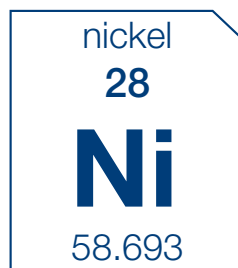


The **REACH** Authorisation Process

– *Key Questions and Answers*

Edition 2 - April 2011





Nickel is a metallic element, making up 0.008% of the Earth's crust. However, when the deeper core of the Earth is included, nickel becomes more abundant, and is the fifth most common element after iron, oxygen, silicon and magnesium.



“ One thing I have learned in a long life: that all our science, measured against reality, is primitive and childlike - and yet it is the most precious thing we have ”

Albert Einstein



Foreword

The REACH Regulation Authorisation title (Title VII) represents a significant challenge for many substance producers and indeed value chains by virtue of the very heavy regulatory burden of proof it poses with respect to continued use of identified “substances of very high concern” (SVHCs). The process involves a number of steps including:

- identification of SVHCs on the basis of criteria contained within Article 57 of REACH;
- their listing on a so-called candidate list for consideration as priority substance for eventual inclusion in Annex XIV of REACH;
- the prioritisation of listed substances to Annex XIV with defined sunset dates after which the substance may no longer be placed on the market or used;
- processes for substance manufacturers/importers and/or users to apply for the authorisation of the use(s) of the substance(s);
- procedures for the approval or granting of an authorisation for the use(s) in defined applications by the Commission based on opinions from ECHA and its supporting risk assessment and socio-economic committees.

Since its inception, the process has attracted a great deal of scrutiny and interest from many stakeholders. A desire to see it move quickly to address concerns over use of SVHCs has seen acceleration of the listing of substances – sometimes controversially. Clearly there is a need to maintain an objective science and data driven approach to addressing concerns over the use of identified SVHCs.

The process is also evolving as the European Chemicals Agency (ECHA), Member States and stakeholders (including industry) get to grips with the different phases of the process and their understanding of what is important for each step. From a business perspective, it is vital that the process be clear, transparent and certain. Presently, none of these parameters can be said to be met.

This document is intended to provide Nickel Institute member companies and members of the Nickel Consortia with an overview of the process to date. In effect it is a “snapshot” of where the process is now. The document has been compiled in a questions and answers format based on questions posed by the Institute to its legal advisors McDermott Will & Emery Stanbrook LLP. The legal advisors have populated the answers with a wealth of information and analysis based on a review of the legal text and its application in situ by ECHA, the Member States and the European Commission. It is the intention of the Institute to update this document and information on a regular basis so as to keep up to date with the evolving nature of the authorisation process.



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Acknowledgements

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Table of contents

1. What are the criteria currently being used (or could be used) by Member States, ECHA and the European Commission for a substance's inclusion in the candidate list for authorisation in REACH Annex XIV? With regard to the "widely dispersed use" criteria where is it defined in the legal text of REACH?	8
Introduction	8
Procedure	9
(i) Substances Not Subject to REACH or to Authorisation	10
(ii) Use Specific Exemptions From Authorisation	11
(iii) Substances of Very High Concern ("SVHC")	12
(iv) Other Considerations For Inclusion in the Candidate List	14
2. What are the relevant criteria and factors in the process of prioritisation for REACH Annex XIV listing that are being used by ECHA and the EU Commission concerning submission made to them or the Member State authorities/entities involved in the process?	16
Criteria Used for Prioritisation of Substances for Authorisation	16
(I) Substances Having PBT or vPvB Properties	17
(II) Substances of Wide Dispersive Use	18
(III) High Volumes of the Substance	21
(IV) "Regulatory Effectiveness and Coherence" of Priority	23
3. What factors could be relevant to ECHA or the EU Commission to slow down or speed up prioritisation for possible listing for authorisation of a nickel substance under REACH?	24
Potential to Speed Up Prioritisation	24
Potential to Slow Down Prioritisation	24
4. What are the relevant criteria and factors in the actual listing process, being used by ECHA and the EU Commission concerning submissions made to them or Member State authorities/entities involved in the process of inclusion in Annex XIV?	26
Sunset date	27
Application date	28
Review periods	29
Uses Exempted from the Authorisation Requirement: Exemptions under Article 58(2) of REACH	29
Uses Exempted from the Authorisation Requirement: Product and Process Oriented Research and Development (PPORD)	30
5. Proportionality Principle: Can this principle be used to avoid the listing of substances if the substance SVHC is already regulated through another Regulation or Directive?	31
6. What criteria are currently being applied by ECHA and the EU Commission for exemption from listing for authorisation under REACH?	32
Restrictions With Exceptions Already in Annex XVII of REACH	34



7. Can a grouping of substances be applied in the listing process for inclusion in Annex XIV (link with the 1st ATP of the CLP Regulation)?	36
8. What obligations and consequences arise if REACH Annex XIV listing is made and authorisation is then granted for a certain use?	39
Civil Liability	39
Downstream Users Requiring Information	39
Authorisation Invalid if No Review Within Time Limits	40
Update Safety Data Sheets and Inform Users/Recipients	40
9. What impact could listing in REACH Annex XIV and an application for authorisation have on (i) a Substance Already Listed as a Restricted Substance in Annex XVII? and (ii) on the Restrictions Applicable to the Substance?	41
10. Who can apply (i) for Authorisation, or (ii) Exemption from listing for Authorisation, in Annex XIV of REACH?	44
Applicants for authorisation	44
Applicant for exemption from authorisation	44
11. What issues should be taken into account (e.g. competition law) if applicants for REACH authorisation make joint applications? Or provide data/information to each other in the context of a joint application for authorisation?	45
EU Competition Law	45
Confidential Business Information	47
Privacy – Personal Data Protection	47
12. What are (i) the time limits in force to apply for, and the grant of, authorisation for a use included in Annex XIV of REACH? And (ii) what time periods are ECHA and the EU Commission currently applying for authorisation applications?	48
Time limits to Apply for, and Grant of, Authorisation	48
Time Periods ECHA and EU Commission are currently Applying for Authorisation applications	49
Sunset Date	49
Last Application Date	49
13. What impact might applicable time periods have on applicants for authorisation, or requests for exemption from authorisation?	50
Impact of Time Periods on Authorisation	50
Impact of Time Periods on Exemptions from Authorisation	50
14. Will all downstream users need to apply for an authorisation to be able to use the substance?	52
15. What fee(s) must be paid and who must pay the fee(s) when seeking listing for authorisation in REACH Annex XIV including the respective payment obligations of joint applicants?	54
Individual application for Authorisation for Use(s) of Substance(s)	54
Joint application for Authorisation for Use(s) of Substance(s)	54



16. Is the review process after grant of authorisation free of charge?	55
17. What information or data could be disclosed to the public if (i) a REACH authorisation application is made? or (ii) a claim is made for exemption from listing for authorisation?	56
Disclosure of Documents	56
Disclosure on Public Databases	57



Glossary

Al-RCF:	Aluminium silicate – Refractory Ceramic Fibres
BfR:	German Federal Institute for Risk Assessment
CARC:	Carcinogenic
CLP:	Regulation (EC) 1272/2008 on Classification, Labelling and Packaging of Hazardous Substances and Mixtures
CMR:	Carcinogenic, Mutagenic, Reproductive Toxicity
CSR:	Chemical Safety Report
CTPHP:	Coal Tar Pitch High Temperature
DIBP:	Diisobutyl Phthalate
DNEL:	Derived No-Effect Level
ECHA:	European Chemicals Agency
EU:	European Union
MDA:	DiAmiroDiphenylMethane
MSC:	Member State Committee
PAH:	Polycyclic Aromatic Hydrocarbon
PBT:	Persistent, Bioaccumulative and Toxic
PNEC:	Predicted No-Effect Concentration
PPORD:	Product and Process Oriented Research and Development
RA:	Risk Assessment
REACH:	Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM:	Risk Management Measure
R&D:	Research and Development
SCCP:	Short Chained Chlorinated Paraffin
SEA:	Socio-Economic Analysis
SIEF:	Substance Information Exchange Forum
SVHC:	Substance of Very High Concern
T:	Toxic
vPvB:	very Persistent very Bioaccumulative
WFD:	Water Framework Directive 2000/60/EC
Zr-Al-RCF:	Zirconia-Aluminium silicate-Refractory Ceramic Fibres



1

What are the criteria currently being used (or which could be used) by Member States, ECHA and the European Commission for a substance's inclusion in the candidate list for authorisation in REACH Annex XIV? With regard to, the "widely dispersed use" criteria where is it defined in the legal text of REACH?

Introduction

- 1 Before proceeding, it is useful to summarise the procedure to be followed under REACH for a recommendation by ECHA that a substance be given priority for inclusion in Annex XIV. Inclusion in Annex XIV means the substance is authorised only for specified use(s) in the EU, subject to the conditions set out in Annex XIV. The process of being recommended by ECHA as a "priority substance" for authorisation is in two parts:
 - Inclusion on the candidate list: Identify the Substances of Very High Concern ("SVHC") that satisfy the criteria in REACH Article 57, and establish a candidate list of such substances for possible inclusion in Annex XIV;
 - Recommendation as a "Priority Substance": Once a substance is included on the candidate list, ECHA may include the substance in a recommendation that the substance be a "priority substance" for inclusion in Annex XIV.
- 2 This first question deals with the first part of the procedure, while the second sentence of Question 1 is only relevant in the context of the second part of the procedure, namely ECHA's recommendation that a substance be considered a "Priority Substance" for eventual listing in REACH Annex XIV. To answer the second part of this question first, in making a recommendation to prioritise a substance (already on the candidate list) for inclusion in Annex XIV, in the legal text of REACH at Article 58(3) in the first paragraph it provides that "... Priority shall normally be given to substances with ... wide dispersive use." There is no definition of this expression in REACH. However, Annex III refers to "dispersive or diffuse use(s) particularly where such substances are used in consumer preparations or incorporated into consumer articles"¹. This indicates that dispersive use may include a substance's use in consumer preparations or incorporated into consumer articles.
- 3 Note that the following deals only with the approach of ECHA to the selection of substances for inclusion in the candidate list. Germany's Federal Institute for Risk Assessment ("BfR") has separately established its own criteria used to identify substances of very high concern ("SVHC").²

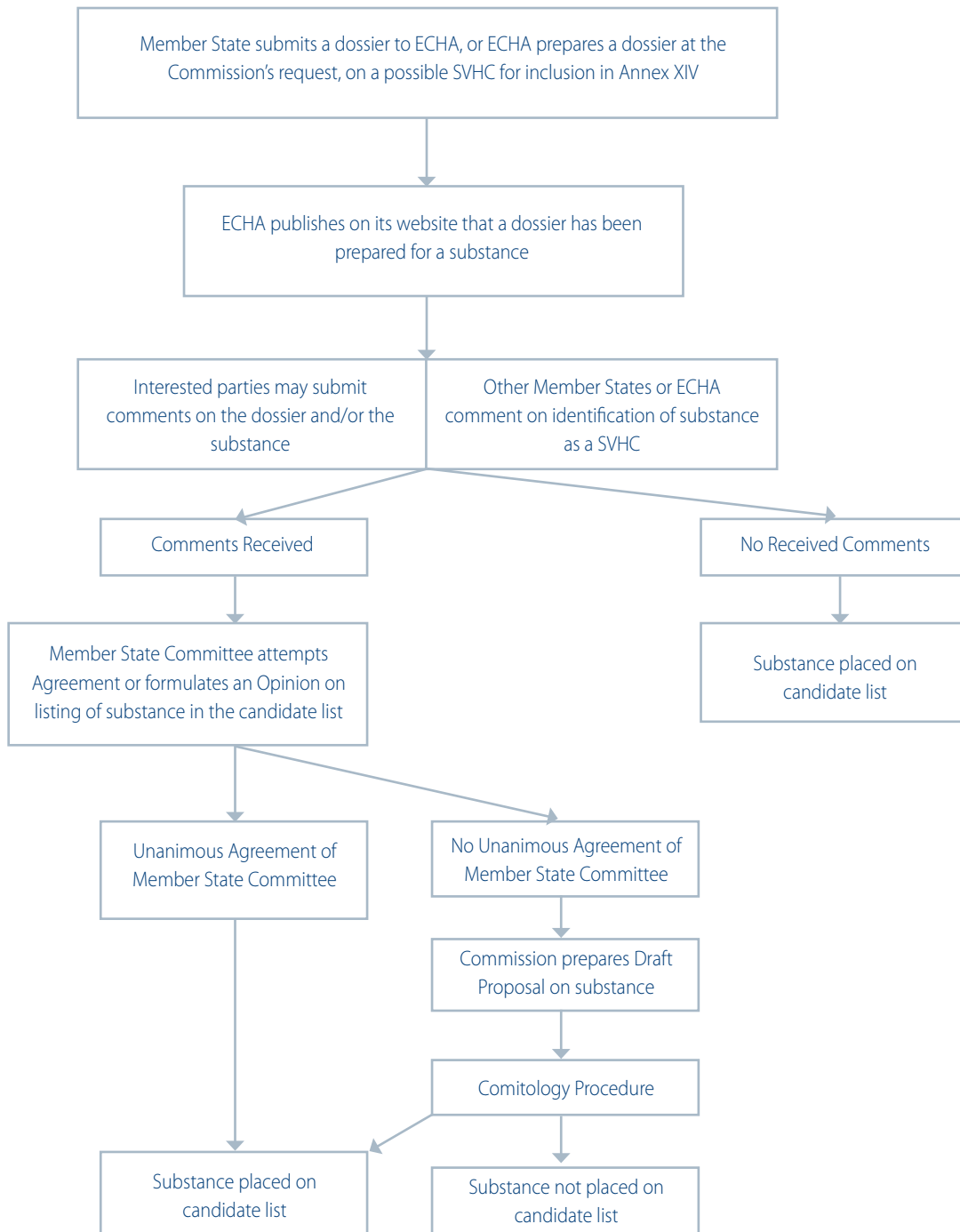


¹ REACH Annex III at (b).

