ECHA
EUROPEAN CHEMICALS AGENCY

# Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)

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# 1. Introduction

Recommending substances from the Candidate List for inclusion in Annex XIV (Authorisation List) is an integral part of the authorisation process described in Title VII of REACH. Prioritisation of Candidate List substances as part of the recommendation step is necessary to define in which order substances should be included in Annex XIV.

Article 58(3) of REACH sets out that priority shall normally be given to substances which meet one of the three criteria specified in that article. From this wording it is clear that on the one hand not all three criteria need to be fulfilled and on the other hand that the three criteria for prioritisation are not exclusive and that a substance may be prioritised for the recommendation for other reasons. However, if prioritisation is based on other factors than those listed in Article 58(3) the reasons for prioritisation must be clearly set out and be in line with the role and purpose of the recommendation step in the authorisation process. Moreover, in prioritising substances for the Annex XIV recommendation account has to be taken of the Agency's capacity to handle applications for authorisation in the time provided for. It is noted that there is no provision in the REACH legal text on how the prioritisation should be done in practice, e.g. with respect to weighting or scoring of the criteria.

This paper presents an updated prioritisation approach[1]. It describes prioritisation in the context of authorisation and sets out the principles of an updated approach. The main focus is on the description and discussion of the Article 58(3) criteria but reference is also made to other considerations to be taken into account in the prioritisation.

# 2. Prioritisation in the context of authorisation

The authorisation procedure aims to progressively replace substances of very high concern (SVHC) by suitable alternatives as soon as technically and economically feasible. Until substitution is achieved authorisation aims to ensure the good functioning of the internal market while assuring that risks arising from SVHCs are properly controlled.

Substances identified as meeting the SVHC criteria are included in the Candidate List for eventual inclusion in Annex XIV (Art. 59(1) of REACH). ECHA prioritises substances from the Candidate List to determine which ones should be included in the Authorisation List (Annex XIV of the REACH Regulation) as a priority. ECHA is required to submit recommendations at least every second year. The European Commission decides, assisted by the REACH Committee, which substances are to be included in the Authorisation List.

It needs to be emphasised that any substance on the Candidate List can be included in Annex XIV. In any particular prioritisation round, the relative priority assigned to a substance needs to be seen in the context of that particular round. A lower priority does not mean that the substance is 'deprioritised'. In subsequent prioritisation rounds, each substance that is not

[1] The description of how the prioritisation was done in 2009 is available at ECHA's website (http://echa.europa.eu/documents/10162/13640/gen_approach_prioritisation_en.pdf.
The prioritisation approach used from 2010 to 2013 can also be found at ECHA's website http://echa.europa.eu/documents/10162/13640/axiv_prioritysetting_general_approach_20100701_en.pdf). This approach was developed before the first registration deadline. As already anticipated in that document (p. 3), a review may be made once registrations are available and some experience on the kind and quality of data available in these registrations has been gained.

already included in Annex XIV will be reassessed, taking into account any new information relevant for the prioritisation.

According to Article 58(3) and Recital (77) of REACH, the number of prioritised substances needs to on the one hand, reflect the capacity of ECHA and the Commission to handle applications in the time provided for but on the other hand to also consider workability and practicality for applicants preparing their applications for authorisation.

According to Article 58(3), priority shall normally be given to substances with

(a) PBT or vPvB properties, or

(b) wide dispersive use, or

(c) high volumes.

It is clear from this wording that these three criteria for prioritisation are not exclusive and that a substance may be prioritised for the recommendation for other reasons. However, in such cases the reasons for prioritisation must be clearly set out and be in line with the role and purpose of the recommendation step in the authorisation process.

The primary basis of the prioritisation is the Article 58(3) criteria. Further considerations on which substances are to be recommended for inclusion in Annex XIV take into account other substances already recommended or included in Annex XIV, in particular the potential interchangeability of substances in (some of) their uses. Other on-going regulatory risk management activities can also be considered when deciding on which substances to include in a specific recommendation. This is to avoid undesired interference between different regulatory actions. However, other potential risk management options and whether they could be more appropriate than the authorisation requirement are not analysed during the prioritisation step. The final conclusion on priority should be drawn based on the assessment of the Article 58(3) criteria and consideration of additional aspects relevant for the recommendation.

The assessment of priority needs to be performed on a substance-specific basis. This is because inclusion in Annex XIV is per substance and not per use. In particular with regard to criterion b) of Article 58(3) ('wide dispersive use'), it is important to remember that all uses of a substance in the scope of authorisation need to be assessed.

