June 2013

How to Handle Substances Listed on ANNEX XIV - Authorisation

Overview

The REACH authorisation process is complex and involves several steps. The first step is the identification of a substance of very high concern (SVHC) through a proposal by a Member State Competent Authority (MSCA) or by ECHA upon request of the European Commission. Once identified, SVHC substances are listed on the so-called Candidate List.

When a substance is included in the Candidate List, companies dealing with substances on the list have to comply with communication obligations. Moreover, companies shall start re-thinking their business strategies, such as considering the availability of technically and economically feasible alternatives, if applicable.

Substances listed on the Candidate List are reviewed currently on an annual basis to determine which ones should be selected for authorisation. This is known as prioritisation process.

Based on the outcome of the prioritization process, the EU Commission takes the final decision on whether to include substances on the REACH Authorisation list (Annex XIV) specifying possible exempted uses, the latest application date and the sunset date.

A substance listed on Annex XIV cannot be placed on the market after the sunset date, unless an authorisation has been granted for a specific use to the applicant or an authorisation application has been submitted to ECHA by the supplier or his immediate downstream user before the relevant deadline (latest application date).

If not already initiated, Companies should organize themselves as soon as the substance is listed on Annex XIV by *urgently* setting up a communication channel through the supply chain, both up and down and through the sector association, working group or consortium to define the real needs in terms of supporting the use or available alternatives (respecting confidential business information and competition law aspects). A Company's business strategy needs review and clarification if not previously carried out.
The focus of this fact sheet is to provide recommendations that companies may consider in advance of applying for an authorisation when substances are listed on the authorisation list (Annex XIV).

Internal Inventory of Chemicals

Companies should check their portfolio to take into account other considerations such as: the importance of the substance to the company; whether the measures implemented are enough to avoid any exposure; whether there are plans to phase out the use of the substance listed on Annex XIV and where substitution may be needed; whether there is an alternative that is technically and economically feasible and available; and if not currently available, will it become so and by when?, etc

Legal obligations:

Substances listed on Annex XIV cannot be placed on the EU market after the sunset date unless an authorisation has been granted for that use or the use has been exempted.
Once authorisation has been granted:

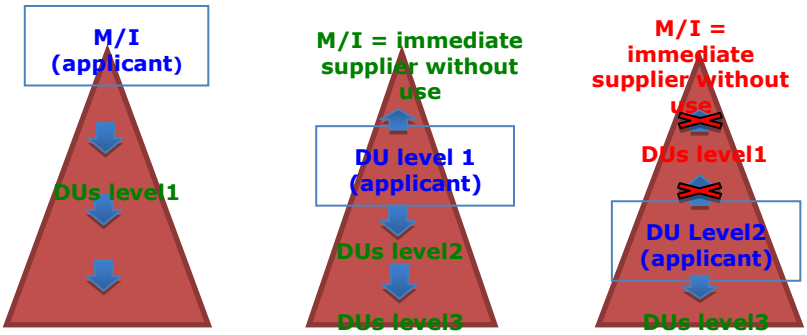
- DUs shall *notify* ECHA within 3 months from first time receiving the substance if this substance is used in accordance with the authorisation granted for that use (Art 66.1 REACH).

- The holders of an authorisation, as well as DUs referred to in Art 56.2 REACH including the substances in a mixture, must include the *authorisation number* on the *LABEL* before they place the substance or a mixture containing the substances on the market for an authorised use.
- The Safety Data Sheet (*SDS*) must be *updated* by mentioning the substance subjected to authorisation in section 15.1.

Information gathering

The preparation of an authorisation dossier is expensive.

1) Firstly, consider *why* you need the authorisation to be granted.
2) Then look at your business and define your *strategy* regarding the uses directly impacted by the targeted substance(s).
3) You need to develop your *communication* channels in your entire supply chain (both up and down)
4) Agree *who* will be the most appropriate entity in the supply chain to prepare and/or *submit* an application (if necessary) considering the legal aspect on who may cover which application.



ECHA source

Be sure your specific use will be covered by a supplier or by yourself. The figure illustrates the different scenarios that may occur:

1. Top-down approach: Application submitted by manufacturer/importer/OR. The application may cover the uses of the entire supply chain down.
2. DU Level 1 approach: Application submitted by a DU which has as first level up, his immediate supplier being the M/I/OR having no other use than supplying the DU at level 1.
3. Bottom-up approach: Application submitted by a DU separated from the manufacturer by several levels in the supply chain. This applicant (DU level 2) may cover in his application, uses down but only one use from his immediate supplier. In this case, as long as the M/I/OR does not successfully submit a separate application for the same use, a supply chain disruption will occur as the uses of the M/I/OR cannot be covered by the DU level 2 application.

