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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 second Recommendation of substances for inclusion in Annex XIV (list of substances subject to authorisation)

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*'.

Article 58(3) indeed requires to take the mentioned 3 criteria 'normally' into account, but there is no provision that this needs to be done in all cases or how it should be done, e.g. with respect to evaluating, weighting or scoring of the criteria. Moreover, consideration of further aspects and criteria for priority setting is not excluded. Hence, it can be assumed that Article 58(3) leaves discretion regarding the development and design of a prioritisation approach that in the end provides the Candidate Substances for which the recommendation to include them in Annex XIV is most relevant and appropriate (both in terms of potential risk and regulatory effectiveness).

This document describes the *updated* general approach taken by ECHA for prioritising the substances that are listed on the candidate list[2] for eventual inclusion in Annex XIV (Candidate List).

During discussions at the Member State Committee meetings 9 and 10 in October and December 2009 several Committee members expressed their preference for a revision of ECHA's so far used prioritisation approach for recommending substances of the Candidate

[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] Only those substances which have not yet been recommended for inclusion in Annex XIV will be considered for priority setting. The Candidate List of Substances of Very High Concern for Authorisation is available at: http://echa.europa.eu/chem_data/candidate_list_table_en.asp

List for inclusion in Annex XIV. In particular, a scoring system for ranking of the substances on the Candidate List substances was suggested and investigations undertaken as to whether further criteria apart from those listed in Article 58(3) and the 'regulatory effectiveness and coherence' considerations already taken into account in ECHA's so far used 'verbal-argumentative' approach would improve the efficacy and transparency of the prioritisation approach.

The present paper describes the final outcome of the revision process, which comprised a discussion paper on options for further development of the prioritisation approach by ECHA, written comments on this paper by the MSC members and observer organisations, and an oral discussion of pending issues at the MSC-11 meeting in April 2010.

The new prioritisation approach foresees a two tiered-process in which the first step delivers a ranked priority list on the basis of the Article 58(3) criteria. In the next step considerations regarding 'regulatory effectiveness and coherence' and any relevant further considerations are considered for final selection of those substances on the Candidate List that should be given priority for inclusion in Annex XIV.

The so far used approach for priority setting amongst the substances on the Candidate List mainly relied on a qualitative, where possible semi-quantitative, evaluation of the criteria provided for in Article 58(3) of REACH, resulting in an overall, verbal-argumentative conclusion on the priority of a substance. This verbal conclusion on the basis of Article 58(3) was as well followed by a second step taking additional regulatory effectiveness and coherence considerations into account in order to conclude whether prioritisation of a substance for inclusion in Annex XIV would from a regulatory point of view be appropriate.

Hence, both prioritisation approaches are quite similar. With the new scoring method the outcome is expressed in quantitative terms (scores), allowing to establish an ordered (i.e. ranked) list, instead of a more qualitative valuation obtained with the verbal-argumentative method. However, although the result of the scoring method is expressed in quantitative terms, it should be considered that the information basis (and the data requirements) for both the scoring method and the verbal-argumentative method are the same and that the assignment of scores bears the same uncertainties regarding the reliability of the data and a similar level of subjectivity as the verbal conclusions drawn with the verbal-argumentative method. This means that although the results are expressed in numbers the outcome of the scoring method is not necessarily more precise or correct than an argumentative verbal conclusion. The decisions (assignment of scores to the different criteria) may however be better traceable and thus the result considered more transparent.

For the next recommendations, the verbal-argumentative prioritisation approach as used for ECHA's first recommendation will be applied in parallel to the new scoring based approach in order to compare both approaches in terms of their efficacy in determining priority, providing transparency of conclusions and resource needs.

All steps of the prioritisation process will be adequately documented and justified, as necessary.

It should be noted that a conclusion to not give priority to the inclusion of a particular candidate list 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 have not already been recommended by ECHA for inclusion in Annex XIV.

2. Outline of the scoring approach for prioritisation

It should be kept in mind that all priority setting approaches are conventions on how to systematically use the information available on the chosen or given prioritisation criteria (i.e. how to weight and combine the criteria in qualitative and/or quantitative terms). These conventions can be science based with regard to the selection and combination of relevant criteria but the scoring of the criteria remains to some extent arbitrary and based on agreement as it is hardly possible to provide 'scientific' justifications for assignment of particular weighting factors, scores or the chosen way to integrate complex bits of different kinds of information in order to draw the overall conclusions. As there is no (at least no absolute) 'scientific truth' on how to reasonably combine and weight different kinds of complex information, opinions on the optimal approach may therefore be divergent and the end result does at its best reflect a procedure considered acceptable by a broad majority.

