

# COMPANY REGULATION

## THE LONG REACH OF “REACH” AND WHAT IT MEANS FOR YOUR BUSINESS

### Dramatic New Changes in EU Chemicals Law and Policy That Could Affect All Manufacturers, Distributors, Retailers and Importers

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The EU REACH Regulation—on the Registration, Evaluation, Authorisation and Restriction of Chemicals—entered into force on June 1, 2007 (REACH),<sup>1</sup> replacing the forty legal acts that previously regulated EU chemicals policy. The aim of this impressive overhaul is to create a single EU legislative framework for all chemical substances. This raises the question of whether chemical producers within the EU and around the globe will be able to manage a painless transition into the REACH world.

The new EU chemicals regime differs significantly from previous EU chemical legislation. A key policy change is the elimination of the distinction between “existing” and “new” chemicals. Under prior EU law, chemicals on the market prior to 1981 did not need to undergo any rigorous testing whereas chemicals placed on the market after 1981 needed to be tested.

The system created by REACH has received extensive media coverage in part because of the breadth of its impact on industry. REACH extends far beyond just the chemicals industry. The two main features of REACH for businesses are registration and authorisation. ‘Registration’ concerns the process by which information on chemicals, produced or imported above a certain threshold, will need to be submitted for registration in a central database. ‘Authorisation’ relates to the procedure whereby substances that are deemed to cause significant concern will need to be expressly authorised before they can be manufactured or imported into the EU, and will even need to be progressively replaced,

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1. Regulation 1907/2006 of the European Parliament and of the Council of December 18, 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, was published on December 30, 2006 in the Official Journal (OJ) of the European Union, OJ L 396, December 30, 2006.

where they are found to cause unacceptable risks to human health and the environment.

Another reason REACH is seen as giving effect to a major revolution in EU chemicals policy, is its dramatic shift of responsibility onto the shoulders of industry. First, REACH transfers the burden of managing risks from chemicals—both risks to humans and to the environment—to private enterprises that use those chemicals. Secondly, those enterprises are made responsible for providing safety information on the substances used in their products. REACH intends to achieve this by requiring manufacturers and importers to gather information on the properties of the chemicals they use. This information will be registered and collected in a central database intended to help manage those substances in a safer manner. The database will be managed by the European Chemicals Agency (ECHA), based in Helsinki. The ECHA will play a key role in evaluating potential risks posed by chemicals as well as having responsibility for the public database containing hazard information on each substance. REACH also requires that the most dangerous chemicals be progressively replaced by more suitable substances, where possible.

#### REGISTRATION

One of the key registration obligations is that manufacturers and importers are obliged to provide information on substances produced or imported into the EU in quantities above one metric tonne<sup>2</sup> per year. In addition, they will need to gather and/or develop information proving that these substances are safe to use, as well as include this type of information in a registration dossier. This dossier will be submitted for registration to the ECHA. The submission of the necessary information for registration purposes is a condition that must be completed for chemicals manufactured in or imported into the EU. The registration requirements apply both to the substance itself and to articles that contain the substance. According to the European Commission's estimates, about thirty thousand substances will need to be registered. A large number of these substances are produced or imported by more than one company. This means that, potentially, a much larger number of registrations might be made. Companies are also encouraged to take a broad view on pre-registration. This means that they should pre-register not only chemicals they actually import or produce but also chemicals they might either import or produce in the future.

A memo released on 1 June 2007 by the ECHA states that the Agency is expecting 180,000 pre-registration files to be submitted in the pre-registration period running from 1 June-1 December 2008. The Agency would then identify the parties intending to register the same substance and put

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2. One metric tonne equals 2,200lbs (U.S.).

those parties in contact with each other.<sup>3</sup> The intention is to allow potential registrants to come together to form a Substance Information Exchange Forum (SIEF) to share available data and discuss the need for further data.

#### EVALUATION

“Evaluation” is the procedure whereby regulatory authorities (the ECHA along with the EU Member State authorities) analyse the information submitted by applicants to evaluate if it will provide the required safe management of the chemicals. The authorities may also conclude during the evaluation phase that the relevant requirements have not been met. In those cases where a risk to health or to the environment is suspected, the applicant may be requested to submit further information. Evaluation of the chemicals can also lead to the restriction of their use or to the conclusion that a particular use of a given substance requires authorisation.

