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

GENERAL APPROACH

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INTRODUCTION

Pursuant to Article 58(3) of the Regulation (EC) No 1907/2006 (REACH) ECHA, taking into account the opinion of the Member State Committee (MSC), has to recommend to the Commission priority substances for inclusion in Annex XIV specifying for each substance recommended for inclusion in Annex XIV the items set out in Article 58(1) of REACH (hereafter referred to as "Annex XIV entries"), i.e., ECHA has to specify in its recommendation the following:

- The identity of the substance
- The intrinsic property (properties) of the substance referred to in Article 57
- Transitional arrangements
    - The sunset date(s)
    - The latest 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.

Pursuant to Article 58(4) of REACH, prior to sending its recommendation to the Commission, ECHA invites all interested parties to submit comments on its draft recommendation, and in particular on uses which should be exempt from the authorisation requirement. The comments are made available to the MSC which considers them when preparing its opinion. ECHA takes the comments submitted by the interested parties and the MSC opinion into account when finalising its recommendation.

This document sets out how ECHA prepares its draft Annex XIV entries.

1. Identity of the substance

Identity of the substance is given as provided in the Candidate List of substances of very high concern for Authorisation (the Candidate List)[1], i.e. the substance name(s), as well as EC number(s) and CAS number(s) where available.

In the consultation of interested parties no comments are expected on the identity of the substances (see also point 2 below).

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), is (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 of REACH, which led to the inclusion of the substance in the Candidate List. These elements can accordingly not be subject to further scrutiny in this phase of the

[1] See https://www.echa.europa.eu/candidate-list-table

authorisation process (recommendation of priority substances for inclusion in Annex XIV) and therefore in principle comments on these elements of the draft recommendation are not considered.

3. Transitional arrangements

For each substance subject to authorisation, Annex XIV entries need to specify so-called "sunset dates" and "latest application dates" (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.*

- **Latest 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.*

The sections below describe information that ECHA takes into account for determining the transitional arrangements to be included in ECHA's recommendation for the prioritised substances. Such information relates to organisational and practical aspects from ECHA's and applicants' perspectives.

3.1. Sunset dates

Article 58(1)(c)(ii) specifies that the latest application date must be at least 18 months before the sunset date. Article 58(1)(c)(i) specifies that the sunset date(s) for uses of a substance should where appropriate take into account the production cycles specified for those uses.

ECHA has so far seen no reasons to deviate from the 18 months set out in the legal text or define criteria for such deviation(s) based on production cycles referred to in Article 58(1)(c)(i). **Therefore, ECHA normally recommends a standard difference of 18 months between the latest application and sunset dates.**

3.2. Latest Application dates[2]

Determining the latest application date slots

Article 58(3) provides that the application and sunset dates shall take account of the Agency's capacity to handle applications for authorisation in the time provided for. To ensure workability for ECHA's Committees and secretariat when processing the applications, it is important that not all applications arrive at the same time. This can be better achieved by setting different latest application dates for (groups of) the recommended substances. Setting different latest application dates will also assist interested parties who may wish, in accordance with the procedure set out in Article 64(2)

[2] The latest 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. Applicants may obviously also submit an application after the latest application date. However, such applicants may not use the substance after the sunset date until authorisation has been granted by the Commission for the applied use.

of REACH, to provide information on alternative substances or technologies for authorisation applications of uses of different substances included in Annex XIV. Finally, setting different latest application dates will assist the Commission, who has to prepare draft authorisation decisions within three months of receipt of the opinions of ECHA's Risk Assessment and Socio Economic Assessment Committees.

To support the efficient handling of the applications, ECHA has established specific time periods for submitting applications for authorisation ("submission windows") with three months intervals in between, which are normally in February, May, August, and November each year. **ECHA normally recommends that the latest application dates are set in three months intervals which coincide with the (last days of) the submission windows.**

To allow the potential applicants adequate time to prepare their authorisation applications for the substances included in Annex XIV, **ECHA normally recommends that for each recommendation the first latest application date is set at least 18 months after the date of inclusion of the substance into Annex XIV.**[3]

In general, the aim is to have a similar workload for each latest application date slot. However, there may be reasons to allocate in a new recommendation less workload to a certain latest application date. This can be the case where the latest application dates of substances already included in Annex XIV or foreseen to be included[4] in this Annex are expected to coincide with those in the new recommendation.