² http://www.bfr.bund.de/cm/252/kriterien_des_bfr_zur_auswahl_von_kandidatenstoffen_fuer_das_zulassungsverfahren_unter_reach.pdf

Procedure

- 4 In diagrammatic form, the following shows the procedure(s) for inclusion of a substance on the candidate list. Note that there is a further procedural step before the substance is recommended by ECHA as a priority substance for inclusion in Annex XIV.



- 5 The following deals with the main (first) part of Question 1, namely the criteria used (or that could be used) for inclusion of a substance in the candidate list for authorisation in Annex XIV of REACH.
- 6 There is only a limited group of substances (noting that “substances” excludes articles, mixtures or alloys), that may be included in REACH Annex XIV. A “substance” is defined in REACH as:

“A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”³

- 7 For a substance not to be included in the candidate list for authorisation, the substance must:
 - be subject to a complete exception from REACH; or
 - be exempt from authorisation under REACH (even if other parts of REACH may apply to the substance);
 - all uses of the substance in the EU are subject to an exemption from authorisation, either for a group of uses or an individual use exemption; or
 - the substance is not a Substance of Very High Concern (SVHC).

It can be seen then, that a substance cannot be placed on the candidate list if (i) the substance itself is excluded or exempted from REACH, or (ii) its uses in the EU are exempt from authorisation, or (iii) it is not a SVHC.

(I) Substances Not Subject to REACH or to Authorisation

- 8 REACH does not apply to the following substances so that they cannot be on the candidate list:
 - (i) radioactive substances;
 - (ii) non-isolated intermediates;⁴
 - (iii) waste;⁵
 - (iv) substances exempted from REACH by Member States “where necessary in the interests of defence.”⁶

In addition, the following substances are exempted from authorisation and so equally, cannot appear on the candidate list:

- (v) on-site isolated intermediates;
- (vi) transported isolated intermediates.⁷



³ REACH Article 3(1)

⁴ Defined at Article 3(15)(a) as : “non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture.”

- 9 It might be noted that in general, the carriage of dangerous substances and dangerous substances in dangerous preparations, by rail, road, inland waterways, sea or air, are also not subject to REACH. However, as soon as the substance stops being transported (and subject to the rules on transport of dangerous goods), REACH and authorisation potentially apply.

(II) Use Specific Exemptions From Authorisation

* Group exemptions

- 10 Substances, if used in certain products groups (indicated below) can not be placed on the candidate list if they are only used in those products. A substance cannot be on the candidate list if the substance is only used:
- (a) in medicines (pharmaceuticals and veterinary medicines);
 - (b) in food or feeding stuffs (including as food and feeding stuffs additives, food flavourings and in animal nutrition);⁵
 - (c) in plant protection or biocidal products;
 - (d) as motor fuel and in fuel for combustion plants of mineral oil products;
 - (e) as fuel in closed systems; and
 - (f) in cosmetics and food contact material, where the substance is regarded as a SVHC only because of hazards to human health.

Note that a substance can still be placed on the candidate list if it also is used in products other than in medicines, food, foodstuffs, cosmetics, fuel, biocides and food contact materials.

* Specific Use Exemption: Individual Exemption

- 11 REACH Article 58(2) provides for certain other uses or categories of uses that may be exempted from authorisation. If the only uses to which a substance is put in the EU are exempt from authorisation, there would be no reason to include the substance in the candidate list. If all uses of a substance is covered by the three considerations discussed below it is very likely ECHA would not include the substance in the candidate list.
- 12 Specific use (individual) exemption is conditional. Uses of a substance may be exempted from authorisation:

“provided that, on the basis of the existing specific Community [EU] 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.”⁹

5 As defined in Directive 2006/12/EC on Waste – Article 2(2) of REACH.

6 REACH Article 2(3).

7 REACH Article 2(8)(b).

8 REACH Article 2(5).

9 Article 58(2).



- 13 ECHA has taken a strictly legal approach to these criteria so far. ECHA has, before a substance's use can be specifically exempted from authorisation, indicated that no exemption should be given unless:
- (a) there is existing EU legislation that addresses the use or categories of use proposed to be exempted; and
 - (b) such EU legislation properly controls the risk to human health and/or the environment from the use of the substance; and
 - (c) such EU legislation imposes minimum requirements for the control of risks arising out of the use.¹⁰

In many cases, there may be certain uses of a substance that do not comply with all these three considerations. In that case it is most likely the EU Authorities will consider that the substance is eligible (if other criteria are satisfied) to be put on the candidate list. The three considerations mentioned above are discussed in more detail in answer to Question 6.

(iii) Substances of Very High Concern (“SVHC”)

- 14 If the substance is not exempt from REACH or all its uses are not exempt from authorisation, the substance can only be placed on the candidate list for authorisation if the substance is an “SVHC.” Substances that may be subject to authorisation are referred to as “Substances of Very High Concern” or “SVHC.”¹¹ The aim of requiring an authorisation for an SVHC is to assure (a) that risks from the SVHC are properly controlled, and (b) that the SVHC are progressively replaced by less hazardous alternatives where the alternatives are economically and technically viable.¹²
- 15 An SVHC listed in Annex XIV cannot be placed on the EU market for a particular use (or be used) unless: (i) that use has been authorised, (ii) the substance or its use has been exempted from authorisation, (iii) the “sunset period” for the substances’ use as established during the authorisation procedure, has not yet expired, or (iv) an application for authorisation has been made before the date at least 18 months before the sunset date and no decision has yet been taken.
- 16 According to REACH Article 57, the only substances that may be placed on the Annex XIV candidate list of SVHC are:
- (a) CMR (Carcinogenic, Mutagenic, Reproductive toxicity) substances of categories 1A or 1B;¹³
 - (b) PBT (Persistent, Bioaccumulative, and Toxic) and vPvB (very Persistent and very Bioaccumulative) substances;¹⁴ and
 - (c) endocrine disruptors and other substances “for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances” mentioned in (a) and (b) above.¹⁵ (Referred to hereafter as “substances of equivalent concern”).



¹⁰ See for example, ECHA Responses to Comments Document for DEHP of 1 June 2009.

¹¹ REACH Article 55.

¹² *Ibid.*

¹³ REACH Article 57(a), (b) and (c).

¹⁴ REACH Article 57(d) and (e).

¹⁵ REACH Article 57(f).

- 17 Before a substance can be placed on the candidate list a dossier must be prepared as required in REACH Annex XV. ECHA encourages Member State Authorities “to engage stakeholders and other interested parties in the development of the dossier as early in the process as possible.”¹⁶ ECHA also suggests that Member State Authorities should consider informing identified interested parties that work related to a possible identification of an SVHC dossier has been initiated.¹⁷
- 18 ECHA recommends that the Member State Authorities should review the primary sources of data (e.g. full study reports), where available for the Annex XV dossier, particularly for key studies.¹⁸ Information from secondary sources should not generally be used as the basis for the proposal to include the substance as an SVHC. Secondary sources can be used if there is a high confidence in the robustness of the approach used to review the data from the secondary source.¹⁹

* CMR Substances

- 19 For CMR substances, ECHA recommends that where a CMR substance is the subject of a dossier for inclusion in the candidate list, the CMR substance should first be proposed and achieve entry for harmonized classification under the CLP Regulation before the substance is proposed to be identified for inclusion in the candidate list for authorisation. ECHA notes that in such a case, identification of a CMR substance for inclusion in the candidate list might also be more easily agreed between the EU Member States.²⁰
- 20 Where there is a harmonized classification for a substance as CMR categories 1A or 1B under CLP²¹ REACH Article 59(2) provides that an Annex XV dossier may be limited, where appropriate, simply to a reference to an entry in Part 3 of Annex VI of Regulation 1272/2008 on Classification, Labelling and Packaging of Hazardous Substances and Mixtures (“CLP Regulation”).²² ECHA’s Guidance nevertheless recommends that the Annex XV dossier include “available information on exposures, alternative substances and risks.”²³ This is because a mere reference to the substances’ harmonized CMR classification may not be enough for the purpose of priority setting. This indicates that even if a substance were CMR Cat. 1A or 1B, a dossier on the substance should contain more than just a reference to its CMR classification.

16 ECHA Guidance on Dossier for Identification of SVHC, June 2007 p. 15.

17 *Op cit.*

18 *Ibid at p. 17.*

19 *Op cit.*

20 ECHA Guidance on Preparation of Annex XV dossier on SVHC, June 2007 at p. 14.

21 *Op cit. at p. 14.*

22 Official Journal 2008 L 353/1.

23 *Op cit. at p. 14.*



* PBT and vPvB Substances

- 21 ECHA notes that for a PBT or a vPvB substance, all of the relevant criteria in REACH Annex XIII have to be demonstrated to be fulfilled for the substance, based on measured or experimental data.²⁴ ECHA also considers that as well as information directly related to PBT or vPvB set out in Annex XIII, information on other areas will be of use, “for example physico-chemical data relevant to the interpretation of other test results. The need to consider other information will depend on the specific case.”²⁵ Hence, it appears ECHA regards the information required by Annex XIII for PBT and vPvB substances to not be exhaustive in determining whether a substance is a SVHC.

* Substances of Equivalent Concern

- 22 Where REACH registration of a substance has PBT properties, but some of the evidence does not relate directly to REACH Annex XIII criteria, ECHA Guidance indicates that a justification for an “equivalent level of concern”, (including scientific evidence of probable serious effect to human health or the environment) will be needed.²⁶ ECHA has suggested that if there is not sufficient evidence for making a proposal that the substance is a SVHC but there are still concerns that the substance may meet the criteria for identification as a SVHC and EU wide action is needed, a substance evaluation could be initiated so as to generate information to clarify the concerns.²⁷

(iv) Other Considerations For Inclusion in the Candidate List

- 23 When assessing possible inclusion of a substance in the candidate list ECHA will also consider:
- whether new data not considered in the dossier may have become available; and
 - whether another Member State or ECHA is already preparing an Annex XV dossier either for classification and labeling purposes or a “restriction” proposal.²⁸
- 24 It is noted that ECHA recommends that the other EU Authorities (Member States and Commission) consider the same prioritisation principles that ECHA uses to prioritise SVHC, when deciding for which substance(s) the Authorities will prepare Annex XV dossiers for inclusion as a SVHC.²⁹ Hence, when an authority proposes to prepare a dossier on a substance, and where evidence is available to support the argument, submissions might be made that it is not appropriate to prepare the dossier because of the prioritisation criteria used by ECHA – considered further in answer to Question 2.



²⁴ *Ibid at p. 17.*

²⁵ *Ibid at p. 18.*

²⁶ *See ECHA Guidance for Preparation of Annex XV Dossier on the Identification of Substances of Very High Concern, June 2007 at p. 12.*

²⁷ *Op cit.*

²⁸ *Op cit.*

²⁹ *Op cit. p. 13.*



2

What are the relevant criteria and factors in the process of prioritisation for REACH Annex XIV listing that are being used by ECHA and the EU Commission concerning submission made to them or the Member State authorities/entities involved in the process?

Criteria Used for Prioritisation of Substances for Authorisation

27 ECHA has, so far, relied heavily on the particular wording of REACH Article 58(3) in determining how it will prioritise SVHC for authorisation in Annex XIV of REACH. ECHA accepts, as set out in recital (78) of REACH, that:

“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.”

28 For prioritising substances for the candidate list for inclusion in REACH Annex XIV, ECHA has, so far, mainly relied on the criteria set out in REACH Article 58(3), namely that “priority shall normally be given to substances with:

- (a) PBT or vPvB properties, or
- (b) wide dispersive use; or
- (c) high volumes.”

29 ECHA supplements these three criteria with the additional criteria of whether inclusion for prioritisation is likely to be effective from a regulatory perspective - called “regulatory coherence and effectiveness.” This concept is considered in more detail below.

30 The above four criteria (PBT or vPvB, wide dispersive use, high volumes, and regulatory effectiveness) are not exclusive. ECHA has indicated it may use additional or different criteria in the future. It is noted that ECHA is under no obligation to use any of these criteria. The only obligatory requirement in REACH for prioritisation (assuming the substance is an SVHC and not exempted/excluded from authorisation) is that ECHA is required to take into account the Member State Committee’s opinion on any prioritisation or “candidate list.”³⁰ While the opinion of the Member State Committee will certainly be very persuasive, there is no legal obligation on ECHA to follow the Committee’s opinion when making its recommendation on priority substances to the European Commission.



30 REACH Article 58(3).

- 31 ECHA recognizes that the three criteria in Article 58(3) – namely, PBT or vPvB properties, wide dispersive use, or high volumes – that normally give priority for inclusion in Annex XIV, are not exclusive. This is indicated by use of the word “normally” in Article 58(3). ECHA also recognizes that any one of the three criteria can be used for prioritisation. Nevertheless, ECHA considers that at this initial stage, in order to further differentiate substances for priority as candidate substances, it will consider (at least initially) how many of the three criteria in Article 58(3), together with the supplementary criteria of “regulatory effectiveness”, are met by a candidate substance and to what degree.
- 32 ECHA suggests that (i) potential releases, and (ii) exposure from uses other than “wide dispersive”, could also be taken into account if such information is available.³¹ It appears however, that ECHA does not currently intend applying these additional two criteria, at least not at this stage. Further, ECHA notes that not fulfilling the PBT or vPvB criteria does not mean that CMR substances having wide dispersive use and/or high volumes will be excluded from prioritisation. ECHA also indicates that as the candidate list becomes longer it may be necessary to further differentiate between substances on the basis of their intrinsic properties (i.e. PBT or vPvB properties versus C, M or R properties) if a similar priority results from the degree of fulfillment of other criteria in REACH Article 58(3), namely wide dispersive use and high volumes.³²
- 33 For many substances, if a Chemical Safety Report (CSR) has been submitted for REACH registration already, the CSR will include an exposure assessment and a risk characterization and this will be a source of information to be used in the prioritisation process for Annex XIV.
- 34 ECHA considers that the criteria it uses and its approach is risk based, since it is based on initial information of (eco) toxicological hazard, potential for release and exposure, and volumes supplied – the higher the hazard, volume used and potential for release of the substance, the higher its potential risk and thus its priority for inclusion in the candidate list for Annex XIV.³³
- 35 Two methodologies are currently used – (i) a “verbal-argumentative” approach and (ii) a two tier scoring system. ECHA’s approach to the four criteria using the two methodologies, are set out below:

(I) Substances Having PBT or vPvB properties

- 36 The first criteria used by ECHA are whether the SVHC is identified as having PBT or vPvB properties under REACH Article 57(d), (e) or (f). The verbal-argumentative methodology applied by ECHA is to consider all the information available on the persistence, toxicity and bioaccumulation of a substance. The more persistent, bio-accumulative and toxic the substance, the higher the priority. CMR properties of a substance are also considered for their potency for health effects. Under the verbal-argumentative methodology no scores are assigned to the substance’s PBT and CMR attributes.

