

February 2009

REACH AFTER THE DECEMBER 1, 2008 PRE-REGISTRATION DEADLINE

I. General

The European Union's REACH Regulation on the Registration, Evaluation, Authorization, and Restriction of Chemicals applies as of June 2007.¹ As explained below, companies should be taking a number of concrete actions now in order to ensure their compliance with this Regulation.

REACH imposes various requirements on manufacturers and importers of both substances and goods containing them. The REACH obligations not only apply to chemical companies but also to companies using substances in the manufacture of goods. Such "downstream users" are in particular affected by the following:

- When they import substances (on their own or in goods in the form of preparations or articles), they may carry the burden for registration.
- They may not manufacture goods in the EU/EEA with substances that have not been duly registered/pre-registered.
- They may be required to provide their customers with REACH information on the content of the goods that they supply to them.
- Unless their suppliers do so, they may be required to apply for the authorization to use substances that are subject to authorization in the manufacture of their goods.
- Their goods will also be subject to the marketing and use restrictions adopted under the Regulation.

There are three main sets of REACH obligations:

1. **Disclosure of Data**: REACH requires, as of June 1, 2008, the registration of virtually all substances manufactured or imported in quantities of one ton or more per manufacturer or importer per year. The obligation applies to substances on their own, in preparations, and in some cases articles (*i.e.*, objects), and to each and every manufacturer or importer that reaches the volume threshold.

Registration requires the submission of large amounts of data on the substance and such data sets may cost up to several hundred thousand Euro to compile.

¹ A copy of the Regulation is available at:

(http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf).

However, REACH grants extended registration deadlines (*i.e.*, December 2010, June 2013, June 2018) to manufacturers and importers of so-called “phase-in substances” **if** they pre-registered such substances by December 1, 2008.

In general, phase-in substances include the around 100,000 substances of the European Inventory of Existing Commercial Substances (“EINECS”) and a limited number of other “old” substances.

Manufacturers and importers who did not ensure the registration of their substances by June 1, 2008, or the pre-registration of their phase-in substances by December 1, 2008, can no longer lawfully market their substances or products containing them in the EU/EEA until they ensure their full registration. As an example, a French Draft Ordinance on REACH enforcement imposes fines up to € 75,000 and two years of imprisonment for non-compliance.

- 2. Provision of Information Through the Supply Chain:** Suppliers of articles must provide their customers with information on the safe use of the articles if they contain substances that the European Chemicals Agency (“ECHA”) lists as “Substances of Very High Concern” (“SVHCs”) in concentrations above 0,1%.²

On October 28, 2008, the ECHA published its first list of 15 substances identified as SVHCs.³ This list will be updated regularly and it is likely to be expanded significantly in the near future. The ECHA must grant interested parties an opportunity to comment before it updates the list.

The Regulation also requires suppliers to provide their customers with safety data sheets if their substances or preparations containing them are classified as dangerous or are listed as SVHCs.

- 3. Phasing-Out of Substances:** The Commission must decide which of the substances included in the SVHCs list must be subjected to a prior authorization requirement. The Commission’s decision must be based on a recommendation from ECHA, who must give interested parties an opportunity to comment.

Where a substance is listed as subject to authorization, no manufacturer, importer or professional user may use or market the substance unless it first obtains an authorization for such specific use. In general, authorizations will be granted only if the risks are adequately controlled and/or there are no substitutes.

On the basis of a recommendation of the Agency, the Commission may also ban the marketing and use of substances that pose “unacceptable risks” to human health or the environment.

² SVHCs may include (i) Category 1 and 2 carcinogens, mutagens and toxic to reproduction substances, (ii) persistent, bioaccumulative and toxic substances (“PBTs”); (iii) very persistent and bioaccumulative substances (“vPvBs”); and (iv) substances identified on a case-by-case basis as raising an equivalent level of concern.

³ (http://echa.europa.eu/chem_data/candidate_list_table_en.asp).