It needs to be kept in mind that authorisation aims in particular at the proper control of risks from SVHCs and their subsequent substitution (the latter, at least in the long term). Risks need to be properly controlled until this objective, substitution, is achieved. Demonstration of the proper control of risk lies with the manufacturers/importers/downstream users. When developing and applying a prioritisation approach it needs to be ensured that the burden of proof placed on industry for providing data and adequate assessment to ensure safe use of chemicals is not shifted back to authorities.

Prioritisation is not the appropriate process for the assessment of the risks and/or exposure of a substance as a whole or, of the risks and/or exposure exerted by a particular use at a particular site/in a particular sector. According to Title VII REACH it is the subsequent step of the authorisation process, i.e. the application for authorisation phase, in which information associated with a particular use and a particular legal entity needs to be assessed. At the applications phase there is a requirement for the applicant to provide adequate data regarding exposure and risks. Similarly, the availability and suitability of alternatives or socio-economic considerations cannot be taken into account within the prioritisation but are considered, based on the information provided by the applicants, in the opinion and decision making within the

application for authorisation process. Therefore, the assessment of the wide dispersiveness of the uses is limited to a general evaluation of the use pattern and exposure potential that a substance may have.

**Summary**

The purpose of the prioritisation is to recommend the substances on the Candidate List in such an order that the more relevant substances are included in Annex XIV before less relevant substances. The approach used for prioritisation needs to differentiate sufficiently among all Candidate List substances to allow for that purpose, however it does not aim to set a "correct order".

The prioritisation is based on the criteria mentioned in Article 58(3) of REACH. The final conclusion on priority takes further considerations into account. However, any further considerations must be clearly set out and be in line with the role and purpose of the recommendation step in the authorisation process.

# 3. Principles of the updated approach

The following requirements were considered for the updated prioritisation approach:

General:

- Information needed for prioritisation should generally be available in registrations[2].
- Enhance transparency and predictability, in particular for stakeholders.
- Ensure consistent assessment across the substances and their uses.
- Aim for required level of assessment of priority keeping in mind the role of prioritisation, i.e. no exposure or risk assessment (see Chapter 2).
- The approach needs to be implementable in practice and it must be capable of addressing a high number of substances. The amount of resources required to implement the approach should be proportionate to the purpose of prioritisation.

Content:

Take account of new cases, such as substances identified as SVHC on the basis of Article 57(f).

[2] Registration is a legal obligation for the relevant actors in the EU. This registration obligation includes standard requirements related to *inter alia* uses and volumes and requires registrants to report information correctly and to update it in due time if necessary, i.e. the registrant is responsible for the accuracy of the registration data. The information generated under the registration obligation is used to support other REACH processes.

# 4. Data sources, quality of registration data and consequences

Registration data are the main source of information for the prioritisation assessment and industry is advised to provide all relevant data directly in registrations. When relevant, classification and labelling notifications, downstream user reports and PPORD notifications can be used as additional data sources for assessing the priority of substances.

Further information can be derived from Annex XV SVHC dossiers and public consultations. The reliability of such further information is assessed based on the following factors:

- ✓ the actual source of the information, e.g. regulatory bodies, national registers, actors involved in supply chain
- ✓ the degree of representativeness for the EU situation
- ✓ the time period it reflects
- ✓ the quality of the data, e.g. methodology used to generate the data

For substances for which the data required for prioritisation are available (in sufficient quality) in the registration dossiers, the assessment is based on these. In case data are lacking, contradicting or of poor quality[3], then realistic worst case assumptions are used. Consequently, missing data does not mean that a substance cannot be assessed for its priority.

Therefore, attention should be paid to the fact that the quality of the underlying data will always affect the prioritisation results regardless of the actual approach used.

# 5. Assessment of the Article 58(3) criteria

The aim of the prioritisation assessment is to assess the relevant information in an integrated manner to conclude on the priority of a substance in a given recommendation round. Generally it needs to be kept in mind that any prioritisation approach is a convention on how to use the information chosen to be the basis for assessing a particular criterion. Although such an assessment can be science-based the actual scoring and weighting of the combined criteria cannot be done by scientific justification but is rather based on expert judgement and agreement among those applying it and using the results obtained. The same applies to the definition of the various categories given for each Article 58(3) criterion, e.g. the tonnage ranges of the volume criterion.

