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Authorization of Chemical Substances Under the REACH Regulation

'Authorization' is one of the procedures for managing the risks of hazardous substances introduced by Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ('REACH'). Substances that are subject to authorization may not be used in the EU, unless the company using them has been authorized to do so. This means that eventually these substances will be phased out for all non-essential uses.

Furthermore, articles can no longer be produced in the EU if they contain substances subject to authorization and such authorization has not been granted for the production of this article.

Substances to which authorization will apply are listed in the Authorization list included in Annex XIV of REACH ('Annex XIV'). The first six substances have recently been added in Annex XIV and the procedure for inclusion into Annex XIV of several other substances is ongoing. Thus, industry should be aware and prepared.

Before a substance is included in Annex XIV, two steps must take place.

- The substance must be identified as a Substance of Very High Concern and included in the "Candidate List of Substances of Very High Concern for Authorization" ('Candidate List') which is managed by the European Chemicals Agency ('ECHA').
- The SVHC in the Candidate List is subject to further evaluation and negotiation which may lead to its inclusion in Annex XIV (and thus to the authorization requirement).

This newsletter briefly describes both steps and focuses on the consequences for industry. It also summarizes the possibilities of legal recourse against decisions on inclusion of a substance into the Candidate List or in Annex XIV.

In addition, MLA has made available an updated list of substances which are currently undergoing any of the following REACH regulatory procedures:

- Authorization procedure (as discussed in this newsletter), with the indication of the current stage of procedure.
- Restriction procedure according to Title VIII of REACH with indication of the current stage of procedure and of the restriction in question.
- Harmonized classification according to the CLP Regulation[1] in categories which might be relevant for possible inclusion in the Candidate List; as stated below in this newsletter, the authorization procedure is likely to be

triggered in case the substance qualifies on the basis of its hazard class according to the CLP Regulation.

The list of substances is available at **REACH - List of Substances**

1) Substances of Very High Concern and their inclusion in the Candidate List

a) Substance of Very High Concern ('SVHC')

A SVHC is a substance which falls within one or more of the following categories:

- Carcinogenic, mutagenic or toxic for reproduction (in category 1 or 2)[2];
- Persistent, bio-accumulative and toxic[3];
- Very persistent and very bio-accumulative[4];
- Substances giving rise to an equivalent level of concern to substances meeting the above criteria, such as substances with endocrine disrupting properties or substances where there is scientific evidence of probable serious effects to human health or the environment. Such substances will be identified on a case-by-case basis.

b) Identification of SVHC and their inclusion on the Candidate List

EU Member States, ECHA and the European Commission have the right to trigger the procedure of inclusion of a substance into the Candidate List.

First, EU Member States or ECHA (on request by the European Commission) prepare a dossier to identify a substance as SVHC (so-called 'Annex XV dossier', as the general principles for preparing the dossier are set out in Annex XV of REACH).

Before completion of the Annex XV dossier, the substance is included in the public Registry of Intentions managed by ECHA. This Registry informs the interested parties about the substances for which the authorities intend to submit or have already submitted Annex XV dossiers.

After submission of an Annex XV dossier, the substance is subject to an assessment managed by ECHA and to consultation of stakeholders.

The decision on inclusion or non-inclusion of the substance in the Candidate List is taken by unanimous vote of the EU Member States' representatives. In case unanimity is not reached, the decision is taken by the European Commission.

c) Consequences of inclusion on the Candidate List

The fact that the substance has been included in the Candidate List will have some direct consequences for producers, importers and downstream users, including:

- EU suppliers of articles have to inform their customers about the presence of the substance and advise on safe use;
- pursuant to Article 7 of REACH, beginning on June 1, 2011, article producers and importers are subject to a notification obligation to ECHA in case SVHCs in their articles exceed 1 tonne in all of their articles

annually, their concentration is above 0.1% w/w, exposure cannot be excluded and the substance was not registered for that use.
- EU suppliers of SVHCs are required to provide their customers with safety data sheets.

d) Current Candidate List and future developments

At present there are 46 substances on the Candidate List.

However, according to statements made by the competent EU Commissioners, the aim is to have 135 substances on the Candidate List by 2012[5], and to include all suspected SVHCs (approximately 1500) in the longer term, due to their characteristics. In addition, there is a joint group of six Member States (Germany, Austria, Denmark, France, Netherlands, Sweden) cooperating on the identification of priority substances for inclusion in the Candidate List. Other Member States are systematically encouraged by ECHA to cooperate with these active Member States. There is also a political drive to expand the Candidate List if the substance qualifies on the basis of its hazard class according to the CLP Regulation (either by way of a harmonized classification or on the basis of the self-classification used in the REACH registration dossiers).

Another relevant source of information regarding substances which are likely to be included in the Candidate List is the "REACH SIN List" administered by the non-governmental organisation ChemSec. At present, this list contains 356 chemicals which are identified as SVHCs and for which inclusion into the Candidate List is proposed. It is anticipated that a SIN 2.0. list with an even greater number of substances will be published by ChemSec, likely in May 2011.

2) Inclusion of the substance in Annex XIV of REACH

Periodically, ECHA checks the substances on the Candidate List and identifies and recommends priority substances to be added to Annex XIV. The European Commission, in collaboration with the Member States and the European Parliament, decides which of these recommendations to take forward for addition to Annex XIV.

In June 2009 and in December 2010 ECHA issued two recommendations identifying several priority substances for inclusion in Annex XIV.

