Press Release:

ECHA/PR/09/01

Helsinki, 14 January 2009

PUBLIC CONSULTATION ON INCLUSION OF SUBSTANCES IN THE AUTHORISATION LIST

ECHA launched today a public consultation on the first draft recommendation of substances to be included in the list of substances subject to authorisation (Annex XIV or Authorisation List). Interested parties can submit comments by using the relevant web forms on the ECHA website until 14 April 2009.

The public consultation on the draft recommendation is part of the process to include substances in Annex XIV of REACH (Authorisation List). For an overview of the process, see Attachment 1 of this document.

PUBLIC CONSULTATION

Interested parties can comment both on:

- ECHA's draft recommendation on seven substances (see below) and its reasoning behind their inclusion in Annex XIV and
- ECHA's justification for prioritising these substances.

Interested parties are invited to comment in particular on uses which should be exempted from the authorisation requirements. The web forms on the ECHA website must be used for commenting. The closing date for comments is **14 April 2009**.

ECHA'S DRAFT RECOMMENDATION

Based on an assessment of the available information, ECHA recommends prioritising seven substances out of the 15 substances that are on the Candidate List (published 28 October 2008). The prioritised substances are:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
- Alkanes,C10-13,chloro (short chain chlorinated paraffins; SCCPs)
- Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified
- 4,4'-Diamino diphenyl methane (MDA)
- Bis (2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP) and
- Dibutyl phthalate (DBP)

In the first draft recommendation ECHA furthermore proposes that:

- applications for authorisations should be submitted between 24 and 30 months after the above substances have been included in Annex XIV of REACH, and
- these substances could not be used after 42 to 48 months after the inclusion date.

ECHA proposes to include exemptions for uses of the prioritised substances that are permitted under specific conditions set out in the current legislation on Restrictions on Marketing and Use Directive (76/769/EEC) as explained in the consultation documents.

ECHA has assessed the available information on the substances included on the Candidate List against the three prioritisation criteria listed in the REACH Regulation, related to 1) the intrinsic properties of a substance, 2) the nature of its uses and 3) the volume supplied to uses subject to authorisation. A weight of evidence approach was used to come to an overall conclusion on the priority of a substance. For some substances the regulatory effectiveness of putting the substance under the authorisation regime was also taken into account. The methodology is explained in the consultation documents.

On the basis of the comments received during this consultation, ECHA may modify the draft recommendation. In this process, it will take into account the opinion of the Member State Committee. After this, the ECHA recommendation is submitted to the European Commission for final decision (see attachment to this press release).

The eight substances that have not been prioritised now may be reconsidered by ECHA for prioritisation at a later stage. Any substance on the Candidate List which is not yet included in Annex XIV can be part of a future priority setting.

Further Information

Public consultation for draft recommendations for priority substances for the inclusion in Annex XIV (authorisation list):

http://echa.europa.eu/consultations/authorisation/draft_recommendations_en.asp

Candidate List published on 28 October 2008:

http://echa.europa.eu/chem_data/candidate_list_en.asp

An overview of the authorisation process under REACH:

http://guidance.echa.europa.eu/authorisation_en.htm

Restrictions on Marketing and Use Directive (76/769/EEC):

http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/index_en.htm

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ATTACHMENT 1. How will the authorisation process look like in practice?

The authorisation process consists of four steps. Industry has obligations in the third step. However, all interested parties have the opportunity to provide input in steps 1 and 2.

Step 1: Identification of substances of very high concern (by authorities)

Substances of very high concern can be identified on the basis of the criteria previously described. This will be done by Member State Competent Authorities or the Agency (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared. The outcome of this identification process is a list of identified substances, which are candidates for prioritisation (the "candidate list"). The list will be published and periodically updated by the Agency.

Step 2: Prioritisation process (by authorities)

The substances on the candidate list are then prioritised to determine which ones should be subject to authorisation. Interested parties are invited to submit comments during this process. At the end of the prioritisation process, the following decisions are taken:

- whether or not the substance will be subject to authorisation;
- which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place);
- the "sunset date" by when a substance can no more be used without authorisation.

Step 3: Applications for authorisation (by industry)

Applications for authorisation need to be made within the set deadlines for each use that is not exempted from the authorisation requirement. They must include among others:

- a chemical safety report covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration)
- an analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives.

If the analysis of alternatives reveals that a there is a suitable alternative, the applicant must submit a substitution plan, explaining how he intends to replace the substance by the alternative. The suitability of available alternatives is assessed taking into account all relevant aspects, including whether the alternative results in reduction of overall risks and is technically and economically feasible.

An applicant can include a socio-economic analysis in his application, but in cases where he is not able to demonstrate adequate control of risks and where no suitable alternative exists, he needs to include one in his application.

A fee has to be paid for each application.

For all applications, the Agency will provide expert opinions. The applicant can comment on these opinions.

Step 4: Granting of authorisations (by the European Commission)

Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. The “adequate control route” does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.

If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

Downstream users may only use such substances for uses which have been authorised.

For this they must either:

- obtain the substance from a company that was granted an authorisation for that use. They must stay within the conditions of that authorisation. Such downstream users must notify the Agency that they are using an authorised substance.
- apply themselves for authorisations for their own uses.

Reviews

All authorisations will be reviewed after a certain time-limit which will be set on a case-by-case basis.

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