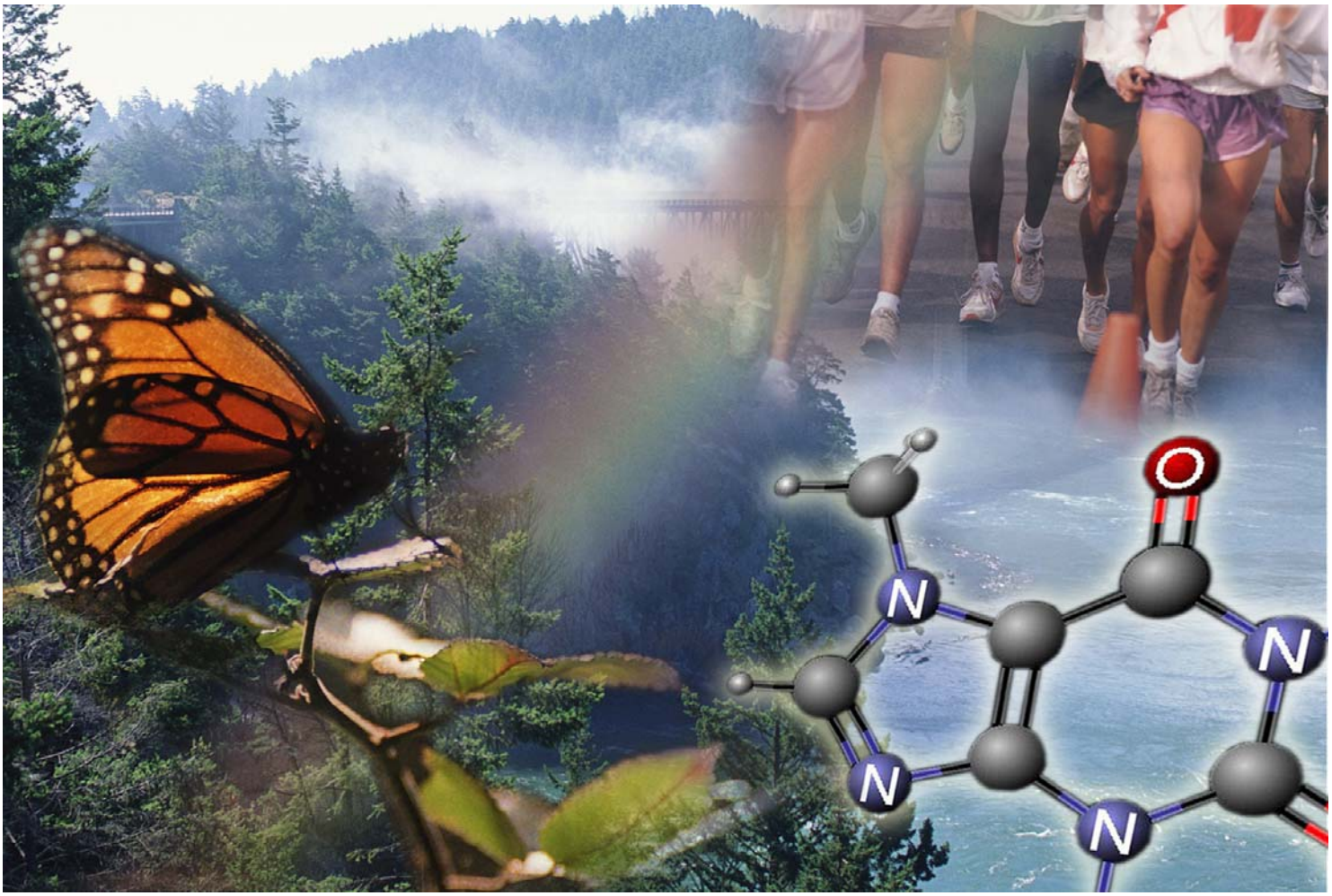
Guidance on inclusion of substances in Annex XIV

(List of Substances subject to Authorisation)



August 2008

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This document describes the socio-economic analysis under the REACH restriction procedure. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

1 Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

CONTENTS

TABLES

FIGURES

1 GENERAL INTRODUCTION

1.1 About this guidance

This document is intended to provide technical guidance to the European Chemicals Agency and the Member State Competent Authorities on the identification of substances with properties of very high concern[2] (SVHC) and inclusion of such substances in Annex XIV (List of Substances subject to Authorisation) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council, of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation). Thus, this guidance relates to Title VII, Chapter 1, Articles 55 to 59 of the REACH Regulation.