5) Check the *timeline* for submitting the application on time in order to minimize the possibility of market disruption. Be clear on the deadlines given: the latest application date – the sunset date – Pre-Submission Information Sessions (PSIS) with ECHA – etc.
6) Do not neglect *contact* with authorities.

Tips and recommendations

1) **Prepare your authorisation dossier**.
   a. Develop an efficient *communication strategy* within your supply chain!
   b. *Gather information* on uses, exposures, socio-economic data (to be provided earlier during the Public consultation of the prioritization step).

c. Assess your *own business strategy*:
    i. Assess the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures
    ii. Evaluate the costs and benefits to your business, industry, economy
    iii. Avoid over-estimation of the costs, the impact or the benefits.
    iv. Identify how to address the risk. Propose realistic combinations of RMO's.
d. Determine *who* will apply and *which uses* need to be covered. – check the list of uses exempted per se from Authorisation. http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
e. Prepare a SEA, look for and assess alternatives, substitution plan, etc.
f. Identify in-house experts or outsource expertise to elaborate your application.
g. *Check the application before submission*; it has to match your business reality, not be theoretical.
h. Your application has to be a *clear demonstration* of your case. Don't overcomplicate it. Remain logical and present it in a *structured* way.
i. The *clearer* your dossier is, the more chance your case will *be understood* by the authorities.

2) **Prepare your input for any possible alternative** you would like to propose as a third party during the public consultation.

More explicitly

1. Do *not miss any public consultation* period prior to the listing of the substance on Annex XIV. All information has to be provided during those fixed time periods (45 days for SVHC identification and 3 months for prioritization).
2. Once listed on the authorisation list (Annex XIV) and the application submitted, the 2 months public consultation will allow third parties to provide information on potential alternatives. As applicant, *prepare your argument* why the proposed *alternative* suits or not with the scope of your application. The following "trialogue" period, set up on request of the applicant, to exchange with the 2 ECHA Committees will take about 3 months. The last opportunity to interact is foreseen during the revision of the committee draft opinions.
3. Investigate whether you can *limit your use* of the targeted substances. Using potential alternatives should be carried out with the agreement of both customers and suppliers (fulfilling e.g. the technical/quality requirements).
4. *Assess* the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures.
5. *Evaluate* the costs and benefits to your business, industry, economy.
6. *Identify* the actors within your supply chain.
7. *Contact* the suppliers (particularly the manufacturer/importer of the substance or mixture) to ascertain if they are considering substitutes or the development of alternatives.
8. *Gather information* on uses and exposures. However, depending on the length and transparency of the supply chain, information on the precise conditions of use and information on potential alternatives are *often better known by the downstream users*.
9. *Communication* up and down the supply chain plays a *key role* in gathering relevant information for the authorisation application.
10. Identify as far as possible *who* in your supply chain will be applying for an authorisation and for which use(s).

11. *Contact the consortium or any working group established to prepare the authorisation application*.
12. Decide on your own substance *strategy* i.e. authorisation, substitution (or exemption) and how it fits with your sourcing/supply chain strategy.
13. *Collecting and generating data* (e.g. for use in the Socio-Economic Analysis (SEA)) is *resource intensive, time consuming* and costly. It is estimated that a SEA takes about 1 year to put together; gathering all data needed for the dossier will take a minimum of 2 years.
14. Due to CBI concerns and legal constraints (Refer to the Cefic document on – do's and don'ts – competition law), if combined actions provide benefits, *joint preparation* of the non-sensitive parts of application can be considered. Dossier completion and *submission* of the application to ECHA should take place *separately* on an individual company basis Some data may be available to registrants, manufacturers or other actors in the supply chain but not directly to the downstream user or end-user of a substance.
15. Some relevant information can be extracted from the *Chemical Safety Report* related to the threshold/non-threshold status, the DNELs and DMELs. It is highly recommended that all applicants use the *same references* to avoid choosing different authorisation routes or using different DNEL references to prove adequate control.
16. In order to beneficiate of the transition arrangement which will avoid market disruption between the sunset date and the decision date of the Commission, it is recommended to submit your application well before the latest application date. Moreover, application may be submitted within the submission window period proposed by ECHA for each Annex XIV substance. As *gathering all data* needed for the dossier will take a *minimum of 2 years*, it is highly recommended to *start* your preparations *as early as possible.*

Starting your SEA early is essential and should be part of the corporate/company decision-making process on whether to apply for authorisation or not.

