

Business for Social Responsibility

ACHIEVING EFFECTIVE REACH IMPLEMENTATION: A BSR Issue Brief on the New European Registration, Evaluation and Authorization of Chemicals (REACH) Regulation

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1. Background

The new EU chemicals regulation for the Registration, Evaluation and Authorization of Chemicals (REACH) entered into force on June 1, 2007. REACH applies to all European companies and to all non-European companies exporting to the EU. Effectively, the new framework **shifts the responsibility** for managing the human health and environment risks of select chemicals from legislators onto industry.

Administered by the newly created European Chemicals Agency (ECHA) in Helsinki, REACH streamlines the existing legal framework on chemicals in the EU into one system. REACH requires that **manufacturers, importers, and downstream users disclose data on hazards and risks** linked to substances and chemicals manufactured in or imported to the EU in quantities of **1 metric ton or more per year per company**.

Registration of chemicals under REACH requires companies to define both how to reduce exposure and prevent negative health and environment impacts. Depending upon the circumstances, upstream companies may have to provide full **life-cycle assessments** of substances that describe how the substance is manufactured, used and disposed, along with recommendations for controlling negative impacts due to exposure. Additionally, downstream companies may need to provide information about specific uses of substances back **up their supply chain to ensure that those uses are covered in the registration dossiers of their suppliers**.

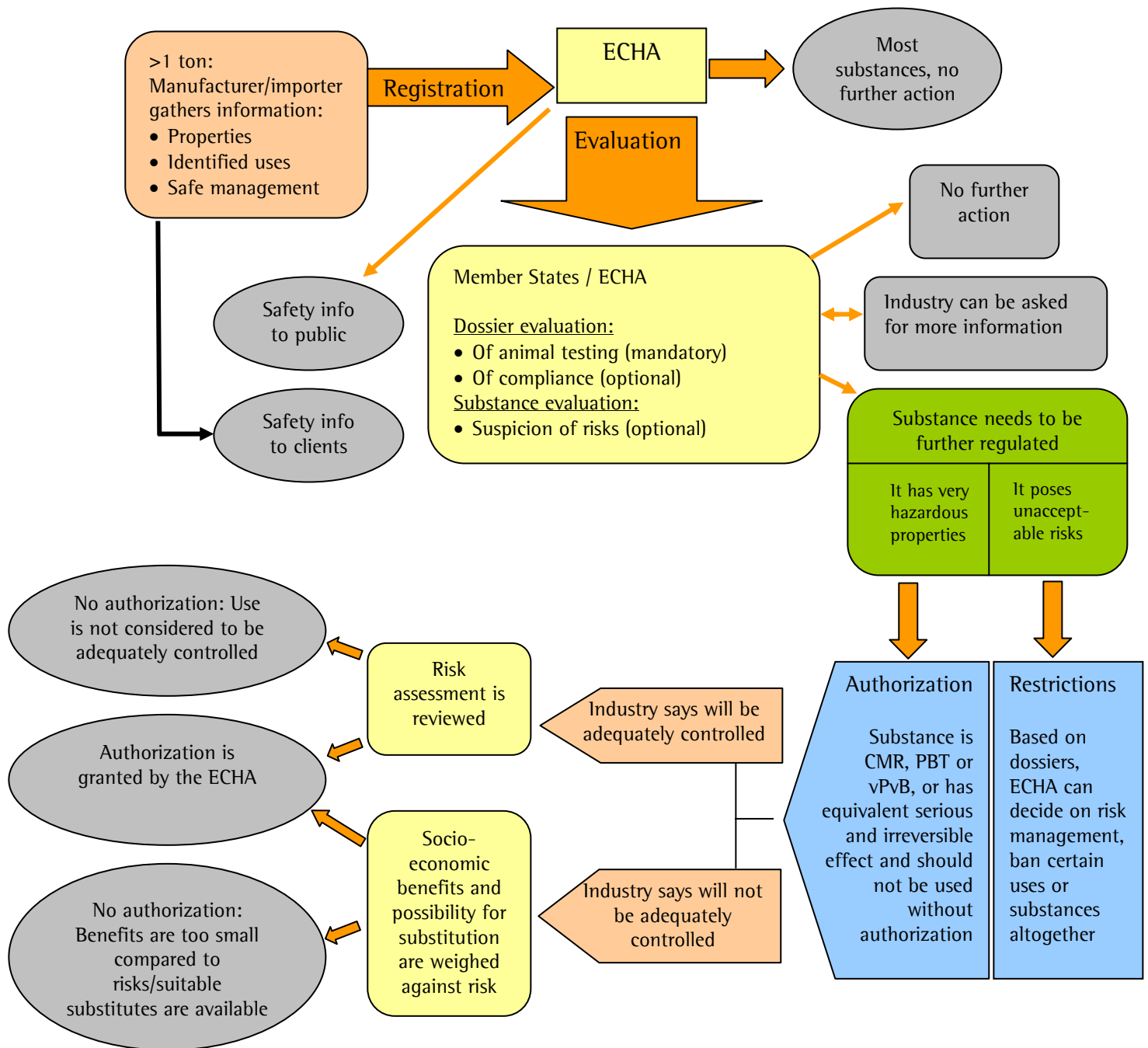
Failure to register information with the ECHA can mean that companies may no longer supply or market certain substances, or may need to reformulate products containing certain substances. Both can affect a company's ability to compete and operate within its markets. Any substance or use not registered will be banned throughout the EU--**no data, no market**.