#### AUTHORISATION

Where the ECHA decides that the use of a given substance, because of its hazardous properties, requires authorisation, applicants will need to formally apply for such authorisation in order to be able to manufacture it in, or import it into, the European Union. Furthermore, the applicant will need to submit the relevant documentation, accompanied by an analysis of potential substitute substances. Where safer substances are available, applicants are required also to submit plans for eventual substitution by those substances. The identification of the substances that will require authorisation will take place through a process that will involve the ECHA, the European Commission and the EU Member States. The ultimate goal of this process is eventually to replace substances of very high concern that are known to cause unacceptable risks to human health and the environment, where the use of those substances is not otherwise justified.

#### UNDER REACH VARIOUS OBLIGATIONS FALL DIRECTLY UPON INDUSTRY

In order to fulfil their obligations, downstream users of chemicals<sup>4</sup> in the supply chain will need to have at their disposal information on the

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3. Questions and Answers on the European Chemicals Agency (ECHA) and the REACH Regulation, European Chemicals Agency, 1 June 2007, [http://ec.europa.eu/echa/doc/press/memo-07-218\\_en.pdf](http://ec.europa.eu/echa/doc/press/memo-07-218_en.pdf).

4. A downstream user is defined in Article 3(13) of the Regulation as “[. . .] any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user.”

chemicals they are using. Downstream users are therefore likely to request their suppliers to provide them with such information. Industries are likely to want to have a mechanism to check the status of compliance by others, or at the very least reassurance that some preliminary compliance activity has been undertaken by suppliers upstream. It will be important that upstream suppliers keep clear records of chemicals used in their products so that they are in position to provide necessary information to their clients. Downstream users will also have to consider whether the use they make of each substance is safe, and, where necessary, adopt their own appropriate risk management measures. In order to be able to comply with this legal requirement, downstream users should seek to establish effective exchanges of information with their suppliers. The more precise downstream users can be in communication with their suppliers as regards the use they make of a particular substance, the more likely it is that the relevant supplier can submit comprehensive Chemical Safety Assessments (CSA), covering all uses of the substances made by downstream users. A CSA is intended to assess risks arising from the manufacture and/or use of a substance and aims to ensure that they are adequately controlled. Should a company decide against registration, for instance, because it intends to end the imports of certain substances completely, it would be well advised to inform its clients well in advance in order to allow them time to find alternative solutions.

As stated above, REACH shifts the risk of proving that chemicals are safe from the public authorities to the businesses that use those chemicals. Although the provisions of REACH apply within the territory of the European Union and therefore, in theory, only impact directly on manufacturers and importers within the European Union, in practice, its impact is global. Many of the substances used in the European Union, either on their own, or in, or as part of, articles, are imported from non-EU Member States, the information that EU importers and manufacturers will need to receive from their suppliers is crucial for their ability to comply with the REACH requirements and the continued use of these substances. The global effect of REACH is illustrated by a press release from the American National Standards Institute (ANSI) on 4 September 2007<sup>5</sup> which states that in response to business concerns about the impact of REACH and other foreign chemical controls, ANSI and the [U.S.] National Association of Manufacturers (NAM) have joined forces to help U.S. companies comply with the REACH registration programme.

Furthermore, REACH has already started to create political pressure from EU Member State authorities and consumer organisations on the industry requiring more concise information, better labelling and safer alternative products. For example, the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety together with the

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5. [http://www.ansi.org/news\\_publications/news\\_story.aspx?menuid=7&articleid=1585](http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=1585).

German Federal Institute for Risk Assessment have encouraged consumers to exercise their rights under REACH and proactively require information from sellers and target their purchasing better. This operation of consumers' rights awareness that consumer organisations seem to have engaged in, suggests that operators of the chemical sector should seriously invest in time and resources to understand to what extent their responsibility is or might be involved in the whole REACH machine.

#### DEADLINES AND IMPORTANT DATES FOR INDUSTRY

It is essential that industry operators have a clear understanding of when specific obligations under REACH would be triggered. The European Commission has indicated that registration is a pre-condition to placing new substances on the market. This key deadline is 1 December 2008; the date by which applicants must pre-register so-called "phase-in substances" (*i.e.*, substances listed in the EINECS list (the European Inventory of Existing Commercial Chemical Substances) or those that have been manufactured in the EU but not placed on the EU market in the last fifteen years, or the so-called "no-longer" polymers" of EU Directive 67/548/EEC). This pre-registration period is relatively short and it is important that companies begin to consider the possible impact of REACH on their business now. Affected businesses should review their portfolio of chemicals in light of the scope of their obligations, role and tasks under REACH. Through pre-registration, companies will be able to benefit from the transitional registration scheme. In effect this means that the duty to register will be phased over a period of time and consequently the companies will facilitate their own workload for completing registration dossiers. If a company chooses not to take part in the pre-registration, it will be required to register all of its substances falling under REACH immediately at the end of the pre-registration period. Below is an outline of some salient deadlines that business operators need to consider depending on different tonnage ranges for different chemical substances:

