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General approach for defining the Annex XIV entries

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

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
- The intrinsic property(ies) of the substance referred to in Article 57
- Transitional arrangements
  - The sunset date
  - The application date
- 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.

1 Identity of the substance

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

2 Intrinsic property (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 of Substances of Very High Concern for Authorisation.

Possible route for authorisation

The draft entries define also whether, on the basis of available information, a threshold can be determined in accordance with Section 6.4 of Annex I. In other words, they indicate whether it appears that pursuant to Article 60(3) an authorisation can be granted in accordance with Article 60(2) (the so-called 'adequate control route') or only in accordance with Article 60(4) (the so-called 'Socio-Economic Analysis (SEA) route'). In cases where an applicant wishes to get an authorisation in accordance with the 'adequate control route' the applicant's Chemical Safety Report needs to document the relevant threshold and demonstrate that the risks arising from the intrinsic properties specified in Annex XIV are adequately controlled in accordance with Section 6.4 of Annex I. It should be noted that such considerations are not relevant for the substances identified as SVHCs due to their PBT and/or vPvB properties. An authorisation may only be granted for these substances in accordance with Article 60(4) and this is also stated in the relevant draft entries.

The main reason to recommend to specify the possible authorisation route in Annex XIV is to increase legal certainty for the applicants.

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 for the substances on the current candidate list, comments provided during the public commenting periods or other available information have not provided sufficient basis for using information on production cycles in 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, **in this**

first recommendation, a standard difference of 18 months between the application and sunset dates is used.

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 the ECHA's Committees and secretariat it is important that not all applications resulting from the first Annex XIV entries arrive at the same time. This can be achieved by setting different application dates for the prioritised substances.[1]

The main reason to recommend 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 is used as a basis to differentiate the application dates for different substances.**

Time needed to prepare an application varies from case to case and depends on many factors. Currently available information allows using two main considerations to envisage the differences in time needed to prepare an application: complexity of the supply chain and availability and nature of alternatives. It should, however, be noted that the available information allows only differentiation in relative terms; whether an average time needed to prepare an application for different uses of one substance is shorter or longer than for other prioritised substances. Furthermore, the available information and its use entail considerable uncertainties. **Therefore, the application dates are spread only over 6 months.** 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.

The authorisation application requirements, in particular the Exposure Scenarios (ES) as a part of Chemical Safety Reports (CSR), Analysis of Alternatives and Socio-economic analysis, are new for all potential applicants. In future the potential applicants can in most cases use the registrants' ESs and information in CSRs as a starting point for their preparation of their application which will not be the case for these first Annex XIV entries. To allow the potential applicants adequate time to prepare their applications for the first substances included in Annex XIV, **24 months**

[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 new and actors have no experience in preparing applications, it is likely that the applicants will use all available time until the specified latest application date to develop their applications.

from the inclusion of the substance into Annex XIV is used in this first recommendation as the earliest application date.

3.*3 Criteria used to differentiate the application dates*

Complexity of the supply chain

The complexity of the supply chain (up, down and/or to aside from the applicant) may affect the time and resources needed to collect information for preparing the different parts of an application. Furthermore, in a complex or actor rich supply chain it may be more time-consuming to decide on the most appropriate actor or actors to prepare an application and to get the group organised.

A supply chain can be complex in two ways:

- The supply chain may contain many levels: counted from the manufacturer/importer via (several) formulators to the last actor affected by the decision to grant or refuse an authorisation for the use, and/or
- One or more levels of the supply chain may have many parallel actors: where the substance as such, in preparation or incorporated into articles has many different uses which furthermore can represent different types of industry branches.

Although the users of articles containing the substance do not need (and can not) apply for authorisation for their activities, their use conditions and their requirements on the quality and function of articles are important for the preparation of the applications (e.g., Chemical Safety Report including Exposure Scenarios and, in particular, Analysis of Alternatives and Socio-economic Analysis). Consequently, when considering the complexity of the supply chain for the purpose of anticipating the time needed to prepare an application, also actors which are not part of the supply chain as defined in Article 3(17)[2] are taken into account.

Following the same line of argumentation, it could be justified to have an earlier application date, e.g., in cases where the supply chain contains only few levels, where all actors in the supply chain belong to well connected and organised industry branches and/or the end products (articles or preparations) are few and highly specialised.

Availability of information on alternatives

An analysis of alternatives (AoA) is an obligatory part of all authorisation applications. To be suitable an alternative must be available and (i) technically and (ii) economically feasible for the use and (iii) reduce the overall risk. How long it takes to prepare an AoA of adequate quality depends, among other things, on the level of information available on the alternatives and the nature of the alternatives.

[2] Actors which are not covered by the definition in Article 3(17) include, e.g., all users of articles containing a substance and consumers using a substance on its own or in preparation.

