lead to disclosure of commercial secrets, or if there is disagreement on selecting data. Companies wishing to opt- out of participating in a consortium need to justify their decision in their registration dossier. Companies pursuing this option are subject to a higher registration fee.

ECHA has published a guidance document on data sharing available at http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf

2. Evaluation

There are two aspects to the REACH evaluation process: (1) dossier evaluation; and 2) substance evaluation. Dossier evaluation refers to the process by which ECHA works to verify that registration dossiers are complete. ECHA is mandated to perform a compliance check on at least 5% of the dossiers submitted for registration. In some cases, ECHA may request that the registrants provide additional information. ECHA also checks the testing proposals submitted as part of the registrations before they are carried out, in order to limit animal testing.

In terms of substance evaluation, each year ECHA and the EU Member States select a number of chemical substances for placement on the "Community Rolling Action Plan", commonly known as "CoRAP", for further evaluation. They focus in particular on those that are manufactured/imported in large quantities and which are persistent and bio-accumulate. Each Member State has a designated agency that performs the evaluation; it is not performed by ECHA. Chemical substances placed on the CoRAP may eventually be subject to authorization or restriction.

3. Authorization

REACH implements a system requiring use-authorizations for "substances of very high concern" (commonly referred to as "SVHCs") for human health and the environment. The policy objective of the authorization process is to ensure that these substances are adequately controlled and that they are progressively replaced by safer alternatives or used only where there is an overall benefit to society.

SVHCs include carcinogens and chemicals that are mutagenic and toxic to reproduction (CMRs); substances which are persistent, bio-accumulative and toxic (PBTs and vPvBs); substances "which give rise to an equivalent level of concern" such as endocrine disruptors. Substances meeting these criteria are placed on a candidate list for inclusion in Annex XIV (list of substances subject to

authorization).

The authorization stage of REACH applies without tonnage limits. Chemical substances manufactured or imported under one ton per year may be subject to authorization even if they are exempt from registration. However, certain uses are excluded from the authorization process. Such uses include: medicinal products; food products; plant protection products and biocides; motor fuels; or substances present in preparations in low concentrations, usually below 0.1%.

The authorization list is published on the ECHA website available at <http://echa.europa.eu/en/addressing-chemicals-of-concern/authorisation>.

a. Applying for authorization

Applications for authorization must be made to ECHA. The European Commission establishes application deadlines for each substance when it is listed on Annex XIV.

In general, authorization will be granted where the applicant can show adequate control of the risks associated with the uses of a substance. The chemical safety report serves as the basis for demonstrating adequate control.

For some chemical substances (PBTs, vPvBs and CMRs for which a safe level cannot be defined), authorization will be given if a company can show that the socio-economic benefits of using the substance outweigh the risks to human health or the environment and that there are no suitable alternative substances or technologies. (This is sometimes referred to as the “substitution principle”.)

All applications for authorization must include an analysis of substitutes. If suitable alternatives exist, a substitution plan must be included. If not, information on R&D activities must be provided.

Applications for authorization can be submitted by EU-based manufacturers, importers, only representatives and downstream users. Businesses must apply for authorization for specific uses. All other non-authorized uses are prohibited. Authorizations are time-limited and have to be renewed on a case-by-case basis.

Authorization will involve the payment of a fee. The amount of the fee ranges between EUR 7,500 and EUR 50,000 depending on the size of the applicant company.

Guidance on preparing an application for authorization can be found at <http://echa.europa.eu/applying-for-authorisation>.

4. Restrictions

The restriction process is another mechanism under REACH that enables the EU to take measures to control the use of dangerous chemical substances circulated within the common market. Any chemical substance on its own, in a preparation or in an article may be subject to EU-wide use restrictions.

For a substance to be placed on the "restriction list" (Annex XV), a national authority must first make a proposal to the Agency to ban or restrict the marketing and use of a substance. Based on the opinion from the Agency, the Commission will make the final decision on the restriction of a substance.

A number of substances subject to restriction under Directive 76/769/EEC, such as the EU ban on asbestos, are carried out under REACH and included in Annex XVII.

5. Preparing for REACH

EU importers and only representatives will require substantial information from U.S. exporters to ensure REACH compliance. They will, for example, need to know the composition of preparations and articles and the uses of substances.

Companies should make an inventory of the substances they export to the EU, either on their own, in preparations and/or in articles, and consider the following questions:

- What are the volumes exported to the EU?
- Do the substances benefit from exemptions under REACH?

- Will they be subject to authorization?
- What data is available?

Companies may also want to ensure their safety data sheet(s) meet REACH requirements.

Companies should also look at the costs associated with REACH compliance including registration and authorization, testing, and costs for joining a consortium.

Guidance documents: ECHA has prepared several guidance documents to assist industry in complying with REACH. These documents are available on the ECHA website at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

The Commercial Service at the U.S. Mission to the EU maintains information on REACH: <http://export.gov/europeanunion/reachclp/index.asp>. This website provides general information on REACH and links to specialized business service providers with experience assisting U.S. based companies in complying with the legislation.

6. Cost of compliance

REACH mandates that only EU based entities can submit a registration dossier. U.S. based businesses that do not have a presence in the EU must therefore rely on their importer or appoint an Only Representative to register on their behalf. U.S. exporters should therefore expect to pay a service charge when registering. The service charge will include the cost to join a SIEF/consortia, filing-fees charged by ECHA, and a payment to the consultant/importer. U.S. companies can expect to pay approximately \$15,000 to register.

The European Commission sets the fees that ECHA charges by regulation. This Regulation was last revised on March 20th, 2013 and is available at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:079:0007:0018:EN:PDF>

It is common practice for consultants specializing in REACH to deliver an itemized estimate of the registration cost in advance of entering into a professional relationship.

7. Useful resources for further information

a. EU websites

The European Commission and ECHA have websites dedicated to providing industry useful information on REACH.

- DG Environment: http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
- DG Enterprise: http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm
- European Chemicals Agency: <http://echa.europa.eu/>

b. Helpdesks

ECHA has a helpdesk to answer questions on registration under REACH. It can be accessed at the following website <http://echa.europa.eu/support/helpdesks/echa-helpdesk>.

EU Member States have also established help desks. The contact information for national helpdesks can be found at <http://echa.europa.eu/support/helpdesks/national-helpdesks/list-of-national-helpdesks>.

Checking if all your chemicals exported to the EU are covered by REACH can be a difficult exercise, given the number of exemptions and the lengthy annexes listing them. The Commercial Service at the U.S. Mission to the EU maintains a list of business service providers specializing in EU chemical regulations who can help you audit your portfolio of substances:

http://export.gov/europeanunion/reachclp/reachbusinessserviceandsolutionproviders/eg_eu_030372.asp

For More Information

The U.S. Commercial Service at the U.S. Mission to the European Union, can be contacted via email at: Matthew Kopetski at matthew.kopetski@trade.gov; Phone: +32 2 811-5684; Fax: +32 2 811-5151; or visit our website: <http://www.export.gov/europeanunion>.

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