It is estimated that more than 30,000 substances will need to be registered. Of those, approximately 1,500 "substances of very high concern" (SVHC) will have to go through an authorization process. Figure 1 provides an overview of the entire REACH process.

This regulation raises some fundamental questions for the companies concerned:

- What information and data do we need to provide and from what sources? How much of it already exists?
- What costs will the company incur and how can we minimize them?
- When should we contact customers, suppliers and/or business partners about REACH and how should we share the new responsibilities?
- What legal deadlines does the company have to meet?

Figure 1: Overview of REACH Process



11. Five Steps Toward Effective REACH Implementation

1. Inventory Priority Chemicals

Since companies will be required to gather information on the properties and uses of their substances, an inventory of the substances that form part of a company's business should be compiled.

- Priority One: Chemicals in your company's products sold into EU markets at a volume greater than 1 metric ton per year
- Priority Two: Chemicals most important to the company's high-margin product lines
- Priority Three: Other chemicals, including substances of very high concern and those in formulated products

2. Communicate with Suppliers and/or Downstream Users

Companies should initiate communications with suppliers and downstream users as early as possible, and certainly not long after launching the inventory process. Given that new information flows up and down the supply chain can lead to issues of intellectual property, it is recommended that companies set the terms of their communications clearly from the start.

REACH requires that downstream users notify their suppliers of all uses for a particular chemical. This information enables a supplier to better understand the exposure risks associated with a given chemical, and ensure that all known uses can be included within the registration dossier. In some cases, suppliers may not support a specific use if the costs involved are too heavy, and may prefer to withdraw the substance from the market unless their customers are willing to share the costs involved in registering it.

The primary tool for communicating chemicals information to suppliers and downstream users will remain the Safety Data Sheet (SDS). The SDS contains details of the hazards associated with a chemical and offers advice on safety precautions, enabling professional users to take the necessary measures with regard to the protection of health, safety and the environment. Under REACH, the role of the SDS will expand to include information from any chemical safety assessment. This means that an SDS must also be provided when supplying substances that are PBT (persistent, bio-accumulative and toxic) or vPvB (very persistent and very bio-accumulative).

Non-EU Manufacturers of Substances or Products Exported to the EU

Manufacturers outside the EU are not covered by REACH. However, non-EU manufacturers will still have to provide their importers in the EU with detailed information on the substances they supply or use to make their products. If they do not supply the information required under REACH, they risk losing that business outlet.

The non-EU manufacturer is free to appoint an “only representative” to fulfill its responsibilities under REACH or to let the importer register the substance. An “only representative” is an EU-based representative of a non-EU manufacturer. By appointing an “only representative,” the non-EU manufacturer obtains more control over the registration process, more knowledge regarding various uses of substances and avoids having to disclose potentially sensitive information to the importer.

If an importer receives products from a non-EU manufacturer that lacks an “only representative,” that company must submit the hazard information for that substance or communicate with its supplier regarding its intentions for registration. In addition, if the importer obtains the same substance from a number of non-EU sources, a single “only representative” is not sufficient and the importer may have to act as registrant or communicate with its multiple suppliers.

3. Pre-Register “Phase-In” Substances

By some estimates, 30,000 substances on the EU market will require registration. To tackle this registration burden, substances currently manufactured or supplied (“phase-in” substances) will be registered in three phases spread over 11 years. In order to take advantage of this transitional provision, companies must pre-register their substances between June 1, 2008 and December 1, 2008.

Through a Substance Information Exchange Forum (SIEF), the ECHA will connect those companies that intend to register the same substances so that they can negotiate data sharing and the costs of generating any new data.

4. Register Chemicals, Jointly or Individually

REACH requires registration of all chemicals intended to be released from products during normal and “reasonably foreseeable conditions” of the products’ use, and present in the products above one ton per year.

In order to create a registration dossier, manufacturers and importers to the EU must generate basic exposure and toxicity data for assessing the safety of, and risk management measures for, every chemical they manufacture or import in quantities of 1 metric ton or more. These data should be specific to given uses and updated as uses vary. For substances of high concern, certain types of high-exposure use may be subject to authorization.

“One substance – one registration” (OSOR) requires a single joint submission of the hazard information for a substance by all its EU manufacturers and importers. However, each legal entity (an EU manufacturer or importer) must still register some information separately. Thus, for each substance manufactured or imported, operators must either: 1) join a consortium and submit information jointly with other EU manufacturers, importers or EU-based representatives of non-EU manufacturers; or 2) opt out and register separately.

