NEWS LETTER
AUTHORISATION

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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Zoom on authorisation procedure of Substances of Very High Concern listed in Annex XIV REACH

REACH* requires from companies an authorisation application for the placing of the market and use of Substances of Very High Concern (SVHC) listed in Annex XIV REACH.

** REACH: Regulation (EC) 1907/2006 for Registration, Evaluation, Authorisation and restriction of CHemicals, entered into force on 1st June 2007*

Authorisation procedure: major steps

Substances proposed to be identified as an SVHC

Member States or the European CHemical Agency (ECHA), on request of the European Commission, may propose a substance to be identified as an SVHC by preparing a dossier Annex XV.

The intention to propose a substance as an SVHC is published by the ECHA in the registry of intentions (Art. 59.4). Companies could follow SVHC proposals in the registry of intention and prepare comments for the public consultation.

SVHC included in the Cadidate List

The Candidate List contains all substances that have been officially identified as SVHC fulfilling the criteria of Art. 57 REACH (procedure described in Art. 59). This evolving list is updated twice a year.

Article containing an SVHC in a concentration >0,1%:

- Supplier of articles: obligation to inform about the presence of SVHC (Art. 33).
- Producer/importer: obligation to notify to ECHA (Art. 7.2), under certain conditions.

Recommendation of priority substances

From the Candidate List, ECHA prioritises the substances to be included in the list of substances subject to authorisation (Annex XIV) and submits its recommendations to the European Commission.

The draft recommendation for Annex XIV inclusion is finalised by ECHA considering the opinion prepared by the Member States Committee and the comments received, by stakeholders like companies, during the public consultation. The recommendations are published on the ECHA website.

Inclusion in Annex XIV: Autorisation list

SVHC are included in Annex XIV REACH (procedure Art. 58) and the list is updated as regulation published in the Official Journal of the European Union.

Application of authorisation

An application can be submitted to ECHA for one or several substances, for one or several uses, by one or several entities (manufacturer/ importer/downstream user) (Art. 62.2 and 62.3). Any application shall be accompanied by a fee that depends on these parameters (see fee calculator proposed by ECHA).

After a transitional period, substances can no longer be placed on the market or used (« use » definition Art. 3.24), in EU, by company unless an autorisation has been granted (procedure described in Art. 64). This **applies to substances on its own or in a mixture or incorporated in an article** (Art. 56.1).

Decision granting or refusing authorisation

Exemptions (see exemptions list)

Some uses are exempted from authorisation (Art. 2.5 and 2.8, Art.56.3 to 56.6), e.g. exemptions specifically set out in Annex XIV, research and development activity (R&D), plant protection products or biocides , in mixtures below certain concentration limits, cosmetic products and food contact materials because they are identified only because of hazards to human health.
The use of an SVHC included in Annex XIV already incorporated in imported articles is not in the scope of autorisation requirement. However, if the European producer of articles incorporates the substance into these articles, that use of the substance may have to be authorised.

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

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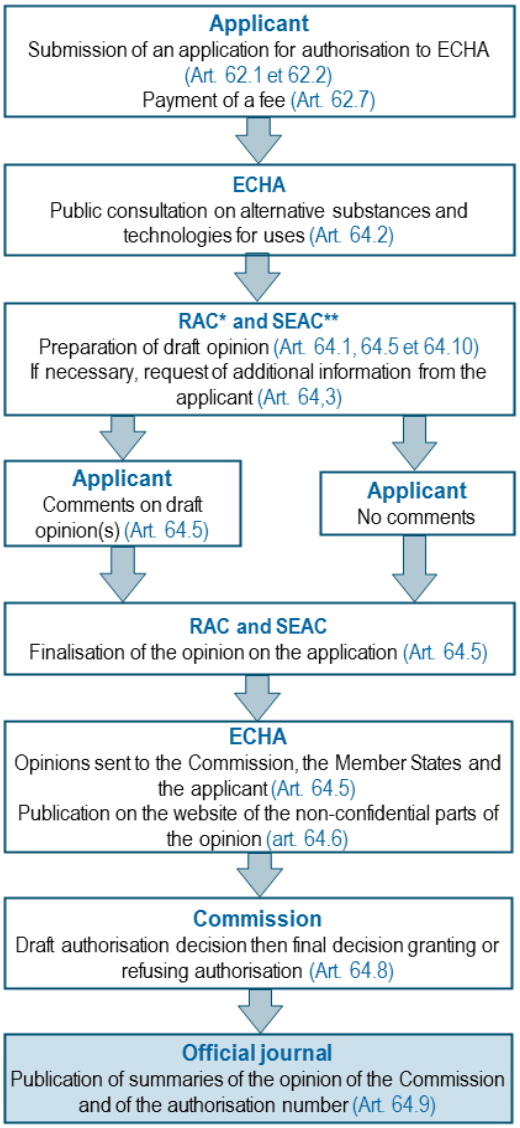
Key dates

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). 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. An application may still be submitted after this date, but the applicant can not benefit from the transitional arrangements of Art. 58.1.c.ii.
For practical reasons, ECHA has set up **specific windows** ("**submission windows**") to submit applications for authorisation. It is recommended to companies to submit their application during these submission window which are established in the three months before the deadline for applications.

