How to Handle Substances LISTED on the Candidate List

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)[1] 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 on the Candidate List could be recommended for inclusion to Annex XIV (see also How to Handle Substances Listed on Annex XIV). This step is known as prioritization and is based on a series of criteria used to score and rank the substances. Substances on the Candidate List are generally reviewed on an annual basis to determine which ones should be selected for authorisation, although according to REACH Regulation (Art 58(3)), ECHA is only required to make such recommendation every second year.

Companies can organize themselves as soon as the substance is listed on the Candidate List by setting up a communication channel through the supply chain, both up and down and through the sector association, working group or consortium.

The focus of this fact sheet is to provide recommendations that companies may consider when substances are included in the Candidate List, namely complying with legal communication duties and gathering information for the potential prioritization and authorisation steps.

Internal Inventory of Chemicals

Companies should have a well maintained inventory of the substances they manufacture, import or use, in order to monitor for SVHC substances (targeted in the registry of intention or already listed on the Candidate List) and determine the relevance to their business. The Company's inventory can be further screened for substances that may be targeted for prioritisation and potentially subject to authorisation. The inventory should be *updated* twice a year when the Candidate List is officially updated (in January and in June each year).

Other considerations to take into account are the importance of the substance to the company or whether there are plans to phase out the use of the substance. This can reduce the number of chemicals subject to continual monitoring.

Legal obligations

Substances on the Candidate List trigger legal obligations for companies (DU, Importer, and Producer) (Art 33.1-2 and Art 7.2 REACH). Companies supplying articles have to fulfil their communication on safe use obligation to customers or consumers using their articles containing SVHC. Companies producing or importing articles have to notify ECHA of the

[1] Substances classified under the CLP regulation as carcinogenic, mutagenic, or reprotoxic to human health; substances which are persistent, bioaccumulative, and toxic to the environment; substances having endocrine disrupting properties; or substances of equivalent concern to those previously listed. REACH Art. 57.

presence of SVHC in the articles, unless the use of the SVHC in articles has already been covered in the registration dossier, or if no exposure to human or environment can be foreseen from that use.

Deadline:

- Upon update of the candidate list in January and June: company to ensure they *monitor* the Candidate List at these intervals each year.

- Within 6 months after inclusion on the candidate list:
  - Importers and producers of articles have the obligation to *notify* ECHA if SVHC substance is produced or imported at more than 1T/y and the concentration in the article is higher than 0.1% w/w. However, if the use of the SVHC in articles has already been covered in the registration dossier, or if no exposure to human or environment can be foreseen from that use, no notification by the article producer/importer needs to be submitted to ECHA.

- Within 45 days after the receipt of the consumers request:
  - Suppliers (DU) of articles have to provide the consumer with sufficient *information* to allow safe use of the article.

Information gathering

Substances on the Candidate List could be recommended for inclusion to the Authorisation list as part of the REACH authorisation process.
To allow a Company to be prepared in advance of this possible occurrence, an efficient *communication channel* needs to be set up through the supply chain, both up and down and through the sector association, working group or consortium, in order to gather information for submission during the next public consultation related to the prioritization exercise.

Gathering information on substance uses, exposure or release resulting from that use, availability of substitutes, socio-economic data, supply chain network and structure, etc.. is time and resource consuming => In any case, prepare yourself!!!! Time is ticking very fast!

Tips and recommendations:

In a nutshell

1) *Inventory* of your portfolio
2) Monitor ECHA website twice a year to *check* Candidate List updates
3) *Inform* your customers and/or consumers and notify ECHA where necessary
4) Prepare your *authorisation strategy*. Even if not prioritized at this time, it may occur and time to gather information and prepare the application will be very short!
   a. Develop an efficient communication strategy within your supply chain!
   b. Gather information on uses, exposures, SEA…. (all relevant information that can be provided during the Public consultation (PC) of the prioritization step if not already submitted during the first PC when Annex XV dossier was submitted).
   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. Identify how to address the risk. Propose realistic combination of RMO's.

iv. Identify resources to prepare a SEA, look for alternatives, prepare a substitution plan, etc…

d. In case of substance being added to the authorisation list, determine *who* in the supply chain will apply and *which uses* need to be covered. – check exemption list

More explicitly

1. Produce an *inventory* for all substances and uses in your business (check the SDS)
2. *Monitor* ECHA website twice a year to check the biannual update of the Candidate List.
3. Check the list of uses exempted *per se* from Authorisation.
   http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf
4. *Compare* and highlight those substances used by your business to those on the Registry of Intentions for SVHC identification, the Candidate List, ECHA's Annex XIV recommendations and Annex XIV itself (look at ECHA website). Substances included in the Candidate List will appear in your suppliers SDS 6 months after its inclusion on the Candidate List. *Check* the SDS.
5. *Article suppliers: Inform* your customers and/or consumers and *notify* ECHA where necessary
6. When a substance enters the Candidate List, as a DU, for threshold substances *provide information* to your industry associations on your use showing there is no risk handling this substance. For non-threshold substances, a demonstration of no exposure might contribute towards preventing prioritisation.
7. *Prepare your authorization strategy*. Even if not prioritized, it may occur and time to gather information and prepare the application will be very short!
8. Do *not miss the public consultation* period. All information has to be provided during the fixed time window. Next one is foreseen during the prioritisation process.
9. Investigate whether to *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).
10. *Assess* the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures.
11. *Evaluate* the costs and benefits to your business, industry, economy.
12. *Identify* the actors within your supply chain.
13. *Contact* the suppliers (particularly the manufacturer/importer of the substance or mixture) to ascertain if they intend to apply for authorisation and if they are considering substitutes or the development of alternatives.
14. *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.
15. *Communication* within the supply chain plays a *key role* in gathering relevant information for the application for authorisation
16. Identify as far as possible *who* in your supply chain will be applying for an authorisation. Have you communicated the importance of the substance for your use?
17. *Contact* the consortium or any working group established to prepare the authorisation application.
18. Decide on an individual basis only (taking into account the competition law rules) on your own substance *strategy* i.e. authorisation, substitution (or exemption) and how it fits with your sourcing/supply chain strategy.
19. *Collecting and generating data* (e.g. for use in the Socio-economic Analysis (SEA)) is resource intensive, time consuming and costly. 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. It is estimated that a SEA takes about 1 year to put together and gathering all data needed for the dossier will take a minimum of 2 years.

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.

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
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