31 *General Approach for Prioritisation of SVHC for Inclusion in List of Substances Subject to Authorisation*, ECHA Document 1 June 2009, at p. 3.

32 *See “General Approach for Prioritisation of Substances of Very High Concern” (SVHC) for Inclusion in the List of Substances Subject to Authorisation*, ECHA document 1 June 2009, at p. 3.

33 *See “General Approach for Prioritisation of Substances of Very High Concern” (SVHC) for Inclusion in the List of Substances Subject to Authorisation*, ECHA document 1 June 2009, at p. 2.



- 37 In parallel to the verbal-argumentative methodology, a scoring system expressed in quantitative terms – the quantitative methodology - is also used. Substances on the candidate list are scored with respect to the extent of their persistency, liability to bio-accumulate and toxicity (“PBT-ness”) or their potency to elicit health effects as follows:

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

(II) Substances of Wide Dispersive Use

- 38 The second criteria ECHA considers for prioritisation for listing in Annex XIV is ‘wide dispersive use’, characterized by:

“... use(s) of a substance on its own, in a preparation or in an article at many places that may result in not insignificant releases and exposure to a considerable part of the population (workers, consumers, general public) and/or the environment.”³⁴

- 39 Wide dispersive use is also described in EU Commission Guidance as:

“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.”³⁵

- 40 This means that uses in many places that do not result in significant releases of a substance would likely be considered as “widespread” but not as ‘wide dispersive’.³⁶ ECHA is of the view that: (i) consumer use can be regarded as wide dispersive if it can reasonably be assumed that this use results in non-negligible releases of a substance, and (ii) professional use can be wide dispersive if it takes place at many sites and is carried out by many workers and if it cannot be excluded that releases are negligible.³⁷



34 See “General Approach for Prioritisation of Substances of Very High Concern” (SVHC) for Inclusion in the List of Substances Subject to Authorisation, ECHA document 1 June 2009, at p. 3.

35 Technical Guidance Document for Risk Assessment of new and existing substances and biocides (2003, Chapter 5).

36 See “General Approach for Prioritisation of Substances of Very High Concern” (SVHC) for Inclusion in the List of Substances Subject to Authorisation, ECHA document 1 June 2009, at p. 3.

37 Op cit.

41 When applying the “verbal-argumentative” methodology ECHA has set out a list of indicators, where there is relevant information available, to assess whether (i) use and resulting release of a substance should be considered “wide dispersive”, and (ii) to obtain at least a qualitative indication on the degree of “dispersiveness”. These are:

- 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 losing its hazardous properties) or incorporated into a matrix (e.g. polymer) in a way preventing release?
- Information on operational conditions and risk management measures;
- 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;³⁸

42 With regard to exposure levels, in 2007 Guidelines, ECHA suggests that information such as PNEC (Predicted No-Effect Concentration) and DNEL (Derived No-Effect Level) exposure values may be useful in priority setting, and would be a relevant consideration for setting priority.³⁹

43 Using the ten parameters listed above, in applying its “verbal-argumentative” methodology, ECHA has then used a weight of evidence approach. The SVHC is given increased priority with the portion (of the total) of the tonnage supplied to the uses identified as wide dispersive and the (estimated) released volumes from those wide dispersive uses. Lesser priority is given when the releases are not significant or comparatively low. ECHA has indicated that “the focus is normally on environmental releases for PBT properties and on releases leading to potential human exposure for CMR substances.”⁴⁰

44 In parallel with the above described verbal-argumentative methodology for wide-dispersive use, ECHA also uses the two tier quantitative methodology. When using the quantitative methodology ECHA assigns scores to (i) the various levels of number of sites and (ii) release scenarios. ECHA considers that 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 lifecycle. This scoring of the ‘wide-dispersive use’ criterion is broken into:

“Site # = the number of sites from which a substance is used;

And

“Release” = describes the releases in terms of pattern, where relevant, and amount versus anticipated risk.

38 *Ibid* at p. 4.

39 *Guidance for Preparation of an Annex XV Dossier on Identification of SVHC, June 2007* at p. 5.

40 *Op cit.* at p. 4.



- 45 These two scores for "Site #" and "Release" are then multiplied together. Uses resulting in insignificant releases are generally scored zero. However, even if the releases arising from one or more uses are considered insignificant, a precautionary element is 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. 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 1.⁴¹

Expressed as a formula, the calculation is:

$$\text{Wide-Dispersive Use (WDU)} = \text{Site \#} \times \text{Release}$$

- 46 ECHA uses the following factors for the corresponding scores in respect of (a) the number of Sites (Site #), and (b) the potential for Release to the environment.

(a) Site #: Number of point sources or number of sites from which a substance is being released;

	Score
No use	0
Small (<10 sites)	1
Medium (10-100 sites)	2
High (> 100 sites)	3

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

- 47 For substances with PBT/vPvB properties the focus is normally on environmental releases and for substances with CMR properties the focus is normally 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, ECHA uses the following terms and definitions:

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 small or medium 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 special scales they are considered to be 'insignificant'.

Controlled: means releases at the workplace may occur but the Risk Management Measures (RMM) 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 (but if Site # > 100 score is 1)
Non-diffuse/controlled	1
Diffuse/uncontrolled/significant	3

(III) High Volumes of the Substance

48 The third criterion used by ECHA for priority listing in Annex XIV is "high volume." Using the "verbal-argumentative" methodology, ECHA regards a "high volume" as an annual volume of equal to or more than 1000 tonnes, and between 100 and 1000 tonnes/year as "relatively high volumes".

49 It is unclear why 100 tonnes per year was chosen as the point above which volumes were considered "high volume". Article 40 of REACH uses this 100 t/y threshold as the point above which testing proposals set out in a registration must be examined by ECHA, so this may explain the choice.

50 It will be noted that the relevant tonnage is for uses not exempted from possible authorisation. Exemptions include, amongst others, uses as on-site isolated intermediates or as transported intermediates, uses in biocides or plant protection products, and uses in scientific research and development. Expressed as a formula, the relevant tonnage taken into account by ECHA is:

$$\text{Volume Supplied} = (\text{Manufacture} + \text{Import}) - (\text{Export} + \text{supply to uses exempted from authorisation}).$$

ECHA notes that "Priority increases with increasing volume."⁴² Using the verbal-argumentative methodology, no scores are applied to the volumes supplied using the above formula.

51 Using the second methodology, the two tier quantitative (scoring) methodology, scores are applied to volumes. The annual volume supplied in the EU, to uses not exempted from authorisation, is taken as the basis for scoring of the Volume criterion. Scores are assigned as follows:

	Score
No volume on EU market in 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



- Weighting and Aggregation of First Three Criteria using Verbal-Argumentative Methodology

Using the verbal-argumentative methodology, ECHA considers the information available on the three criteria as a whole (i.e. PBT/vPvB, wide-dispersive use and volumes) to come to an initial conclusion on priority. ECHA regards the assessment of the three criteria in combination as a proxy for potential risk to human health or the environment (i.e. the higher the hazard, volume used and potential for release of the substance, the higher its potential risk and thus the higher its priority.)

- Weighting and Aggregation of First Three Criteria Scores using the Quantitative Methodology

- 52 In using the quantitative (scoring) methodology, when giving a weighting to the three criteria (PBT/vPvB, wide-dispersive use & volume) ECHA takes into account 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, 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 has chosen to take further into account the differences in potency and "PBT-ness" of the substances on the candidate list.
- 53 In view of the above, the relative maximum weights of the criteria 'Inherent properties', 'Volume' and 'Wide-dispersive use' are set by ECHA at 18:41:41%. ECHA considers that further increasing the weight for the 'PBT/vPvB – inherent properties' criterion toward 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.

- 54 The individual criteria scores are added to the total score as follows:

Score Total = Score Inherent Properties (PBT/vPvB) + Score Volume + Score Wide-Dispersive Use,
with

Score (min/max): (0/22) = (0/4) + (0/9) + (0/9)
Score relative weight maximum (%) – 18%: 41%: 41%

- 55 ECHA also envisages a situation where a substance of very high concern might never be given priority. It states in a recent document that:

“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.”⁴³



⁴³ General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation, ECHA 28 May 2010, p.7.

(IV) “Regulatory Effectiveness and Coherence” of Priority

- 56 The final consideration is the regulatory effectiveness and coherence of recommending the substance for priority. Assessment of this fourth criterion is the same using either the Quantitative (scoring) or the Verbal-Argumentative methodology. Essentially, the two questions asked are: Would the priority recommendation be likely to result in benefits to human health or the environment? And, would prioritisation be coherent with other measures already in place for the substance?
- 57 ECHA recognizes that situations can occur where inclusion in Annex XIV will most likely not result in benefits for human health or the environment, and so not achieve the desired regulatory effect, or where authorisation may hamper the use of other risk management instruments while not contributing significantly to achieving the risk reduction.
- 58 In arriving at the overall conclusion on the priority of a substance, so far the following ‘regulatory effectiveness’ criteria have been taken into account:
- (i) 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;
 - (ii) 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);
 - (iii) 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.
- 59 In the first case, ECHA considers that 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, ECHA notes that a grouping approach could be considered in order to prevent simple replacement of a substance that will be subjected to authorisation by another form of the substance.⁴⁴
- 60 It will be noted that ECHA has signaled it will review the above prioritisation approach after December 2010 when much more information will be available from REACH registration dossiers that must be submitted by 1 December 2010.⁴⁵

⁴⁴ *Ibid* p. 11.

⁴⁵ ECHA ‘General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation’ 28 May 2010, at p. 3.



3

What factors could be relevant to ECHA or the EU Commission to slow down or speed up prioritisation for possible listing for authorisation of a nickel substance under REACH?

- 61 Speeding up or slowing down prioritisation can result from factors relating to (i) the procedure, or (ii) to the properties associated with a substance and its use. As far as the properties and use of the substance are concerned, when assessing a SVHC for priority inclusion in Annex XIV, ECHA has indicated it will use a weight of evidence approach in a qualitative and where possible semi-qualitative manner, in order to arrive at a conclusion on priority of a SVHC. The higher the hazard rating of the SVHC as a PBT or vPvB, the more wide dispersive the uses, and the higher the volumes not exempted from authorisation, then the more likely the SVHC will be prioritised. Further, the more likely listing will have regulatory effectiveness, the more likely the SVHC will be prioritised.
- 62 Other factors that can influence the speed of placing a substance on the priority list for Annex XIV authorisation, are procedural factors. The following table sets out likely factors influencing speed of priority listing. The table is split into Part A for Substance and Use Specific Factors, and Part B for Procedural Factors.

Potential to Speed Up Prioritisation	Potential to Slow Down Prioritisation
(A) Substance and Use Specific Factors	
Higher PBT hazard rating.	Lower PBT hazard class.
Higher vPvB hazard rating.	Lower vPvB hazard rating.
Is an endocrine disruptor.	Is not an endocrine disruptor.
Annual manufacture + import volumes exceed 10,000 t/y (Very High volumes) or 1,000 t/y (High volumes) and finally exceeding 100 t/y (Relatively High volumes). ⁴⁶	Annual manufacture + import volume less than 100 t/y (Relatively Low volumes). ⁴⁷
Substance is used in many places resulting in significant releases of the substance.	Substance is not used in many places. Substance's use does not result in significant releases of the substance.
Potential release and exposure could result in higher risk(s) of harm.	Potential release and exposure could result in lower risk(s) of harm.
Substance largely placed on the market in the form of the substance itself.	Substance mainly placed on the market as an alloy, mixture or article with limited release scenarios.
Complex and higher number of actors in supply chain.	Relatively simple and fewer actors in supply chain.
Typical size of actors in supply chain is large.	Typical size of actors in supply chain is relatively small.
Substance has relatively high extent of release during service life of an article, alloy or other mixture into which the substance is incorporated.	Substance is transformed so as to lose or lower its hazardous properties. Substance is incorporated into a matrix so as to prevent its release.



⁴⁶ These volumes exclude exports and uses exempted from authorisation.

⁴⁷ Ibid.

Higher occupational exposure.	Operational conditions of the substance's use and risk management measures required/typical for such use reduces/prevents release.
Higher releases of substance in the working environment. Lower occupational exposure limits.	Lower consumer exposure to substance as shown by things such as: - lower possible consumer use - limited/reduced health effects in consumer use - higher limit values.
Higher release into the environment to air, water, soil.	Lower or limited release into the environment to air, water, soil.
High possibility of releases during waste phase.	Low possibility of releases during waste phase.
(B) Procedural Factors	
EU Commission asks ECHA to prepare a dossier on the SVHC.	Insufficient information on substance so that ECHA requires a substance evaluation before submitting dossier.
Member State Committee opinion in favour of listing in the candidate list and/or for prioritisation.	Dossier simply lists a CMR Category 1A or 1B property but has no information on exposures, alternative substances and risks.
ECHA has capacity to handle applications for authorisation within time limits.	For a CMR substance without harmonized classification, a harmonized classification is proposed for CLP Regulation Annex VI Part 3. A Member State is dissuaded from preparing a dossier on the SVHC. If a Member State can be persuaded to prepare a dossier on another SVHC rather than a nickel compound, the limited resources available to ECHA and the Member States may mean that a dossier preparation on the nickel compound would be delayed. Interested party(ies) provide information to a Member State preparing a dossier, or to ECHA after dossier submitted, showing new or additional information relevant either to inclusion on the candidate list or inclusion on the priority list. A Member State comments on identification of the substance as a SVHC ⁴⁸ at the end of the 60 day period following circulation of a dossier for inclusion in the candidate list. Interested party(ies) submit detailed comments to ECHA a day before the deadline on the content of an Annex XV dossier prepared for a substance. ⁴⁹ Interested party(ies) submit detailed comments to ECHA, a day before the deadline, on ECHA's proposed recommendation for the substance's priority inclusion in the Annex XVI list. ⁵⁰



48 REACH Article 59(5).

49 REACH Article 59(4).

50 REACH Article 59(4).

4

What are the relevant criteria and factors in the actual listing process, being used by ECHA and the EU Commission concerning submissions made to them or Member State authorities/entities involved in the process of inclusion in Annex XIV?

