



ECHA

<http://echa.europa.eu>

Press Release:

ECHA/PR/10/15

Helsinki, 1 July 2010

PUBLIC CONSULTATION ON INCLUSION OF SUBSTANCES IN THE AUTHORISATION LIST

ECHA launches today a public consultation on its draft recommendation of eight substances to be included in the Authorisation List (i.e. Annex XIV of the REACH-Regulation). Interested parties can submit comments until 30 September 2010.

Comments are particularly welcome on any uses which merit exemption from the authorisation requirement.

To comment use the web form on ECHA's website.

ECHA'S DRAFT RECOMMENDATION

Based on an assessment of the available information, ECHA recommends eight substances from the fifteen substances that were added to the Candidate List early 2010 for inclusion to the Authorisation List. These substances are:

- Diisobutyl phthalate (DIBP)
- Diarsenic trioxide
- Diarsenic pentaoxide
- Lead chromate
- Lead sulfochromate yellow (C.I. Pigment Yellow 34)
- Lead chromate molybdate sulfate red (C.I. Pigment Red 104)
- Tris (2-chloroethyl) phosphate (TCEP)
- 2,4 – Dinitrotoluene

On the basis of the comments received during this consultation, ECHA may modify the draft recommendation which also proposes sunset dates by which users of substances must have submitted an application for authorisation to be able to continue to use these substances. In

this process, it will also take into account the opinion of the Member State Committee. Thereafter, the ECHA recommendation will be submitted to the European Commission for final decision.

It is recalled that the ultimate aim of authorisation is that the inherent risks of these high concern chemicals are properly controlled and that they are progressively replaced by suitable alternatives.

Further Information

Public consultation on ECHA's second recommendation of priority substances to be included in Annex XIV (web forms for commenting, recommendation documents and background information):

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

Candidate List for eventual inclusion in Annex XIV:

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

How does 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 set out in Article 57 of the REACH-Regulation, which are:

- Carcinogenic, Mutagenic or Toxic to Reproduction (CMR) classified in category 1 or 2,
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria set out in Annex XIII of the REACH Regulation, and/or
- identified, on a case-by-case basis, where there is scientific evidence of probable serious effects to human health or the environment, which give rise to an equivalent level of concern to those substances listed above.

Such identification will be proposed by the Member States Competent Authorities or ECHA (on behalf of the European Commission) by preparing dossiers in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared. If no comments are received for a substance, it is included in the Candidate List for eventual inclusion in Annex XIV. If comments are received, the Annex XV dossier and the comments are referred to ECHA's Member State Committee (MSC). If the MSC unanimously agrees that the substance concerned fulfils the criteria of Article 57, the substance is included in the Candidate List. In case the MSC fails to reach unanimous agreement, the Commission decides, by Committee procedure, on the identification of the substance.

Step 2: Recommendation process (by authorities)

ECHA has to make at least every second year a recommendation of priority substances to be included in Annex XIV. As preparatory step for establishing a recommendation, the substances on the Candidate List are prioritised in order to determine which ones should be recommended for authorisation.

Then the draft recommendation, providing the identity of the prioritised substances and draft Annex XIV entries for these substances, is developed. The draft Annex XIV entries comprise, inter alia:

- Sunset date(s): the date(s) from which placing on the market and use of the substance shall be prohibited, unless an authorisation is granted;
- Application dates(s): the date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market after the sunset date;

- Review periods for certain uses, if appropriate;
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

The draft recommendation is made public on ECHA's website and interested parties are invited to submit comments, in particular on uses which should be exempt from the authorisation requirement.

Comments received during public consultation as well as the opinion of the Member State Committee are taken into account by ECHA in updating the recommendation. The final recommendation is submitted to the Commission, who decides by Committee procedure on inclusion of the recommended substances in Annex XIV.

Step 3: Applications for authorisation (by industry)

Applications for authorisation need to be made by the application date(s) set for uses not exempted from the authorisation requirement. They must include, inter alia:

- a chemical safety report covering risks related to those properties that caused inclusion of the substance in the Candidate List (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 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 a reduction of the overall risk and whether it 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 such an analysis in his application.

A fee has to be paid for each application.

On all applications ECHA's Committees for Risk Assessment and Socio-Economic Analysis will provide (draft) opinions. The applicants can comment on the drafts opinions.

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

Authorisations will be granted if the applicant can demonstrate that the risk from his 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 it cannot be demonstrated that the risk is adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and that 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 authorisation decisions will include a review period.