

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 agreed with the Member State Committee (MSC). The approach is available at:

https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf

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

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

According to the 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 assigned¹. 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 can be considered negligible 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 is used to assign scores for WDU.

First, an initial WDU score is 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) are assigned in this first step only when the 'confirmed' use in this category is ≥ 10 t/y or where the volumes used by different types of actors are unknown².

At the second step, the score is refined, where relevant, to take into consideration tonnage information indicating minor use, article service life, and uncertain uses as described further below. In case more than one refinement scenario is relevant, only

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 ≥ 1 t/y if the total volume in the scope of authorisation is < 10 t/y

that refinement is applied which leads to the higher score, i.e. only one refinement is considered.

Please note further that the maximum WDU score is 15. For example, a WDU score of 15 is assigned for a substance with confirmed CONS uses even if in addition release from articles is assumed.

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 volume³ (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) is 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 = 5 + 2 = 7 (IND + minor PROF)

Article service life (ASL)

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, 1 or 2 points are added to the WDU score 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 are added to the initial WDU score. If the tonnage is <10 t/y, only one point is added.

For example, for 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 considered not negligible):

Initial score = 10 (PROF); Refined score = 10 + 2 = 12 (PROF + ASL)

Uncertain uses

If there are indications that a substance may be used by certain type of actors (IND/PROF/CONS) in uses in the scope of authorisation but it is 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) is assigned. The same approach of half-way score is applied for uncertain article service life, i.e. if there are some indications that a substance is used in articles but it is not possible to confirm it with high enough certainty, only one point (instead of two) is added to the initial WDU score.

³ The description 'very low volume' (<10 t/y) is the same as used when categorising volumes (see Section 5.2 of the prioritisation approach)

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 information from other reliable⁴ sources) also be used by professional workers in uses that are in the scope of authorisation but it is not possible to conclude it with high certainty:

Initial score = 5 (IND); Refined score = 5 + 2 = 7 (IND + uncertain PROF)

See also the next section regarding the scoring in cases when it is assessed as not being possible to conclude on a specific score with high enough certainty and consequently a range is assigned.

2. Interpretation of registration data in cases of contradicting or unclear information

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

The main uncertainties for the priority assessment resulting from the contradicting or unclear information are 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 is followed for assigning the score.

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

Similarly, uses reported in registration dossiers which are restricted in accordance with Annex XVII entries are not considered when assigning priority scores. For example, the use of a CMR Cat 1A/B substance on its own or in mixtures in consumer products reported in a registration dossier is not considered in the priority assessment (i.e. WDU score of 15 for CONS uses is not given). 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). However, even if the use was in breach with a restriction, it

⁴ See section 4. of the prioritisation approach for information on reliability criteria applied for information not coming from registration dossiers (https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf)

is not taken into account for prioritisation since such a case should be subject to enforcement.

In case of contradicting or unclear information where it is assessed as not being possible to conclude on a score with high enough certainty, scores can also be assigned as a range to reflect the uncertainty. For example, if based on sources of comparable reliability the volume could be in the low or medium range⁵, a volume score of 6 to 9 can be assigned. In such cases a middle value for the total score is derived by rounding up to the next full number, e.g.

Inh. property score:	1
Volume score:	6 – 9
WDU score:	5
Total score:	12 – 15
Middle value (round up):	14

3. Grouping in the prioritisation assessment

As described in Section 6 of the prioritisation approach, in addition to the scores for inherent property, volume and wide-dispersiveness of uses further considerations can be taken into account to decide on which substances to include in a given recommendation.

One aspect of these further considerations is grouping of substances. This means that within the priority assessment a substance can be grouped with other not yet recommended substances on the Candidate List, or substances already recommended or included in Annex XIV. The aim is to avoid replacing high-priority Candidate List substances by other Candidate List substances that are (currently) of lower priority.

Such grouping can be applied to substances with similar structure and common uses unless reliable information is available showing that substitution is technically not possible in those uses. Therefore, the assumed interchangeability is not based on proof that replacement can or will happen in practice, or that it is economically feasible. Furthermore, as such grouping within the priority assessment takes account of the technical possibility to interchange substances in (some of their) uses, it can also be applied to substances not registered for the use the grouping is based on, or even to non-registered substances based on information from other sources than registrations.

⁵ See categorisation as described in the prioritisation approach