63 ECHA is required to make at least every second year a recommendation of priority substances to be included in Annex XIV. It has done so in June 2009 and published a draft second set of recommendations in July 2010. Before establishing a recommendation, the substances on the candidate list are prioritised to determine which ones should be recommended for authorisation (See answers to questions 1 to 3 concerning the candidate list and Prioritisation). Then ECHA develops the draft recommendation. The draft recommendation for Annex XIV entries includes:

- Sunset date(s): the date(s) from which placing on the market and use of the substance shall be prohibited, unless an authorisation is granted;
- Application date(s): the 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 after the sunset 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.

64 The draft recommendation is publicised on ECHA's website and interested parties are invited to submit comments. Comments received during the public consultation as well as the opinion of the relevant Member State Committee are taken into account by ECHA in updating the recommendation. The final recommendation is submitted to the Commission, who decides by Committee procedure on inclusion of the recommended substances in Annex XIV.

65 If all uses of a Substance have been prohibited (i.e. banned) by Restrictions imposed by REACH or by other EU legislation, the substance cannot be listed in Annex XIV for Authorisation.⁵¹

66 Substances which as a result of new information no longer meet the requirements of Substances of Very High Concern (SVHC) also cannot be listed in Annex XIV.⁵² It will be remembered that a SVHC is one that is:

- (a) carcinogenic, mutagenic or toxic to reproduction (CMR) Categories 1A or 1B; or
- (b) persistent, bioaccumulative and toxic to reproduction (PTB); or
- (c) very persistent and very bioaccumulative (vPvB); or
- (d) endocrine disruptors and other substance of equivalent concern to substances falling within (a) to (c) above.⁵³



⁵¹ REACH Article 58(7).

⁵² REACH Article 58(8).

⁵³ REACH Article 57.

67 REACH Article 58(1) provides that 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 (i.e. CMR, PBT/vPvB, endocrine disruptor or other properties of equivalent concern);
- 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.

68 Further, REACH Article 56(3) 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.

69 The identity of the substance and its intrinsic properties are already taken into account when including the substance in the candidate list (see answer to question 1). The other considerations and criteria used by ECHA and the EU Member State authorities, for actual listing of a substance in Annex XIV are discussed in the following. These are the sunset date (last date to market without authorisation), application date (last date by which application for authorisation can be made), Review period (if any), and Exemption from authorisation requirement (if any). ECHA reconsiders all these issues after public consultation on the proposed recommendation of substances for inclusion in Annex XIV. They are considered, in turn, in the following.

Sunset Date

70 The sunset date is defined as: 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.⁵⁴

71 It will be noted that REACH 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. Article 58(1) (c) (ii) specifies that the application date must be at least 18 months before the sunset date. ECHA has indicated that there has so far been no information to support the use of other criteria to distinguish sunset dates for different substances or to deviate from the 18 months set out in REACH. In that case ECHA is using a standard difference of 18 months between the application and sunset dates. In the 2009 draft recommendations for priority substances, ECHA proposed sunset dates between 42 and 48 months after inclusion in Annex XVI. In its 1 July 2010 draft recommendation ECHA proposed sunset dates between 36 and 42 months after inclusion of the substances in Annex XIV.

⁵⁴ REACH Article 58(1)(c)(i).



Application Date

- 72 The application date is "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."⁵⁵
- 73 REACH specifies that the application date must be at least 18 months before the sunset date. 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. ECHA has made it clear that "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)..." the minimum required period of 18 months will be used⁵⁶. Applicants for an authorised use have a possibility to submit their applications at any time before the application date. However, ECHA recognises that, since the authorisation requirement is still new and most actors might have no experience in preparing applications, most applicants will use all available time until the specified latest application date to develop their applications.⁵⁷
- 74 REACH 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, ECHA regards it as important that not all applications arrive at the same time. Hence, ECHA has proposed different application dates for priority substances so as to better ensure more equal distribution of ECHA's workload.⁵⁸
- 75 For the first recommendations on priority in 2009, information on the complexity of the supply chain and on the availability of information about alternatives was used to estimate the differences in time needed to prepare applications. Periods of between 24 and 30 months after publication of inclusion in Annex XIV were recommended as the application dates. However, taking into account the 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 second recommendation in 2010.
- 76 For ECHA's second (2010) recommendations on priority substances, ECHA proposes to spread the application dates over 6 months so that the substances with similar properties and uses get the same application date. This was in order to avoid potential evasion of the authorisation requirement by substituting a substance subject to authorisation by another one with similar hazard properties, but which however does not yet require authorisation.
- 77 For example, ECHA's first recommendation in 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. The second (2010) recommendation includes one more phthalate (diisobutyl phthalate, DIBP), which has similar uses to the three earlier phthalates. For that reason, ECHA proposes 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, ECHA took the view that there should be a minimum of 12 months, allowing potential applicants to prepare applications of the required quality.



⁵⁵ REACH Article 58(1)(c)(ii).

⁵⁶ *Preparation Of Draft Annex XIV Entries For The Second Recommendation Of Substances To Be Included In Annex XIV General Approach*, ECHA 1 July 2010 at p.3.

⁵⁷ *Preparation of Draft Annex XIV Entries for the Second Recommendation of Substances to be Included In Annex XIV General Approach*, ECHA 1 July 2010 p. 3 at footnote 1.

78 When more information on manufacture and uses is available from the registration dossiers towards the end of 2010, ECHA expects that its current approach used to differentiate the application date will be reconsidered.

79 ECHA notes that 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 nevertheless facilitates better processing of the applications by ECHA's Committees and the secretariat⁵⁹. ECHA expects that this differentiation will also assist interested third parties who wish to provide information or comments on several substances. Finally, ECHA expects that application dates spread over 6 months will assist the Commission, which has to prepare draft authorisation decisions within three months of receipt of ECHA's opinions.

Review periods

80 According to Article 58(1) of REACH it is possible to set review periods for certain uses, if appropriate, in Annex XIV. If there is no background information in any of:

- Annex XV SVHC dossiers of the substances prioritised for the recommendation being considered;
- comments provided on the dossiers/substances during the public commenting period in the context of the SVHC identification process, or;
- other available information that would support defining an 'upfront' review period for any uses of the prioritised substances, ECHA will not do so.

ECHA has so far refrained from proposing to define any review periods. ECHA has indicated it would only define a review period in its recommendation if information was provided during the public consultation on the draft recommendation that would suffice for defining a review period. In this context, it might be noted that all decisions to grant an authorisation must include case specific review period(s).

Uses Exempted from the Authorisation Requirement: Exemptions under Article 58(2) of REACH

81 REACH Article 56(i) provides that:

“A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:(b) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2)”.

58 ECHA is of the view that the quality of the applications is important for the practical implementation of the authorisation procedure and for achieving the aims of the authorisation system. For that reason, 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 recommendations made in 2009.

59 Op cit at p. 4.



- 82 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'.
- 83 This exemption is discussed in further detail in answer to Questions 5 and 6. ECHA has so far taken a relatively strict legal approach to any exemption requested pursuant to Article 58(2). ECHA makes it clear it will consider the following elements when deciding whether to include an exemption for 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;
 - 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;
 - This Community legislation imposes minimum requirements for the control of risks of the use.
- 84 For ECHA's second (2010) recommendations on priority substances, ECHA proposes to spread the application dates over 6 months so that the substances with similar properties and uses get the same application date. This was in order to avoid potential evasion of the authorisation requirement by substituting a substance subject to authorisation by another one with similar hazard properties, but which however does not yet require authorisation.
- 85 ECHA will use the above considerations when assessing information regarding exemptions in accordance with Article 58(2), including information submitted during the public consultation on ECHA's draft recommendation. It remains unclear whether ECHA will use other criteria before recommending an exemption for certain use(s) be granted pursuant to REACH Article 58(2).

Uses Exempted from the Authorisation Requirement: Product and Process Oriented Research and Development (PPORD)

- 86 REACH Article 56(3) provides that authorisation "shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 (i.e. authorisation) apply to product and process orientated research and development as well as the maximum quantity exempted". This means substances recommended for inclusion in Annex XIV may include a specific exemption for use of the substance in product and process oriented research (PPORD) up to a defined quantity.⁶⁰ ECHA will consider information on the use of substances in PPORD submitted during public consultation on the draft recommendation. So far, in respect of substances recommended in draft for inclusion in Annex XIV, no information has been submitted to ECHA. Hence, ECHA has not made any draft recommendation with respect to an exemption based on PPORD.



⁶⁰ REACH Article 56(3).

Proportionality Principle: Can this principle be used to avoid the listing of substances if the substance SVHC is already regulated through another Regulation or Directive?

87 In relation to existing EU rules that already regulate an SVHC, the proportionality principle is used indirectly in Article 58(2) of REACH by allowing an exemption from listing in Annex XIV if other EU legislation already imposes minimum requirements for use of the SVHC concerned. It states:

“Uses or categories of uses may be exempted from the authorisation requirement 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. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.”

88 ECHA is of the view that exemptions for SVHCs, already regulated through other EU legislation, allows the authorisation process to concentrate on the uses of substances that are likely to pose the greatest risk rather than devoting resources to considering uses of SVHCs whose risks are considered to be sufficiently addressed by other legislation and to correspond to the proportionality principle.⁶¹

89 The ultimate responsibility for deciding on which uses should be exempted lies with the European Commission. The Commission, as an institution of the European Union, must comply with Art 3b of the Lisbon Treaty. Article 1 of the Protocol to the Lisbon Treaty “On the application of the Principles of Subsidiarity and Proportionality”, requires that “Each institution shall ensure constant respect for the principles of subsidiarity and proportionality, as laid down in Article 3b of the Treaty on European Union.”



61 ECHA Guidance On Inclusion Of Substances In Annex XIV 2008, pp. 39-40.

90 Article 3b of the Treaty on European Union provides that:

“Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality as laid down in the Protocol on the application of the principles of subsidiarity and proportionality.”

91 Existing EU legislation may already regulate the same risks (to human health and the environment) posed by all uses of an SVHC, that listing for REACH authorisation would address. Note that existing EU legislation may only address health and environmental risks arising out of some uses but not necessarily all uses of the substance. On the basis of the proportionality principle the Commission should, where other EU legislation addresses relevant risks from all uses of the SVHC, exercise its discretion to exempt the SVHC from listing in Annex XIV. In such circumstances, if the Commission did not grant an exemption from listing for authorisation, the Commission could be applying an additional administrative burden with no change in achieving the objectives of REACH authorisation, thereby exceeding what is necessary to achieve the same objective(s) already established by other EU rules.

6

What criteria are currently being applied by ECHA and the EU Commission for exemption from listing for authorisation under REACH?

92 Article 58(2) of REACH states that:

“Uses or categories of uses may be exempted from the authorisation requirement 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. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.”

It will be noted first; that the words “may be exempted” makes it clear the grant of an exemption pursuant to this Article 58(2) is discretionary. Second, the exemption can only be granted for “uses or categories of uses” of the substance. Third, the exemption can only be granted if the three criteria in Article 58(2) are satisfied – (i) there is existing specific Community legislation, (ii) such legislation imposes minimum requirements relating to the protection of human health or the environment for the use of the substance; and (iii) the risk is properly controlled.



93 It is emphasized that only certain uses or categories of uses, can be exempted from authorisation under this Article 58(2). ECHA's guidance on inclusion of substances in Annex XIV indicates that 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;
- 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;
- This Community legislation imposes minimum requirements 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). 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.⁶²

94 ECHA is also of the opinion that 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.⁶³

95 In some cases, ECHA has been reluctant to make a recommendation for exemption where it considered it was "not in a position to fully assess the possible consequences of existing Community legislation" on implementation of authorisation under REACH. In the first round of recommendations (2009), ECHA seemed favourable to granting an exemption to uses of a substance in medical devices and in packing of medical products but was not prepared to recommend an exemption from authorisation for such use. ECHA left it to the Commission as to whether to include these proposed exemptions or not. ECHA stated that "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". It seems likely that ECHA considered that the European Medicines Agency (EMA), CEN or the Commission itself was better qualified to assess use of the substance in medical devices or packaging for medicines.