Based on the discussions with the members of the Member State Committee and the observers from stakeholder organisations, ECHA has therefore chosen to **implement a two-tiered prioritisation approach** for its next recommendation(s) of substances to be included in Annex XIV.

- In **tier 1** a scoring approach will be used based on the criteria 'Intrinsic properties (PBT/vPvB)', 'Volume' (t/y supplied in the EU to uses in the scope of authorisation) and 'Wide-dispersive use' (with the sub-criteria 'site-numbers'(use) and 'release'). See section 2.1.
- In **tier 2** the results of the scoring/ranking will be complemented by regulatory effectiveness considerations as described in section 2.2 of this document for drawing final conclusions on priorities of the substances on the Candidate List.

2.1 Scoring system for the Article 58(3) criteria

As regards the implementation of a scoring system it needs to be considered that the same conditions that led to the development of the so far used 'verbal-argumentative' approach still exist. These conditions regard the generally limited availability of information on market volumes, uses, releases and exposures of humans and the environment, which however, varies substance by substance. This implies that a scoring approach ideally should not require more information and quantitative data than the so far used approach does, because it may not, or only with much efforts in terms of human and financial resources, be possible to meet any increased information requirements. This situation may change soon for those substances with (potential) SVHC profiles for which registration dossiers must be submitted by 1st December 2010. However, after that deadline substances may be proposed and identified as SVHC for which still no registration dossier will be available[3], or for which information on uses, releases and exposures still will be limited[4].

Therefore, a review to enhance the prioritisation approach for including SVHCs in Annex XIV may be made once these registration dossiers are available and clarity on the kind and quality of data available can be obtained from real registration dossiers.

In the meantime, any modification of the so far used 'verbal-argumentative' priority setting approach with the objective to enhance its efficacy and transparency needs to focus on

[3] No use in the EU or market volume below volume thresholds for substances classified as CMR cat 1 or 2 (i.e. 1 t/y) or as very toxic to aquatic organisms which may cause long-term effects in the aquatic environment (R51/53) (i.e. 100 t/y), or not recognised as SVHC.

[4] Because of small market volumes and the lacking need to develop a chemical safety assessment.

options that can be realised with the kind of information and data that currently is available or can be made available with reasonable efforts.

2.2 Scoring algorithm

Instead of verbally assessing the three prioritisation criteria included in Article 58(3) ('Inherent properties' (PBT or vPvB properties), 'Volume' and 'Wide-dispersive use') the information available is scored and then the scores added to obtain a total score. The total score can 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 scoring algorithm outlined in the following can be considered as risk-based. ECHA would not support a concept where the mere number of criteria that are met would be decisive for the priority rank of a substance. The quantitative aspects of meeting the criteria (i.e. to which degree are the criteria met) need to be considered as well for prioritisation[5].

2.2.1 Inherent properties

In addition to the provision of Article 58(3) that priority shall normally be given to substances with PBT or vPvB properties the inherent properties of substances on the Candidate List are scored with respect to the extent of their persistency, liability to bioaccumulate and toxicity ('PBT-ness') or their potency to elicit health effects (threshold versus non threshold mode of action) as follows:

Inherent properties	Score
PBT and vPvB or PBT with T non-threshold C or M	*4*
PBT or vPvB properties	3
C or M properties (without effect threshold)	*1*
C,M or R properties (with effect threshold)	0

This scoring considers that priority shall normally be given to substances with PBT or vPvB properties but also reflects differences in the characteristics of the hazard potential of substances. This helps to further discriminate substances on the candidate list if volumes and release pattern are similar.

2.2.2 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)

[5] For example, a substance which is not PBT/vPvB (but with wide-dispersive use and high volume) may rightfully get priority over a PBT/vPvB substance if volumes and releases of the non-PBT substance are higher.

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 characterised by use(s) of a substance on its own, in a preparation or in an article at many places (sites) 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.

The extent to which a use is 'wide-dispersive' is roughly a function of the number of sites at which a substance is used and the magnitude of releases caused by those uses over all steps of the life-cycle.

Therefore, the scoring of the 'wide-dispersive use' criterion has been broken up in the two sub-criteria 'Site-#', which is basically the number of sites where the substance is used (i.e. the number of point sources or number of sites from which a substance is being released), and 'Release', which describes the releases in terms of pattern (where relevant) and amount versus anticipated risk (see definition of release terms below).

