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GETTING READY FOR REACH: SUBSTANCES OF VERY HIGH CONCERN

On October 28, 2008, the European Chemicals Agency published the first list of 15 substances identified as “substances of very high concern” (“SVHC”) that are candidates for the authorization procedure of the European Union’s Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (the so-called “REACH Regulation”).¹

- The 15 substances identified as SVHCs are: Anthracene; 4,4'- Diaminodiphenylmethane; Dibutyl phthalate; Cobalt dichloride; Diarsenic pentaoxide; Diarsenic trioxide; Sodium dichromate; 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene); Bis (2-ethyl(hexyl)phthalate) (DEHP); Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α – HBCDD, β -HBCDD, γ -HBCDD); Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins); Bis(tributyltin) oxide; Lead hydrogen arsenate; Triethyl arsenate; and Benzyl butyl phthalate.² Cyclododecane was finally dropped from the list.
- The Regulation provides for the regular updating of the list of SVHCs, and it is likely that Member States and the Agency will submit additional proposals within the coming months. 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.
- Substances that are identified as SVHCs are subject to information and notification requirements, which are also likely to apply to products that are already in the European supply chain and recycled products. They are also candidates to be subject to the prior authorization procedure and to marketing and use restrictions when they are used in articles. These requirements may apply to the substances on their own or to goods containing them. SVHCs are also likely to be candidates to be banned under other EU environmental vertical legislation.
- The Regulation requires the Agency and the Commission to allow interested parties to comment before subjecting the identified SVHCs to the REACH prior authorization and

¹ A copy of the Regulation is available at:

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

² The list of substances identified as SVHCs is available at:

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

restrictions procedures. Manufacturers should use these opportunities to defend their substances and improve their legal standing in future legal challenges before the EU Courts.

This memorandum discusses the substances that may be listed as SVHCs and the requirements that will apply to them. It also describes the process that the Agency and the Commission must follow to submit the substances identified as SVHCs to the prior-authorization requirement and to decide on authorization applications, as well as the opportunities that manufacturers will have to comment.

I. Substances of Very High Concern

The REACH Regulation provides a procedure for the regular update of the list of SVHCs and inclusion of additional substances if they meet any of 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”). The Agency’s Guidance on the identification of substances of very high concern suggests that a Member State or the Agency may propose a substance for its inclusion in the SVHC list by merely providing a reference to its classification as a Category 1 or 2 CMR in Annex I to the Dangerous Substances Directive, which includes the lists 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 Annex I to the Dangerous Substances Directive, provided that it meets the classification criteria of this Directive.
2. A substance that is persistent, bioaccumulative, and toxic (“PBT”) in accordance with the criteria of Annex XIII to the Regulation.
3. A substance that is very persistent and very bioaccumulative (“vPvB”) in accordance with the criteria of Annex XIII to the Regulation. The European Commission is currently in the process of amending 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 Category 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. The Agency’s Guidance emphasizes that these substances must be identified on the basis of “scientific evidence of probable serious effects to humans or the environment” and explains that this means that the substance’s effects on human health or the environment “need to be demonstrated.” However, the Guidance warns 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.

In addition, the Agency's guidance currently 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 Regulation imposes different requirements on manufacturers and importers of SVHCs and goods containing them depending on whether they are (i) substances in bulk, or preparations 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. Preparations are defined as mixtures or solutions of two or more substances. Examples of preparations include detergents, cosmetics, inks, tobacco products, the ink contained in ink-cartridges, 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 Regulation is likely to impose the following requirements on SVHCs and the goods containing them:

1. Information Requirements

As of **October 28, 2008**, suppliers of these substances and preparations containing them must provide a safety data sheet to their customers, while suppliers of articles containing the substances must provide their customers with information on the safe use of their articles.

Specifically, suppliers of substances 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 preparations containing PBTs, vPvBs or equivalent concern substances in concentrations of 0,1% or more, upon the request of their customers (suppliers of CMRs or preparations containing CMRs were already required to provide a safety data sheet as soon as the substances met the CMR classification criteria of the Dangerous Substances 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 cosmetics, medicinal products for human and veterinary use,

food and feedingstuffs and in certain 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 preparations include manufacturers, importers, downstream users and distributors placing on the market a substance or preparation. Therefore, the requirement to provide safety data sheets may also apply to substances that are already in the EU/EEA supply chain.

