ECHA's strategy to support registrants in applying the REACH Annex III criteria

REGULATORY BACKGROUND

Under REACH, companies that manufacture or import a substance at or more than one tonne per year, need to document the properties and uses of their substances and demonstrate that the substances can be used safely in a registration dossier submitted to ECHA.

For each tonnage band, REACH defines the minimum information that registrants have to provide on the intrinsic properties of the substance. The information requirements are tiered, since the potential exposure increases with volume.

For the lowest tonnage level, the standard information requirements are defined in Annex VII, and when a new tonnage level is reached, the requirements of the corresponding annex have to be added. Annex VII is, itself, divided with:

- Information on physicochemical properties required for all 1-10 tonnes/year substances (Annex VII, section 7); and

- Information on toxicological and ecotoxicological properties, (Annex VII, sections 8-9).

To try to reduce the necessary testing on low volume phase-in substances where there is no predicted risk, Annex III was introduced in the REACH Regulation in the first reading of the European Parliament in 2005.

As a result, Annex VII, section 8-9 information is only required for phase-in 'priority substances' that meet the criteria of Annex III. In other words, toxicological and ecotoxicological information is required in the registration dossier if it is predicted, for example, by the application of (Q)SARs or other evidence that a substance is likely to meet the criteria for:

- category 1A or 1B for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity; or

- criteria in Annex XIII (identification of persistent, bioaccumulative and toxic susbtances, and very persistent and very bioaccumulative substances);

or substances:

- with dispersive or diffuse uses particularly where such substances are used in consumer mixtures or incorporated into consumer articles; and

- for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under the CLP Regulation ((EC) No 1272/2008).

If potential registrants can demonstrate that their substance does not fulfil any of the above criteria, the standard information requirements are restricted to all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrants and as a minimum the physicochemical endpoints in Annex VII, section 7. Annex III is not applicable to non-phase in substances (i.e. full Annex VII information set needs to be submitted).

However, demonstrating that a substance is unlikely to meet the Annex III criteria is known to be resource-consuming and also requires considerable expertise on interpreting (Q)SARs and other potential evidence. Therefore, through this strategy ECHA aims to advise and help the low tonnage registrants, including many SMEs, to execute their duties as intended by REACH.

Moreover, ECHA aims to support registrants to help them avoid mistakes when applying the Annex III criteria, such as referencing to an inappropriate (Q)SAR application. The activities are described in detail below.

INVENTORY OF SUBSTANCES LIKELY TO MEET THE ANNEX III CRITERIA

To limit registrants' efforts in considering whether their substance meets the Annex III criteria or not, ECHA will generate an inventory of substances for which there is evidence that they would possibly fulfil these criteria.

The inventory will contain substances that are known for their carcinogenic, mutagenic and reprotoxic (CMR), persistent, bioaccumulative and toxic (PBT)/very persistent, very bioaccumulative (vPvB) properties, or any other health or environmental hazard classes as deduced from Annex VI to the CLP Regulation and from publicly available experimental databases.

In addition, predictions generated by a selected set of publicly available (Q)SAR models, for example, the alerts in the OECD QSAR Toolbox, and other tools will be used. The entries in the inventory will be indicative and serve as a guideline to registrants for those specific substances. The list will not be exhaustive.

If a substance features in the inventory, potential registrants will most likely need to generate full Annex VII data for their registration dossier. However, it should be noted that, registrants will be able to deviate from the indicative result presented in the inventory if they can justify it in their dossiers.

The first version of the inventory will be published in the second half of May 2016. For the evidence collected from predictions and experimental data, ECHA focuses on those substances that are pre-registered, and have not been registered yet.

The inventory may be updated if ECHA gathers evidence on more substances. The number of entries is estimated to be in the range of thousands (approximately 70000 entries).

TEMPLATE FOR JUSTIFICATIONS FOR NOT MEETING ANNEX III CRITERIA

Companies who want to demonstrate that their substance is not meeting the Annex III criteria will be able do so by using a specific template in IUCLID when building their dossier. In other words, the template will be relevant only for registrants that intend to register a substance providing only physicochemical data.

The rationale of the template is that the registrants are guided step-by-step through a checklist on the different possibilities for a substance falling under Annex III so that they can decide on the applicability of its criteria to their substance. For each block of questions of the checklist, registrants will be able to justify their conclusion with a free text explanation and by attaching supporting documents.

The template will be a new IUCLID section published with IUCLID 6 in Q2 2016.

SUPPORT MATERIAL

ECHA will develop support material outlining an effective workflow for companies to consider Annex III in the context of their registration and advice on how to use the inventory, including illustrative examples. The support material will include a dedicated web page on ECHA's website, and will be published at the same time as the inventory.

In addition, as part of the REACH 2018 Roadmap activities and particularly phase 4 'Assess your hazard and risk' of the Roadmap, further SME-oriented support is being considered. The launch of phase 4 is scheduled for Q3 2016.

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