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General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation

Document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV

1 Introduction

Pursuant to Article 58(3) of the Regulation (EC) No 1907/2006[1] (REACH), whenever a decision is taken to include substances referred to in Article 57 of REACH in Annex XIV, priority shall normally be given to substances with *PBT or vPvB properties, or wide dispersive use, or high volumes.* As indicated in recital 78 of REACH "*the Agency should provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments*".

This document describes the general approach taken by ECHA for prioritising the substances that are listed on the present list[2] of candidate substances for inclusion in Annex XIV.

ECHA decided to use a pragmatic approach for the priority setting of the substances on the current 'candidate list', which mainly relies on the legal criteria provided for in Article 58(3) of REACH. The approach to assess the criteria is a qualitative, where possible semi-quantitative, evaluation resulting in an overall conclusion on the priority of a substance. The conclusion based on the criteria of Article 58(3) may, however, be superseded by additional considerations indicating that prioritisation of a substance for inclusion in Annex XIV would from a regulatory point of view either be appropriate or not be appropriate.

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[1] Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

[2] Candidate List of Substances of Very High Concern for authorisation: http://echa.europa.eu/chem_data/candidate_list_table_en.asp

It should be noted that a conclusion to not give priority to the inclusion of a particular candidate substance in Annex XIV is only relevant for the respective priority setting operation in which this conclusion has been drawn. In subsequent priority setting operations, this substance may be re-considered for inclusion in Annex XIV together with all other substances on the candidate list which are not already included in Annex XIV.

Although the present low number of substances on the candidate list does not necessarily warrant an advanced priority setting mechanism capable of differentiating and prioritising among many substances on the basis of detailed information on properties, uses and volumes of a substance, the chosen approach is developed to ensure a coherent priority setting for substances, taking into account the fact that the list will likely grow as a result of regular future updates. The approach, while it can be kept consistent with regard to the criteria applied, could be further enhanced and refined when more data on the individual substances becomes available (e.g. due to more elaborated Annex XV dossiers and/or the increasing availability of registration dossiers).

2 Outline of the priority setting approach

The information used in accordance with the criteria of REACH Article 58(3) refers to (eco)toxicological properties (hazard), to potential for release and exposure as well as to volumes supplied. This information, in particular when assessed in combination, could be seen as a proxy for potential risk to human health or the environment (i.e. the higher the hazard, the volume used and the potential for release of a substance, the higher its potential risk and thereby its priority). Hence the approach outlined in the following can be considered as risk-based. It should be noted that the actual assessment of the risks to human health and/or the environment should be included by the applicant when submitting the chemical safety report as part of the application for authorisation.

2.1 Prioritisation criteria and their parameterisation

According to Article 58(3) priority for inclusion in Annex XIV shall normally be given to substances with

a) PBT or vPvB properties; or
b) wide dispersive use; or
c) high volumes.

The term “normally” implies that the criteria mentioned in Article 58(3) do not need to be seen as exclusive, allowing other considerations to be taken into account which may warrant a higher or lower priority for a substance, in particular in relation to the regulatory effectiveness of selecting the substance.

Given that the listing of the criteria is connected by the term *‘or’*, this means that meeting one criterion could in principle be sufficient to prioritise a substance for inclusion in Annex XIV. However, in order to allow further differentiation the approach actually followed for prioritising the candidate substances for inclusion in Annex XIV also considers how many of these three criteria are met by the candidate substance concerned and to what degree.

Therefore, it is necessary to consider the rationale of the criteria and to identify and select parameters by which the rationale of the criteria can be reflected. The following parameterisation of the above criteria *a), b) & c)* has been used for prioritisation.

a) PBT or vPvB properties

Substances that have been identified as having PBT or vPvB properties under Article 57 (d), (e) or (f) meet criterion *a)* on *'PBT or vPvB properties'* and may be prioritised for inclusion in Annex XIV. However, not fulfilling criterion *a)* does not preclude that CMR properties of substances meeting criteria *b) 'wide dispersive use'* and/or *c) 'high volumes'* can be considered in the prioritisation[3].