Suppliers of articles containing a SVHC 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 Guidance of the Agency 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 guidance of the European Chemicals Agency suggests that the concentration threshold should be measured on the basis of the whole article that is supplied, but six Member States have published 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 European Chemicals Agency if their articles contain a substance already identified as a SVHC 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 the substances to humans or the environment during normal or reasonable foreseeable conditions of use, including 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 Guidance of the Agency 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.

3. Prior Authorization Requirements

Substances identified as SVHC are candidate substances to be listed as subject to prior authorization. During **the second half of 2009**, the European Commission is expected to include the first list of substances subject to authorization in Annex XIV to the Regulation. Annex XIV will specify 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 first sunset date is not expected until at least **March 2011**.

The prior authorization requirement may affect virtually all manufactured or imported goods in the form of preparations 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 Dangerous Preparations Directive for Category 1 and 2 CMRs. Exempted uses are those in medicinal products, food and feedingstuffs, plant-protection products and biocides, and motor fuels.

The use of Category 1 and 2 CMRs in cosmetic products may never be authorized, and the 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 Category 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 preparations that use SVHCs on their own or in preparations in their EU/EEA manufacturing processes in concentrations above the specified thresholds. However, the prior authorization requirement is not likely to apply to imported articles even if they are intended to release a SVHC 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 is likely to apply to the same imported equipment.

EU/EEA manufacturers and importers of goods will not be allowed to use 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 preparations, 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 European Chemicals Agency within three months of the first supply of the substance.

4. Restrictions

The REACH Regulation also establishes a fast-track procedure through which the Commission may ban, from **mid 2009** onwards, 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.

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 Commission draft proposal to revise the RoHS Directive provides that additional substances may be banned under the RoHS Directive "in line with the REACH methodology."

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 identification of SVHCs, the listing of SVHCs in Annex XIV as substances subject to the prior authorization requirement, and the granting of authorizations. Among other requirements, the Regulation provides that:

1. On the basis of the substances identified as SVHCs, the Agency must prepare a draft recommendation on the substances to be included in Annex XIV as subject to authorization after taking into account the opinion of the Agency's Member State Committee. The Regulation requires the Agency to prioritize PBTs, vPvBs, and

substances with dispersive use or high volumes.

2. By **January 2009**, the Agency is expected to publish on its website its first draft recommendation and invite all interested parties to comment within three months of such publication. According to the Regulation, these comments must be considered by the Agency when drafting its final recommendation to the Commission. The Agency's first recommendation to the Commission is expected by **June 1, 2009**, as also required by the Regulation.
3. On the basis of the Agency's recommendation, the Commission must adopt a decision to subject SVHCs to the prior authorization requirements by including them in Annex XIV. This Commission's decision must be adopted through the regulatory with scrutiny committee procedure. In practice, this means that the Parliament may block the decision by a majority of its component members while the Council may also do so by a qualified majority vote. This will provide additional opportunities to interested parties to influence the adoption of Annex XIV, which is not expected until at least **September 2009**.
4. The Regulation also provides authorization applicants and interested parties with further opportunities to comment before the Agency sends its opinion on the granting of authorizations to the Commission for their adoption. 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 Agency must send the draft opinion to the authorization applicant and give him one month to comment before finalizing its opinion and sending it to the Commission. Applicants and interested parties will also have opportunities to educate policy makers in the Agency, Commission and Member States.

Manufacturers, importers and users of substances identified as SVHCs and wishing to continue to supply and use such substances should actively make use of their opportunities to comment and influence the authorization process. The submission of comments will require the Agency to reconsider its proposals and, in some cases, will even make more difficult their adoption. Furthermore, the submission of comments may enhance parties' standing before the EU Courts if they later decide to challenge the Commission's or Agency's decisions.

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 Agency's website.

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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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