5. Evaluation

Once a chemical is registered, ECHA will undertake two types of evaluation:

- Dossier evaluation: Conducted to ensure that unnecessary animal testing is avoided, and to ensure compliance with registration requirements
- Substance evaluation: Evaluated by a Member State to determine whether further information is required for substances that may pose risks to human health or the environment

III. Opportunities Associated with Implementation

One of the objectives of REACH is to promote research and development and innovation. Other opportunities associated with implementation include:

- The REACH threshold for registration of 1 ton per year is much higher than the current threshold of 10 kg per year for new substances.
- The costs of registering a new substance will be significantly lower than the current cost of notification, and registration will be quicker than in the current process, thus reducing the time to market.
- The certification and guarantees of safety required through REACH can lead to greater consumer confidence in and loyalty to products.

For **downstream users** of chemicals in the EU, REACH presents a similar set of opportunities:

- The flow of information up and down the supply chain results in stronger communication and collaboration with suppliers for cleaner and safer alternatives.
- Confidential uses of substances related to core business strategy can remain confidential from suppliers.

III. Challenges Associated with Implementation

REACH will have an impact on both the global chemicals industry and any industry that uses or processes chemicals. It will affect businesses at every point of production, from chemical manufacturers to distributors to companies assembling components for specific products.

One challenge associated with REACH is that companies may face supply chain disruptions. Fragmentation and increased outsourcing within supply chains will mean that companies will need a cross-functional effort to collect data from multiple sources both internal and external to the organization. Successful REACH compliance will be based on efficient communication up and down the supply chain.

A second challenge is that many key decisions are still pending. Of particular relevance to companies are pending questions pertaining to:

a) Criteria to identify persistent and bio-accumulative chemicals

All persistent and bio-accumulative substances (PBTs and vPvBs) and those that are toxic to reproduction (CMR) can only be authorized for use if no suitable substitute is available, and if it is demonstrated that the socio-economic benefits from the particular use of the substance outweigh the risks to human health and the environment. The ECHA has yet to make clear how these guidelines will be determined. Thus, the potential for inconsistent regulation may be high. All PBTs and vPvBs will be reviewed and updated by the ECHA within 18 months of entry into force of REACH.

b) Definitions of “adequate control” and substitutes for substances of very high concern

“Adequate control” refers to exposures throughout the life cycle that are reduced to a point below which any adverse effects are likely to occur to health or the environment. Adequate control applies when a threshold can be established, and exposure is below this threshold. Many different control measures can be applied. These range from technical measures to reducing environmental concentrations (e.g. workplace ventilation or air extraction), product design (e.g. packaging and closures), personal protective equipment (e.g. respiratory filters), safe work and use procedures (e.g. worker training or maximum frequency and duration of exposure), and exclusion of use by specific sub-populations (e.g. pregnant women). Authorities have instruments to check the adequacy of these measures, either in the Evaluation step of REACH or through enforcement by local authorities.

If an exposure threshold for safe use cannot be established, then the question of adequate control cannot be conclusively addressed. If this is the case, REACH requires additional

safeguards to ensure that exposures are minimized. However, the authorization of such uses of substances may be granted if socio-economic benefits are shown to outweigh the risks and if there are no suitable alternative substances or technologies.

The Institut for Miljøvurdering warns that it will be "a major challenge to make sure that balanced and well-informed socio-economic analyses are produced,"¹ and questions whether industries, competent authorities and NGOs possess the tools necessary to undertake reliable assessments. Additionally, an open letter to EU Commissioners from a coalition of EU environmental NGOs, including Friends of the Earth Europe, World Wildlife Fund, Greenpeace and the European Environment Bureau, states that "it is far too early to celebrate" REACH since the regulation has "flaws and loopholes and is vulnerable to further weakening in the future."² It is particularly concerned about pending reviews that may permit the use of hazardous chemicals that cause disruptions to the endocrine system.

However, the focus on socio-economic analysis can be a positive outcome of REACH. Various interest groups will have the possibility to supply information and resources to the process, with the potential of providing manufacturers and importers of chemicals with a more informed decision basis through a more systematic appraisal of costs and benefits. REACH may in turn induce manufacturers of substances of very high concern to withdraw these substances from the market completely. The use of safer alternatives in consumer products can lead to greater consumer confidence in the chemicals industry and increased brand reputation and consumer loyalty for retailers and consumer products companies.

¹ EurActive.com (2007). "EU's REACH law enters into force amid controversy," May 31, 2007, last accessed on August 18, 2007 from <http://www.euractiv.com/en/environment/eu-reach-law-enters-force-amid-controversy/article-164165>.

² From "Open Letter," May 25, 2007 to the European Commission, access from http://assets.panda.org/downloads/reach_eif_open_letter_version_final.pdf.