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Guidance Fact Sheet

INCLUSION OF SUBSTANCES IN ANNEX XIV

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Guidance on inclusion of substances in Annex XIV (List of Substances Subject to Authorisation)

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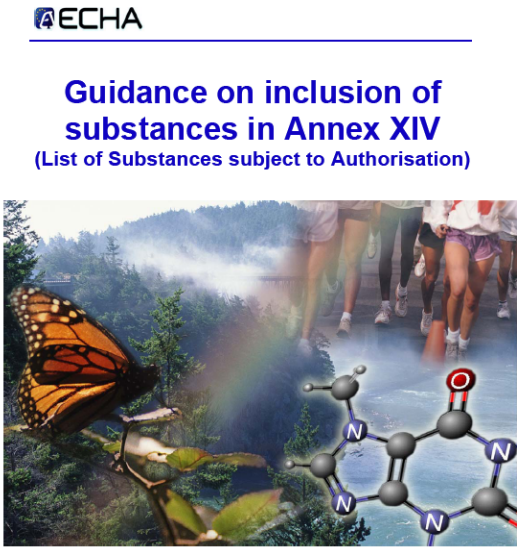
A Guidance Fact Sheet provides a short summary of the key aspects of the respective REACH Guidance Document including bibliographic information and other references.

If you have questions or comments in relation to this Fact Sheet please send them by e-mail to info@echa.europa.eu quoting the Fact Sheet reference, issue date and language version, shown above.



Guidance Fact Sheet
Inclusion of substances in Annex XIV

WHO SHOULD READ THE GUIDANCE DOCUMENT?

The REACH Regulation sets up a system under which the placing on the market and the use of Substances of Very High Concern (SVHCs) may be subject to prior authorisation.

The aim of authorisation is to ensure that risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies, where these are economically and technically viable.

The guidance is mainly addressed to Member State Competent Authorities and the European Chemicals Agency (ECHA). It provides background information on the identification of SVHCs, their inclusion in the Candidate List of Substances of Very High Concern for Authorisation (the 'candidate list') and their possible inclusion in Annex XIV (the List of Substances subject to Authorisation or so-called 'authorisation list'). The Guidance will also be useful for manufacturers, importers and downstream users placing on the market and/or using SVHCs so they can better understand and follow the authorisation process.

Furthermore, the guidance is a reference document to any interested party that may want to provide comments or input. Comments can be provided during the process of establishing the 'candidate list'. Similarly interested parties will be entitled to comment on the Agency's recommendation. The comments shall in particular be focused on uses that should be exempted from the authorisation requirement.

Interested parties are informed via the Agency's website on the deadlines for commenting. Interested parties that have subscribed for the mailing list dealing with the "Registry of Intentions" will be informed automatically on any update of the list of Annex XV dossiers including those Annex XV dossiers dealing with SVHCs.

WHAT IS THIS GUIDANCE ABOUT?

The guidance provides an overview on the various steps of the process from the identification of SVHCs and their inclusion in the 'candidate list' to their eventual inclusion in the 'authorisation list'. It addresses the following topics:

- **Authorisation procedure** including the roles of the different actors
- **Scope of authorisation** addressing the kind of substances that can be subjected to authorisation and providing the general and specific rules for exempting uses from authorisation;
- **Procedure to include substances in the authorisation system**, detailing the establishment of the 'candidate list', prioritisation of substances from the 'candidate list' and establishment of the 'authorisation list';
- **Details of what should be included in the Agency's recommendation** of priority substances to be included in the 'authorisation list'. It shall encompass the substance identity, the intrinsic properties of the SVHCs, the transitional arrangements, review periods for certain uses, uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions;
- **Consultation** of the Member State Committee and of interested parties with regard to the identification of substances for the 'candidate list' and the Agency's draft recommendation of substances to be included in the 'authorisation list'.

HOW TO READ THIS GUIDANCE?