Uses resulting in *insignificant* releases should in general be scored 0. In order to allow for this option, the sores for sub-criteria 'Site-#' and 'Release' need to be multiplied.

However, even if the releases arising from one or more uses are considered insignificant, a precautionary element should be included in the evaluation and scoring of such releases. The probability that releases are not at all sites 'insignificant' rises with the number of sites at which a substance is used. Therefore, if a use normally resulting in 'insignificant' releases is carried out at a high number of sites (i.e. 100 or more), the scoring for 'insignificant' release is shifted from 0 to 1.

Wide-Dispersive Use (WDU) = Site-# * Release

With:

a) Site-#

(Number of point sources or number of sites from which a substance is being released.)

As regards the 'Site-#' , some few (i.e. <10) are considered as *'small'*, numbers in the tens as *'medium'* and numbers in the hundreds or more as *'high'*. If there is no use of a substance in the scope of authorisation the score is 0.

	Score
no use	*0*
small	1
medium	2
high	3

b Release

(Potential for releases to the environment, for worker exposure and for consumer exposure in all steps of the life-cycle.)

For substances with PBT/vPvB properties the focus is normally on environmental releases and for substances with CMR properties on potential human exposure (worker, consumer and man indirectly exposed via the environment). In order to describe and score the different situations that may occur with respect to releases to human beings or the environment, the following terms and definitions are used:

Insignificant:	means negligible (i.e. very low) releases in relation to the likelihood that these releases could cause environmental or health effects.
Significant:	means non-negligible releases in relation to the likelihood that these releases could cause environmental or health effects.
Diffuse:	means releases to the environment (outdoor or indoor) from a high number of sources/sites to an extent that the overall amount cannot be considered as '*insignificant*'.
Non-diffuse:	means releases to the environment (outdoor or indoor) from a small or medium number of sources/sites. The releases may on the local level be 'non negligible' but on higher spatial scales they are considered to be '*insignificant*'.
Controlled:	means releases at the workplace may occur but that risk management measures are in place to control workplace exposure. It is however not clear whether the RMMs in place render workplace releases negligible (if this is clear workplace exposure is considered '*insignificant*').
Uncontrolled:	means releases at the workplace may occur and no or insufficient risk management measures are in place to control resulting worker exposure or such information is not available.

	Score
insignificant	0 (if Site-# > 100 the score is 1)
non-diffuse / controlled	1
diffuse / uncontrolled / significant	3

2.2.3 Volume

The annual volume supplied in the EU to uses not exempted from the authorisation requirement[6] is taken as basis for scoring of this criterion, i.e.:

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

	Score
no volume on EU market in the scope of authorisation	*0*
low (<10 t/yr)	1
relatively low (10-100 t/yr)	3
relatively high (100-1000 t/yr)	*5*
high (1000-10000 t/yr)	7
very high (>10000 t/yr)	*9*

[6] 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.

2.2.4 Weighting and aggregation of criteria scores

With regard to the weighting of the 3 criteria it should be considered that the substances on the Candidate List are already a selection of substances with very severe hazard properties and that for a ranking considering potential risks[7] not too much weight should again be given to these hazard properties. In principle, the 'hazard' of a substance only needs to be considered for complying with the provision of Article 58(3) that priority shall normally be given to substances with PBT/vPvB properties. However, ECHA chose to further account for the differences in potency and PBT-ness of the substances on the Candidate List (see section 2.2.1).

The relative maximum weights of the criteria 'Inherent properties', 'Volume' and 'Wide-dispersive use' are set to 18:41:41 %. Further increasing the weight for the 'PBT/vPvB - inherent properties' criterion towards equity with the other criteria would result in (hazard driven) high ranking of PBT/vPvB substances although volumes used and releases may potentially be low.

The individual criteria scores are added to the total score:

$$\mathbf{Score_{Total}} = \mathbf{Score_{Inherent\ properties}} + \mathbf{Score_{Volume}} + \mathbf{Score_{Wide\text{-}dispersive\ use}}$$

with

Score (min/max):	(0/22),	(0/4)	(0/9)	(0/9)
Score relative weight (%):		18	41	41

If a cut-off point (i.e. the minimum total score above which substances might be considered for inclusion in Annex XIV) will need to be set, this cut-off point may be different for each case a recommendation is developed as this point may depend on the number of substances that are addressed, the quantitative or qualitative arguments used, combined with regulatory effectiveness issues, as well as possibly in future the resources available to ECHA for handling the subsequent authorisation applications resulting from inclusion of the prioritised substances into Annex XIV.

