Are You Ready for REACH?
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EU Environmental Regulation - Recent Developments

Revisions of REACH Exemptions: Important for Pre-Registration and Nanotechnology

The deadline imposed by REACH (EU Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals) for preregistering chemical substances is looming. After 1 December 2008 it will no longer be lawful to manufacture in, or import into, the EU or the EEA (EU plus Iceland, Liechtenstein and Norway) chemical substances (including in formulations and, in some cases, in other products) which have not been preregistered or registered unless the substance benefits from exemption from registration. Recent amendments to the exemptions have important implications for preregistration. Some substances which were previously exempt must now be preregistered (or registered) by 1 December 2008.

Annexes IV and V to REACH list a number of naturally occurring substances which are exempt from the requirement to register. Annex IV comprises substances about which sufficient information is known that they are considered to cause minimum risk because of their intrinsic properties, such as ascorbic acid, glucose, carbon dioxide and water. Annex V comprises substances whose registration is deemed inappropriate or unnecessary and whose exemption does not prejudice the objectives of REACH, such as substances resulting from certain chemical reactions, minerals, ores, crude oil, hydrogen and oxygen. Annexes IV and V have been revised with effect from 12 October 2008.

Krypton, fructose, galactose and lactose have been added to Annex IV on the basis that they meet the criteria for inclusion. Magnesia, certain types of glass and ceramic frits, compost and biogas have been added to Annex V.

More significantly, vitamin A, carbon and graphite have all been removed from Annex IV, vitamin A because it may present significant risks of reproductive toxicity and carbon and graphite principally because the relevant EINECS (European Inventory of Existing Commercial Chemical Substances) and/or CAS (Chemical Abstract Service) numbers are used to identify forms of carbon or graphite at the nanoscale, which do not meet the criteria for inclusion in Annex IV. It is, however, not just the nano-forms of carbon and graphite which have lost the benefit of the exemption (although it is likely that the exemptions will be reinstated once a formula which unambiguously excludes the nano-forms has been found); moreover, graphite which has not been chemically modified may be exempt as a mineral, ore or ore concentrate under Annex V.

This is significant in two respects. First, these substances are no longer exempt from the requirement of (pre-)registration. Companies which manufacture such a substance in the EU/EEA, or import it into the EU/EEA, whether alone or in a preparation, in quantities of one metric ton or more per year should accordingly pre-register or register it before 1 December 2008 to ensure that manufacture, import and supply remain lawful.

Second, the reasons given for the removal of carbon and graphite from Annex IV confirm that the European Commission, which is the author of the amending regulation, takes the view that nanosubstances are within the scope of REACH, a matter about which there has been some debate in the nanotechnology industry. Although the Commission’s view is not decisive (only the European Court of Justice is competent to give definitive rulings on the interpretation of EU legislation), it is none the less of weight.

Guidance on Pre-Registration of Certain Substances Exempt from REACH Registration

REACH provides that companies which (i) re-import substances which have been exported from the EU/EEA, (ii) manufacture in, or import into, the EU/EEA polymers containing monomer substances or (iii) produce in, or import into, the EU/EEA articles containing substances intended to be released are (provided certain conditions are met) exempt from the requirement to register those substances if they have already been registered. There has been great uncertainty in industry (and inconsistent advice from national REACH helpdesks) as to whether, as a corollary, a manufacturer or importer in such circumstances is exempt from the requirement to preregister the substance if it has already been preregistered by another company (e.g. the supplier of the substance). Following discussion with the European Commission legal service, ECHA has now advised that manufacturers and importers in such circumstances is exempt from the requirement to preregister the substance if it has already been preregistered by another company (e.g. the supplier of the substance). Following discussion with the European Commission legal service, ECHA has now advised that manufacturers and importers should preregister such substances, even if they have already been preregistered by another company, unless they are certain that the full registration will have been submitted by the deadline of 1 December 2008.
REACH Candidate List Published

REACH lays down a procedure for the identification of Substances of Very High Concern (SVHCs) by their inclusion on a “candidate list”. The term reflects the fact that SVHCs so identified are candidates for subsequent inclusion (after prioritisation and further procedural steps) in Annex XIV to REACH. Once a substance has been included in Annex XIV, it will be unlawful to use it or to supply it for a use unless the use has been authorised by the European Commission.

A number of consequences flow from the inclusion of SVHCs on the candidate list.

First, manufacturers in the EU/EEA of products containing SVHCs, and importers of such products into the EU/EEA, will in certain circumstances be under an obligation to notify the European Chemicals Agency (ECHA). That requirement, however, will not apply before 1 June 2011.

Second, suppliers (including manufacturers, distributors and retailers in the EU/EEA and importers into the EU/EEA) of products containing an SVHC at more than 0.1% w/w are required to provide the recipient of the product and, within 45 days of receipt of a request, consumers with sufficient information to allow safe use of the article, including at least the name of the substance.

Third, EU/EEA suppliers of an SVHC have to provide a safety data sheet to their customers, and EU/EEA suppliers of certain preparations containing an SVHC have to provide the recipients, on request, with a safety data sheet.

The second and third requirements apply as soon as SVHCs have been identified on the candidate list.

The first 15 SVHCs have now been identified and included on a candidate list published on 28 October 2008 on the ECHA website. The second and third requirements mentioned above are accordingly now in force.

The substances which have been identified as SVHCs are:

- Anthracene
- 4,4’-Diaminodiphenylmethane
- Dibutyl phthalate
- Cobalt dichloride
- Diarsenic pentaoxide
- Diarsenic trioxide
- Sodium dichromate
- Musk xylene (1,2,4,6-tetrabromo-3-trinitrobenzene)
- DEHP (Bis(2-ethylhexyl)phthalate)
- HBCDD (Hexabromocyclododecane) and all major diastereoisomers identified (α-HBCDD, β-HBCDD, γ-HBCDD)
- Short Chain Chlorinated Paraffins (Alkanes, C10-13, chloro)
- Bis(tributyltin)oxide
- Lead hydrogen arsenic
- Triethyl arsenate
- Benzyl butyl phthalate

NB The candidate list is a moving target: it will be constantly added to and will therefore need constant monitoring. NGOs estimate that some 1,500 substances meet the criteria for SVHCs.

Batteries

A new EU Batteries Directive (Directive 2006/66 on batteries and accumulators and waste batteries and accumulators) has recently entered into force. It has significant implications for manufacturers of batteries containing cadmium and mercury and it imposes new obligations on manufacturers of battery-powered appliances to design so as to enable the batteries to be readily removed.

In particular, manufacturers of batteries, both those established in the EU/EEA and those which export to the EU/EEA, should be aware that the Directive requires that, by 26 September 2008, countries in the EU/EEA must:

- Prohibit the supply or import of batteries and accumulators (including those incorporated in appliances) containing more than 0.0005% by weight of mercury (except for button cells, which must have a mercury content of less than 2% by weight)
- Prohibit the supply or import of portable batteries and accumulators (including those incorporated in appliances) with a cadmium content by weight of more than 0.002% (except for portable batteries and accumulators for use in emergency and alarm systems, medical equipment or cordless power tools)
- Require manufacturers to design appliances in such a way that waste batteries and accumulators can be readily removed and to provide instructions for removal
- Ensure that all batteries, accumulators and battery packs are appropriately marked with a prescribed symbol showing a crossed-out wheeled bin

Batteries and accumulators which were legally placed on the market before 26 September 2008 can remain on the market even if they do not comply with the Directive.
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