REACH

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THE REACH REGULATION AND SUBSTANCES OF VERY HIGH CONCERN

The European Union's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH Regulation") requires the European Chemicals Agency ("ECHA") to identify so-called Substances of Very High Concern ("SVHCs") and to list them in the Candidate List of Substances of Very High Concern ("Candidate List").[1]

- SVHCs listed in the Candidate List are subject to stringent information and notification requirements that apply to the substances on their own as well as to products containing them. For example, starting as of 1 June 2011, manufacturers and importers of objects, such as textiles, paper, electronic components (so-called "articles"), containing a Candidate List substance in concentrations of more than 0,1% may be required to submit a notification to the ECHA. Similarly, since October 2008, as soon as a substance is listed in the Candidate List, suppliers of articles containing such substance in concentrations of more than 0,1% are required to inform their customers. Suppliers of Candidate List substances and mixtures containing them may also be required to supply safety data sheets to their customers.

  Furthermore, products containing Candidate List substances may also be subject to the REACH prior authorization requirement and to marketing and use restrictions, and may also be restricted under other EU environmental legislation.

- SVHCs may include Category 1 and 2 carcinogens, mutagens and toxic to reproduction substances ("CMRs"); persistent, bioaccumulative and toxic substances ("PBTs"); very persistent and very bioaccumulative substances ("vPvBs"); and substances raising an equivalent level of concern.

- Currently, the Candidate List contains 46 substances, including Bis (2-ethyl(hexyl)phthalate) (DEHP); Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins); acrylamide; anthracene; boric acid; Dibutyl phthalate (DBP); and Sodium dichromate.[2] The ECHA updates the Candidate List around twice a year, and the List is

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[1] A copy of the Regulation is available at:

(http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20110221:EN:PDF).

[2] The Candidate List is available at:

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

likely to increase significantly during the next years.

- Importantly, the Regulation allows private parties to comment before a substance is listed in the Candidate List and subjected to different REACH procedures. Manufacturers should use these opportunities to defend their substances and improve their legal standing in eventual legal challenges against adverse decisions before the EU Courts.

This memorandum discusses the substances that may be listed as SVHCs in the Candidate List and the requirements that may apply to them. It also briefly describes the opportunities that private parties have to comment during the processes whereby the ECHA and Commission list substances in the Candidate List, subject them to the prior authorization requirement, and decide on authorization applications.

I. Substances of Very High Concern

SVHCs that may be listed in the ECHA Candidate List include those with the following properties:

1. A substance that meets the criteria for classification as a Category 1 or 2 carcinogen, mutagen, or toxic to reproduction substance ("CMRs") of the Regulation on the Classification, Labeling and Packaging of Substances and Mixtures ("CLP Regulation"). The ECHA Guidance on the identification of substances of very high concern suggests that a Member State or the ECHA may propose a substance for its inclusion in the SVHC list by merely providing a reference to its classification as a Cat. 1 or 2 CMR in Annex VI to the CLP Regulation, which includes the list of substances for which the EU has agreed a harmonized classification. The Guidance also makes clear, however, that a substance may be proposed as a SVHC Category 1 or 2 CMR even if it is not listed in the Annex VI list, provided that it meets the classification criteria of the CLP Regulation.

2. A substance that is persistent, bioaccumulative, and toxic ("PBT") in accordance with the criteria of Annex XIII to the REACH Regulation.

3. A substance that is very persistent and very bioaccumulative ("vPvB") in accordance with the criteria of Annex XIII to the REACH Regulation.

4. A substance for which there is scientific evidence of probable serious effects to human health or the environment that give rise to an equivalent level of concern to Cat. 1 and 2 CMRs, PBTs or vPvBs, and that is identified on a case-by-case basis ("equivalent concern" substances). These substances may include those with endocrine disruption properties or substances that, while do not meet the end-point criteria of Annex XIII, have PBT or vPvB properties. ECHA's Guidance emphasizes that these substances must be identified on the basis of "scientific evidence of probable serious effects to humans or the environment," *i.e.*,

the substance's effects on human health or the environment "need to be demonstrated." However, the Guidance also suggests the need to apply a precautionary approach as it states that an additional aspect in the identification of these substances is the uncertainty of standard risk assessment for substances with such effects and the consequences of the risk assessment being wrong.

The ECHA Guidance also suggests that a substance may be proposed as a SVHC if it: (i) contains a constituent that has PBT, vPvB, or "equivalent concern" properties in concentrations of 0,1% or more; or (ii) degrades or transforms into substances with PBT, vPvB, or "equivalent concern" properties that are already present in the substance in concentrations of 0,1% or more.

II. Requirements on Substances of Very High Concern and Goods Containing Them

The REACH Regulation imposes different requirements on manufacturers and importers of SVHCs and goods containing them depending on whether they are (i) substances in bulk, mixtures, or articles containing them; and (ii) manufactured in, or imported into, the EU/EEA. Substances are, in general terms, defined as chemical elements and their compounds in the natural state or obtained by any manufacturing process. Mixtures are mixtures or solutions of two more substances, and examples include detergents, cosmetics, inks, tobacco products, and the detergent contained in wet wipes. 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, electronics, vehicles, and the packaging of all goods.