Allocation of substances to the latest application date slots

Article 62(3) stipulates that applications may be made for several substances that meet the definition of a group of substances in Section 1.5 of Annex XI of REACH. As for such substances common applications are expected to be received, **ECHA normally recommends to allocate substances potentially fulfilling the definition of a group to the same latest application date slot**.

Although the time differences between the latest application dates set out in a recommendation (i.e. 3-6 months) can be considered as minor compared to the total time reserved for the potential applicants to prepare their applications, it is suggested to allocate to the "later" latest application date slots substances with uses which may require more time to prepare an application.

In a recommendation, latest application date slots will normally correspond to 18, 21 and 24 months after inclusion in Annex XIV.

Some of the aspects that can be taken into account by ECHA when comparing recommended substances in terms of the time required to prepare applications are described in detail in the Practical implementation document for the Annex XIV entries approach[5]. These include:

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[3] It should be recalled that it is the Commission who decides on the actual latest application and sunset dates taking into account ECHA's recommendation. Thus, the Commission may decide on different latest application dates and sunset dates than those proposed in the recommendation. In addition, the final dates in the Commission decision may be adjusted to coincide with the submission windows. Finally, the exact date when the Commission takes such decision cannot be predicted at the time the recommendation is finalised. Therefore, the recommendation does not provide a numerical date for the first latest application date.

[4] i.e. substances of previous recommendations which have not yet been included by the Commission into Annex XIV.

[5] Link to the Practical implementation document for the Annex XIV entries approach: https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

- structure and complexity of supply chain;
- registration requirements

It should be emphasized 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. These aspects are considered in the next phase of the authorisation process, i.e. when assessing an authorisation application. Article 55 of REACH 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)). This information will 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 on an authorisation application. This may have an impact on the decision to grant an authorisation for the use(s) applied for and the length of the time limited review period of the authorisation.

As mentioned above, when allocating the recommended substances to the determined slots, the associated (foreseen) workload should also be taken into account. The prediction of the workload resulting from inclusion of different substances in Annex XIV is highly uncertain. The current experience, number of registrations and of registered uses (in the scope of authorisation), are used as rough indicators to estimate ECHA's workload.

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.

All decisions granting an authorisation will include review periods which will be based on case specific information provided in the applications for authorisation. ECHA has published guidance[6] on the type of information in an application for authorisation which may influence the length of the review period when granting an authorisation, in order to increase the predictability of review periods for granted authorisations.

As a consequence, it does not seem appropriate to propose a draft Annex XIV entry for review periods. Therefore, **ECHA normally does not recommend review periods**.

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*'.

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6 See RAC's and SEAC's approach for establishing the length of the review period (https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf).

The decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the Commission, based on ECHA's recommendation. The Commission enjoys discretion in deciding whether or not to provide exemptions from authorisations pursuant to Article 58(2) of REACH within the limits of EU law, including the proportionality principle. It should however be recalled that the discretion to grant an exemption provided for in Article 58(2) of REACH is an exception to the rule that the placing on the market and the use of substances of very high concern should be subject to authorisation, one of the purposes of which is to ensure they are phased out where economically and technically feasible (Article 55 of REACH).

ECHA further recalls that it is apparent from the terms of Article 58(2) that:

(a) The obtaining of an exemption is a possibility and not an entitlement;
(b) The discretion afforded to the Commission only ever arises where there is specific minimum EU legislation in place imposing minimum requirements relating to the protection of human health and/or the environment for the use of the substance ensuring the risk is properly controlled; it should be noted that in the absence of existing specific EU legislation in force, the Commission cannot grant an exemption on the basis of Article 58(2) of REACH in respect of the substance listed in Annex XIV of REACH; thus, national legislation or non-binding EU acts addressing such use is not a sufficient ground for the Commission to grant such an exemption[7];
(c) Risk assessment and the question as to whether individual operators are able to control risks associated with the use of a substance of very high concern are not included among the criteria that may constitute a basis for the granting of exemptions of a use. In the absence of specific Union legislation the Commission has no discretion to grant an exemption under Article 58(2) of REACH regardless of the outcome of risk assessment.