b) Wide dispersive use

The term "wide dispersive use" is explained in Chapter R.16.2.1.6 of the Guidance on Information Requirements and Chemical Safety Assessment as follows: "*Wide dispersive use refers to many small point sources or diffuse release by for instance the public at large or sources like traffic. … Wide dispersive use can relate to both indoor and outdoor use"*. In the Technical Guidance Document for Risk Assessment of new and existing substances and biocides (2003, Chapter 5) this term is defined as follows: "*Wide dispersive use refers to activities which deliver uncontrolled exposure. Examples relevant for occupational exposure: Painting with paints; spraying of pesticides. Examples relevant for environmental/consumer exposure: Use of detergents, cosmetics, disinfectants, household paints."* In addition, the ECETOC Report No. 93 on Targeted Risk Assessment (Appendix B) states: *"A substance marketed for wide dispersive use is likely to reach consumers, and it can be assumed that such a substance will be emitted into the environment for 100% during or after use."*

Wide dispersive uses are hence characterised by use(s) of a substance on its own, in a preparation or in an article at many places that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers, general public) and/or the environment. This means that uses taking place at many places, which however do not result in significant releases of a substance, may be considered only as 'widespread' but not as 'wide dispersive'.

In general, consumer use can be considered as wide dispersive if it can be reasonably assumed that this use results in non-negligible releases. Professional use can be wide dispersive as well if it takes place at many sites and is carried out by many workers and if it cannot be excluded that releases are negligible.

To assess the criterion *'wide dispersive use'*, it might be useful to consider also potential releases and exposure from uses other than 'wide dispersive', as not only wide dispersive uses may result in releases and contributions to exposure. However, for the current prioritisation no information was available allowing this aspect to be taken into account.

[3] For the present prioritisation, a differentiation was only made between PBT or vPvB properties and CMR properties of the candidate substances. If in future the candidate list will become substantially longer, it may be necessary to further differentiate between substances on the basis of their intrinsic properties (i.e. PBT or vPvB properties versus C, M or R properties) if a similar priority results from the degree of fulfilment of criteria *b)* and *c).*

Depending on the information available, as many as possible of the following parameters are used as indicators to assess whether a use (and the resulting release) should be considered 'wide dispersive' and to get an at least qualitative indication on the degree of its 'dispersiveness':

- Tonnage going to the use.
- The complexity of the supply chain and the number of actors in the chain. In how many settings/locations does the use take place? What are the typical sizes of these settings?
- In which form is the substance placed on the market (e.g. as such, as part of a preparation, in/on an article)?
- Can the substance be released (and to which extent) during the service life of an article or a preparation (e.g. paints, adhesives, detergents) or is it transformed (thereby loosing its hazardous properties) or incorporated into a matrix (e.g. polymer) in a way preventing release?
- Information on operational conditions and risk management measures.
- Information on whether there is occupational exposure (quantitative or qualitative; e.g. approximate number of exposed workers, information on releases to the working environment, occupational exposure concentrations, health effects, OELs).
- Information whether there is consumer exposure (quantitative or qualitative; e.g. possibility of consumer use, information on consumer exposure, health effects, limit values).
- Releases to the environment (mainly for PBTs/vPvBs; e.g. t/y to the different compartments air, water, soil).
- Possibility of releases during the waste phase.
- Monitoring information for a substance in environmental compartments such as water, sediment, soil or in biota.

The parameters listed above are used in a weight of evidence approach. The priority of a substance increases with the portion of its uses (respectively the tonnage supplied to these uses) identified as wide-dispersive and the (estimated) released volumes from those wide dispersive uses. Likewise, no or lesser priority will be given when no significant releases occur from these uses or when the releases are comparatively low. As regards the releases, the focus is normally on environmental releases for substances with PBT properties and on releases leading to potential human exposure for CMR substances.

c) High volumes

The annual volume supplied in the EU to uses not exempted from the authorisation requirement[4] is taken as parameter for this criterion, i.e.:

[4] Appendix 1 to this document provides a list of uses specifically exempted from the authorisation requirement. Exemptions relevant in the context of the present prioritisation exercise are, for example, uses as on-site isolated intermediates or as transported intermediates, uses in biocidal products and uses in scientific research and development.

Volume supplied =

(Manufacture + Import) – (Export + supply to uses exempted from authorisation)

The total annual tonnages are considered as:

Low volumes, if	<10 t/y;
Relatively low volumes, if	10 - <100 t/y;
Relatively high volumes, if	100 - <1,000 t/y;
High volumes, if	1,000 - <10,000 t/y;
Very high volumes, if	>10,000 t/y.

Priority increases with increasing volume.

Note that the 'volume' criterion is considered not to be met if:

- There are no identified uses of the substance in the EU;
- There are no uses identified that are not exempted from the authorisation requirement.

No use of a substance or no use in the scope of the Authorisation Title of REACH implies logically that the criterion 'wide dispersive use' is not fulfilled for this substance.