On this basis, the REACH Regulation is likely to impose the following requirements on SVHCs and the goods containing them:

1. Information Requirements

As of the day the substances are included in the Candidate List, suppliers of the substances and mixtures containing them may have to provide a safety data sheet to their customers, while suppliers of articles containing the substances may have to provide their customers with information on the safe use of their articles.

A. Substances and Mixtures

Specifically, suppliers of Candidate List substances that are identified as PBTs, vPvBs, or equivalent concern substances must provide their customers with a safety data sheet. Subject to the same requirement are suppliers of mixtures containing PBTs, vPvBs or equivalent concern substances in concentrations of 0,1% or more, upon the request of their customers (suppliers of Cat. 1 or 2 CMRs or mixtures containing them were already required to provide a safety data sheet as soon as the substances met the CMR classification criteria of the CLP Regulation or the Dangerous Preparations Directive).

The safety data sheets must be provided for free on paper or electronically and in an official language of the Member State where the substance or preparation is placed on the market, unless the Member State provides otherwise. Suppliers are not required to provide a safety data sheet for products that are sold to the general public (*e.g.*, detergents) if they provide sufficient information to ensure the protection of human health and safety and the environment by other means, unless downstream users or distributors of the products require the safety data sheets. Similarly, suppliers of mixtures in the form of cosmetics, medicinal products for human and veterinary use, food and feeding stuffs and, in limited cases, medical devices, are not required to provide a safety data sheet to their customers (*e.g.,* distributors) if the products are "in finished state, intended for the final user."

Suppliers of substances and mixtures include manufacturers, importers, downstream users and distributors placing on the market a substance or mixture. Therefore, the requirement to provide safety data sheets may also apply to substances and mixtures containing them that are already in the EU/EEA supply chain.

B. Articles

Suppliers of articles containing a Candidate List substance in concentrations above 0,1% weight by weight must provide their professional customers with sufficient information to ensure the safe use of the article, including at least the name of the substance. The ECHA Guidance indicates that such information should address the life-cycle of the substance and may include information on personal protection, handling and storage, disposal considerations and fire fighting measures. Similar information must also be provided free of charge to consumers within 45 days of their request.

The ECHA Guidance suggests that the concentration threshold should be measured on the basis of the whole article that is supplied, but six Member States plus Norway have made public dissenting views on this. It is also likely that the 0,1% concentration limit should be calculated on the basis of each individual substance listed as SVHC -- and not the cumulation of two or more substances -- that is present in the articles.

Suppliers of articles include article producers, importers, distributors and any other actor in the supply chain placing an article on the market. Thus, this information requirement may also apply to articles that are already in the EU/EEA supply chain and to recyclers.

2. Notification Requirements

As of June 1, 2011, producers and importers of articles will be required to submit a notification to the ECHA if their articles contain a Candidate List substance in concentrations above 0,1% weight by weight, and the following three thresholds are met:

(i) the substance is present in the articles in quantities above one ton per producer or

importer per year;

(ii) the producer or importer cannot exclude exposure of humans or the environment to the substance during normal or reasonable foreseeable conditions of use of the article, including its disposal; and

(iii) the substance has not already been registered for the specific use in the article by any other third party.

As with the information requirements, the ECHA Guidance suggests that the concentration threshold must be measured on the basis of the whole article. It is also likely that the 0,1% concentration limit should be calculated on the basis of each individual substance listed as SVHC -- and not the cumulation of two or more substances -- that is present in the articles.

The Guidance also suggests that the one ton volume threshold must be calculated on the basis of all the articles that the producer produces or importer imports per year and that contain more than 0,1% of the SVHC. It is likely that this requirement will also apply to re-imported articles as well as to recycled articles.

3. Prior Authorization Requirements

As the name suggests, Candidate List substances are candidates to be listed as subject to prior authorization in Annex XIV to the REACH Regulation. In February 2011, the European Commission adopted a first Annex XIV list of six substances subject to authorization,[3] which includes musk xylene; 4,4'-Diaminodiphenylmethane (MDA); Hexabromocyclododecane (HBCDD); DEHP; BBP; and DPB. Annex XIV specifies the following: (i) the date by which EU/EEA manufacturers, importers, and downstream users of the substances or the goods containing them must ensure that they or their suppliers/downstream users have applied for an authorization; (ii) the date (so-called "sunset date") after which those who do not hold or did not apply for an authorization must no longer market or use the substance; (iii) any exempted use categories; and (iv) any applicable authorization review periods. The earliest application date in Annex XIV is January 2013 and the earliest sunset date is July 2014.

The prior authorization requirement may affect virtually all manufactured or imported goods in the form of mixtures that contain substances listed in Annex XIV in concentrations above 0,1% for PBTs, vPvBs, and equivalent concern substances; or the lowest concentration specified in the CLP Regulation for Category 1 and 2 CMRs. Exempted uses are those in medicinal products, food and feeding stuffs, plant-protection products and biocides, and motor fuels.