Tips for Downstream Users

1. If you use an Annex XIV substance to *produce an article*, communicate your use upstream and check if your supplier has obtained an authorisation application number. If not, consider making your own application for authorisation of use.
2. An authorisation application submitted by a DU can only cover the DU's uses, the uses of "his" downstream supply chain (i.e. your customers, their customers etc), and only the "placing on the market of the substance" by his immediate supplier (i.e. one level up his supply chain). *A DU cannot cover other uses up his supply chain*.
3. When determining the date to *submit your application*, make sure you consider enough time (3 months) to get time to review your copy before the LAD in case the business rules check will not pass the first time. Therefore it is recommended to submit your dossier during the *submission window period* suggested by ECHA. Submitting just before the LAD will imply the check of the business rules after the LAD. In case of failure of the business rules check, you will not be able to take advantage of the transitional arrangements.
4. ECHA will start the assessment when receiving the *fees*.
5. Substitution of substances falling under the scope of authorisation is recommended for new developments if technically and economically feasible and available. Consider the hazard profile of the replacement substance in your assessment.
6. For existing products, if production containing the targeted substance is going to *cease prior to the sunset date*, substitution will not be necessary for that use.

7. For existing products, if production is going to *continue after the sunset date*, you will need to consider substitution of the substance requiring authorisation unless an authorisation for this specific use has been granted.
8. Consider the contractual requirements between you and your supplier. You may want your supplier to inform you about their intentions to authorise or substitute the Annex XIV substance.
9. Once authorisation is granted the *review period* may, in principle, be suspended at any time by the Commission for the following reasons: new information on potential alternative become available, changes in the assessment of the risk for human health or environment, use already banned in another legislation, etc.
10. A flexible strategy is needed in your business; do not entirely rely on the review period given as part of the European Commission's final decision.

Further information may be found on Cefic website under authorisation: http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

Glossary and acronyms

AfA
Application for authorisation
AoA
Analysis of Alternatives
Annex XIII
Sets out the criteria for the identification of PBT and vPvB substances
Annex XV dossier
A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report. The Annex XV dossiers submitted for inclusion in the registry of intentions are under one of the three decision-making processes: identification of SVHC substances, restrictions or harmonised classification and labelling.
Annex XIV
List of substances subject to authorisation.
Article
An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition
BIU
Broad information on uses
Candidate List
List of substance identified as being SVHC.
Competent authority
The authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;
Distributors
Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.
Distributors may not import from outside the EU or repack the substances or preparation.
DNEL
Derived No Effect Level (substance with a threshold)
DMEL
Derived Minimal Effect Level (substance without a threshold)
Downstream user
Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user.
EC

European **C**ommission

ECHA

European **Ch**emicals **A**gency

Importer

Any natural or legal person established within the Community who is responsible for import.

LAD

Latest application date. Any application for authorisation submitted and paid before the LAD will ensure market continuity while waiting for the Commission final decision. Any uses covered by an application (re-)submitted after the LAD will not benefit from the transitional arrangement. Uses have to stop after the sunset date.

LE

Legal entity is used to refer to such a natural or legal person having rights and obligations under REACH. (Details of legal aspects please refer to ECHA guidance on registration p20).

Manufacturer

Any natural or legal person established within the Community who manufactures a substance within the Community

MSCA

Member State Competent Authority (see above "Competent Authority").

PBT

Persistent, Bioaccumulative and Toxic substance

PSIS

Pre submission information session

RAC

Risk Assessment Committee (or Committee for Risk Assessment)

RMM

Risk Management Measure

RMO

Risk Management Option

RoI

Registry of Intention, available at ECHA website: http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions

SEA(C)

Socio-Economic Analysis (Committee)

Substance

Means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

SVHC

Substance of Very High Concern

Transitional arrangements

Period between the sunset date and the European Commission's decision to grant or refuse the authorisation.

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 utilization.

vPvB

Very Persistent, very Bioaccumulative substance