62 *Preparation Of Draft Annex XIV Entries For The Second Recommendation Of Substances To Be Included In Annex XIV General Approach*, ECHA 1 July 2010 at p.5

63 *Preparation Of Draft Annex XIV Entries For The Second Recommendation Of Substances To Be Included In Annex XIV General Approach*, ECHA 1 July 2010 at p.5



Restrictions With Exceptions Already in Annex XVII of REACH

- 96 ECHA considers that where an entry in Annex XVII exempts a specific use of a substance from the restrictions, Article 58(2) could be used to exempt that 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 by way of authorisation.
- 97 Use of a substance subject to a restriction listed in REACH Annex XVII can satisfy the requirements for exemption from authorisation in REACH Article 58(2). Such a restriction is existing Community legislation and may address the use (or categories of use) that is proposed to be exempted. The restriction in Annex XVII could properly control 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, and the restriction could impose minimum requirements for the control of risks of the use.
- 98 An example of the relationship between authorisation and restriction under REACH is the situation for alkanes, C10-13, chloro (SCCPs). For this substance there is a restriction listed in REACH Annex XVII with some allowed uses. There was disagreement between ECHA and some Member States as to how to deal with this. In its draft recommendation ECHA considered that since the restriction permits the use of SCCPs in mixtures for metalworking or fat liquoring of leather in preparations in concentrations at or lower than 1%, such use should be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation.
- 99 In its opinion of 20 May 2009 ECHA's Member State Committee (MSC) considered that further legal interpretation is required in order to take a position whether this use of SCCP should be exempted from authorisation. After examining the opinion of the MSC, ECHA still considered that from a legal point of view this use should be exempted from authorisation pursuant to Article 58(2) of the REACH Regulation. ECHA seemed to take the view that the Commission could exercise its discretion not to grant an exemption for such use, but ECHA would strictly follow the terms of REACH Article 58(2) when making its recommendation for an exemption. Nevertheless, in this case, ECHA urged the European Commission to review the legal analysis made by ECHA and to clarify under what conditions specific exemptions to restrictions set out in Annex XVII should be taken into account when determining exemptions from the authorisation requirement under Article 58(2) of REACH.
- 100 Another example concerns entries 28 to 30 of Annex XVII which provides that all substances classified as CMR (Category 1A and 1B) may not be used in substances and mixtures placed on the market for sale to the general public. However, these entries exempt from restriction the use of such substances in artists' paints. In the draft recommendation published by ECHA on 14 January 2009 ECHA noted that the substance "MDA" is one of the CMR substances concerned by entries 28 to 30 of Annex XVII and that recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction. For that reason ECHA recommended an exemption from the authorisation requirement should be granted pursuant to Article 58(2) of the REACH Regulation for the use of MDA in artists' paints. This was on the basis that this use had been specifically exempted from restriction in Annex XVII, and satisfied all the requirements of Article 58(2) for exemption from authorisation.



- 101 In its opinion of 20 May 2009 ECHA's Member State Committee (the MSC) considered that no exemption should be granted from the authorisation requirement for the use of MDA in artists' paints. This opinion was based on the following considerations.
- 102 First, some members of the MSC expressed doubts as to whether the exemption from restrictions of the use in artists' paints could be regarded as meeting the criteria for exemption from authorisation set out in Article 58(2) as the exemption to the restriction was based on socio-economic grounds rather than on health and risk considerations. On this point ECHA considered that in determining whether an exemption to a restriction should benefit from an exemption from the authorisation requirement it is not possible to simply dissociate the exemption from the restriction. The restriction and its related exemptions must be examined as a whole in order to determine whether an exemption under Article 58(2) of the REACH Regulation should be granted.
- 103 Second, all members of the MSC (Member States Committee) considered that an exemption should not be granted for the use in artists' paints on the basis that the exemption from the restriction requirement in Annex XVII covers a category of substances (i.e. all CMRs) rather than a specific substance (i.e. only MDA or a group of specified substances). In the MSC's view an exemption to a restriction covering a wide range of substances may not necessarily meet the requirements for exemption from authorisation under Article 58(2) of the REACH Regulation. On this second point ECHA shared the MSC's concern. On the basis of the information available ECHA took the view that it cannot determine whether such an exemption can be justified under Article 58(2) of the REACH Regulation. ECHA therefore decided on the basis of the MSC's opinion and the deliberations leading to that opinion, to amend its recommendation and not propose an exemption from the authorisation requirement for the use of MDA in artists' paints. ECHA however, urged the European Commission to examine on the basis of the information at its disposal whether such exemption should nevertheless be introduced, and to further clarify under what conditions specific exemptions to restrictions set out in Annex XVII should be taken into account when determining exemptions from the authorisation requirement under Article 58(2) of REACH.
- 104 In view of the above, it may be that ECHA could change its approach to restrictions listed in Annex XVII and the impact of such restrictions on the grant of an authorisation pursuant to Annex XIV.



7

Can a grouping of substances be applied in the listing process for inclusion in Annex XIV?

105 Article 58(1) requires that: “Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall specify for each substance: (a) the identity of the substance as specified in Section 2 of Annex VI; ...” The decision to list a substance in Annex XIV must therefore be with respect to a ‘substance’ as defined in REACH (i.e. it cannot concern a mixture, alloy or article) and it must specify for each substance the identity of the substance as specified in Section 2 of Annex VI.

106 Section 2 of Annex VI of REACH states that:

“2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance ...⁶⁴

2.2. Information related to molecular and structural formula of each substance ...⁶⁵

2.3. Composition of each substance ...⁶⁶

107 The above indicates that for every substance that is the subject of authorisation, information must be given to enable each substance to be identified. In Section 2 of Annex VI of REACH, the continued and repetitive use of “each substance” under the sub-headings of ‘Name or other identifier’, ‘Molecular and structural formula’, and ‘Composition’, reinforce the view that each substance must include in any authorisation decision, sufficient information to enable each substance to be identified. This implies that the identification of a substance for authorisation cannot simply be a list of a vague group of substances for which insufficient information has been given to enable “each substance” falling within the group to be identified.

64 Section 2.1, Annex VI REACH with criteria:

- 2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)
- 2.1.2. Other names (usual name, trade name, abbreviation)
- 2.1.3. EINECS or ELINCS number (if available and appropriate)
- 2.1.4. CAS name and CAS number (if available)
- 2.1.5. Other identity code (if available)



65 Section 2.2, Annex VI REACH with criteria:

- 2.2.1. Molecular and structural formula (including SMILES notation, if available)
- 2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
- 2.2.3. Molecular weight or molecular weight range

66 Section 2.3, Annex VI REACH with criteria:

108 An example of a group in the 1st ATP to CLP is the group of substances described as “salts of hydrogen cyanide with the exception of complex cyanides such as ferrocyanides, ferricyanides and mercuric oxycyanide and those specified elsewhere in this Annex.”⁶⁷. At first sight, it is questionable (without the benefit of advice from an expert in chemistry) whether this description would satisfy the requirement that sufficient information is given to identify each substance that falls within the description. The description seems too vague to be able to achieve the level of information required to identify each substance in the group to which an authorisation decision could apply. (However, if “complex cyanides” was a precise descriptor of substances to which each substance in the group could be sufficiently identified, the description may be sufficient). Indeed, it may be that another description of a group of substances in the 1st ATP to CLP would be sufficient to identify each substance in the group. The description of “selenium compounds with the exception of cadmium sulphoselenide and those specified elsewhere in this Annex”⁶⁸, might provide sufficient information to enable each substance in the group to be identified.

109 The above view appears to coincide with the view of ECHA and the Member States Committee when, in 2009, they considered that an exemption from a restriction in Annex XVII that covers a wide category of substances (i.e. all CMRs) rather than a specific substance, could not be the subject of an exemption from authorisation pursuant to Article 58(2). It should be noted however, that the EU Commission has not commented publicly on this issue.

110 Another example of the relationship between substances falling within a group listed under the same CLP index number is that of Aluminum silicate refractory ceramic fibres (Al-RCF) and Zirconia aluminium silicate refractory ceramic fibres (Zr-Al-RCF). Whilst listing the substances separately in its draft recommendation, ECHA nevertheless treated these two substances together. ECHA stated that the current identification of Al-RCF and Zr-Al-RCF on the candidate list covers only a part of the RCFs on the European market. ECHA recommended not prioritising Al-RCF and Zr-Al-RCF now in order to avoid unjustified preferential treatment and market distortion in favour of RCF types not yet identified as SVHC. ECHA suggested waiting with prioritisation until all RCF types falling under index number 650-017-00-8 of Annex VI of Regulation (EC) No. 1272/2008 – the CLP Regulation - are included in the candidate list.⁶⁹

111 As demonstrated with Al-RCF and Zr-Al-RCF, what is clear is that ECHA does take into account groups of substances when making its recommendations for inclusion in Annex XIV. This has so far generally been suggested or done in the context of whether inclusion of a substance for authorisation would have regulatory effectiveness and/or coherence. Other examples are:

- **Diarsenic pentaoxide** - ECHA concluded that as it had already been decided to prioritise diarsenic trioxide, diarsenic pentaoxide should be prioritised also because otherwise it may be used to bypass the authorisation requirement by substitution.
- **Diisobutyl phthalate (DIBP)** can be used to replace dibutyl phthalate and may as well be suitable to replace other phthalates already recommended in 2009 for inclusion in Annex XIV. ECHA recommended that the sunset date for Diisobutyl phthalate (DIBP) be as close as possible to the sunset date of the already recommended (2009) phthalates.⁷⁰

112 The above examples show that ECHA is arriving at its draft recommendations by taking into account whether there are substitute substances that can be used for the substance under consideration and to treat substitutable substances as a group.

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance

and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

67 Commission Regulation (EC) No 790/2009 of 10 August 2009, OJ 2009 L235/1 at p.3.

68 Op cit at p.12.

69 Draft recommendation of priority substances to be included in Annex XIV of the REACH-Regulation ECHA 1 July 2010

70 Draft recommendation of priority substances to be included in Annex XIV of the REACH-Regulation ECHA 1 July 2010



113 The most recent ECHA draft recommendation list for Annex XIV also suggests that substances could be treated as a group depending on the main hazard that they pose to human health or the environment. ECHA did not recommend prioritisation of separately listed Anthracene oils and Pitch, coal tar, high temperature (CTPHT). This was because:

- (1) *“In particular, PAH [Polycyclic Aromatic Hydrocarbon] emissions resulting from the use of CTPHT in the production of electrodes and refractories (~92 % of the total use) and their use in metal industry, should be looked at in a holistic way together with other metal industry sources of PAH emissions to ensure that an overall reduction of PAH emissions is achieved”*; and
- (2) *“as already mentioned with regard to a potential prioritisation of pitch, coal tar, high temperature, it is noted that it would be useful to consider these PAH emissions in conjunction with more general objectives for reduction of PAH emissions from industry, incineration processes and other emission sources.”*⁷¹

114 This suggests ECHA will look at PAH emissions as a whole if this is the main hazard of these two substances as well as (numerous) other substances. The suggestion being that ECHA would consider whether all substances with PAH emissions as the main hazard causing factor, be reviewed together as a group (e.g. PAH emissions from the group of substances processed by the metals industry).



⁷¹ Results of the prioritisation of the SVHCs on the candidate list with the objective to recommend priority substances for inclusion in Annex XIV, ECHA July 2010 at pp. 6 and 7

What obligations and consequences arise if REACH Annex XIV listing is made and authorisation is then granted for a certain use?



Civil Liability

115 When the authorisation is granted there arises a general legal duty, irrespective of any conditions under which the authorisation is granted, that the authorisation holder must ensure that the exposure is reduced to as low a level as is technically and practically possible.⁷² To reduce exposure to the lowest level possible, REACH indicates that measures must be taken to ensure adequate control of the authorised use of a substance. In that case, these measures (i) should be identified in any Chemical Safety Report, (ii) should be applied, and (iii) where appropriate, recommended to other actors down the supply chain.⁷³

116 The general legal duty to reduce exposure to the lowest level possible will be important from the point of view of an authorisation holder's potential liability for damage or injury arising out of use, or placing on the market for a use, of the authorised use of the substance. This is because the general legal duty imposed by REACH would likely be considered a statutory duty in at least some EU Member States. In those Member States where it is a statutory duty, the law typically provides that compensation be granted to an injured person (or for property damage) for breach of a statutory duty. Hence, any breach of this general statutory duty to reduce exposure to the lowest level possible, could give rise to civil claims for breach of statutory duty as well as fines and/or other sanctions for breach of REACH itself.

Downstream Users Requiring Information

117 If a SVHC is included in the candidate list for possible inclusion in Annex XIV, and such SVHC is contained in an article in a concentration above 0.1% weight by weight, the supplier of the article must provide the recipient with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the SVHC.⁷⁴ This means suppliers of SVHCs that might be included in the candidate list, can expect to receive from downstream users requests (i) for confirmation that their substance has not been included in the candidate list, and/or (ii) to be informed immediately the substance is included in the candidate list.

118 Further, on request by a consumer, any supplier of an article containing a SVHC on the candidate list for possible inclusion in Annex XIV, in a concentration above 0.1%, the article supplier must provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the SVHC.⁷⁵ The information must be provided free of charge, within 45 days of receipt of the request. For this reason also, suppliers of SVHCs that may potentially be placed on the candidate list for authorisation, may receive requests from downstream users to be informed promptly of inclusion of the substance in the candidate list.



72 REACH Article 60(10).

73 REACH Preamble at (70).

74 REACH Article 33(1).

75 REACH Article 33(2).

Authorisation Invalid if No Review Within Time Limits

119 One post-authorisation obligation is to provide further information in the context of the required review of the authorisation. It will be remembered that the authorisation must specify a time limited review period.⁷⁶ The authorisation must be reviewed by the European Commission before expiry of this review period. The authorisation is regarded as valid only until the Commission decides to amend or withdraw the authorisation in the context of a review, “provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time limited review period.” This means that if the authorisation holder does not submit a review report prior to 18 months before the end of the review period, the authorisation may be regarded as invalid. If the review report has not been submitted by this deadline, the authorised use, or placing on the market for the authorised use, may be contrary to the Regulation.

120 As part of the above mentioned authorisation holder’s review report, there must be submitted (if applicable) an update of:

- the analysis of alternatives to use of the substance the subject of the authorisation;
- information about any relevant research and development activities of the authorisation holder (if appropriate);
- any substitution plan submitted in the original application that showed suitable alternatives are available.⁷⁷

121 If originally there was no substitution plan and the update of the analysis of alternatives shows there is now a suitable alternative available, the authorisation holder must submit a substitution plan, including a timetable for proposed actions by the authorisation holder. If the holder cannot demonstrate the risk is adequately controlled, he must also submit an update of the socio-economic analysis contained in the original application.⁷⁸ The review report must contain an update of any change to any element of the original application for authorisation.