1.2 Structure of the guidance

The guidance provides an overview on the authorisation procedure from the identification of the substances subject to authorisation until their inclusion in Annex XIV (List of Substances subject to Authorisation) of REACH Regulation and addresses the following topics:

- Authorisation procedure including the roles of the different actors
- Scope of authorisation addressing the substances subject to authorisation and a listing of the general and specific rules for use of substances and uses exempted from authorisation
- Procedure to include substances into the Authorisation detailing establishment of the candidate list[3], prioritisation of substances from the 'candidate list' and establishment of the List of Substances subject to Authorisation (Annex XIV)[4]
- Details of what should be included in the recommendation for inclusion of a SVHC in Annex XIV including the substance identity, the intrinsic properties of the SVHCs, the transitional arrangements, review periods for certain uses, uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions
- Consultation of the Member State Committee and of interested parties with regard to the identification of substances for the 'candidate list' and the decision to include substances in Annex XIV.

1.3 Who is the guidance for?

This guidance is primarily intended for use by those within the Member State Competent Authorities and the Agency, who are dealing with the identification of substances with properties of very high concern and inclusion of such substances in Annex XIV. It comprises both guidance on the activities and workflows required to identify SVHCs and the inclusion of SVHCs in the 'candidate list' for inclusion in Annex XIV after prioritisation of these substances.

The guidance will also be useful for registrants and others involved with a SVHC so as to better follow the process and understand the basis of the identification of substances with identified properties of very high concern and inclusion of substances in Annex XIV. Consequently, this document is also a reference document for manufacturers/importers and downstream users of

[2] Substances of Very High Concern (SVHCs) are CMRs (cat. 1 or 2), PBTs, vPvBs or substances of equivalent concern according to Art. 57(a-f).

[3] Candidate list of substances for eventual inclusion in Annex XIV will be abbreviated in the text as 'candidate list'

[4] List of Substances subject to Authorisation will be abbreviated in the text as 'authorisation list'

substances that might be subjected to an authorisation procedure and for the interested third parties that might have interest to provide comments or input in different stages of the process.

1.4 Links to other REACH guidance

This guidance is not intended to be used as stand alone guidance and takes into account other REACH guidance and processes, in particular the preparation of Annex XV dossiers and the development of a prioritisation tool for selection of priority substances for inclusion in Annex XIV, the development of an authorisation application and the requirements for substances in articles.

The IT system is set up to support the REACH implementation, i.e. the preparation of chemical safety reports, the information requirements, the preparation of an application for authorisation, requirements for substances in articles and their links to the guidance related to the authorisation procedure.

1.4.1 Chemical Safety Assessment and Chemical Safety Report

The guidance on how to conduct a Chemical Safety Assessment (CSA) and document it in the Chemical Safety Report (CSR) (see Guidance on information requirements and chemical safety assessment for more details) is also relevant for the process of inclusion of substances in Annex XIV. The authorities (Agency or Member States) need to use the relevant parts of sections 1 to 4 of Annex I and document their justification in a CSR format when preparing Annex XV dossiers for identification of SVHCs. The CSRs provided by registrants, where required, as a part of their registration dossier are an important source of information on intrinsic properties, the uses of and the exposure to a substance that may be used for preparing Annex XV dossiers and for prioritisation of substances within the 'candidate list' for inclusion in Annex XIV.

1.4.2 Preparation of an Annex XV dossier

The guidance on preparing an Annex XV dossier when an Authority (the Commission or a Member State) considers that a substance may meet the criteria for identification as a PBT or vPvB substance, or that it has properties with an equivalent concern, or when an Authority wishes to initiate the inclusion of a CMR (cat 1 or 2) substance in the 'candidate list', is covered in the Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern. This may lead to the identification of substances as SVHC and to inclusion of a substance in Annex XIV. Unless specified otherwise, it is implicitly assumed in the text that an Annex XV dossier in this guidance relates to the identification of SVHCs[5]. Details of this process are not repeated here. Instead this guidance indicates when to refer to the guidance for the production of an Annex XV dossier (Guidance on identification of SVHC).