The categorisation and scoring for each Article 58(3) criterion are given in the following sections. The assessment should always include a verbal description which illustrates why a particular score has been allocated. The categories presented per criterion are always given in qualitative and quantitative terms which should be used in parallel for the verbal and the scoring assessment.

[3] Poor quality of data can relate to various shortcomings in registration dossiers, for example, use descriptions being too generic or very scarce, an inconsistent or conflicting assignment of use descriptors or claim of an intermediate use although the definition of REACH Article 3(15) appears not to be fulfilled.

Scores on individual criteria and total scores can be seen as 'labels' allowing an easier comparison between different substances than verbal description alone. However, these numerical scores are based on the same information and assessment as the verbal descriptions and are not more or less exact or reliable than the verbal description.

All three Article 58(3) criteria get the same maximum score, i.e. all three have the same relative maximum weight.

## 5.1. Inherent properties

The legal text requires giving priority to substances with PBT or vPvB properties, therefore PBT/vPvB substances get significantly higher priority (i.e. score) compared to non-PBT substances. To reflect the current focus on concerns related to substances having endocrine disrupting (ED) properties, these properties get a medium score.

The different categories for the inherent property criterion are given according to the respective Article 57 property that the identification of a substance as SVHC is based on.

The inherent property score is assessed as follows:

| **Inherent property** | **Category** | **Score** |
|---|---|---|
| *57(a) or/and 57(b) or/and 57(c) or/and 57(f)* [4,5] | low | 1 |
| *57(f) (ED)* | medium | 7 |
| *57(d) or (e)* | high | 13 |
| *57(d) and (at least) one other SVHC property* | high | 15 |
| *or* | | |
| *57(e) and (at least) one other SVHC property* | high | 15 |

The highest relevant score is always given, e.g. a carcinogenic substance also being identified as having endocrine disrupting properties, i.e. fulfilling Article 57(a) and 57(f) (ED), gets an inherent property score of 7.

## 5.2. Volume

The annual volume used in the scope of authorisation is taken as the basis for assessing this criterion[6].

The volume score is assessed as follows:

[4] 57(f) in this category relates to substances not being endocrine disruptors.
[5] In case of PBT-like substances identified under Article 57(f), these should be considered in the PBT score.
[6] Please refer to http://echa.europa.eu/documents/10162/17232/generic_exemptions_authorisation_en.pdf for a list of uses specifically exempted from the authorisation requirement.

| Tonnage | Category | Score |
|---|---|---|
| *no volume* | zero | 0 |
| *<10 t/y* | very low | 3 |
| *10 to <100 t/y* | low | 6 |
| *100 to <1,000 t/y* | medium | 9 |
| *1,000 to <10,000 t/y* | high | 12 |
| *≥ 10,000 t/y* | very high | 15 |

In addition to the score there should be a verbal description illustrating how the score was derived.

## 5.3. Wide-dispersive use

The wide dispersiveness of uses is primarily assessed based on the types of actors which are relevant for the use of a substance. There are three main use types: industrial (IND), professional (PROF) and consumer (CONS) uses.

These main types are described as follows[7,8,9]

- ***Industrial use (IND)****: Application of the substance as such or in a mixture in an industrial process with the purpose of incorporating the substance into an article, or technically supporting the production process but not intentionally becoming part of the product (processing aid). As a result of the use the substance has reacted, or become part of an article, or it has been released, and/or is contained in waste from this use. Uses are carried out at industrial sites (small or large).*

- ***Professional use (PROF)****: Application [...] in skilled trade premises. Professional use may include the use of substances as such or in mixtures, in order to deliver services to business or private customers. This may include sophisticated equipment and specialised, trained personnel. Uses by professional workers are considered to take place in a wide-dispersive manner. Compared to the use at single industrial sites, wide dispersive uses take place everywhere (corresponding to a municipal structure) by multiple actors each at low scale. The risk management capacity of the single actor is low, e.g. there is no site-based technical infrastructure to control releases.*

- ***Consumer use (CONS)****: includes the use of substances as such or in mixtures carried out by consumers leading to dispersive uses. It is assumed that the user is not trained. Use can take place in closed systems (lubricants for vehicles or hydraulic systems) or open systems (lubricants for bicycles). It may also include processing of material.*

[7] Guidance on information requirements and chemical safety assessment, Chapter R.14: Occupational Exposure Estimation, ECHA, Version 2.1, November 2012.
[8] ECHA IUCLID 5 End-user manual on ECHA's website (2013)
[9] In the guidance on occupational exposure estimation there is a note stating that it is not always easy to choose between 'industrial' and 'professional' use. Although in many cases this choice is clear, there are some situations in which the difference may not be obvious, e.g. spray painting in a car repair shop, repair and building work at industrial sites and work in a small 'wood working factory'. Reference is made to the ECETOC Report 107 for more information.