Where a lot of work to identify and assess the alternatives has already been done, it may take less time to make an AoA. This is regardless of the outcome of the assessment; i.e., that there are no identified alternatives, that there are suitable potential alternatives, or that there are several potential alternatives but there are feasibility or risk concerns related to the uses applied for. Experience on the use of alternatives in similar applications may assist in preparing an AoA for other uses. This applies also to cases where these alternatives are assessed not to be applicable for the uses applied for.

In other words, this part of the assessment is not judging whether the alternatives are feasible or safer or how long it could take to transfer to the alternatives, but whether or not information seems to be available that facilitates compiling an AoA.

In cases where the main alternatives seem to be alternative techniques, a change in the process to make the step requiring the substance superfluous or the use of (totally) different materials, it may be more demanding for the applicant to assess the technical and economic feasibility. In addition, it may also be more complicated to arrive at a conclusion on whether the overall risk is reduced. Furthermore where the suitable alternatives are alternative techniques, processes or materials the 'non-use scenario' (authorisation is refused), which is essential for the socio-economic analysis, would require consideration of totally different types of supply chains compared to the supply chain of the substance and by that collection of different information and involvement of different actors.

3.4 Recommended transitional arrangements

The above described approach results in this first recommendation to application dates between 24 and 30 months from the inclusion of the substance in Annex XIV and to sunset dates between 42 and 48 months.

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. The available Annex XV SVHC dossiers for the substances on the current candidate list, comments provided during the public commenting periods or other available information have not provided 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, **this first recommendation does not include review periods for any uses of the prioritised substances.** It should be noted that all decisions to grant an authorisation have to specify a time-limited review period(s).

5 Uses or categories of uses exempted in accordance with Article 58(2) of REACH

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement some 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 has considered the following elements when deciding whether to include an exemption of a use of a substance in Annex XIV:

- 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 use in question should also specifically refer to the substance to be included in Annex XIV either by naming the substance specifically 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 requirements[3] for the control of risks of the use. Legislation setting only the aim of measures or not clearly specifying the actual type and effectiveness of measures required 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 on 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 in the existing legislation.

For the purposes of this first recommendation ECHA used these considerations when assessing the requests for exemptions submitted during the public consultation on ECHA's draft recommendation. On the basis of the submitted comments and other available information, ECHA did not see grounds for recommending further exemptions in accordance with Article 58(2) of REACH. However, with regard to the use of the prioritised substances in medical devices and in primary/immediate packing of medicinal products ECHA was not in a position to fully assess the possible consequences of the existing Community legislation on the implementation of the provisions in Title VII of the REACH Regulation. In particular in these cases, ECHA

[3] Legislation imposing minimum requirements means that
- The Member States may adopt 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 similar minimum level of control of risks throughout the EU and that this level can be regarded as proper.

urges in its recommendation for the European Commission to examine these requests for exemptions.

Exemptions on the basis of existing restrictions

Some of the SVHC recommended for inclusion in Annex XIV are substances subject to a restriction under Annex XVII of REACH[4].

Directive 76/769/EEC set out rules concerning the placing on the market of dangerous substances and preparations. The recitals of Directive 76/769/EEC and the directives amending it provide that these rules have an objective to protect human health and/or the environment.

Accordingly Directive 76/769/EEC was legislation imposing minimum requirements relating to the protection of human health and the environment of the use of a substance. The restrictions developed under Directive 76/769/EEC have been incorporated in the Annex XVII of the REACH Regulation.

In addition Recital 80 of the REACH Regulation requires that a proper interaction should be ensured between the provisions on authorisation and restriction.

Therefore, the conditions set out in specific entries of Annex XVII under which a substance can be used can constitute an exemption from the authorisation requirement of that (those) use(s) within the meaning of Article 58(2) of the REACH Regulation for that particular substance. ECHA considers that Article 58(2) could be used to exempt a specific use from authorisation in the two following situations:

> i) Annex XVII includes a restriction on a specified use of a substance and this restriction specifies condition(s) under which the restriction does not apply
>
> ii) Annex XVII includes a generic ban on a substance and a specified use is exempted from this generic ban. Such an exemption can be subject to further conditions.

In this first recommendation ECHA suggests to exempt from the authorisation requirement the specified uses of one substance that are permitted under conditions set out in Annex XVII. Furthermore, in its recommendation ECHA urges the European Commission to examine whether and under what conditions other exemptions from the authorisation requirement should be introduced on the basis of specific exemptions from restrictions as detailed in the entries of Annex XVII.

6. Application of authorisation to product and process oriented research and development

In addition the draft Annex XIV entries for substances recommended for inclusion in Annex XIV may include a specific exemption for the use of the substance in product

[4] Annex XVII shall apply from 1 June 2009, until that Directive 76/769/EEC applies.

and process oriented research and development (PPORD) up to a defined quantity (Article 56(3)).

The Annex XV SVHC dossiers, comments provided during the public commenting periods or other available information do not provide background information justifying PPORD exemptions for any of the substances prioritised for the inclusion in Annex XIV. Therefore, **no PPORD exemptions are included in this first recommendation.**