Update Safety Data Sheets and Inform Users/Recipients

122 Suppliers must update the Safety Data Sheet without delay once an authorisation has been granted or refused.⁷⁹ REACH Annex II setting out Guidelines on Safety Data Sheets provides that “If the substance or preparation covered by this safety data sheet is the subject of specific provisions in relation to protection of man or the environment at Community level (e.g. authorisations given under Title VII or restrictions under Title VIII) these provisions shall, as far as is possible, be stated.” (emphasis provided)

123 If a Safety Data Sheet is not required but the substance is subject to authorisation, the supplier of the substance (on its own or in a preparation) even if he does not have to supply a Safety Data Sheet, must still provide the recipient of the substance with details of any authorisation granted or denied in his supply chain.⁸¹ Further, suppliers must update this information without delay whenever an authorisation is granted or refused.⁸²

124 Holders of an authorisation, as well as downstream users including the substance in a preparation, must include the authorisation number on the label before they place the substance (or a preparation containing the substance) on the market for an authorised use. This must be done without delay once the authorisation number has been made publicly available in the EU’s Official Journal.⁸³

125 Finally, downstream users must notify ECHA within three months, of first supply of a substance for an authorised use, or for a use subject to the authorisation procedure.⁸⁴ ECHA keeps a database of such downstream users.



⁷⁶ REACH Article 60(9)(f).

⁷⁷ REACH Article 61(1) Second Paragraph.

⁷⁸ *Ibid.*

⁷⁹ REACH Article 31(9)(b).

⁸⁰ REACH Annex II Safety Data Sheet Guidelines at 15. REGULATORY INFORMATION.

What impact could listing in REACH Annex XIV and an application for Authorisation have on (i) a Substance Already Listed as a Restricted Substance in Annex XVII? and (ii) on the Restrictions Applicable to the Substance?

9

126 REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to health or the environment. ECHA takes the view that restriction is designed as a “safety net” to manage risks that are not addressed by the other REACH processes, including the authorisation process.

127 Any substance on its own, in a preparation or in an article may be subject to a restriction if it is demonstrated that risks need to be addressed on a Community-wide basis. A restriction dossier needs to justify that the proposed restriction is the most appropriate risk management measure to address these risks. Proposals for restrictions can be prepared by Member States or by ECHA on request of the Commission.

128 ECHA considers that elements to be considered when choosing between the authorisation and restrictions route are the availability of alternatives, exposure and the urgency of the required measures. ECHA takes the view that generally, the restrictions process is the preferred option in cases where it is justified to prohibit all uses of a substance or to ban some (well known) uses because of unacceptable risks for man or the environment. ECHA also takes the view that when considering whether to use the restriction procedure or authorisation process, preference should be given to the authorisation process in cases where a clear picture on alternatives is missing, or in cases where not all the uses causing the risk are known.

129 Point (79) of the Preamble to REACH states that:

“A total ban on a substance would mean that none of its uses could be authorised. It would therefore be pointless to allow the submission of applications for authorisation. In such cases the substance should be removed from the list of substances for which applications can be submitted and added to the list of restricted substances.”

130 If a substance is restricted and all uses are banned (i.e. there is no exception allowing use of a restricted substance in Annex XVII) an authorisation cannot be granted for any use of the substance.⁸⁵ Further, REACH Article 60(6) provides that: “A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVII”.

81 REACH Article 32(1)(b).

82 REACH Article 32(3)(b).

83 REACH Article 65.

84 REACH Articles 66 and 56(2).

85 Article 58(7).



131 It is clear then, that an authorisation cannot be granted for a use if it is banned through listing in Annex XVII without any exception, or the authorisation would mean relaxation of the restriction imposed on the substance.⁸⁶

132 At point (80) of the preamble to REACH, it is stated that:

“The proper interaction between the provisions on authorisation and restriction should be ensured in order to preserve the efficient functioning of the internal market and the protection of human health, safety and the environment. Restrictions that exist when the substance in question is added to the list of substances for which applications for authorisation can be submitted, should be maintained for that substance. The Agency should consider whether the risk from substances in articles is adequately controlled and, if it is not, prepare a dossier in relation to introduction of further restrictions for substances for which the use requires authorisation.”

133 A restriction in Annex XVII should therefore be maintained even if an authorisation for a particular use is granted. Of course, as indicated above, an Annex XIV authorisation can never relax any restriction on a substance in Annex XVII.

134 The restrictions and authorisation processes are related and they can in practice have similar effect on the uses of a substance. However, they have some differences. These include:

- (i) Authorisation can only address SVHCs while restrictions may generally be imposed on any substance where there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market, which needs to be addressed on a Community-wide basis;⁸⁷
- (ii) Authorisation requirements apply only to placing on the market for a use, and uses of, a substance included in Annex XIV, so authorisation cannot apply for example, to import only. Restriction can apply to import only;
- (iii) Generic exemptions from the restriction procedure are limited. Restriction does not apply to scientific research and development or to the use of the substance in cosmetic products in relation to human health risks;⁸⁸
- (iv) Generic exemptions from the authorisation procedure are wider than for restriction, and includes for example, exemption for uses in biocides, motor fuels and plant protection products.

135 Further, authorisation requires applicants to prepare an analysis of alternatives⁸⁹ whereas the restrictions procedure requires authorities to provide available information on alternative substances or technologies. It should be noted that in the authorisation procedure it is not possible to specify upfront in Annex XIV the uses for which an authorisation will not be granted. Therefore, the authorisation procedure does not ensure that a specified use stops at the sunset date while under restriction a specified use can be banned from a determined date. Otherwise either procedure could be used depending on the circumstances.



⁸⁶ Art. 60(6).

⁸⁷ Art. 68(1).

⁸⁸ REACH Art. 67(1) and Art. 67(2)

⁸⁹ REACH Article 62(4)€.

136 It will be noted that a restriction can cover also import and use of articles containing the substance. The (a) import, or (b) use of articles containing a substance, is not covered by the REACH authorisation system. While incorporation of the substance in articles is a substance use that may require an authorisation, the use of articles containing a certain substance is not covered by authorisation. In that case, (new) restrictions can be introduced even though the substance is listed in Annex XIV if its presence in articles poses an unacceptable risk for man or the environment and this risk needs to be addressed on a Community-wide basis.⁹⁰ However, a substance included in Annex XIV (i.e. substance subject to authorisation) may not be subjected to new restrictions addressing risks related to the intrinsic properties already specified in Annex XIV.

137 Point (80) of the Preamble to REACH encourages ECHA to (re)consider imposing restriction for a substance recommended for authorisation, particularly in respect of the risks arising from the substance in articles and whether that risk is adequately controlled. Should ECHA follow the exhortation in this point (80), recommendation for authorisation and/or authorisation for a use, may trigger an investigation into whether the risk from the substance in articles is adequately controlled. In any event, after the sunset date for a substance defined in Annex XIV, ECHA has a duty to consider whether the use of the substance in articles poses risks that are not adequately controlled and, where needed, prepare an Annex XV dossier for a restriction⁹¹.

138 It can be seen then, that:

- (a) prior to being included in Annex XIV for authorisation, any substance which is a potential candidate for authorisation may be subject to restriction;
- (b) substances for which all uses are prohibited under the restriction procedure can not be included in Annex XIV (i.e. authorisation) or must be removed from it;⁹²
- (c) a restriction in Annex XVII should be maintained even if an authorisation for a particular use is granted;
- (d) an Annex XIV authorisation can never relax any restriction on a substance included in Annex XVII;
- (e) once a substance is included in Annex XIV (i.e. authorisation), it can not be subjected to new restrictions in Annex XVII which cover the risks to human health and the environment from the use of the substance on its own, in a preparation or incorporation of a substance in an article, which arise from the properties specified in Annex XIV;⁹³
- (f) new restrictions can still be included in Annex XVII in cases where unacceptable risks to human health and the environment arise from properties other than those specified in Annex XIV;
- (g) recommendation for authorisation and/or authorisation for a use, may trigger an investigation into whether the risk from the substance in articles is adequately controlled.

⁹⁰ Article 58 (5) and (6).

⁹¹ REACH Article 69 (2).

⁹² Article 58(7).

⁹³ Art. 58(5)



10

Who can apply (i) for authorisation, or (ii) exemption from listing for authorisation, in Annex XIV of REACH?

Applicants for Authorisation

139 It is clear from REACH Article 62(1) that manufacturers, importers and downstream users of a substance may apply for REACH authorisation of a substance. These entities are defined as:

Manufacturer: “means any natural or legal person established within the Community who manufactures a substance within the Community”⁹⁴

Importer: “means any natural or legal person established within the Community who is responsible for import”⁹⁵

Downstream User: “means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user”⁹⁶

140 An application for authorisation may be made by one or several persons, for one or several substances.⁹⁷

Applicant for Exemption from Authorisation

141 There is no mechanism in REACH for any person to “apply” for an exemption from listing for authorisation. REACH Article 58(2) simply provides that “Uses or categories of uses may be exempted ...”. Article 60(1) provides that it is the Commission who “shall be responsible for taking decisions on applications for authorisations...”. It appears therefore that any person could suggest to the Commission, (or ECHA or the Commission on their own initiative) that it exercise its discretion and exempt a use from authorisation where the requirements of Article 58(2) are satisfied.



⁹⁴ REACH Article 3(9).

⁹⁵ REACH Article 3(9).

⁹⁶ REACH Article 3(9).

⁹⁷ REACH Article 62(2).

142 Article 58(4) indicates that ECHA is under an obligation to invite “all interested parties” to submit comments on its draft recommendation for a substance’s inclusion in Annex XIV, “in particular on uses which should be exempt from the authorisation process”. This clearly indicates that any “interested party” can submit comments to ECHA that an exemption from authorisation ought to be granted, and ECHA must update its recommendation taking into account the comments received from such interested party.

11

What issues should be taken into account (e.g. competition law) if applicants for REACH authorisation make joint applications? Or provide data/information to each other in the context of a joint application for authorisation?

EU Competition Law

143 ECHA has commented on the potential competition issues that might arise under the authorisation procedure where joint applications for authorisation are made. In ECHA’s Final Draft of Guidance on the Preparation of an application for Authorisation, it states:

“The EU competition rules also apply in the context of REACH-related activities. Although none of the obligations under REACH require exchanging information or other actions that are in breach of the competition rules, when preparing a joint application for an authorisation, applicants need to be aware of the competition rules. While a single exchange of information about the use of a substance will not generally give rise to antitrust concerns, competitors should abstain from organising periodic exchanges of information or from exchanging information on markets, prices, or customers. Also, certain decisions between competitors as to whether an alternative is or is not suitable could be seen as unlawful collusion. Therefore, the use of an independent third party could be considered by competitors making a joint analysis of alternatives or a joint substitution plan (particularly) if they have large market shares). Exchanges of information on uses and on whether an alternative is suitable between manufacturers/importers and their downstream users will generally not give rise to antitrust concerns.”⁹⁸



98 ECHA Draft Guidance on Preparation of an application for Authorisation 20 May 2010 – not yet published, at p. 72.

144 Unlike the requirements for a SIEF (Substance Information Exchange Forum) to provide information and to collectively identify, and arrange for the carrying out of, further studies required for REACH registration, there is no such requirement in respect of application(s) for authorisation. Applicants for authorisation are free to apply individually or together as a group of several persons.⁹⁹ Nevertheless, the competition law issue is virtually the same.

145 Two potential competition law concerns are:

- Exchange of information between competitors;
- Agreements between competitors that an alternative is, or is not, suitable.

146 If there are periodic exchanges of commercially sensitive information between competitors, in for example, the supply, manufacture, import or use of a substance the subject of authorisation, this may be considered as anti-competitive conduct. This is particularly so in markets where there are only a few players (i.e. oligopolistic markets). Further, a joint application for authorisation could very well involve disclosing to joint applicants different specific uses of the substances, allowing competitor(s) to have a good appreciation of the customers or markets that could be affected by an authorisation application. This, in turn, may allow competitors to become aware of another joint applicant's market strategies. There may even be an issue if an applicant exchanges information with competitors (e.g. other co-applicants) details of an intention to place a substance on the market for a particular use. It is noted that the Commission will only publish on its website "broad information on uses" and not specific details of uses. The exchange of such details on uses could be seen as anti-competitive if it gave "rise to conditions of competition which did not correspond to the normal conditions of the market in question."¹⁰⁰

147 While the competition risk may be limited, the EU Commission's Draft Guidance on cooperation agreements indicates that an analysis of both the market concerned as well as the nature of the information being exchanged, needs to be considered on a case-by-case basis before any conclusion can be made on the anti-competitive effect of an information exchange.¹⁰¹ EU Commission Guidance and EU Court decisions indicate there is greater scrutiny of information exchange by the EU authorities where the information exchange "is liable to enable undertakings to be aware of market strategies of their competitors if it may lead to restrictive effects on competition."¹⁰²

148 Finally, competitors could agree amongst themselves that a certain alternative is not suitable, or is suitable as an alternative, thereby favoring their own products and/or making it more difficult or impossible for a potential alternative competing substance to enter or continue in a market. This would amount to collusion contrary to EU competition law.

149 To minimise the risk any of the above issues arising, an independent third party could be appointed to co-ordinate a joint application made by a number of companies wishing to apply for authorisation, rather than each applying individually. The independent third party could, for example, (i) ensure commercial business information is not exchanged between competitors, and (ii) an independent assessment is made on the suitability of alternative substances/technologies.



⁹⁹ REACH Article 62(2).

¹⁰⁰ EU Court of Justice Case C – 238/05 *Asnef-Equifax v. Ausbanc*, para. 52.

¹⁰¹ Commission Draft Guidance on Horizontal Cooperation Agreements, SEC (2010) 528/2 at 54-97.

¹⁰² See EU Court of Justice Case C-7/95 P, *John Deere* [1998] ECR I-311 and Draft Commission Guidelines on Horizontal Cooperation Agreements EC (2010) 528/2 at 58.

