REACH

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REACH
AND ITS IMPACT ON DOWNSTREAM USES

The European Union has just adopted Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (the "REACH Regulation"),[1] which will enter into force in June 2007.

The REACH Regulation does not only affect chemical manufacturers and importers, but also imposes, for the first time, sweeping requirements on virtually all producers using substances in their goods and manufacturing processes. In effect, the entire supply chain will have to examine and disclose the properties of the substances they use, and ensure that the safety in their specific downstream use is adequately supported. While in some cases producers of goods will be able to rely on their chemical suppliers for compliance, the Regulation also imposes direct obligations and it is likely that for many important ingredients downstream users will have to be actively involved in the regulatory strategy. In addition, over time, producers of goods could also face more limited choice as chemical suppliers seek to specialize their portfolios by narrowing the number of substances on offer and thus reducing cost of compliance with REACH.

The Regulation imposes different requirements on products depending on whether they are substances or preparations, or articles. Substances are, in general terms, defined as chemical elements and their compounds in the natural state or obtained by any manufacturing process. Preparations are defined as mixtures or solutions of two or more substances. Examples of preparations include detergents, cosmetics, and inks. Articles, on the other hand, are objects that during production are given a special shape, surface or design that determines their function to a greater degree than does their chemical composition. Examples include paper, textiles, and packaging. The status of some goods, however, such as ink cartridges or cigarettes, is unclear. The Regulation also imposes different requirements depending on whether the materials are manufactured in, or imported into, the EU.

On this basis, the Regulation is likely to impose the following requirements on producers of goods:

1. Disclosure of Information Through the Supply Chain

The REACH Regulation assumes the existence of an information chain to which all actors of the supply chain must contribute. It requires chemical suppliers to communicate information on their substances, in many cases through safety data sheets ("SDS"). Producers of goods, and in some cases their distributors, must review the information provided to them and disclose updated information in the following way:

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[1] A copy of the Regulation is available at: (http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf).

- ✓ By June 2007, EU manufacturers of articles and preparations and importers of preparations will be required to report to their suppliers any new information they have available on the hazardous properties of the substances they use, and any information affecting the risk management measures indicated in the SDS that suppliers provide to them and affecting their identified uses. The same information must also be provided to national authorities or the European Chemicals Agency upon their request.

- ✓ By June 2009, the European Chemicals Agency is likely to have identified the first list of "substances of very high concern," which may later be subject to the prior authorization requirement. Substances of very high concern may include Cat. 1 and 2 carcinogens, mutagens and toxic to reproduction substances ("CMRs"), persistent, bioaccumulative and toxic substances ("PBTs"), very persistent and very bioaccumulative toxic substances ("vPvBs"), and other substances giving rise to "an equivalent level of concern." EU manufacturers, importers or distributors of goods in the form of articles containing more than 0.1% of a substance that the Agency has listed as being of very high concern must provide their professional customers with the name of the substance and information allowing the safe use of the article. They must also supply the same information to consumers upon their request.

- ✓ By December 2010, importers of goods in the form of preparations will be required to report to the European Chemicals Agency the chemical classification of substances classified as "dangerous" or subject to registration (*e.g.*, imported in quantities of one ton or more per importer per year) that are contained in their imported preparations. The same requirement will apply to EU manufacturers importing substances or preparations classified as "dangerous" or subject to registration. Furthermore, importers of goods in the form of articles will also have to report to the Agency the chemical classification of substances in their articles that are subject to registration.

- ✓ As from December 2010 onwards, the Commission could have issued the first authorizations to use substances of very high concern that have been listed as subject to authorization. All producers marketing goods in the form of preparations that contain a substance that has been authorized will be required to label their preparations with the authorization number. In addition, all users benefiting from an authorization to their suppliers to use a substance (in goods in the form of preparations or during the EU manufacturing process of goods in the form preparations or articles) will be required to notify their use to the European Chemicals Agency.

2. Registration of Substances

The REACH Regulation requires the registration of substances that are manufactured or imported on their own or in preparations in quantities of one ton or more per chemical manufacturer or importer per year. Both new and old substances, including those that were listed in the EU's EINECS list, will be subject to the registration requirement. So-called "phase-in" substances (mostly EINECS listed substances) will benefit from a phase-in period of eleven years only if they are pre-registered.