2.3 Consideration of regulatory effectiveness and coherence

ECHA's so far used prioritisation approach is a two-tiered procedure, in which in tier 1 the potential priority of a substance on the basis of the criteria of Article 58(3) was estimated before in tier 2 'regulatory effectiveness' considerations have been taken into account, in order to conclude on the final priority that should be given to a substance for recommending it for inclusion in Annex XIV (see section 3.3).

This second tier was introduced because situations may occur where inclusion in Annex XIV will require regulatory efforts but most likely will not result in benefits for human health or the environment, or where authorisation may hamper the use of other risk management instruments while not contributing significantly to achieving the risk reduction.

Therefore a second tier will in the same manner be used with the scoring algorithm as with the verbal-argumentative prioritisation.

However, the regulatory effectiveness criteria used so far are rather specific examples that were derived from a limited number of existing cases and do clearly not cover all situations

[7] Risk as a function of hazard and exposure [volume and release]

where regulatory effectiveness aspects would need to be taken into account in order to arrive at a well founded conclusion as to whether to recommend a substance to Annex XIV.

Therefore, it has been decided that for tier II of the scoring based prioritisation approach all available information will be taken into account that is relevant for drawing a conclusion in the prioritisation process as to whether a substance should be prioritised and recommended for inclusion in Annex XIV.

Sources for such information will most probably comprise the documents provided by the Member States on the substance, e.g. the Annex XV dossiers and risk management option (RMO) analyses, or comments received during public commenting as documented in the response to comments documents (RCOM). ECHA may, however, undertake own investigations and data surveys if for instance the available information would indicate some questions regarding the regulatory effectiveness of the Annex XIV inclusion but does not allow drawing firm conclusions.

2.4 Conclusion on the priority of a Candidate List substance

The whole prioritisation process is structured as follows:

Tier I	*Priority based on scoring of the Article 58(3) criteria*
Tier II	*Consideration of relevant information regarding regulatory coherence and effectiveness*
Final Conclusion	*Final conclusion on priorities of the substances to be included in ECHA's recommendation*

In the first Tier I the substances on the Candidate List are scored on the basis of the scoring algorithm describe in section 2.2. In Tier II all information will be taken into account that is relevant for drawing a conclusion in the prioritisation process as to whether the risk reduction objectives will be best achieved via the authorisation route. Finally, the conclusion is drawn as to whether the substance considered should be recommended for inclusion in Annex XIV.

3 Outline of the 'verbal-argumentative' priority setting approach

The 'verbal-argumentative approach' has been used to prioritise substances for ECHA's first recommendation of substances for inclusion in Annex XIV. It will be used in parallel to the scoring based prioritisation approach described in section 2.

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, like the scoring approach, the verbal-argumentative approach outlined in the following can be considered as risk-based[8].

3.1 Prioritisation criteria and their parameterisation

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

[8] 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.

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 substances[9] meeting criteria *b) 'wide-dispersive use'* and/or *c) 'high volumes'* can be considered in the prioritisation.

b) Wide-dispersive use

The definition of the term 'Wide-dispersive use' as used in the context of the prioritisation approaches described in this document is provided in section 2.2.2.

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 releases) 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.

[9] Or substances giving rise to an equivalent level of concern (Article 57(f) of the REACH-Regulation).

- 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[10] is taken as parameter for this criterion, i.e.:

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.

[10] 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.

3.2 Regulatory effectiveness and coherence related considerations for prioritising substances on the candidate substance

The same approach for taking regulatory effectiveness and coherence related considerations into account as described in section 2.3 will be used as Tier II of the verbal-argumentative approach.

In arriving at the overall conclusion on the priority of a substance, so far the following 'regulatory effectiveness' criteria haven been taken into account:

- *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[11] *in order to prevent simple replacement of a substance that will be subjected to authorisation by another 'form' of the substance.*

3.3 Conclusion on the priority of a Candidate List substance

In **Tier I** the three prioritisation criteria related to the intrinsic properties of a Candidate List 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.

In **Tier II** the same regulatory effectiveness and coherence related considerations as described in section 2.3 will be taken into account for finally concluding as to whether the substance considered should be recommended for inclusion in Annex XIV.

[11] 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)}.