II. Areas of REACH Concern for Companies after the December 1, 2008 Pre-Registration Deadline

After December 1, 2008, there are four main REACH areas that require immediate action from companies manufacturing or marketing substances or goods in the EU/EEA:

- 1. Provision of Information Up and Down the Supply Chain:** Companies should be in the process of drafting or receiving REACH compliance letters. First, as the ECHA pre-registration list does not identify the entities that have pre-registered, companies should confirm that their suppliers have pre-registered their substances and they can therefore continue to market their products in the EU/EEA.

Second, professional customers (e.g., distributors) have already started asking their suppliers whether the substances they supply to them on their own, in preparations or articles are included in the list of identified SVHCs and are contained above the specified thresholds.

In both cases, there will be a chain of requests for information all the way up the supply chain (retailer, distributors, importer, foreign manufacturer, and foreign chemical supplier).

Action Item: Companies should prepare template letters requesting and providing information on pre-registration and SVHCs to their suppliers and customers respectively. In doing this, companies should find ways to obtain the data necessary to prove compliance without compromising the confidential business information of their suppliers and customers. On the basis of the information that they receive, companies should also prepare REACH compliance dossiers for their products and ingredients that they can quickly make available to enforcement authorities.

- 2. Entities that Have Missed the Pre-Registration Deadline:** Some companies will realize that they and their suppliers have missed the pre-registration and registration deadlines and that, therefore, they may no longer lawfully market their products in the EU/EEA until they ensure the full registration of their substances.

Action Item: Companies that have not pre-registered should consider different strategies to avoid the immediate registration obligation. Among other measures, these may include shifting to new suppliers and changing their import and distribution patterns in Europe to make use of the REACH late pre-registration exceptions.

- 3. Pre-Registrants Who Must Get Ready for Registration:** Companies that did pre-register will automatically become members of a Substance Exchange Information Forum ("SIEF") for each particular substance. SIEFs are intended to ensure that registrants share testing data and make joint submission of certain parts of the registration dossier.

Pre-registrants will start receiving information on the initiation of activities in the SIEFs. In addition, some companies may join private consortia intended to regulate the generation and sharing of the data required for registration and the common defense of a substance.

Action Item: Participation in the SIEFs and consortia will raise legal questions on REACH regulatory issues, contractual liability, anti-trust law, and protection of confidentiality. Companies should therefore designate a lead person within the company to coordinate SIEF

and consortia activities and develop strategies to advance the company's REACH compliance objectives.

4. **Listing of Substances as Subject to Authorization:** In January 2009, the ECHA presented its draft recommendation for a first list of substances subject to authorization, and a final recommendation will likely be submitted in June 2009.⁴ The ECHA will also be publishing its updated list of identified SVHCs. Over time, it is likely that the list could comprise hundreds of substances and significantly affect whether products can be marketed in Europe at all or whether they need to be significantly reformulated.

Action Item: Companies need to establish an internal mechanism now to monitor the development of the list, where appropriate to advocate that substances not be listed and if listed to coordinate the company's defense to ensure the least restrictive impact on its product line. Companies may defend the uses of their substances by participating in the Agency's consultation procedures and also by informally approaching the European Commission and other European policy makers. The submission of comments may enhance the chances of successfully challenging any final decisions before the EU courts. Companies may submit comments on the first draft recommendation for a first list of substances subject to authorization until April 14, 2009.

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The REACH Regulation is technical in nature and many of its provisions are open to different interpretations. It is important to monitor how the rules are being implemented in more detailed provisions and guidelines.

The information in this memorandum is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned here.

For further information, please contact:

Peter Bogaert	+32.2.549.5243	pbogaert@cov.com
Cándido García Molyneux	+32.2.549.5261	cgarciamolyneux@cov.com

Further information on the REACH requirements, its impact on specific product categories, and on Covington's REACH practice is also available at:
[\(http://www.cov.com/practice/environmental_carbon_markets_and_clean_technology/reach/\)](http://www.cov.com/practice/environmental_carbon_markets_and_clean_technology/reach/).

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⁴ (http://echa.europa.eu/consultations/authorisation/draft_recommendations/recommendations_en.asp).