- ✓ Registration will require submitting (i) a technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will entail substantial testing and data gathering; and (ii) a chemical safety report assessing the hazards, exposure, and risks of use during the entire life cycle for substances manufactured or imported in quantities of 10 tons or more per chemical manufacturer or importer per year. The testing costs of registration are estimated to be between 55,000 and 2,000,000 Euro depending on the substance's volume and characteristics.

- ✓ Registration will be substance specific and chemical manufacturer or importer specific: only those chemical manufacturers and importers that have registered within the deadlines will be allowed to market their substances. The Commission expects that around 30,000 substances will be registered and that around 140,000 technical dossiers will be submitted during the first 11 years of the Regulation.

- ✓ Substances in articles (*e.g.*, paper, textiles, equipment), are also subject to registration or notification requirements unless the use of the substance in the article has already been included in the registration of any third party. In particular, manufacturers and importers of articles must register substances (i) present in their articles in quantities exceeding one ton per manufacturer per importer per year; and (ii) intended to be released during normal and reasonably foreseeable conditions of the article's use. They must also notify substances contained in their articles if the following four conditions are met: (i) the substances have been listed by the Agency as substances of very high concern (*i.e.*, Cat. 1 and 2 CMRs, PBTs, vPvBs, and substances raising "an equivalent level of concern"), (ii) the substances are present in the articles in quantities above one ton per manufacturer or importer per year, (iii) the substances are present in the articles in concentrations of more than 0.1%, and (iv) exposure to humans or the environment cannot be excluded. In certain cases, the Agency may also require the registration of any substance contained in articles.

- ✓ The registration requirement affects differently EU manufacturers and importers of goods depending whether they produce preparations or articles:

  a. EU manufacturers and importers of goods in the form of articles will be liable for registration, pre-registration and/or notification of the substances contained in the articles unless any third party has already registered the use of the substance in the article.

  b. Importers of goods in the form of preparations will be liable for pre-registration and registration for the substances contained in the preparations unless they ensure that their foreign suppliers do so. Similarly, EU manufacturers importing substances or preparations will also be liable for pre-registration and registration unless their foreign suppliers do so. The Regulation allows foreign chemical suppliers to appoint a representative who will pre-register and register the chemicals on the supplier's behalf. In that case, the importer of the substance on its own or in a preparation (including finished products) registered through the legal representative of the supplier is considered a "downstream user" who must not pre-register or register.

c. In contrast, EU manufacturers purchasing their chemicals from EU chemical suppliers are considered "downstream users" as defined by REACH (except for substances contained in the articles they manufacture and that are subject to registration and/or notification) and may only rely on their suppliers' pre-registrations and registrations; in effect, it is likely that they will not be able to pre-register and register the substances on their own. Thus, it is strongly in the interest of these manufacturers to ensure their EU chemical suppliers file such pre-registrations and registrations.

✓ By June 2008, producers of goods in the form of preparations or articles will have to ensure the registration of "new" substances (mostly not EINECS listed substances) contained in, or used in the EU manufacture of, the goods.

✓ Between June 2008 and December 2008, producers of goods in the form of preparations or articles must ensure that all "phase-in" substances contained in, or used in the EU manufacture of, their goods are pre-registered. Where the substance is not pre-registered within the deadline, producers must ensure that the substance is fully registered by December 2008 before continuing its use.

✓ Between December 2010 and June 2018, producers of goods in the form of preparations or articles must ensure that pre-registered "phase-in" substances contained in, or used in the manufacture of, their goods are registered. The first deadline (*i.e.,* November 30, 2010) applies to Category 1 and 2 CMRs, R50/53 substances (*i.e.,* classified as very toxic to aquatic organisms that may cause long term adverse effects in the aquatic environment) if manufactured or imported in quantities of 100 tons or more per manufacturer/importer per year, and other substances manufactured or imported in quantities of 1000 tons or more per manufacturer/importer per year.

✓ By June 2011, producers of goods in the form of articles must notify the Agency of the presence in their articles of substances listed as being of very high concern unless the use of the substance in the article has already been included in the registration of any third party.

3. Downstream User Obligations

✓ Where suppliers register their substances (because they are established in the EU or through a legal representative), the Regulation imposes obligations (obligations on "downstream users" as defined by REACH) on EU manufacturers using substances in their manufacturing processes, and on importers of goods in the form of preparations.