In general, it can be assumed that the control of releases and the wide-spreadness of a use are inversely proportional in relation to the use type, i.e. moving from consumer to professional to industrial uses, the expected control of releases increases and the expected wide-spreadness decreases, i.e. the wide dispersiveness of a use decreases:

| | | |
|---|---|---|
| Generally | → Release control: | **CONS < PROF < IND** |
| | → Wide-spreadness: *i.e. number (and distribution) of sites* | **CONS > PROF > IND** |

It is acknowledged that these assumptions are simplistic and coarse. Specific use situations can vary widely in particular for industrial uses but also for professional uses. Therefore, this can only be used for a general categorisation of the use types, for example in such an assessment as needed for prioritisation purposes.

According to Annex XVII REACH the use of CMRs as substances, constituents of other substances or in mixtures[10] for supply to the general public is banned. Therefore, the CONS score can normally be applied only to non-CMRs. However, if registration data or other relevant information demonstrate 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, this can be taken into account in assigning the WDU score. In such case (which applies for any substance, not only for CMRs) a score between 5 and 15 can be considered, depending on the specific situation and the available information (see also Section 5.3.1 below).

The use type is mandatory information in registrations. The registered uses must be structured in Section 3.5 of IUCLID "Life cycle description" as follows: formulation, uses at industrial sites (IND), uses by professional workers (PROF), consumer uses (CONS). Formulation is covered by industrial use for the purpose of prioritisation[11].

The highest applicable score is always assigned, e.g. if there are professional and industrial uses, the PROF use score is applicable.

The WDU score is assessed as follows:

| **Use type** | **Category** | **Score** |
|---|---|---|
| *no use* | zero | 0 |
| *IND* | low | 5 |
| *PROF* | medium | 10 |
| *CONS* | high | 15 |

In addition to the score there should be a verbal description illustrating how the score was derived.

[10] When individual concentration in the substance or mixture is equal to or greater than either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or the relevant concentration specified in Directive 1999/45/EC.

[11] It is noted that the conditions under which formulation could take place can vary widely as it could at times also be done by professionals. Similarly there might be situations where the level of control is high for a professional use compared to an industrial application. However, generally formulation takes place at industrial sites therefore that life cycle step is considered to be covered by IND.

### 5.3.1. Possible further refinement if required information is available

The WDU score can be refined if the quality of registration data, in particular volume per use information, or data from other reliable sources[12] allow such.

In case a substance would be assigned to a certain category because of a single CONS or PROF use and it is known that the respective use corresponds to a very low volume (i.e. < 10 t/y) and that most of the volume is used in a lower-score category, a more balanced score could be considered by assigning a score between the two categories. For example, for a substance with both IND and PROF uses, but PROF corresponding to a very low tonnage (< 10 t/y), the score to be assigned could be between five and ten, e.g. seven.

As mentioned in the previous section, if a substance without consumer uses ends up in articles and there is no reliable information that releases are unlikely during article service life and waste phase, this can lead to an increase of its WDU score, too.

In any such cases of further refining the WDU score the verbal description is of particular importance to transparently and comprehensibly describe the reasoning for a given score.

## 5.4. Overview of scoring for each criterion

The table below shows a summary of the three criteria, their ranges and the respective scores.

**Table 1 Overview of scoring and ranges for each criterion**

| Inherent properties | | Volume | | Wide dispersive use | |
|---|---|---|---|---|---|
| 57(a) or/and 57(b) or/and 57(c) or/and 57(f) [13,14] | 1 | no volume | 0 | no use | 0 |
| 57(f) (ED) | 7 | < 10 t/y | 3 | IND | 5 |
| 57(d) or 57(e) | 13 | 10 – <100 t/y | 6 | PROF | 10 |
| 57(d) and (at least) one other SVHC property or 57(e) and (at least) one other SVHC property | 15 | 100 – <1,000 t/y | 9 | CONS | 15 |
| | | 1,000 – <10,000 t/y | 12 | | |
| | | ≥ 10,000 t/y | 15 | | |

[12] Please refer to Chapter 4 for reliability considerations regarding information from other sources than registrations.
[13] 57(f) in this category relates to substances not being endocrine disruptors.
[14] In case of PBT-like substances identified under Article 57(f), these should be considered in the PBT score.

