Newsletter

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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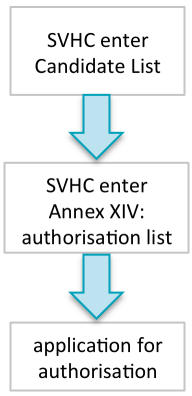
Authorisation of Substances of Very High Concern listed in Annex XIV REACH

Producers, importers and downstream users, plan your authorisation application!

REACH* requires from companies an authorisation application for the placing on the market and use of Substances of Very High Concern (SVHC) listed in Annex XIV REACH. Since February 2011, the first authorisation applications can be submitted.

Authorisation procedure: Three major steps



The Candidate List contains all substances that have been officially identified as SVHC fulfilling the criteria of Article 57 REACH (procedure see Art. 59).

Selected by applying predefined risk-based criteria, certain SVHC are included in Annex XIV REACH (procedure see Art. 58).

After a transitional period, SVHC in Annex XIV can no longer be placed on the market or used by any manufacturer, importer or downstream user unless an authorisation has been granted (procedure see Art. 64). Authorisation applies to a substance on its own, in a mixture and the incorporation of the substance into an article.

The first six substances were included in Annex XIV REACH in February 2011 (Regulation (EU) 143/2011 and its Corrigendum). Authorisation application can be submitted for these substances.

GOAL
Control the risk from SVHC and aim for the substitution of the most dangerous substances (Art. 55 REACH)

Exemptions from authorisation obligation

- On-site + transported isolated intermediates (Art. 2(8))
- Substances in:
  - Medical products for human/veterinary use (Art. 2(5))
  - Food and feedingstuff (Art. 2(5))
  - Plant protection and biocidal products (Art. 56(4))
  - Motor fuels and fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems (Art. 56(4))
  - Mixtures when present below a certain concentration (details see Art. 56(6))
  - Imported articles (Art. (56(1), however a notification of SVHC in imported articles may be necessary)
- If authorisation obligation only due to hazards to human health, substances in (Art. 56(5)):
  - Cosmetic products
  - Food contact materials
- Uses in scientific research and development (Art. 56(3))
- Exemptions specifically defined in the Annex XIV entry of the substance, e.g. for:
  - Product and process oriented research (Art. 56(3))
  - Certain uses when risk is already properly controlled by other existing specific Community legislation (Art. 58(2))

Substance	Danger	Main uses	Latest application date	Sunset date
• **HBCDD** Hexabromocyclododecane	PBT**	Flame retardant, e.g. in polystyrene (used for insolation)	21/02/2014	21/08/2015
• **DBP** Dibutyl phthalate	Reprotoxic	Plasticizers used in a wide range of PVC and other polymers	21/08/2013	21/02/2015
• **DEHP** Bis (2-ethylhexyl) phthalate	Reprotoxic	Plasticizers used in a wide range of PVC and other polymers	21/08/2013	21/02/2015
• **BBP** Benzyl butyl phthalate	Reprotoxic	Plasticizers used in a wide range of PVC and other polymers	21/08/2013	21/02/2015
• **Musk xylene** 5-tert-butyl-2,4,6-trinitro-m-xylene	vPvB***	Fragrance enhancer in detergents, softeners and conditioners in cosmetics and perfumery industries	21/02/2013	21/08/2014
• **MDA** 4,4'-Diaminodiphenylmethane	Carcinogenic	Hardener, e.g. in epoxy resins and adhesive	21/02/2013	21/08/2014

* *Regulation (EC) 1907/2006 for registration, evaluation, authorisation and restriction of chemicals, so called REACH came into force on 1 June 2007.*
** *PBT = persistent, bio-accumulative and toxic*
*** *vPvB = very persistent and vey bio-accumulative*

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Key dates

The **sunset date** is the "*date from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted*" (Art. 58(1)c)i) REACH). The **latest application date** is the date 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(s) until a final decision is taken (Art. 58(1)c)ii)). The latest application date is at least 18 months before the sunset date. For practicality reasons, ECHA asks companies to submit their application only during four submission windows during the year (click here for the planning).

Procedure for authorisation decision (Art. 64)

An application can be made for one or several substances, for one or several uses, and by one company or in a joint application by several producers, importers or downstream users (Art. 62(2)+(3)). The fees depend on these parameters (see fee calculator proposed by ECHA).

Applicant: Application to ECHA - Art. 62(1-2)

Applicant: Pays fee alone or in a joint application - Art. 62(7)

Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC) (max. 10 months after application, 5 months if an authorisation already exists): Completeness check + preparing draft Opinion(s) - Art. 64(1,3,4,10)

ECHA: Public consultation - Art. 64(2)

Applicant (1 month after reception of draft Opinion(s)): Indicate if he intends to comment on draft Opinion(s) - Art. 64(5)

comments

no comments

Applicant (2 months after reception of the draft Opinion(s)): Written argumentation - Art. 64(5)

ECHA's RAC + SEAC (2 months after the applicant's argumentation): Final Opinion(s) - Art. 64(5)

ECHA (15 days after the final Opinion(s)): Opinions sent to Commission, Member States and applicant + Decision on publication on ECHA website - Art. 64(5-6)

Commission (3 months after receipt): Draft authorisation, final decision granting or refusing authorisation (via comitology) - Art. 64(8)

Official Journal: Publication - Art. 64(9): summaries, authorisation number

DEFINITION

Use = "*means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation*" (Art. 3 REACH)

How to use IT Tools for application submission?

