

**PREPARATION OF DRAFT ANNEX XIV ENTRIES
FOR THE SECOND RECOMMENDATION OF
SUBSTANCES TO BE INCLUDED IN ANNEX XIV**

GENERAL APPROACH

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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 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, and which led to the identification of the substance as a substance of very high concern (SVHC), are taken from the candidate list for eventual inclusion in Annex XIV (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 phase of the process that led to the inclusion of these substances 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 Annex XV SVHC dossiers of the substances prioritised for the current recommendation, comments provided on them during the public commenting period in the context of the SVHC identification process or other available information do not provide information on lengths of production cycles that would suffice as basis for setting the sunset dates.

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 neither support the use of other criteria 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

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 the prioritised substances.¹

The main reason to propose different application dates for priority substances is to ensure more equal distribution of ECHA's workload. As the quality of the applications is important for the practical implementation of the authorisation procedure and for achieving the aims of the authorisation system, the estimated differences in the time needed to prepare an application was used as a basis to differentiate the application dates for different substances in the first recommendation.

For the first recommendation information on the complexity of the supply chain and on the availability of information about alternatives was used to estimate the differences in time

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. However, since the authorisation requirement is still new and most actors might have no experience in preparing applications, it is possible that most applicants will use all available time until the specified latest application date to develop their applications.

needed to prepare applications. However, taking into account the fairly small differences in the proposed application dates (at most 6 months) and the workload related to gathering and analysing the information on the supply chains and the level of knowledge on alternatives, this approach was not deemed needed or justified for the current (second) recommendation. For ECHA's second recommendation it is therefore suggested **to spread the application dates over 6 months so that the substances with similar properties and uses get the same application date**². When information on manufacture and uses is available from the registration dossiers, the approach used to differentiate the application date should be reconsidered.

While the difference of 6 months in application dates can be considered as minor compared to the total time reserved for the potential applicants to prepare their applications it still 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 assist the Commission, who has to prepare draft authorisation decisions within three months of receipt of ECHA's opinions.

To allow the potential applicants adequate time to prepare their applications for the substances included in Annex XIV, **it is proposed to use as the earliest application date 18 months from the inclusion of the substance into Annex XIV**. ECHA's first recommendation of 1 June 2009 included three phthalates (DEHP, DBP, BBP) with a proposed application date of 30 months and sunset date of 48 months from the inclusion in Annex XIV. This second recommendation includes one more phthalate (diisobutyl phthalate, DIBP), which has similar uses than the three earlier phthalates. Therefore, it is proposed to set the application and sunset dates for DIBP as near as possible to the final dates of the other phthalates. However, between the inclusion in Annex XIV and the application date there should be a minimum of 12 months, allowing potential applicants to prepare applications of the required quality.

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 Annex XV SVHC dossiers of the substances prioritised for the current recommendation, comments provided on them during the public commenting period in the context of the SVHC identification process or other available information do not provide background information that would support 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 second 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).

5 Uses or categories of uses exempted from the authorisation requirement

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

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’*.

Accordingly, in light of this provision and the guidance on inclusion of substances in Annex XIV, 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;
- This 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;
- This Community legislation imposes minimum requirements³ 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 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 regarding reasons for exemptions in accordance with Article 58(2) that has been submitted during the public consultation on the draft recommendation.

5.2 Exemption of product and process oriented research

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 (PPORD) up to a defined quantity (Article 56(3)).

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

³ 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.