On February 21, 2011, the substances listed in the 2009 recommendation were included, by Regulation 143/2011[6], in Annex XIV as its first entries.

Annex XIV thus contains the following 6 substances:

- 4,4'-Diaminodiphenylmethane (MDA)
- 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)
- Benzyl butyl phthalate (BBP)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Dibutyl phthalate (DBP)
- Hexabromocyclododecane (and all major diastereoisomers identified, i.e. alpha-, beta- and gammahexabromocyclododecane) (HBCDD)

After inclusion in Annex XIV, each listed substance will have a specified date after which it may no longer be used without authorization (so called 'Sunset date'). For example, the Sunset date for the substances mentioned above varies

between 42 and 48 months from February 21, 2011.

If an application for authorization of a substance included in Annex XIV is made at least 18 months before the Sunset date, then, unless already rejected, the applicant can continue using the substance after the Sunset date has passed, until a decision on the application is taken (so called 'Latest application date').

3) Consequences of inclusion of the substance in Annex XIV, authorization procedure

If a substance appears on Annex XIV, industry must either substitute the substance or submit an application for authorization. Alternatively, companies should check whether their suppliers intend to submit an authorization application and whether they can benefit from this application.

Companies should keep in mind that even if they do not use a substance listed in Annex XIV, they may still be affected if the substance is used further up their supply chain. If a company uses goods which were manufactured by its EU supplier using a substance listed in Annex XIV and if the authorization has not been granted for that use to the supplier, the company will no longer be able to use these goods. Thus, each company must be aware of its supply chain.

We emphasize however that articles which contain substances listed in Annex XIV and which were produced outside of the EU can continue to be used in the EU.

An application for authorization for use of an Annex XIV substance must be submitted to ECHA and will need to include a Chemical Safety Report covering the risks related to the properties that led to identification as an SVHC and must provide an assessment of alternatives. It should also include a substitution plan if the conclusion is that there is a feasible alternative substance, and possibly a socio-economic benefits analysis in case a safety threshold cannot be established.

Recently, ECHA has published two guidance documents relative to authorization applications. The Guidance on the preparation of an application for authorization under the REACH Regulation[7] describes in detail how companies can make an application for authorization and a plan for substitution – including guidance on alternatives analysis and substitution plans. The Guidance on the preparation of the socio-economic analysis[8] discusses how to prepare the socio-economic analysis if the risks of the substance cannot be adequately controlled.

Decisions on whether or not to grant authorizations will be taken by the European Commission. The Commission will take into account the advice of ECHA's advisory committees and any information received from third parties about alternative substances or technologies.

However, some uses of substances listed in Articles 2 and 56 of REACH are automatically exempt from the authorization requirement (mostly because they are controlled under other more appropriate laws). Finally, each entry in Annex XIV of a substance may be followed by uses or categories of uses which are exempted from the authorization requirement. However, based on the current six examples (see above) it would appear that the exemption option will be used only very rarely. Almost all requests for exemptions put forward by industry during the consultation procedure were rejected by the European Commission.

4) Recourse against decisions on inclusion of a substance on the Candidate list or Annex XIV

Both ECHA's decision on inclusion of a substance into the Candidate List and any future European Commission decision on inclusion of a substance in the Annex XIV can be challenged in front of the General Court.

At present, there are several cases pending where manufacturers demand an annulment of a decision of ECHA to include a substance into the Candidate List. The applications are based, for example, on the alleged deficiencies of the Annex XV dossier, on the fact that the substance does not meet the criteria for SVHCs, on the breach of the principle of proportionality etc.

It is difficult to predict the approach that the General Court will take. Thus far, any requests to the General Court for interim measures suspending the inclusion of a substance into the Candidate list were rejected.

Conclusion

If a company supplies or uses a substance which is likely to appear in Annex XIV, it should consider whether the substance can be substituted by a less-hazardous alternative substance. the company must decide whether to phase-out the use of the substance by the Sunset date or to apply for authorization.

Producers of articles will be obliged to make changes to their manufacturing process and in product design, unless the products are produced outside the EU. Users of articles which were manufactured in the EU by their EU suppliers using a substance listed in Annex XIV for which authorization was not granted, will no longer be able to use these goods.

As a consequence, downstream users producing or using articles must gather information from their EU suppliers about the presence of SVHC in their supplies (which they must do anyway to fulfill their article 33 REACH communication requirements). If this presence is confirmed, companies should contact their suppliers to find out if they intend to submit an authorization application and whether they can benefit from this application. If suppliers do not intend to apply for authorization, then one approach is to find an alternative supplier who will be able to include the company in its authorization dossier. Alternatively, the company could apply for an authorization itself and potentially become a valuable business partner for the customers who do not intend to ask for the authorization themselves.

Inclusion of a substance on the Candidate list or in Annex XIV can be challenged in front of the General Court.

1 - *Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures*.
2 - *According to criteria set out in the CLP Regulation.*
3 - According to criteria set out in Annex XIII of REACH.
4 - *Ibid.*
5 - *We note however that Geert Dancet, Executive Director of ECHA, admitted that reaching this target will be "difficult".*
6 -Available at ***http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:044:0002:0006:EN:PDF***
7 -*Available at* ***http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf***
8 -*Available at* ***http://guidance.echa.europa.eu/docs/guidance_document/sea_authorisation_en.pdf***

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