In preparing its recommendation ECHA will consider the following elements in deciding whether to recommend an exemption of a use of a substance[7]:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific 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 definition of use set out in Article 3(24) of REACH. Furthermore, the reasons for and effect of any exemptions from the requirements set out in the legislation have to be assessed;
- The existing EU 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 a group of substances that is clearly distinct from other substances. A mere reference to carcinogenic, mutagenic or reprotoxic substances is too general and requires case-by-case assessment;
- The existing EU legislation imposes minimum requirements which properly control the risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures (e.g., EU legislation which provides Member States the possibility to impose less stringent

[7] For further information, see the judgment of the General Court in Case T-360/13, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) vs European Commission.*

requirements than that suggested by the EU legislation in question) 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) of REACH. 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 consultation on the draft recommendation in the context of suggestions for exemptions from the authorisation requirement in accordance with Article 58(2).

Interested parties when preparing any suggestions on exemptions for authorisation under Article 58(2) of REACH are advised to take into account ECHA's responses to comments on similar requests for exemptions submitted by interested parties in earlier consultations on ECHA's draft recommendations.[8] Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation (see Annex 1), there is no need to propose an additional specific exemption.

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)).

So far ECHA has not considered it appropriate to recommend specific exemptions for PPORD. However, ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of REACH.

[8] These responses to comments can be found at the following webpage: https://www.echa.europa.eu/previous-recommendations

Annex 1. Generic exemptions from the authorisation requirement

1. Exemptions for all intrinsic properties

On-site isolated intermediates and transported isolated intermediates (Art. 2(8)(b) REACH).
Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products* and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Art. 2(5)(a) REACH). * Directive 2001/82/EC will be repealed and replaced by Regulation (EU) 2019/6 on veterinary medicinal products from 28 January 2022
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* of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption; - as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC* as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production and Commission Decision 1999/217/EC** of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council; - as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition; - in animal nutrition within the scope of Council Directive 82/471/EEC*** of 30 June 1982 concerning certain products used in animal nutrition (Art. 2(5)(b) REACH). * Council Directive 89/107/EEC and Council Directive 88/388/EEC have been replaced by Regulation (EC) No 1333/2008 on food additive from 20 January 2010 ** Commission Decision 1999/217/EC has been replaced by Regulation (EU) No 872/2012 from 22 April 2013 *** Council Directive 82/471/EEC has been replaced by Regulation (EC) 767/2009 from 1 September 2010
Scientific research and development, i.e., use in scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year (Art. 3(23) and 56(3) REACH).
Use in plant protection products within the scope of Council Directive 91/414/EEC* (Art.56(4)(a) REACH). * Directive 91/414/EEC has been replaced by Council Regulation (EC) No 1107/2009 from 14 June 2011

Use in biocidal products within the scope of Directive 98/8/EC* (Art. 56(4)(b) REACH). * Directive 98/8/EC has been replaced by the Biocidal Product Regulation (EU) No 528/2012 from 1 September 2013
Use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (Art. 56(4)(c) REACH).
Use as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems (Art. 56(4)(d) REACH).
Use of substances when present in mixtures below a concentration limit of 0.1% weight by weight (w/w) for substances referred to in Article 57(d), (e) and (f) REACH. For all other substances, use of substances when present in mixtures below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which result in the classification of the mixture as hazardous. (Art. 56(6)(a) and (b) REACH).

2. Exemptions specific to certain intrinsic properties

Use in cosmetic products within the scope of Council Directive 76/768/EEC* in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health (Art. 56(5)(a) REACH). * Council Directive 76/768/EEC has been replaced by the Cosmetic Regulation (EC) No 1223/2009 from 11 July 2013
Use in food contact materials within the scope of Regulation (EC) No 1935/2004 in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a),(b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health (Art. 56(5)(b) REACH).
Use in medical devices, within the scope of Directives 90/385/EEC*, 93/42/EEC* or 98/79/EC** in the case of substances that are subject to authorisation only because of hazards to human health (Art. 60(2) and 62(6) REACH) * Council Directives 90/385/EEC and 93/42/EEC will be mainly repealed and replaced by the Medical Devices Regulation 2017/745 from 26 May 2020 ** Council Directive 98/79/EC will be mainly repealed and replaced by the In Vitro Diagnostic Medical Devices Regulation 2017/746 from 26 May 2022

Further details on the application of these exemptions can be found in ECHA's Q&As on authorisation published on ECHA's website at the following link:
http://echa.europa.eu/support/qas-support/qas