Procedure for authorisation decision



Why to apply for authorisation?

- For the company the first question that must be asked is: "What will be the impact on my business if I can no longer use my substance in the European Union?"
  ⟹ From there **the company need to decide to apply for authorisation or to substitute.**
- Submit or not an application for authorisation?

YES: if the use of the substance clearly adds value in the European Union and the risks related to its use are low.
NO: if the use of the substance does not add a lot of value in the European Union and the risks are relatively high.

- If the company decides to substitute several solutions may be available, e.g. switch substances, adapt technologies and processes or develop new ones, stop producing or using… However, this also has an impact, e.g. technical performance, costs, environmental and health risks…

Preliminary steps before submitting an application for authorisation

Before submit an application for authorisation, the applicant may be concerned by:

- **Notification to ECHA**: the applicant informs ECHA of his intention to submit an application for autorisation.
- **Pre-submission information session**: when notifying to ECHA, the applicant can request a pre-submission information session with ECHA to ask case-specific questions on regulatory aspects and the application process.

Where to find information and tools?

- **REACH&CLP Helpdesk Luxembourg website**
  - Thematic newsletters on autorisation
  - Event documentation (e.g. REACH&CLP Coffee on authorisation)
- **ECHA website**:
  - Section "authorisation"
  - Support section "Applying for authorisation"

Note: in this last section you will find various tools available to you at each step of the submission of an application for authorisation.

- **ECHA guidances**:
  - "Guidance on the preparation of an application for authorisation"
  - "Guidance on the preparation of socio-economic analysis as part of an application for authorisation"
  - Data Submission Manual 22
- **Tutorial video**: "How to preprare and submit an application for authorisation to ECHA"
- **Seminars** on application for autorisation in "Events" section of ECHA website.
- **ECHA FAQs**: don't hesitate to consult!

Note: The authorisation specifies the person(s) to whom it is granted, the identity of the substance(s), or the use(s), possible conditions, the limited review period and possible follow-up (Art. 60.9).

**RAC = Risk Assessment Committee,*
***SEAC = Socio-Economic Analysis Committee*

Information to be provided by the applicant

The informations to include in the application for authorisation are listed in Art. 62:

- identity of the substance,
- name and contact details of the applicant(s),
- use(s) for which the autorisation is sought,
- chemical safety report (unless already submitted with a registration),
- analysis of alternatives including risks, feasibility and relevant R&D activities,
- substitution plan, if suitable alternatives are available.

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).

In addition, an application may also include:

- socio-economic analysis (SEA), mandatory in case socio-economic assessment route is chosen,
- justification for not taking into account risks to human health and the environment generated by emissions (Integrated Pollution Prevention and Control Directive 96/61/EC respectively Industrial Emmissions Directive 2010/75/EU) or releases (Water Framework Directive 2000/60/EC) (Art. 62(5)b).

The two routes of the authorisation

- Art. 60.2 and 62.3: an authorisation can be granted if the "***risk*** *to human health or the environment from the use of a substance arising from the intrinsic properties […] is* ***adequately controlled*** *[…] as documented in the applicant's chemical safety report*" and taking into account the **opinion of RAC**. This route cannot be applied to PBT and vPvB, as well as CMRs* for which it is not possible to determine a threshold (Art. 60.3).
- Art. 60.4: If an authorisation cannot be granted risk-based, an authorisation may only be granted "*if it is shown that* ***socio-economic benefits*** *outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies".* A **SEA is then an obligatory part of the application** and SEAC prepares an opinion.

Note: A substance may be placed on the market for use if an authorisation has been granted to the immediate downstream user for that use (Art. 56.1.e).
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).

Requirements resulting from the granting or refusing of an authorisation

Holders of the authorisation and downstream users: include the authorisation number on the label without delay before placing substance/ mixture on the market for an authorised use (Art. 65).

Suppliers: inform the downstream users without delay via the update of the Safety Data Sheet (SDS) (Art. 31.9) or with a declaration if the SDS is not required (Art. 32.1).

Registrants: must update the registration dossier (Art. 22.2).

Review periods for authorisations

The authorisations are subject to a review period whose lenght is decided by the Commission (Art. 60.8 and Art. 61.1) based on the recommendations of the RAC and SEAC. The lenght of the review period is decided on a case by case basis (Art. 60.8). According to certain criteria three review periods are defined: **normal review period** (7 years), **short review period** (e.g. 4 years) and **long review period** (12 years).

The holders of the authorisation must submit a review report at least 18 months before the end of the review period. The review report should cover an update of the analysis of alternatives including relevant R&D activities, substitution plan and further changes.

The Commission may also amend or withdraw the authorisation if the context has changed, that is to say, if the risk to human health or the environment, or the socio-economic impact are affected, and/or if information about suitable alternatives become available (Art. 61.2 and 61.3). A company's decision on whether to apply for authorisation or to substitute the substance should consider the **risk of refusal, suspension and repeal of an authorisation** by the commission.

**PBT = persistent, bioaccumulative, toxic; vPvB = very persistent and very bioaccumulative; CMR = carcinogenic, mutagenic, toxic to reproduction*