PREPARATION OF DRAFT ANNEX XIV ENTRIES FOR SUBSTANCES RECOMMENDED TO BE INCLUDED IN ANNEX XIV

GENERAL APPROACH

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CONTENTS

INTRODUCTION

Pursuant to Article 58(1) of the REACH Regulation (REACH), the draft entries for substances recommended for inclusion in Annex XIV shall specify for each substance:

- The identity of the substance as specified in section 2 of Annex VI
- The intrinsic property (properties) of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date(s)
    - The application date(s)
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any

In addition, Article 56(3) of REACH provides that Annex XIV shall specify if the authorisation requirement applies to product and process oriented research and development (PPORD) and if so, the maximum quantity exempted.

1. Identity of the substance

All the available name(s) for the substance and its EC number(s) are taken from the Candidate List of Substances of Very High Concern for Authorisation. In addition, where available, CAS numbers are provided.

2. Intrinsic properties of the substance referred to in Article 57 of REACH

The intrinsic property (properties) referred to in Article 57 of REACH, which led to the identification of the substance as a substance of very high concern (SVHC), are taken from the Candidate List.

The identity of the substance and the intrinsic properties referred to in Article 57 of REACH were confirmed and concluded in the earlier SVHC identification process in accordance with Article 59, which led to the inclusion of the substance in the Candidate List. These elements are no longer subject to scrutiny in this phase of the process (recommendation of priority substances for inclusion in Annex XIV) and therefore no comments are requested on these elements of the (draft) recommendation.

3. Transitional arrangements

Annex XIV entries need to specify so-called "sunset dates" and "application dates" for each substance (Article 58(1)(c) of REACH):

- **Sunset date:** *The date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted […] which should take into account, where appropriate, the production cycle specified for that use.*

- **Application date:** *A date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken.*

3.1. Sunset dates

Article 58(1)(c)(i) provides that, where appropriate, the production cycle specified for a use should be taken into account when setting the sunset dates for the uses of the substance. However, the registration dossiers of the substances prioritised to date (June 2013), the Annex XV SVHC dossiers and comments provided during public consultation on them in the context of the SVHC identification process or other available information did not provide information on lengths of production cycles that would suffice as basis for setting the sunset dates for these substances.

Article 58(1)(c)(ii) specifies that the application date must be at least 18 months before the sunset date. The above mentioned sources of information do not provide enough basis to discriminate the sunset dates for different substances or to deviate from the 18 months set out in the legal text. **Therefore, it is proposed to use a standard difference of 18 months between the application and sunset dates, unless information provided during the public consultation on the draft recommendation would give grounds to recommend a longer interval between application and sunset date(s).**

3.2. Application dates[1]

Article 58(3) provides that the application and sunset dates shall take account of the Agency's capacity to handle applications in the time provided for. To ensure workability for ECHA's Committees and secretariat it is important that not all applications arrive at the same time. This can be achieved by setting different application dates for (groups of) the recommended substances. To support the efficient handling of the applications, ECHA has established specific time periods for submitting applications for authorisation with 3-month intervals in between. Furthermore, substances with inherent properties and uses that are similar to substances recommended previously are assigned to the groups with earlier application dates, in order to reduce the potential transient evasion of the authorisation requirement for the previously recommended substances[2].

Therefore the time intervals between the latest application dates of the different (groups of) recommended substances are set to 3 months.

While the time differences between the latest application dates of a recommendation can be considered as minor (i.e. 3 months) compared to the total time reserved for the potential applicants to prepare their applications, it facilitates better processing of the applications by ECHA's Committees and the secretariat. This differentiation will also assist interested 3rd parties who wish to provide information or comments on several substances on the basis of published broad information on uses applied for. Finally, it will

1 The application date is the latest date by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date. The applicants have a possibility to submit their applications at any time before the application date.

2 In order to avoid potential evasion of the authorisation requirement by substituting a substance subject to authorisation by a similar one with similar hazard properties, which however does not require authorisation yet.

assist the Commission, who has to prepare draft authorisation decisions within three months of receipt of the opinions of ECHA's Risk Assessment and/or Socio Economic Assessment Committees.

To allow the potential applicants adequate time to prepare their applications for the substances included in Annex XIV, it is proposed to use 18 months from the inclusion of the substance into Annex XIV as the standard application date.

Further aspects to be taken into account by ECHA when determining the latest application dates and sunset dates and assigning the recommended substances to particular groups with the same application dates include:

- Potential overlaps with the application dates of substances already included in Annex XIV or foreseen to be included[3] in this Annex (in order to take account of ECHA's capacity to handle authorisation applications in the time provided for).
- Substances with apparently complex uses and supply chains[4] will normally be assigned to the groups with longer intervals between the date of inclusion in Annex XIV and the latest application date, to account for potentially greater time requirements for the preparation of the application.

It should be noted that the present lack of alternatives to (some of) the uses of a substance or the time needed to transfer to alternatives is not considered as a viable reason for prolonging the latest application dates. This is because authorisation, inter alia, aims to promote the development of alternatives.[5]

4. Review periods for certain uses

According to Article 58(1) of REACH it is possible to set review periods for certain uses, if appropriate, in Annex XIV. However, the registration dossiers of the substances prioritised for the current recommendation, the Annex XV SVHC dossiers and comments provided on them during the public commenting period in the context of the SVHC identification process or other available information did not provide background information that supported defining such 'upfront' review periods for any uses of the substances prioritised for the inclusion in Annex XIV. As a consequence, **it is not proposed to define review periods in the current recommendation, unless information provided during the public consultation on the draft recommendation would suffice for defining such review periods.** It should be noted that all decisions to grant an authorisation will include (a) case specific review period(s).

3 I.e. substances of previous Recommendations which not yet have been included in Annex XIV.

4 Qualitative factors relevant for assessing the complexity of the supply chains include: length and number of layers in a supply chain (vertical complexity); parallel supply chains (horizontal complexity); diversity of uses, diversity of actors (including those not directly requiring authorisation, e.g. users of articles).

5 Article 55 explicitly stipulates that applicants for authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution (this has to be included in the analysis of alternatives to be submitted as part of the authorisation application in accordance with Art. 62 (4e)). Therefore, this information will rather be taken into account by the Risk Assessment and Socio-Economic Analysis Committees when forming their opinions and by the Commission when taking the final decision. It may impact the decision on granting the applied for authorisation and the conditions applicable to the authorisation, such as e.g. the length of the time limited review period of the authorisation.

5. Uses or categories of uses exempted from the authorisation requirement

5.1. Exemptions under Article 58(2) of REACH

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA will consider the following elements when deciding whether to include an exemption of a use of a substance in its recommendation:

- There is existing Community legislation addressing the use (or categories of use) that is proposed to be exempted. Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definitions. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- The existing Community legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to the group the substance belongs to e.g. by referring to the classification criteria or the Annex XIII criteria;
- The existing Community legislation imposes minimum requirements[6] for the control of risks of the use. Legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

ECHA will use the above considerations when assessing information that is submitted during the public consultation on the draft recommendation in the context of suggestions for exemptions from the authorisation requirement in accordance with Article 58(2).

5.2. Exemption of product and process oriented research and development

The Annex XIV entries for substances recommended for inclusion in Annex XIV may include a specific exemption for the use of the substance in product and process oriented research and development (PPORD) up to a defined quantity (Article 56(3)).

6 Legislation imposing minimum requirements means that:
- The Member States may establish more stringent but not less stringent requirements when implementing the specific Community legislation in question.
- The piece of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper.

ECHA will consider information on the use of substances in PPORD submitted during the public consultation on the draft recommendation.