✓ In particular, these producers will be required to verify if their specific use of the substance is covered by the exposure scenarios communicated in their supplier's safety data sheets, which should reflect the supplier's registration and chemical safety report. If their use of the substance is not covered, the producers may be required to submit a limited notification to the Agency and prepare a chemical safety report of their particular uses if the substances or the preparations containing them are classified as "dangerous," PBTs, vPvBs or substances raising an "equivalent level of concern;" and they use the substance in quantities of one ton or more per year and in

concentrations above specified thresholds (*e.g.*, 0.1%).

The chemical safety report of EU manufacturers of goods must assess the environmental and health risks resulting from the use of the substance during the manufacturing of the product and as part of the final product. In contrast, the chemical safety report of importers of goods must assess the health and environmental risks resulting from the use of the substance when contained in the product.

4. Prior Authorization Requirements

The REACH Regulation establishes a procedure to impose a prior authorization requirement for substances of very high concern (*i.e.*, Category 1 and 2 CMRs, PBTs, vPvBs, and substances raising "an equivalent level of concern"). This procedure is designed to encourage chemical manufacturers, importers, and users to search for alternatives to substances of very high concern and to progressively ensure their phase-out.

The prior authorization requirement may affect any goods in the form of preparations that contain substances of very high concern, subject to some limited exemptions. It will also effect any use of substances of very high concern during the manufacturing process of goods (in the form of articles or preparations) in the EU. The authorization requirement, however, is not likely to apply to imported articles. Producers of goods can comply with the authorization requirements on their own, or by ensuring that their suppliers do so by themselves or through a legal representative if they are not established in the EU.

✓ By the end of 2009, the European Commission could adopt its first list of substances of very high concern subject to authorization. Priority substances to be listed include PBTs and vPvBs and substances with wide or in high volume use.

The list will specify the date by which EU producers of goods must ensure that they or their suppliers have applied for an authorization and the date (so-called "sunset date") after which persons who do not hold or did not apply for an authorization must no longer market or use the substance.

In particular, EU manufacturers of goods must ensure that they or their suppliers apply for the authorization of the specific use of listed substances that they use in specified concentrations (*e.g.*, 0.1%) in the manufacture of their goods (in the form of preparations or articles), or that are contained in specified concentrations in their goods in the form of preparations. In contrast, importers of goods in the form of preparations (but not articles) must ensure that they or their suppliers apply for the authorization of the use of substances present in specified concentrations (*e.g.*, 0.1%) in their preparations.

EU manufacturers and importers of goods will not be allowed to use the listed substances after the sunset date unless they or their suppliers have applied for authorization.

Authorization applicants will be required to show that the risks resulting from the use of their substances are adequately controlled, or that the socio-economic benefits of the use outweigh the risks and there are no suitable alternative technologies. Applicants will also have to search for substitutes and present a substitution plan where substitutes are available.

Applicants who do not obtain an authorization will be banned from using listed substances, unless their supplier or downstream user has obtained such authorization. Only authorization holders will likely be entitled to apply for the renewal of the authorization once it expires.

5. Restrictions Procedure

✓ The REACH Regulation also establishes a fast track procedure through which the Commission may ban, from the end of 2009 onwards, the marketing and use of substances that pose a "unacceptable" health or environmental risk. This procedure may apply to goods both in the form of preparations or articles. In particular, the Regulation foresees that the restrictions procedure should, among others, apply to substances that have been identified as being of very high concern (*i.e.,* Category 1 and 2 CMRs, PBTs, vPvBs and substances raising "an equivalent level of concern") and that are contained in articles.

6. Exceptions for Specific Categories of Goods

- Medicines, Foods and Feed: The Regulation exempts to a large extent substances "used in" medicinal products, food and feeding stuffs, but it is not clear whether these exemptions also apply to ingredients before they are incorporated into the medicinal, food or feed products.

- Biocides and Pesticides: Active substances and coformulants "for use in" plant protection products and active substances "for use in" biocides that have been authorized or are subject to review under the pesticides/biocides rules are exempted from registration. The use of these substances in pesticides and biocides is also exempted from authorization.

- Cosmetics, Medical Devices and Food Contact Materials: The Regulation also provides some limited exceptions for substances used in cosmetics, medical devices, and food contact materials.

- Waste: Waste will be excluded from all the requirements of the Regulation until their recycling or recovery results in a new product.

- Military Equipment: The Regulation does not exclude military equipment, but allows Member States to provide exemptions in specific cases for substances, on their own, in preparations or articles "where necessary in the interest of defense."

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The REACH Regulation is technical in nature and several important provisions are open to different interpretations. It will be 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 herein.

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