November 2012

How to Handle Substance Proposals for 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] by a Member State Competent Authority (MSCA) or by ECHA upon request of the European Commission. This is followed by preparation of an Annex XV dossier, which will be published on the ECHA website for a 45-day public commentary period.

Companies can prepare themselves by taking action before a substance is identified as an SVHC and included on the Candidate List. The focus of this fact sheet is to provide recommendations that companies may consider to prepare in advance for substances that may potentially be included, or proposed to be included, to the Candidate List.

Internal Inventory of Chemicals

Companies should have a well maintained inventory of the substances they manufacture, import, or use, in order to monitor the potential proposal of these substances as SVHCs subject to authorisation. This inventory can be further screened for substances that potentially meet Art. 57 criteria based on available information on the substances' intrinsic properties. The list should be updated at regular intervals as new information – either on corporate-relevant substances, or on SVHC intentions - become available.

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 substances subject to continual monitoring.

Keeping Track of potential future SVHCs

ECHA maintains a website of Registry of Intentions (ROI) for SVHC proposals.[2] This list allows stakeholders to see which substances have an Annex XV dossier under preparation. Although MSCAs are encouraged to notify ECHA of their intentions, many proposed SVHCs remain unknown until the Annex XV dossier is made available for public comment. As soon as the ROI is published, it can be beneficial to enter into contact with the authority working on the dossier to ensure the Annex XV dossier is accurate and up to date as much as possible, since once published, it is generally not updated.

There are also other lists, for example those developed under other regulations that may be monitored.

Keeping Track of SVHC Criteria Developments

Not all potential Candidate List substances are publicly listed; therefore, it is equally important to understand the criteria used for identifying an SVHC. Substances that are PBT, vPvB, or having endocrine disruptor properties or those that fall under "substance of equivalent concern" are not currently well-defined. Therefore, it is important to be vigilant of on-going activities where these criteria will be further discussed and refined.

---

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

[2] http://echa.europa.eu/web/guest/registry-of-current-svhc-intentions .

Questionnaires and Public Consultations ahead of SVHC proposals

Some Member States send out questionnaires and invite stakeholders to attend public meetings and provide early input. This is one opportunity to provide input on a substance that is under consideration for SVHC proposal and development of an Annex XV dossier. ECHA also sends out questionnaires to registrants via REACH-IT. Sometimes, the questionnaires are also circulated by sector and federal industry associations to their members.

When you receive these questionnaires:

- Verify source and purpose of the questionnaire.
- Consider providing as much information on the use of the substance as possible. Many of these questionnaires are aimed at understanding the hazards and exposure profile, and release patterns associated with uses of the substance throughout its life-cycle. They may help ensure accuracy of the Annex XV dossier, which becomes publicly available once published. Annex XV dossiers are typically not revised after the public consultation period. Information received indicating substance's uses will be considered for further exemption or prioritisation. For instance, intermediate uses are exempted from authorisation, however Annex XV dossier may cover other non-intermediate uses. If those uses, even if only minor quantities are concerned, are considered as wide dispersive, it is recommended to contact the authorities to assess the most efficient way to control the risk (determine the appropriate risk management option to apply).
- Consider whether to respond to the questionnaire as part of a group or consortium. One advantage to the group approach is to ensure consistency in the information provided to the regulators.
- Be careful with confidential information. Notify if the information you provide has to be kept confidential

Another opportunity to provide input on a substance is to consider a voluntary update of your registration dossier to provide the most accurate information on tonnages and uses, as Member States and ECHA will also base their best-RMO analysis on the data submitted via the registration process.

Annex XV Dossier Consultation for SVHC identification

The Annex XV dossier is used as the basis for identification of a substance as an SVHC. Other types of information included are substance identity and intrinsic properties, use information down the supply chain, and availability of alternatives. Although the Annex XV dossier contains all this information, the only factor used to determine whether a substance will be included to the Candidate List is relevant substance intrinsic properties. The additional information on uses, release patterns, and alternatives are used to prepare the next phase of the authorisation step, prioritising a substance on the CL for possible inclusion to Annex XIV.

Consider whether to submit comments during the public consultation period for the Annex XV dossier. When there is harmonized classification, there is no dispute on the intrinsic properties. However, there are several reasons to provide comments. When harmonized classification is not yet available, there are some consultations on proposed classification within SVHC issues.

When commenting on the Annex XV dossier, consider whether to respond to the comments as part of a consortium or via a sector association. Since there are only 45 days to respond, planning ahead of time is key to ensuring that all relevant comments are compiled. Specific subject matter expertise may be required to review and provide input on each part of the document. This may include:

- People with expert knowledge of your process and understanding of availability of alternatives (both substance and process),

- People who knows the use of the substance up and down the supply chain. This can be the most challenging. The better you understand how a substance is released to the environment or used, the better you can support arguments on whether there is wide-dispersive use, or whether there is significant human exposure to the substance during use,
- Toxicologists and Risk assessors,

Planning ahead is the key to be able to provide a rapid response. Even though there are only **45 days** to comment on the Annex XV dossier, there are many things you can already do even before the Annex XV dossier is published.