1.4.3 Prioritisation tool for selection of priority substances for inclusion in Annex XIV

Guidance on prioritisation of substances for inclusion in Annex XIV will be developed[6]**.** Priority setting under REACH for inclusion in Annex XIV can be regarded as a staged process, in which at the lowest stage a larger number of substances is screened, selected and possibly ranked with

[5] The two other types of Annex XV dossier that authorities may prepare are:
- Annex XV dossier to propose and justify harmonised classification and labelling
- Annex XV dossier to propose and justify restrictions of the manufacture, placing on the market or use of a substance

[6] ECHA will develop the prioritisation method while gaining experience during the development of the draft recommendations of priority substances to be included in the List of Substances subject to Authorisation.

respect to the different criteria applicable for the prioritisation. The information in the Annex XV dossiers will need to be considered for prioritisation.

1.4.4 Authorisation applications

Guidance to industry on preparing an application for authorisation, required as a consequence of inclusion of a substance in Annex XIV in order to be able (to continue) to use it or place it on the market unless an exemption applies, will be developed under the Guidance on the preparation of an application for authorisation. This document will guide industry in preparing an application. This will include how to develop an analysis of alternatives (Art. 62(4)(e)) and how to include any information on his relevant research and development activities and, depending on the outcome of this analysis, if required, a substitution plan (Art 62(4)(f)). It will also provide guidance for interested third parties in submitting information about alternative substances or technologies (Art. 64(2)) that will be taken into account by the Agency Committees and the Commission during the authorisation decision procedure.

1.4.5 Requirements for substances in articles

The 'candidate list' containing SVHCs for inclusion in Annex XIV is the driver for the provisions on substances in articles under Art. 7 (2) and Art. 33. Guidance on the registration, notification and communication of information in the supply chain with regard to SVHCs in articles is addressed within the Guidance for articles.

2 GENERAL INFORMATION ON AUTHORISATION

2.1 General overview of the authorisation procedure

Figure 1 gives an overview of the key processes and the involvement of the different actors in the authorisation procedure. In this guidance document the authorisation process is considered to commence when a Member State or the Agency on behalf of the Commission initiates work in order to prepare an Annex XV dossier suggesting the identification of a substance as a SVHC.

The REACH Regulation sets up a system under which the use of SVHCs and their placing on the market may be made subject to authorisation. The aim of authorisation, besides ensuring the functioning of the internal market through an equal treatment of such substances, is to ensure that risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies, where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives, consider their risks, and the technical and economic feasibility of substitution (Art. 55).

The substances that may be included in the authorisation system have intrinsic hazardous properties of such concern that the Community needs to decide about the adequacy of the control of the risks arising from their uses or whether the socio-economic benefits outweigh the risks arising from the use of such substances.

When an Authority (Commission or Member State) considers that a substance may meet the criteria for identification as a SVHC, the Authority (Agency or Member State) will prepare an Annex XV dossier (see also Guidance on identification of SVHC for details). Following completion of an Annex XV dossier the Agency shall publish a notice that an Annex XV dossier has been prepared for a substance. The substance may be included in the 'candidate list' for possible inclusion in Annex XIV through a procedure specified in Art. 59. Interested parties, Member States and Agency may comment during this procedure. The Agency shall publish the 'candidate list' on its website with an indication which substances within this 'candidate list' are on its work programme. The Agency shall make its first recommendation of priority substances for inclusion in Annex XIV by 1st June 2009. The Agency shall make further recommendations on substances to be included in Annex XIV at least every second year. Priority will normally be given to substances with PBT or vPvB properties, with wide dispersive uses or that are manufactured or imported in high volumes[7].

According to Art. 58, the Commission, through the regulatory procedure with scrutiny (Art.133(4)), shall include substances in the Annex XIV (list of substances which are subject to authorisation), considering the capacity of the Agency to process the authorisation applications, and shall specify:

(1) the identity of the substance;

(2) the intrinsic properties of the substance;

(3) the date after which the placing on the market and all uses are prohibited (called the sunset date), except for those uses for which either an authorisation was granted or an application has been submitted to the Agency at least 18 months before the sunset date;

[7] ECHA will develop the prioritisation method while gaining experience during the development of the draft recommendations of priority substances to be included in the List of Substances subject to Authorisation.

(4) the date(s) at least 18 months before the sunset date by which authorisation 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; which also grant provisional continuation of the use after the sunset date until a decision has been taken,

(5) review periods for certain uses, if appropriate, and

(6) the uses and categories of uses which would be exempt from the requirements to apply for authorisation, if any and the conditions for such exemptions if they apply .