Confidential Business Information

- 150 If making a joint authorisation application, certain information such as the specific use(s) for which authorisation is sought, use in substances and/or articles, economic feasibility of an alternative, R&D activities of the applicants, and a substitution plan for alternatives (if applicable), would almost inevitably be disclosed to other joint applicants.¹⁰³ Much of this information would normally be considered confidential business information. Some of it may be subject to intellectual property rights, or the subject of restrictive licences or disclosure arrangements with person(s) not part of the joint application. Hence, care needs to be taken that disclosure of sensitive business information to other joint applicants does not lead to loss of legal protection of the information as, for example, a trade secret, know-how or confidential information. Once this legal protection is lost the information can be used freely and further disclosed by the person to whom it has been given.
- 151 If making a joint application, consideration could be given to having agreement(s) restricting, and protecting against, the use and disclosure of confidential business information. An arrangement where such information is provided to an independent third party for submission to ECHA is one suggested by ECHA.
- 152 In the context of authorisation, unlike information for registration, it will be noted that there is no obligation to share information (or its cost) with other applicants, or with later applicants seeking to refer to parts of a previous applicant's information. Referral to an earlier application can only be made with "permission from the previous applicant."¹⁰⁴

Privacy – Personal Data Protection

- 153 While it is unlikely to be a major concern, there is a possibility that personal data could be provided from one joint applicant to another. Personal data is any information relating to an identified or identifiable natural person ("data subject"). No personal data may be "processed" unless, most relevantly, the data subject has given his consent.¹⁰⁵ This issue may arise where, for example, a scientist discloses personal information in his biography or Curriculum Vitae in order to show that testing or an opinion, submitted as part of a joint application, has been done by a qualified and experienced professional. Essentially, the making available or disclosure of the personal data in the Curriculum Vitae amounts to 'processing' of such data and if no consent to such disclosure has been given, this could breach the EU rules on protection of personal data. There may be other circumstances where personal data is disclosed to other joint applicants. A mechanism needs to be in place to ensure such personal data is dealt with in accordance with EU law.

¹⁰³ REACH Article 62.

¹⁰⁴ REACH Article 63(1) and (2).

¹⁰⁵ Article 7(a) Directive 95/46 on Protection of Individuals with Regard to the Processing of Personal Data OJ 1995 L 281/31 as amended.



12

What are (i) the time limits in force to apply for, and the grant of, authorisation for a use included in Annex XIV of REACH? And (ii) what time periods are ECHA and the EU Commission currently applying for authorisation applications?

Time limits to Apply for, and Grant of, Authorisation

- 154 When a substance is included in Annex XIV, it must include the date(s) from which placing on the market and use of the substance is prohibited unless authorisation is granted ("sunset date"). An application for authorisation of a use or category of uses must be made at least 18 months before this sunset date.
- 155 ECHA's Committees on Risk Assessment ("RA") and Socio-Economic Analysis ("SEA") must give their draft opinions on the application within 10 months of receipt of the application.¹⁰⁶ Within one month and seven days of ECHA sending these draft opinions to the applicant, the applicant must give notice that he wishes to comment (if applicant wishes to do so). The applicant then has one more month to send his written argumentation to ECHA.¹⁰⁷ The ECHA Committees RA and SEA must then finalise their opinions within a further two months and ECHA must send these final opinions to the Commission within another 15 days.¹⁰⁸
- 156 The Commission then has three months to prepare a draft authorisation decision taking into account the ECHA Committees final opinions. A final decision is then taken either refusing or granting the authorisation in accordance with the so-called "comitology procedure." This procedure involves submission of the Commission's draft decision to a Member State Committee who must deliver its opinion within a time limit set by the Committee's chairman. This Committee gives its opinion by "qualified majority."¹⁰⁹ If the Member State Committee's opinion is positive the Commission can immediately adopt the draft decision.¹¹⁰
- 157 If the Member State Committee's opinion is negative or no opinion is delivered within the time limit fixed by the Committee's chairman, the Commission must, without delay, (i) submit to the EU Council the proposed decision, and (ii) inform the EU Parliament.¹¹¹ If within 3 months the EU Council does not adopt the proposed Commission decision nor indicates any opposition to it, the Commission adopts the decision. If within these 3 months the Council indicates, by qualified majority, that it opposes the Commission's proposed decision, the Commission must re-examine it.¹¹² The Commission may then either submit an amended proposal to the EU Council, or re-submit its proposal as a legislative proposal based directly on the EU Treaty (rather than on the basis of REACH Article 60).¹¹³ It will be noted that the role of the EU Parliament is very limited for the grant of authorisation for a use of a substance included in Annex XIV.



¹⁰⁶ REACH Article 64(1).

¹⁰⁷ REACH Article 64(5).

¹⁰⁸ REACH Article 64(5).

¹⁰⁹ Article 5(2) Council Decision 1999/468/EC.

¹¹⁰ *Op. cit.* Article 5(3).

¹¹¹ *Op. cit.* Article 5(4).

Time Periods ECHA and EU Commission are currently Applying for Authorisation applications

Sunset Date

158 In the 2009 draft recommendations for priority substances, ECHA proposed sunset dates between 42 and 48 months after inclusion in Annex XIV. In its 1 July 2010 draft recommendation ECHA proposed sunset dates between 36 and 42 months after inclusion of the substances in Annex XIV. ECHA seems to take the view that there should be at least 12 months between inclusion in Annex XIV and the last application date so the sunset date is a minimum of 30 months after inclusion in Annex XIV. This is to allow potential applicants to prepare applications of the required quality. ECHA has indicated that there has so far been no information to distinguish sunset dates for different substances or to deviate from the 18 months set out in REACH. In that case ECHA is using a standard difference of 18 months between the last application date and sunset date.

Last Application Date

159 The last 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. ECHA has made it clear that “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).” the minimum required period of 18 months will be used¹¹⁴. Applicants for an authorised use have a possibility to submit their applications at any time before the last application date. However ECHA recognises that, since the authorisation requirement is still new and most actors might have no experience in preparing applications, most applicants will use all available time until the specified last application date to develop their applications.¹¹⁵

160 For the first recommendations on priority in 2009, information on the complexity of the supply chain and on the availability of information about alternatives was used to estimate the differences in time needed to prepare applications. Periods of between 24 and 30 months after publication of inclusion in Annex XIV were recommended as the application dates. However, taking into account the small differences in the proposed last 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 second recommendation in 2010.

161 For ECHA's second (2010) recommendations on priority substances, ECHA proposes to spread the last application dates over 6 months so that the substances with similar properties and uses get the same last application date. This was in order to avoid potential evasion of the authorisation requirement by substituting a substance subject to authorisation by another one with similar hazard properties, but which however does not yet require authorisation.

162 For example, ECHA's first recommendation in 2009 included three phthalates (DEHP, DBP, BBP) with a proposed last application date of 30 months and sunset date of 48 months, from the inclusion in Annex XIV. The second (2010) recommendation includes one more phthalate (diisobutyl phthalate, DIBP), which has similar uses to the three earlier phthalates. For that reason, ECHA proposes 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, ECHA took the view that there should be a minimum of 12 months.



112 REACH Article 133(3) and Council Decision 1999/468/EC Article 5(6).

113 Article 5(6).

114 Preparation Of Draft Annex XIV Entries For The Second Recommendation Of Substances To Be Included In Annex XIV General Approach, ECHA 1 July 2010 at p.3.

115 Preparation of Draft Annex XIV Entries For the Second Recommendation of Substances to be Included In Annex XIV General Approach, ECHA 1 July 2010 p. 3 at footnote 1.

163 When more information on manufacture and uses is available from the registration dossiers towards the end of 2010, ECHA expects that its current approach used to differentiate the last application date will be reconsidered.

164 ECHA notes that while there is a difference of 6 months in the last application dates for the various recommended substances proposed for inclusion in Annex XIV, this difference can be considered as minor compared to the total time reserved for the potential applicants to prepare their applications. This 6 months difference is regarded as nevertheless facilitating better processing of the applications by ECHA's Committees and the secretariat.¹¹⁶ ECHA expects that this differentiation will also assist interested third parties who wish to provide information or comments on several substances. Finally, ECHA expects that last application dates spread over 6 months will assist the Commission, which has to prepare draft authorisation decisions within three months of receipt of ECHA's opinions.

13

What impact might applicable time periods have on applicants for authorisation, or requests for exemption from authorisation?

Impact of Time Periods on Authorisation

165 When a decision is taken to include a substance in Annex XIV, the Commission must also give:

- the date(s) from which placing on the market and use is prohibited unless an authorisation is granted (i.e. a "sunset date"); and
- a date or dates at least 18 months before this "sunset date by which applications for an authorised use must be received (hereafter "last application date").

166 One clear impact of these time periods is that if an application for authorisation is made by the last application date, the applicant can continue to use the substance and to place it on the market even after the sunset date, but only for so long as no negative decision has been made on the application. Hence, if the authorisation application is ultimately rejected, there is a possibility that use of the substance can continue after the sunset date but only until the date of a negative decision.

Impact of Time Periods on Exemptions from Authorisation

167 There are no specific time periods for requests for exemption from authorisation. However, there are time periods applicable to the procedure for inclusion of a substance in Annex XIV (i.e. authorisation). Before any decision on authorisation, (a) the relevant substance must be the subject of an Annex XV dossier for inclusion on the candidate list,¹¹⁷ and (b) ECHA must have included the substance in its recommendations on prioritisation of substances that could be subject to authorisation.¹¹⁸



¹¹⁶ *Op cit at p. 4.*

¹¹⁷ REACH Article 59(4).

¹¹⁸ REACH Article 58(4).

168 In coming to any conclusion on recommendations for priority substances to be included in Annex XIV (authorisation), ECHA may consider a claim that a substance's use should be exempt from authorisation. If a claim for exemption has not been made and dealt with by ECHA, it is unlikely ECHA will recommend that a use of a substance be exempted from authorisation. A claim for exemption should therefore be made either (i) during the commenting period on the Annex XV dossier¹¹⁹ for inclusion of a substance in the candidate list, or (ii) during the commenting period for inclusion by ECHA of the substance on its draft list of priority substances for Annex XIV. ECHA publishes on its website the draft list of priority substances and invites interested parties to submit comments within three months of publication.¹²⁰ Thereafter, ECHA must update its recommendation, taking into account the comments received. It would therefore be in the interest of a claim for exemption from authorisation, that the claim be made to ECHA latest within this three month period.

169 A decision to include a substance for authorisation in Annex XIV would (at least by implication) also include a rejection of any claim for exemption of a use, or category of uses, from authorisation. The decision to include a substance in Annex XIV is made under a "Committee procedure" referred to in REACH.¹²¹ Under this Committee procedure the EU Commission, having received ECHA's recommendation, submits a draft decision on inclusion of the substance in Annex XIV, to a Committee of the Member States. This Committee gives its opinion on the proposed inclusion in Annex XIV within a time limit fixed by the chairman of the Committee. The Committee gives its opinion on the draft decision by "qualified majority." The Member State Committee's opinion may be positive or negative, or no opinion may be forthcoming from the Committee within the time limit fixed by its chairman. The Commission then submits the draft decision to the EU Council and EU Parliament for scrutiny.¹²²

170 The EU Council or EU Parliament can object to the Commission's proposed decision:

- within 3 months if the Member State Committee's opinion is positive; or
- the EU Council within 2 months or the EU Parliament within a further 2 months, if the Member State Committee's opinion is negative or no opinion is delivered by the Committee.

171 If any objections of the EU Council or EU Parliament are sustained, a decision to include the substance in Annex XIV cannot be adopted.¹²³

172 It can be seen then, that if the Member State Committee agrees (by qualified majority) to accept the Commission's proposed decision on a substance's listing for authorisation, a claim for exemption can only be sustained by having either the EU Council or EU Parliament oppose the proposed decision within 2 months of referral of the proposed decision to the EU Council, or within 4 months of referral to the EU Parliament.



119 REACH Article 59(4).

120 REACH Article 58(4).

121 Article 5a (1) to (4) of Council Decision 1999/468/EC and REACH Articles 58(1) and 133(4).

122 Article 5a (3) of Decision 1999/468/EC.

123 Article 5a (4) of Decision 1999/468/EC.

14

Will all downstream users need to apply for an authorisation to be able to use the substance?

173 It will be remembered that an authorisation is required not only for uses by a person of a substance in Annex XIV. Authorisation is also required to “place a substance on the market for a use.”¹²⁴ The application for an authorisation of one (or more) uses of one (or a “group” of several) substances can be submitted individually by a manufacturer, importer or downstream user, or jointly by several legal entities.¹²⁵ So, in principle, the uses applied for in an application for authorisation can include:

- (a) the applicant’s own use(s) (e.g. an individual downstream user’s application on its own for its own use);
- and/or
- (b) uses for which the applicant will place the substance on the market (e.g. a manufacturer or importer applies for a use of his downstream user(s)).¹²⁶

174 All downstream users may use an Annex XIV substance provided it is in accordance with the conditions of an authorisation granted to an actor up his supply chain.¹²⁷ In such a case, the downstream user must notify ECHA within three months of the first supply of the substance for the authorised use.¹²⁸ When a substance has been authorised for a specific use, the downstream users who are both:

- (a) further down the supply chain of the applicant for authorisation;
 - and
 - (b) use the substance for the authorised use;
- the authorisation granted will cover such use by these downstream users.

175 Such downstream users in the applicant’s supply chain need make no additional or joint application for authorisation of the use.¹²⁹ It is emphasized however, that only downstream users in the applicant’s supply chain are covered by the authorisation. Other downstream users outside the applicant’s supply chain are not covered by the authorisation.

176 If the holder of an authorisation is the downstream user (using the substance for the authorised use), in order to place the substance on the market, the immediate upstream supplier of such downstream user does not need to obtain additional authorisation, or be a joint applicant for authorisation.¹³⁰ In this case such an upstream supplier can place the substance on the market for the use granted in the authorisation to his immediate downstream user.

177 It can be seen then, that it is not enough to have one applicant of an authorisation to cover all EU users. Only downstream users in the same supply chain as that of the applicant may rely on the authorisation of the applicant. Further, only the immediate upstream supplier who supplies directly to a downstream user holding an authorisation, may place the substance on the market for the authorised use.

