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General prioritisation approach: practical implementation examples

ECHA has the obligation to recommend substances included in the Candidate List for inclusion in Annex XIV (Article 58 of REACH).

The Candidate List substances are assessed against the criteria set out in Article 58(3) of REACH to determine in which order they should be recommended for inclusion in the Authorisation List (Annex XIV of REACH). To this end ECHA applies the general approach for prioritisation of substances discussed with, and agreed by, the Member State Committee (MSC). The approach is available at:

http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf.

In the paragraphs below, some examples are provided to indicate how certain aspects of that approach are implemented in practice.

Wide-dispersiveness of uses (WDU) score: assignment in cases of unconfirmed uses, minor uses, or article service life

According to the revised prioritisation approach, the WDU score is assessed considering three use/actor types (industrial (IND), professional (PROF) and consumer (CONS)) that determine the score (5, 10, or 15 accordingly); with the highest applicable score assigned[1]. The WDU score is refined if volume per use information allows this.

In addition, if registration data or other relevant information demonstrates that the substance ends up in articles and that there is no reliable information that releases are unlikely during article service life and waste phase, the approach states that the presence in articles can as well be taken into account to refine the WDU score.

In practice, the following two-step approach has been used to assign scores for WDU.

First, an initial WDU score has been derived taking into account the actors (IND / PROF / CONS) for which there is sufficiently reliable information that uses by the respective actors in the scope of authorisation occur in the EU (considered as 'confirmed'). However, the higher categories (PROF and CONS) were assigned in this first step only when the 'confirmed' use in this category was $\geq$ 10 t/y[2] or where the volumes used by different types of actors were unknown.

[1] The highest applicable WDU score is assigned, e.g. score is 15 if the substance has a consumer use(s); the score is 5, if the substance has industrial use(s) but no professional or consumer uses. The WDU score is 0 if no uses in scope of authorisation seem to occur in the EU

[2] Or $\geq$1t/y if the total volume in the scope of authorisation was <10t/y

At the second step, the score has been refined, where relevant, to take into consideration tonnage information indicating minor use, article service-life, and uncertain uses as follows[3]:

Minor uses:

In case a substance would be assigned to a certain category (actor) because of CONS or PROF use(s) and it is known that the respective use(s) corresponds to a very low volume[4] (i.e. < 10 t/y) and that most of the volume is used in a lower-score category, a score half-way between the two categories (and rounding down to the nearest whole number) has been assigned.

For example, for a substance with both IND and PROF uses, but PROF corresponding to a very low tonnage (< 10 t/y):

Initial score=5 (IND); Refined score= 7 (IND+minor PROF)

Article service life

If a substance without consumer uses in the scope of authorisation ends up in articles and there is no reliable information that releases are unlikely during article service life and waste phase, the WDU score has been added with 1 or 2 points depending on the total volume of the substance that can be assumed to be present in articles produced in the EU. If the total tonnage in articles is > 10 t/y or unknown, 2 points were added to the initial WDU score. If the tonnage was < 10 t/y, only one point was added.

For example, a substance with both IND and PROF uses, which is in addition used in articles in volumes >10 t/y (and assuming that the release from those articles is not considered negligible):

Initial score=10 (PROF); Refined score=10+2 =12 (PROF+article service-life)

Uncertain uses

If there were indications that a substance may be used by certain type of actors (IND/PROF/CONS) in uses in the scope of authorisation but it was not possible to conclude it from the available information with high enough certainty, then a score half-way between the confirmed actor and the unconfirmed actor (and rounding down to the nearest whole number) has been assigned. The same approach of half-way score has been applied for uncertain article service-life; i.e. if there were some indications that a substance is used in articles but it was not possible to confirm it with high enough certainty, only one point (instead of two) was added to the initial WDU score.

For example, a substance registered only for IND uses for which there are indications that it might (based on contradictory information in registration or further use

[3] In case more than one refinement scenarios were relevant, only that refinement was applied which would lead to the highest score, i.e. no more than one refinements were applied to increase the WDU score

[4] The description 'very low volume' (<10 t/y) is the same as used when categorising volumes (see section 5.2 of the prioritisation approach)

information from other reliable[5] source) also be used by professional workers in uses that are in the scope of authorisation but it was not possible to conclude it with high certainty:

Initial score=5 (IND); Refined score= 7 (IND+uncertain PROF)

Interpretation of registration data in cases of contradicting or unclear information

Unless there was justified reason to doubt the validity of the registration information, e.g. due to contradicting information, the registration data was used as the basis for the priority assessment.

The main uncertainties for the priority assessment resulting from the contradicting or unclear information were related to i) is the use in the scope of authorisation, ii) which is the actual actor / life cycle stage (IND/PROF/CONS/ASL) relevant for an identified use, or iii) which is the actual break down of volume to uses in/outside the scope of authorisation. In such cases, a weight of evidence approach was followed for assigning the score.

For example, if based on the available description in the registration dossier a use appeared not to be use as intermediate although claimed as such, it was counted (for assigning volume and WDU score) as a use in the scope of authorisation. Accordingly, if no article service life was reported in registration despite the fact that the use of the substance clearly results in inclusion on an article, then the article service life was taken into account for scoring.

Similarly, uses reported in the registration dossiers which are banned in accordance with Annex XVII entries were not considered when assigning priority scores. For example, the use of a CMR Cat 1A/B substance on their own or in mixtures in consumer product reported in a registration dossier has not been considered as a justification of WDU score 15. In some cases it could be assumed that the use in mixtures supplied to consumers is below the relevant concentration limit and, therefore, not restricted and not in the scope of authorisation (as the same concentration limits apply). Even if the use was in breach with a restriction, it would not be taken into account for prioritisation as such a case should be subject to enforcement.

[5] See section 4. of the current prioritisation approach for information on reliability criteria applied for information not coming from registration dossiers (http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)