Once a substance (or a group of substances meeting the definition of a group of substances from Section 1.5 of Annex XI, see also Art. 62(3)) from the 'candidate list' is included in Annex XIV, it can only be used or placed on the market by any manufacturer, importer or downstream user for any use of the substance on its own, in a preparation or the incorporation into an article if:

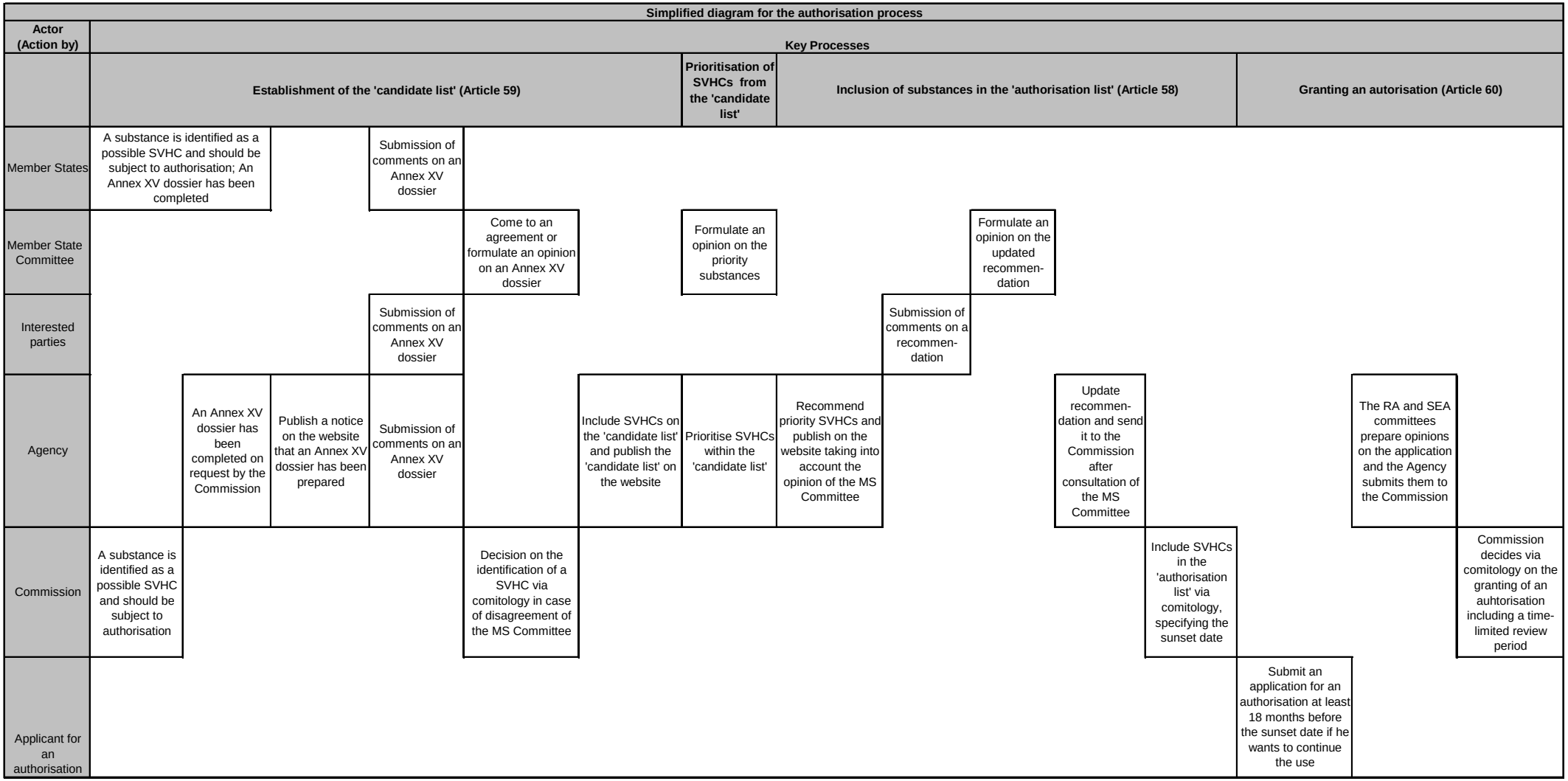
- the use has been authorised to himself or an immediate downstream user or his supplier, or
- the use is exempted from the authorisation requirement, or
- the sunset date has not yet been reached or
- an application has been made before the date at least 18 months before the sunset date and no decision has been taken yet.