- *June 2007*: entry into force of REACH Regulation;
- *June 2008*: The European Chemicals Agency becomes operational;
- *1 June 2008 - 1 December 2008*: Pre-registration of 'phase-in' substances;
- *By 1 December 2010*: Registration deadline for substances manufactured or imported in quantities of one thousand tonnes and above, as well as carcinogens, mutagens and substances toxic to reproduction above one tonne per year, and substances classified as very toxic to aquatic organisms above one hundred tonnes;
- *June 2013*: Registration deadline for substances manufactured or imported in quantities of one hundred tonnes and more; and
- *June 2018*: Registration deadline for substances manufactured or imported in quantities of one tonne and more.

## CRITICISM OF REACH

The REACH Regulation has caused significant concern amongst certain industry sectors that fear that the impact of REACH has not yet been made sufficiently clear. Additionally, critics have questioned the effectiveness of the Commission's efforts to avoid any overlap with existing legislation, particularly in fields that are expressly excluded from the scope of REACH. For example, concerns have been expressed that for pharmaceuticals, some REACH provisions are confusing in that they appear to require the same chemical to follow different procedures depending on the product into which it is incorporated, or its intended use.

## THE ROAD AHEAD FOR BUSINESSES

The European Commission's Working Group on the Practical Preparations for REACH is currently in the process of preparing for full implementation of REACH. Guidance and support tools are essential in assisting stakeholders to understand their tasks and fulfil their obligations. So-called REACH Implementation Projects (RIPs) are well under way. These cover the development of IT systems, guidance documents for industry, guidance documents for authorities, helping the ECHA becoming fully operational, process descriptions, guidance for downstream users, guidance on data-sharing, guidance on dossier evaluation, guidance on the preparation of chemical safety reports, *etc.* The RIPs are coordinated by the European Chemicals Bureau of the Joint Research Centre (JRC).

A formal review of the Regulation has been scheduled for 2012, five years after its entry into force. Clearly, in anticipation of such a review, it is important to determine well in advance potential consequences and/or opportunities of any changes to the REACH Regulation. This is highly important, especially if one takes into consideration that one of the aims of REACH is not to overlap with any legal regime already existing for some industrial uses of certain chemicals, and the fears that such overlap may, somehow, already be a reality. If such fears are justified, the effectiveness of REACH, as well as the need for legal certainty would be dramatically undermined.

Furthermore, the changes business operators would need to look out for may go beyond the text of the REACH Regulation itself. One related development, for example, concerns the European Commission proposal for Regulation on the classification, labelling and mixtures, which was put forward on 27 June 2007.<sup>6</sup> This proposed Regulation is designed to complement REACH and align the EU labelling system with the United Nations Globally Harmonized System (UN GHS). It is but one example of the on-going regulatory impact of REACH that points at the need for industry to stay closely involved. In addition, the REACH Implementation

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6. Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006" (COM(2007) 355 final.

Projects are still ongoing and a number of guidance documents are in the process of being written on the extent and consequences of REACH.<sup>7</sup> There is, therefore, still an opportunity for advocacy by both EU and non-EU operators to try and make REACH more acceptable and less burdensome for the chemicals industry.

The impact of REACH is significant and far-reaching and will affect manufacturers and suppliers within, as well as outside, the European Union. Few pieces of proposed EU legislation have required such extensive deliberations within the EU, or caused such international debate before their final adoption, as the REACH Regulation. Many non-EU countries have followed the debate on REACH very closely, including the U.S., Switzerland, Norway, Canada, Japan, Korea, New Zealand, and China. In the U.S., Congress is currently debating whether current U.S. chemical legislation provides adequate protection to humans and the environment. REACH is referenced in these debates. It is not unrealistic to conclude that REACH could inspire other countries around the globe to adopt new, more rigorous, legislative frameworks for chemicals that mirror REACH.

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7. More information can be found on the Guidance page of the ECHA website which contains links to some guidance documents which are already prepared and states that further guidance is in the process of being written: [http://reach.jrc.it/guidance\\_en.htm#GD\\_PROCC\\_I](http://reach.jrc.it/guidance_en.htm#GD_PROCC_I).