178 Depending on whether an application for authorisation covers one or more applicants for the use(s) of a substance(s) included in Annex XIV, the following scenarios in Question 16 can be envisaged in terms of the level of fees payable to ECHA (note that the examples below are based on standard fees as set out in Table 1 of Annex VI to the Fees and Charges Regulation).¹³¹



124 REACH Article 56(1).

125 Article 62(2) of the REACH Regulation.

126 Article 62(3) of the REACH Regulation.

127 Article 56(2) of the REACH Regulation.

128 Article 66(1) of the REACH Regulation.



129 REACH Article 56(2).

130 REACH Article 56(1)(e).

131 *The Fees and Charges Regulation provides for a reduced base fee and reduced additional fees in the case of individual applications by a medium-sized, small or micro size enterprises as well as in the case of certain joint application by these enterprises: Article 8(3) of Regulation (EC^o No. 340/2008 on fees and charges payable to ECHA. Additional guidance on the size of enterprises can be found in Recommendation 2003/361/EC.*

15 *What fee(s) must be paid and who must pay the fee(s) when seeking listing for authorisation in REACH Annex XIV including the respective payment obligations of joint applicants?*

179 Any application for an authorisation of a substance included in Annex XIV to REACH is subject to a fee payable to ECHA.¹³² In accordance with Commission Regulation (EC) No. 348/2008 on fees and charges payable to ECHA (“Fees and Charges Regulation”), this fee consists of a base fee that covers one substance, one use (i.e. one exposure scenario) and one applicant. If applicable, an additional fee is payable for any additional substance, use or applicant covered by the application.¹³³

Individual application for Authorisation for Use(s) of Substance(s)

180 If a manufacturer (or importer) makes an application for an authorisation on its own to cover one specific use of a substance by himself and/or all downstream users in his supply chain in the EU, he needs to pay a standard base fee of 50,000 Euros.¹³⁴ Should however, his downstream users use the same substance for different uses, then the application fee is the sum of a standard base fee of 50,000 Euros + (additional standard fee of 10,000 Euros X number of additional uses).¹³⁵ The same applies in the case where the same application for authorisation covers more than one substance (note that this is only possible if several substances meet the definition of a group of substances in Section 1.5 of Annex XI).¹³⁶ So, for example, if the application covers two substances (one having two uses and the other having three uses), the application fee is the sum of a base standard fee of 50,000 Euros + additional standard fee of 10,000 Euros for the additional substance + additional standard fee of 10,000 Euros X the remaining 4 additional uses.¹³⁷

Joint application for Authorisation for Use(s) of Substance(s)

181 Where different actors decide to prepare a joint application for authorisation (e.g. members of the Nickel Institute supplying, to downstream users for the same use, a nickel compound included in Annex XIV to REACH) the cost of a joint application is a sum of a base standard fee of 50,000 Euros plus additional standard fee of 37,500 Euros X number of applicants. If the application covers more than one use of the nickel compound, an additional fee of 10,000 Euros per use is added. Note that the additional standard fee per each additional applicant depends on the size of the applicant. A fee lower than 37,500 Euros may be applicable per additional applicant if that additional applicant is a micro, small or medium-sized enterprise as defined in EC Recommendation 2003/361/EC.¹³⁸

182 Note also that, in contrast to a joint submission for registration, in the case of a joint application for authorisation, only one invoice that covers the whole costs of the application is generated. No separate invoices are issued to each of the joint applicants covered by the application. It is up to the applicants to make the necessary arrangements to divide the cost of the application fee amongst themselves.¹³⁹



¹³² Article 62(7) of the REACH Regulation, see also Article 74(1) of the REACH Regulation.

¹³³ Article 8(2) of Regulation (EC) No. 340/2008 on fees and charges payable to ECHA.

¹³⁴ Annex VI to Regulation 340/2008 on fees and charges of ECHA.

¹³⁵ Table 1 of Annex VI to Regulation (EC) No. 340/2008 on fees and charges payable to ECHA.

¹³⁶ Article 62(3) of the REACH Regulation.

¹³⁷ See also the Commission's Practical information about the Commission Regulation on fees and charges payable to the European Chemicals Agency (ECHA), available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/fees/index_en.htm.

Is the review process after grant of authorisation free of charge?

16

183 The short answer is: No. An authorisation granted for the use of a substance included in REACH Annex XIV is subject to review. To continue benefiting from an authorisation, its holder must submit a review report at least 18 months before the expiry of the time-limited review period.¹⁴⁰

184 Not only an application for an authorisation is subject to a fee. REACH empowers ECHA to collect “charges” for other services it provides¹⁴¹ To this end, the Fees and Charges Regulation imposes a charge for a review of an authorisation (i.e. for submission of a review report under Article 61 of the REACH Regulation).¹⁴²

185 The charges for submission of a review report are set out in Annex VII to the Fees and Charges Regulation. They are identical to the fees payable for applications for authorisation. That is, the charge is based on the same structure (a base charge and an additional charge), the same principle (covers a review report for one substance, one use, and one applicant), and is of the same level as fees for the original application. In addition, both base charge and additional charges, under the same principles, may be reduced for micro, small and medium-sized enterprises.

186 As in the case of fees for the original application, invoicing of charges for a review report is addressed only to the authorisation holder that submits the review report. No separate invoices are issued (see above).



138 Table 1 of Annex VI to Regulation (EC) No. 340/2008 on fees and charges payable to ECHA.

139 The Commission's Practical information about the Commission Regulation on fees and charges payable to the European Chemicals Agency (ECHA), available at http://ec.europa.eu/enterprise/sectors/chemicals/reach/fees/index_en.htm.

140 Article 61 of REACH.

141 Article 74(5) of the REACH Regulation.

142 Article 9 of Regulation (EC) No. 340/2008 on fees and charges payable to ECHA.

17

What information or data could be disclosed to the public if (i) a REACH authorisation application is made? or (ii) a claim is made for exemption from listing for authorisation?

Disclosure of Documents

187 If ECHA receives an application for access to a document originating from an applicant for authorisation, or from a person claiming an exemption from authorisation, ECHA is bound by both EU Regulation 1049/2001 on Access to Documents, and by a 2009 Decision of ECHA's Management Board¹⁴³ to follow certain procedures. ECHA must examine the document to check whether one of the exceptions to disclosure, as set out in Regulation 1049/2001 on access to documents, applies. These are:

- disclosure would undermine protection of privacy and integrity of an individual particularly regarding protection of personal data;
- protection of the commercial interests, including intellectual property, of a natural or legal person would be undermined;
- protection of court proceedings or legal advice would be undermined;
- disclosure would undermine the purpose of inspections, investigations or audits.¹⁴⁴

188 Except for protection of privacy, the latter three exceptions to disclosure, (b) to (d) above, would not be applied where there is "an overriding public interest in disclosure" of the document.

189 It will be noted that if a document request concerns "emissions into the environment", ECHA may consider that there is an overriding public interest and disclose the relevant parts of documents even if disclosure would undermine the commercial interests of the author of the document.¹⁴⁵

190 Information that would normally not be disclosed, since it is regarded as information that would undermine the commercial interests of the concerned person, is:

- (i) details of full composition of a preparation;
- (ii) precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;
- (iii) precise tonnage of the substance or preparation manufactured or placed on the market;
- (iv) links between a manufacturer or importer and his distributors or downstream users.¹⁴⁶

191 Note however, that where urgent action is essential to protect human health, safety or the environment, such as emergency situations, ECHA may disclose the information referred to at (i) to (iv) above.¹⁴⁷



¹⁴³ *Decision on Implementations of Regulation (EC) 1049/2001 Regarding Public Access to Documents of 25 March 2009 Doc:MB/12/2008 final.*

¹⁴⁴ *Article 4(1)(b) and 4(2) of Regulation 1049/2001 on Public Access to EU Institution Documents, OJ 2001 L 145/43.*

¹⁴⁵ *Article 6(1) of Regulation 1367/2006 on Access to Information on Environmental Matters.*

¹⁴⁶ *Article 118(2) REACH.*

¹⁴⁷ *Ibid.*

192 In an emergency situation, environmental information may be released by ECHA where it enables an affected public to mitigate or prevent harm to human health, life or the environment. Article 8 of Regulation 1367/2006 provides that:

193 "In the event of an imminent threat to human health, life or the environment, whether caused by human activities or due to natural causes, [ECHA] shall, upon request of public authorities ... collaborate with and assist those public authorities in order to enable the latter to disseminate immediately and without delay to the public that might be affected, all environmental information which could enable it to take measures to prevent or mitigate harm arising from the threat, to the extent that this information is held by or on behalf of ECHA and/or those public authorities."

194 ECHA will not consult the applicant before disclosure of a document if the document has already been disclosed, or it is clear disclosure or partial disclosure of the document's contents would obviously not effect one of the interests mentioned at (a) to (d) above.¹⁴⁸ It will be noted that if only part of a document is covered by one of the interests mentioned above, the remaining parts of the document shall be released.¹⁴⁹

Disclosure on Public Databases

195 If an authorisation application is made, ECHA must make available on its website "broad information on uses" but taking into account limitations on access to information as set out in REACH and Regulation 1049/2001 on public access to EU institution information.¹⁵⁰ (See above.)

196 ECHA must also determine, and then make publicly available on its website, those parts of (i) any opinions it adopts on the authorisation application, and (ii) any written argumentation of the applicant concerning the draft opinion of ECHA, as it deems appropriate.¹⁵¹

197 Summaries of the EU Commission decision on authorisation are published in the EU Official Journal and in a public database managed by ECHA.¹⁵²

198 While ensuring that disclosure of documents would (notably) not undermine privacy, commercial interests, court proceedings, legal advice, or audits, - as indicated above - ECHA is also required to make available and to disseminate on its database(s):

- authorisations with a significant impact on the environment; and
- environmental impact studies and risk assessments concerning environmental elements.¹⁵³

¹⁴⁸ Article 5(3) ECHA Decision MB/12/2008 final and Article 4(4) Regulation 1049/2001.

¹⁴⁹ Article 4(6) Regulation 1049/2001 and Article 8(3) ECHA Decision MB/12/2008 final. ECHA may also disclose to the public any

document from an authorisation applicant that has already been disclosed by their author or with his consent, including documents already disclosed following a previous application for disclosure.

¹⁵⁰ Article 64(2) of REACH.

¹⁵¹ Article 64(6) of REACH.

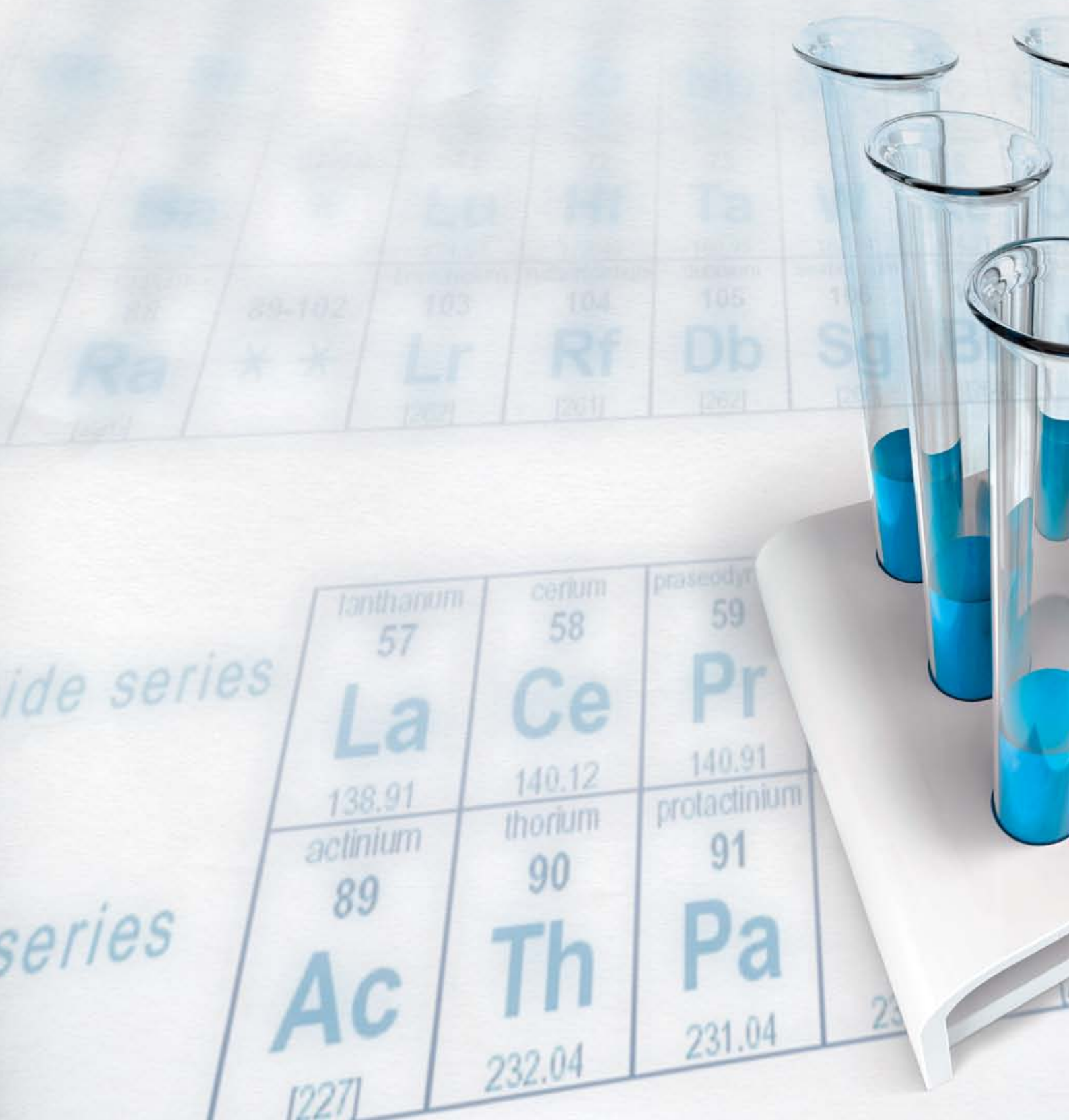
¹⁵² Article 64(9) of REACH.

¹⁵³ Article 4(2)(f) and (g) of Regulation 1367/2006 on Access to Information in Environmental Matters.





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lanthanum 57 La 138.91	cerium 58 Ce 140.12	praseodymium 59 Pr 140.91
actinium 89 Ac [227]	thorium 90 Th 232.04	protactinium 91 Pa 231.04