Not prioritising a substance that has no identified uses in the EU will help to prevent developing Annex XIV into a list of obsolete substances.

2.2 Additional considerations for prioritising a candidate substance

In arriving at the overall conclusion on the priority of a substance, the 'regulatory effectiveness' of including the substance into the authorisation process is also taken into account. Situations may for instance occur where inclusion in Annex XIV will only require regulatory efforts but most likely will not result in benefits for human health or the environment. For example:

- All identified uses are subject to specific Community legislation imposing minimum requirements relating to the protection of human health or the environment ensuring that risks are properly controlled.
- All or most known uses can easily be replaced by another 'form' of the substance with a similar (or even worse) hazard profile, which is not on the candidate list (e.g. one metal salt on the candidate list can be replaced by another salt of the same metal with the same hazard profile, but this salt is not on the candidate list).
- Uses have been identified but the resulting releases are insignificant as such or insignificant compared to releases resulting from natural sources and/or uses not in the scope of the Authorisation Title of REACH.

In the first case, risks are already properly controlled by other Community legislation, and in the second case the authorisation requirement can easily be circumvented by replacement of the substance subjected to the authorisation requirement by the other 'form' of the substance not requiring authorisation.

Regarding the second case, a grouping approach could be considered[5] in order to prevent simple replacement of a substance that will be subjected to authorisation by another 'form' of the substance.

2.3 Conclusion on the priority of a candidate substance

The three prioritisation criteria related to the intrinsic properties of a candidate substance, the nature of its uses and its volume supplied to uses in the scope of the Authorisation Title of REACH are assessed together in a weight of evidence approach in a qualitative, where possible semi-quantitative manner, resulting in an overall conclusion on the priority of the substance. The number of criteria met and the extent to which the criteria are fulfilled (i.e. the higher the rating of the intrinsic properties, the more wide dispersive the uses and the higher the volumes not exempted from Authorisation) are important factors in deciding whether or not to prioritise a substance.

However, in arriving at the final conclusion on the priority of a substance the additional considerations regarding 'regulatory effectiveness' outlined in section 2.2 may also play an important role.

[5] Whether grouping of substances with similar properties is required in order to ensure the efficacy of authorisation in terms of the envisaged benefits for human health and/or the environment should already be considered in the planning-phase of Annex XV dossiers for identification of substances as SVHCs. A prerequisite for being able to group substances with the objective to subject them as a group to the authorisation requirement is their prior identification as SVHCs and inclusion in the candidate list.

APPENDIX 1: USES EXEMPTED FROM AUTHORISATION

On-site isolated intermediates and transported isolated intermediates {Art. 2(8b)}.
Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)}.
Use in food or feedingstuffs according to Regulation (EC) No 178/2002 including use as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC, as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC or on foodstuffs drawn up in application of Regulation (EC) No 2232/96, as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 and in animal nutrition within the scope of Council Directive 82/471/EEC {Art. 2(5b)}.
Use in scientific research and development {Art. 56(3)}.
Use on plant protection products within the scope of Council Directive 91/414/EEC {Art. 56(4a)}.
Use in biocidal products within the scope of Directive 98/8/EC {Art. 56(4b)}.
Use as motor fuels covered by Directive 98/70/EC {Art. 56(4c)}.
Use as fuel in mobile or fixed combustion plants of mineral oil products and use of fuels in closed systems {Art. 56(4d)}.
Use in cosmetic products within the scope of Council Directive 76/768/EEC (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5a)}.
Use in food contact materials within the scope of Regulation (EC) No 1935/2004 (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5b)}.
Use of substances when present in preparations below a concentration limit of 0.1% by weight. This applies only to substances listed in Annex XIV on the basis of being persistent, bioaccumulative and toxic (PBT) as defined by Art. 57(d), very persistent and very bioaccumulative (vPvB) as defined by Art. 57(e), or listed in Annex XIV on the basis that there is scientific evidence of probable serious effects to human health or the environment which give an equivalent level of concern to substances with PBT or vPvB properties, or an equivalent level of concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 and 2, as defined by Art. 57(f) {Art. 56(6a)}.
Use of substances when present in preparations below the lowest concentration limits specified in Directive 1999/45/EC or in Annex I to Council Directive 67/548/EEC which results in the classification of the preparation as dangerous. This applies only to substance listed in Annex XIV on the basis of their classification as CMR category 1 and 2 {Art. 56(6b)}.