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[3] A copy of this first Annex XIV is available at (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:044:0002:0006:EN:PDF)

The use of Cat. 1 and 2 CMRs in cosmetic products may never be authorized, and the REACH Regulation also clarifies that uses in cosmetics and food-contact materials may only be subject to the prior authorization requirement if the substance is a PBT, vPvB, or a substance raising equivalent concerns to PBTs or vPvBs. Similarly, the human health risks resulting from the use of Cat. 1 and 2 CMRs may not be considered when deciding to authorize the use of the substance in medical devices, unless no exposure threshold can be determined.

The prior authorization requirement may also apply to any EU/EEA manufacturers of goods in the form of articles or mixtures that use Annex XIV substances on their own or in preparations in their EU/EEA manufacturing processes in concentrations above the specified thresholds. However, the prior authorization requirement does not apply to imported articles even if they are intended to release an Annex XIV substance under the article's normal or reasonably foreseeable conditions. For example, while the EU/EEA manufacture of information technology equipment may be subject to authorization, no authorization requirement applies to the same imported equipment.

EU/EEA manufacturers and importers of goods will not be allowed to use or market a substance listed in Annex XIV after the sunset date unless they or their suppliers have applied for an 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. Where alternatives are available, applicants will also have to search for the substitutes and present a substitution plan.

Applicants who do not obtain an authorization will be banned from importing, marketing or using Annex XIV substances, unless their supplier or downstream user has obtained such authorization. It is likely that only authorization holders will be entitled to apply for the renewal of the authorization once it expires.

Goods in the form of mixtures, such as cosmetics, tobacco products and detergents, containing a substance that has been authorized must be labeled with the authorization's number. Downstream users benefiting from the authorization obtained by their suppliers must notify their use of the substance to the ECHA within three months of the first supply of the substance.

The European Commission is expected to update Annex XIV regularly, and the ECHA has already published a new recommendation proposing the listing of eight additional substances, including diisobutyl phthalate (DIBP) and lead chromate.[4]

4. Restrictions

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[4] ECHA's Recommendation of 17 December 2010 is available at (http://echa.europa.eu/doc/authorisation/annex_xiv_rec/second/annex_xiv_subst_inclusion_second.pdf)

SVHCs may also be banned under the restrictions procedure of the REACH Regulation. This is a fast track procedure through which the Commission may ban the marketing and use of substances that pose an "unacceptable" health or environmental risk. In particular, the Regulation foresees that the restrictions procedure should also apply to SVHCs listed in Annex XIV (and therefore subject to authorization) and contained in goods in the form of articles. Substances banned under the restrictions procedure are listed in Annex XVII to the REACH Regulation and their marketing and use may no longer be authorized under the authorization procedure.

Furthermore, SVHCs are likely to be candidate substances to be banned under other EU environmental vertical legislation, such as the Directive on the Restriction on the Use of Certain Hazardous Substances in Electrical and Electronic Equipment ("RoHS Directive"), the Packaging and Packaging Waste Directive, or the End of Life Vehicles Directive. For example, a new draft RoHS Directive provides that additional substances may be banned under the RoHS Directive taking into account Annexes XIV and XVII to the REACH Regulation

III. Next Steps and Recommendations

The REACH Regulation specifies different procedural rights for manufacturers and importers of substances or goods containing them to ensure they have the opportunity to comment during the listing of SVHCs in the Candidate List and Annex XIV and decisions on authorization applications. Among other requirements, the Regulation provides that:

1. Before listing a SVHC in the Candidate List, the ECHA must publish a notice of the proposal and ask all interested parties to submit comments. Where interested parties submit comments, the ECHA may list the substance in the Candidate List only if there is a unanimous agreement in the ECHA's Member State Committee. Where the Member State Committee does not reach a unanimous agreement, the Commission must take a decision.

2. Before making a recommendation to update the Annex XIV of substances subject to authorization, the ECHA must invite all interested parties to comment within three months of such publication. ECHA must consider any comments submitted when drafting its final recommendation to the Commission.

3. The Regulation also provides authorization applicants and interested parties with further opportunities to comment before the Agency sends its opinion on authorization applications to the Commission. In particular, the Agency must publish on its website broad information on uses for which applications for authorization have been submitted and grant interested parties the opportunity to provide information on alternative substances or technologies. Furthermore, the ECHA must send the draft opinion to the authorization applicant and give him one month to comment before finalizing its opinion.

Similarly the scientific committees of the ECHA must also give private parties an opportunity to comment before adopting opinions on proposed Annex XVII restrictions.

Comments should take the form of legal, scientific and technical arguments; they should be substantiated as it is likely that they will be published on the ECHA's website. The submission of comments may also enhance private parties' standing before the EU Courts if they later decide to challenge the decisions of the ECHA or Commission.

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The REACH Regulation is technical 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.

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