The **first chapter** provides a brief summary of the topics that are covered in the document and highlights its target audience. In addition it gives an overview of the links to the REACH Guidance documents that are relevant for the authorisation process.

After a general introduction to the authorisation process, the **second chapter** elaborates the roles, obligations and rights of the different actors involved in the authorisation process. It also describes the relation with restriction procedures (Title VIII of the REACH Regulation) which may involve the same substance. The possible reciprocal influence must be carefully assessed by the Authorities before initiating an Annex XV dossier. The chapter clarifies the scope of the authorisation process, focusing on the substances and uses subject to this process and exemptions from authorisation.

The **third chapter** explains in depth the procedure to include substances into the authorisation system. It starts with the preparation of an Annex XV dossier aiming at the identification of a substance as SVHC on the initiative of the Commission or a Member State. Three steps must be distinguished:

- **Identification of SVHCs**, which establish the 'candidate list';
- **Prioritisation** of substances on the 'candidate list': substances will normally be prioritised according to predefined criteria;
- **Inclusion** of substances in the 'authorisation list' based on the preceeding prioritisation step.

Chapter four provides detailed guidance on the preparation of a draft 'authorisation list' (Annex XIV) entry, specifying substance identity, intrinsic properties of the SVHC in question, the transitional arrangements, review periods for certain uses, uses or categories of uses exempted from the authorisation requirement and conditions for such exemptions.

The fifth **chapter** delves into the consultation of the Member State Committee and the role of interested parties in providing comments.

Appendix 1 summarises the roles, obligations and rights of the actors with reference to the articles in the REACH Regulation.

Appendix 2 provides a format for a notice that an Annex XV dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern according to Art. 59 has been prepared.

Appendix 3 suggests a format for the 'candidate list'.

The draft Annex XIV entry for substances recommended for inclusion in the 'authorisation list' is described in **Appendix 4**.

Commenting forms on the identification of the substance to be included in Annex XIV with regard to the notice published by ECHA and on the draft Annex XIV entry for substances recommended for inclusion in the 'authorisation list' to the Commission to be completed by interested parties are given in **Appendices 5 and 6**.

Appendix 7 provides a list of definitions and abbreviations.

KEY ASPECTS

Substances of Very High Concern

The properties of SVHCs are defined in Article 57 of the REACH Regulation: carcinogenic, mutagenic or toxic to reproduction (CMRs category 1 and 2), persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), or substances, identified on a case by case basis, for which there is scientific evidence that they give rise to an equivalent level of concern.

The 'candidate list'

When an Authority (the Commission or a Member State) considers that a substance may meet the criteria for identification as a SVHC in accordance with Article 57 of the REACH Regulation it will prepare an Annex XV dossier. Substances fulfilling one of the criteria of Article 57 shall be included in the 'candidate list' if agreement on the proposal for identification as a SVHC has been reached through the

procedure specified in Article 59 of the REACH Regulation.

The 'authorisation list'

A SVHC on the 'candidate list' may be included in the 'authorisation list'. The Agency shall make recommendations of substances to be included in the 'authorisation list' at least every second year; the first recommendation has been sent to the Commission by 1 June 2009. Priority shall normally be given to substances with PBT or vPvB properties, with wide dispersive uses or to those that are manufactured or imported in high volumes.

Sunset date(s)

The date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted which should take into account, where appropriate, the production cycle specified for that use.

Application deadline

A date 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 for certain uses after the sunset date(s).

LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006
REACH Guidance website is a single point of access to general and detailed technical guidance on REACH, including REACH Guidance Fact Sheets. Frequently Asked Questions (FAQs) can be found in the REACH section of the ECHA website.

BIBLIOGRAPHIC INFORMATION ON THE GUIDANCE DOCUMENT

The Guidance on inclusion of substances in Annex XIV (List of Substances subject to Authorisation) can be downloaded from the ECHA website.

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