June 2013

How to Handle Substances Recommended for Prioritization for Inclusion to Annex XIV

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, SVHCs 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.

Before ECHA makes its recommendations to the Commission, ECHA publishes the draft recommendations for a 3-month public consultation. Based on the comments received, ECHA may update the draft recommendations which are provided to the MSC for further comment and agreement before the final recommendations are submitted to the European Commission. The European Commission has the final decision on the whether to include the substance on the Authorisation List (Annex XIV) and the determination of the sunset date.

If not already initiated, companies should organize themselves as soon as the substance is listed on the recommended prioritization list by *urgently* 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 proposed for prioritization by ECHA. This includes gathering information to explain uses, checking possible exemptions, describe the socio-economic situation and impacts of authorisation, how the exposure related to the use may be already under control (e.g. covered by other legislations), sector specific uses, etc.

Internal Inventory of Chemicals

Companies should have a well maintained inventory of the substances they manufacture, import, or use, in order to monitor for substances 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). Currently, the prioritization process is launched every year with a *public consultation scheduled from June to September*.

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[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.

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:

A substance selected for prioritization does not trigger additional obligations of the Candidate List substance.

Information gathering

Substances recommended for prioritization may, according to the outcome of the process (COM decision), be included on the REACH authorisation list (Annex XIV).

Parameters used for the prioritization selection are based on a two tiered approach.

- ⇨ Tier 1, a scoring approach will be used based on 3 criteria:
  - Intrinsic properties (PBT/vPvB) substances,
  - Wide dispersive use (number of sites where the substance is used and the type of release) and
  - Volume (tonnage per year supplied in the EU to uses in the scope of authorisation).
- ⇨ Tier 2, is the results of the scoring/ranking complemented by regulatory effectiveness considerations.

Since this is the last step before the decision is taken on whether to include the substance in the authorisation list or not, the related public consultation represents a very critical part of the process.

If not done so yet, it is time to speed up the process to gather information on uses, exposure, risk management measures, socio-economic status, etc…and to submit relevant information during the Public Consultation!

To allow companies to be prepared to react to the Public Consultation, an efficient *communication channel* needs to be set up through the supply chain, both up and down in order to gather information and be ready on time for the submission of the data.

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

1) Do not miss the *public consultation* period. This is your last chance to be heard before Annex XIV listing.
2) *Collect information* on uses and possible exemption(s). Downstream users can comment for example that some specific uses shall be exempted from authorisation or some uses need a longer review period.
3) Develop a *communication strategy* within your supply chain!
4) Contact your sector association to submit *harmonised data* during the public consultation.
5) *Gather information* on SEA, look for alternatives, substitution plan, etc., to help determine your business strategy.
6) Companies should be prepared to provide additional information in a *short timeframe*.
7) Identify *how to address the risk*. Propose realistic combination of *RMO's*.
8) Be sure your information will be submitted (by you, your association or working group) during the public consultation. Data considered to be confidential should be submitted with a *justification for confidentiality*.

9) *Submitted information* may cover uses (including data on exposures or releases resulting from the uses), the availability of safer alternative substances and techniques, the description of the structure of the supply chain and socio-economic information.
10) All information would be taken into account to determine the *review period* and the *sunset date* if the substance is subsequently added to Annex XIV.
11) Continue to build your *business strategy* in case of authorisation.
12) Determine *who* in the supply chain will apply and *which uses* need to be covered.
13) Consider that getting organized and *agreeing on a strategy takes time*!
14) Propose Use exemptions from authorisation where applicable

At each step, for each public consultation, the most effective method for commenting is via your industry sector groups, your trade association, at both National and European levels. They will consolidate the input from their member companies to submit to the authorities during the public consultation. *The earlier they receive this information the more effective the consolidated comments will be*.

Also refer to the recommendation list addressed in the Cefic paper explaining "How to Handle Substance LISTED on the Candidate List".

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

MSC

ECHA Member State Committee

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