### 5.5. Total score

The individual scores are added to the total score as follows:

$$\mathbf{Score_{Total} = Score_{Inh\ prop} + Score_{Volume} + Score_{WDU}}$$

with

| | | | | |
|---|---|---|---|---|
| Score [min – max]: | [1 – 45] | [1 – 15] | [0 – 15] | [0 – 15] |
| Relative maximum weight (%): | | 33.3 | 33.3 | 33.3 |

## 6. Further considerations to be taken into account

As described in Chapter 2, further considerations can be taken into account for the final conclusion on which substances to recommend for inclusion in Annex XIV. Such further considerations could relate to other substances already recommended or included in Annex XIV, in particular the potential interchangeability in (some of) their uses. Other on-going regulatory risk management activities can also be considered when deciding on which substances to include in a specific recommendation. This is to avoid undesired interference between different regulatory actions.

The above mentioned considerations are based on specific examples derived from existing cases. There could be situations in which other additional aspects not mentioned above need to be considered in order to arrive at a well-founded recommendation. These further considerations can be very varied and need to be taken account of on a case-by-case basis.

In any case, any further considerations taken into account must be clearly set out, transparently described and be in line with the role and purpose of the recommendation step in the authorisation process.

## 7. Priority of a substance

The final conclusion on priority should be drawn based on the assessment of the Article 58(3) criteria and consideration of additional aspects relevant for the recommendation.

The concluding assessment result should be verbally described as well as expressed by the score derived per Article 58(3) criterion and the total score, i.e. both the quantitative and qualitative assessment should complement each other.

It needs to be kept in mind that the information basis for the qualitative and the quantitative assessment is the same and that therefore the assignment of scores bears the same uncertainties as the verbal description.

# 8. Conclusions

The purpose of prioritisation is to recommend the substances on the Candidate List in such an order that the more relevant substances are included in Annex XIV before less relevant substances. The approach used for prioritisation needs to differentiate sufficiently between all Candidate List substances to allow for that purpose based on a justified and agreed method.

The concluding assessment result on the priority of a substance should be verbally described as well as expressed by the score derived per Article 58(3) criterion and the total score, i.e. both the quantitative and qualitative assessment should complement each other.

In cases where a tonnage breakdown per use is available that information will be used to weight the wide dispersiveness of different uses thereby arriving at an overall priority score that more realistically reflects the use pattern of a substance.

Registration data are the main source of information for the prioritisation assessment. In addition, other REACH and CLP data, in particular downstream user reports, are taken into account. Information from other sources can be used, too, if these are representative and reliable.

Further considerations can be taken into account for the final conclusion on which substances to be recommended for inclusion in Annex XIV. Such further considerations must be clearly set out and be in line with the role and purpose of the recommendation step in the authorisation process.

In each prioritisation round, substances added in June of the previous year (or earlier) and not yet recommended will be assessed. Substances added to the Candidate List in December of the previous year will not be considered for the priority setting immediately in the following year. Instead they will be considered in subsequent rounds (e.g., if added in December year 1 the substance will be considered in year 3).

# 9. Outlook

In future, further review of the approach for prioritisation can be considered to take account of an improved quality in registration (and other REACH and CLP) data. In particular utilisation of use descriptors[15] can be considered once they are assigned in a more consistent manner. Generally consistent availability of information on tonnage per use will largely improve the possibilities to weight different uses thereby arriving at an overall priority score that more accurately reflects the use pattern of a substance.

[15] Use descriptor system as described in Chapter R.12 of Guidance on information requirements and chemical safety assessment http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf.

# 10. Glossary

| | |
|---|---|
| Category | Ranges a criterion is assessed by, e.g. the volume criterion has six categories. The term is also used for verbally describing these ranges, e.g. the ranges of the volume criterion are described by qualitative categories ranging from “zero” to “very high”. |
| Criterion (Criteria) | Refers to one (or more respectively) Article 58(3) criteria which are “PBT or vPvB properties”, “wide dispersive use”, “high volumes”. |
| Score | Quantitative expression of the ranges a criterion is assessed by, e.g. the volume criterion can be given a score ranging from “0” to “15”. |
| Relative maximum weight | Percentage of total score one criterion gets when maximum score is given to all criteria. |