NEWS LETTER
RESTRICTION

helpdesk luxembourg
REACH & CLP
Un service du Centre de Recherche Public Henri Tudor
En partenariat avec le Ministère du Développement durable et des Infrastructures, et le Ministère de l'Economie et du Commerce extérieur

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REACH Restriction process for dangerous substances - an overview

REACH

REACH* restricts the use of hazardous substances when there is an unacceptable risk to human health or the environment - industry must comply!

** REACH: Regulation (EC) 1907/2006 for Registration, Evaluation, Authorisation and restriction of Chemicals*

Title VIII REACH - Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles

Key Steps

Preparatory work to investigate a potential risk

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ECHA Notification on intention to prepare a restriction dossier

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Submission of the restriction dossier to ECHA

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Opinion of ECHA's Committees

Opinion RAC - 9 months
Opinion SEAC - 12 months

← Public consultation on restriction proposal - 6 months

← Forum advice on enforceability to RAC/SEAC

← Public consultation on SEAC draft opinion - 60 days

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COM prepares Draft Amendment of Annex XVII

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Adoption of restriction decision via comitology Publication in the Official Journal

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Companies must comply after adoption

Enforcement of restriction by MS →

SCOPE (Art. 68)

Restriction should control unacceptable risk to human health or the environment which needs to be addressed at a Community-wide basis.

Restriction Process

New restrictions and amendments of current restrictions can be proposed by Member States (MS) or upon request from the Commission by the European Chemicals Agency (ECHA) (Art. 69 (1,4)) with a dossier conforming to Annex XV REACH.

The intention to prepare as well as the submission of a restriction dossier are published by ECHA in its registry of intentions (Art. 69 (5,6)). Registrants of the substance will be informed. Companies can follow restriction proposals for hazardous chemicals in the registry of intentions and prepare comments for the public consultation and get ready for compliance in time.

After conformity check and publication of the dossier, interested parties like industry, NGOs or other regulatory agencies world-wide may provide comments on the restriction proposal within six months (Art. 69(6)). The Forum for Exchange of Information on Enforcement shall examine restriction proposals with a view on enforceability (Art. 77(4)). Taking into account public comments submitted by interested parties, Forum advice and the restriction dossier, ECHA's scientific committees for risk assessment and socio-economic analyses (RAC and SEAC) formulate an opinion on the restriction proposal.

The proposal and the opinions of the Committees are submitted to the European Commission (COM) for decision making. A draft amendment of the REACH restriction list (Annex XVII) is prepared within three months. The proposal is adopted in the REACH Committee and after a scrutiny period for Council and Parliament published in the Official Journal.

As soon as published in the Official Journal, manufacturers, importers, downstream users, distributors and retailers must comply with the condition of the restriction when manufacturing, placing on the market or using that substance (sometimes transitional arrangement are defined). The restriction is enforced at MS level.

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Scope:

Title VIII REACH on Restriction applies to the manufacture, placing on the market (supplying and importing) and use of certain dangerous substances on their own, in a mixture, or in an article (Art. 67), whereas "use" is any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container into another, mixing, production of an article or any other utilisation (Art. 3(24)).

Exemptions:

In general, REACH does not apply to radioactive substances, substances in customs supervision, non-isolated intermediates, waste and to transport of dangerous substances (Art. 2(1-2)). Restrictions do not apply to substances in scientific research and development. An Annex XVII entry can also specify an exemption for product and process oriented research and development and the maximum quantity exempted (Art. 67(1)). Substances used as an on-site isolated intermediate may not be subject to new restrictions or amending current restrictions (Art. 68(1)).

Public consultation:

Interested parties are invited to comment on the suggested restriction, the Annex XV restriction dossier, and provide information contributing to a socio-economic analyses. Restrictions currently under consideration are listed in the ECHA webpage section "chemicals of concern". ECHA Committees cannot take into account comments received after the deadline in their opinion making process.

Harmonised Classification and Labelling CMR Cat 1A/1B

For substances with a harmonised and thus legally binding classification and labelling (CLH) as carcinogenic, mutagenic, or toxic for reproduction cat. 1A or 1B according to CLP*, and which may be **used by consumers**, Appendix 1-6 to **entry 28-30 of Annex XVII** is amended accordingly without the restriction proposal procedure as set out in Art 69-73 REACH (Art.68(2)) :

- **No placing on the market or use for supply to the general public** of substances as such, as constituents of other substances, or, in mixtures, when the individual concentration in the substance or mixture is equal to or exceeding the specific or generic concentrations limits specified in CLP or DPD*.
- **Suppliers** shall ensure that the packaging of such substances and mixtures is marked "Restricted to professional users".

ECHA support and links

* Annex XVII REACH - restriction list
* ECHA's Website section on "addressing chemicals of concern" and "substances of potential concern"
* Restriction section on ECHA's website
* ECHA's work on restrictions
* ECHA's registry of intentions
* Q&A on restriction

Keep track on your substances and check regularly ECHA's registry of intentions and substances of potential concern!

… anticipate!

Committee opinions:

The Risk Assessment Committee (RAC) evaluates whether a proposed restriction on manufacture, placing on the market or use of a substance is appropriate to reduce the risk to human health and the environment. This includes the assessment of comments submitted by third parties.
The Committee for Socio-Economic Analysis (SEAC) evaluates the socio-economic impact of the proposed restriction including the assessment of comments and socio-economic analyses submitted by third parties.

Documentation:

Adopted Committee opinions and all further available information on the restriction proposals including the Annex XV dossier, the Commission proposals for decision, and adopted restrictions, are available via the ECHA website section "Adopted opinions on restriction proposals". Consult also the Website of the European Commission on restrictions: REACH Restrictions.

Restrictions for SVHC

- For Substances of Very High Concern (SVHC) included in Annex XIV REACH (Authorisation List), authorisation application on uses in scope of a restriction listed in Annex XVII REACH will not be granted (Art. 60(6)).
- The use of **Annex XIV SVHC (authorisation obligation) already incorporated in articles** is not in the scope of authorisation requirement. After the "sunset date" , the date from which the placing on the market and the use of an Annex XIV SVHC is prohibited unless an authorisation is granted, ECHA will consider whether the use of that substance in articles poses a risk that is not adequately controlled. ECHA may then propose a restriction for the placing on the market and use of articles containing these SVHC (Art. 69(2)).
- Before a restriction process or an identification of a substances as SVHC for later authorisation obligation is initiated, ECHA will analyse the risk management options (**RMO**) appropriate to the particular substance of concern.
- See also our thematic Newsletter on Authorisation from March 2014.

** CLP = Regulation (EC) No 1272/2008 on classification, labelling, and packaging of substances and mixtures; DPD = Dangerous Preparations Directive (1999/45/EC)*