Identify the applicant	Download IUCLID 5 Create a LEO and import LEO XML
Create the reference substances	Download pre-filled reference substances + EC inventory in IUCLID 5
Create substance dataset (SD)	For the substance in Annex XIV in IUCLID 5 by the feature "new"
Enter information in the SD	Enter information and indicate links to the reference substances
Create application form	Download application form from the web-form 1 or web-form 2 (if joint application) + receive a code
Link both elements	Under section 13 add the application form (pdf) to the substance dataset
Create a dossier	Create an application for authorisation dossier in IUCLID 5
Export the dossier	Export the application for authorisation dossier from IUCLID 5
Submit the dossier	Submit the dossier to ECHA in web-form 3 (use the code) via REACH IT

For further technical information:
Data Submission Manual 22 "How to prepare and submit an application for authorisation using IUCLID 5"

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Information to be provided by the applicant

The following information has to be provided in an authorisation application (Art. 62(4)) REACH:

- Identity of the substance
- Name and contact details of the applicant(s)
- Uses for which the authorisation is sought
- Chemical safety report, unless already submitted with a registration
- Analysis of alternatives including risks, feasibility and current activities
- Substitution plan, if alternatives are available (including time table)

In addition, an application can also include (Art. 62(5)):

- Socio-economic analysis (SEA), if socio-economic assessment route is chosen
- Justification for not considering risks to human health and the environment arising either from an installation with an IPPC authorisation (integrated pollution prevention and control, Directive 96/61/EC) or a point source requiring a prior regulation under the water framework directive 2000/60/EC.

The two routes of authorisation

Adequate control route (Art. 60(2-3) REACH)

This route can be applied if the chemical safety report shows that the risk to human health and the environment is adequately controlled. Then, an SEA is not mandatory and only RAC (Committee for Risk Assessment) prepares an opinion. This route cannot be applied to PBT and vPvB, as well as CMRs for which it is not possible to determine a threshold.

Socio-economic assessment route (Art. 60(4) REACH)

For PBT, vPvB and non-threshold CMR substances or if an adequate control of risk cannot be demonstrated, the SEA route can be applied. Here, an SEA is obligatory and also the SEAC (Committee for SEA) prepares an opinion. An authorisation can be granted, if it is shown that socio-economic benefits outweigh the risk and if there are no suitable alternative substances or technologies.

After an authorisation has been granted

- Holders of the authorisation and downstream users: Include authorisation number on the label without delay before placing substance/mixture on the market for an authorised use (Art. 65).
- Suppliers: Update the safety data sheet without delay (Art. 31(9)), or, if you do not need to prepare a safety data sheet, inform your recipients otherwise of granted or denied authorisations (Art. 32(1)).
- Registrant: Update your REACH registration (Art. 22(2))

A subsequent applicant may refer to the appropriate parts of a previous application, if the previous applicant or holder of the authorisation permits it and after updating the information of the original application (Art. 63).

Where to find further information?

REACH&CLP Helpdesk website

Section REACH procedures: authorisation
Thematic Newsletter: Notification of SVHC in articles

ECHA (European Chemicals Agency) website

Section Authorisation
Questions and answers on authorisation
Fee calculator
FAQs REACH, section 12
Navigator tool: Helps you to define your role and obligations under REACH.

ECHA guidance and seminars

Guidance on the preparation of an application for authorisation
Guidance on Socio-Economic Analysis
Seminar on application for authorisation held on 12 April 2011 (download presentations)

AUTHORISATION SPECIFIES (ART. 60(9)

- Identity of authorisation holder
- Identity of substance
- Authorised use(s)
- Time-limited review period (authorisation is time-limited and is regularly reviewed!)
- Possible conditions and monitoring arrangements

NOTE: A downstream user may use a substance "*provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use*" (Art. 56(2)).

If so, he notifies ECHA within three months after the first supply of the substance (Art. 66).

Keep you informed!

- More substances to enter Annex XIV: Eight additional SVHC recommended in December 2010 (inclusion expected end of 2011/beginning of 2012) + annual update of Annex XIV planned
- ECHA's voluntary system to notify intentions to apply for an authorisation: Future applicants are recommended to register their application (by sending an email to echa_application_for_authorisation@echa.europa.eu.) as it allows them to ask for clarifications on how to prepare and submit an application!

These FAQs should help you!

- 12.1 Are any substances already subject to authorisation?
- 12.2 Where do I find the Candidate List?
- 12.3 How is a substance included in the Candidate List?
- 12.4 How is a substance from the Candidate List included in the Authorisation List?
- 12.5 How are authorisations granted for substances on the Authorisation List?

GOAL

Holders of an authorisation should ensure that the exposure is as low as technically and practically possible (Art. 60(10))