An authorisation decision will be taken by the Commission in accordance with the procedures described in Art. 60, 61 and 64. In order to obtain an authorisation, manufacturers, importers or users of substances included in Annex XIV must apply for an authorisation for each use, regardless of the quantity of the substance used, within deadlines set by the Commission. Manufacturers, importers and downstream users may apply jointly for an authorisation. Applications for authorisations are made to the Agency, according to the procedure outlined in Art. 62.

The Agency via its Committees for Risk Assessment and Socio-economic Analysis provides opinions on the applications, which the Commission will use for its decisions on applications via the comitology procedure (Art. 133(2)). Summaries of the Commission decisions will be published in the Official Journal of the European Union.

All authorisation decisions will include a time-limited review period which shall be set on a case by case basis in accordance with Art. 61. Authorisation decisions may need to be amended or withdrawn, taking into account the principle of proportionality, as a result of a review. This can be done at any time when circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact or new information on possible substitutes becomes available. The Commission is empowered to suspend the authorisation in cases of serious and immediate risk such as releases that would incur immediate or delayed serious health effects for workers and the general public or irreversible significant and widespread damage to the environment. In addition, an authorisation can be reviewed when the environmental objectives as defined under the IPPC Directive (96/61/EC) or the Water Framework Directive (2000/60/EC) are not met because of diffuse emissions to water and/or air.

Figure 1: Overview of the key processes and the involvement of the different actors in the authorisation procedure.



The need to withdraw an authorisation could for example arise as a consequence of a cause-effect relationship between the exceedance of the standard and the use of the substance for which an authorisation has been granted.

The Commission shall withdraw the authorisation for the use of a substance that is prohibited or restricted under the Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29.04.2004 on persistent organic pollutants[8].

This guidance shall focus on procedures and workflows required on the Agency and Member States for the identification of SVHCs and their inclusion in Annex XIV.

2.2 Roles, obligations and rights of the actors

This section gives an overview of the duties of the actors involved in the authorisation procedure leading up to inclusion of a substance in Annex XIV. Their major responsibilities in the establishment of the 'candidate list', the identification of priority substances and establishment of Annex XIV are summarised. The tasks and responsibilities for each of these actors as described in the REACH Regulation are worked out in detail in chronological order in Tables 2-6 in Appendix 1. Most of the tasks are self-explanatory whereas other tasks are implicitly assumed and will be further elaborated in chapter 4 describing the procedure to include substances into the authorisation system. Some tasks could be iterative. Distinction is made between mandatory and optional tasks. Under Title VII of the REACH Regulation, the actors' obligations for authorisation are summarised as follows.

- The *Agency* shall:
  - manage the decision making process up until its recommendations (Annex XIV entries for substances recommended for inclusion in Annex XIV) are transmitted to the Commission, coordinate the processes of identification of SVHCs and generally the information flow between the actors including the consultation of the Member State Committee, Member State Competent Authorities and interested parties;
  - compile, update, make available and publish on the internet relevant information (notices that Annex XV dossier has been prepared, 'candidate list', recommendations for Annex XIV, work programme);
  - prepare an Annex XV dossier if requested by the Commission and handle the comments received after consultation (Art. 59(2));
  - coordinate any follow-up activities including removal of a substance from Annex XIV (e.g. because all uses have been restricted, or because on the basis of new information the substance no longer meets the criteria of Art. 57);
  - participate, present and give information in the Regulatory Committees on:
    - identification of SVHCs in those cases where the Member State Committee fails to reach unanimous agreement (Art. 133(3));
    - inclusion/removal of SVHCs in/from Annex XIV(Art. 133(4)).

[8] OJL 158, 30.4.2004, p.7. Corrected in OJL 229, 29.6.2004, p.5.

– include and prioritise substances on the 'candidate list', indicate which substances on the 'candidate list' are in its work programme and include priority substances in its recommendation.

The *Agency* may:

– comment on an Annex XV dossier for identification of a SVHC;

– include substances on the 'candidate list' in its work programme;

– prioritise[9] and if necessary further develop risk-based priority criteria for selection of substances on the 'candidate list' for inclusion in Annex XIV;

– manage and establish the registry of intentions referred to in the Guidance on identification of SVHC;

- The *Member State Competent Authorities* shall:
  – participate and present their views in the Regulatory Committees[10] on:
    - the identification of SVHCs in case the Member State Committee fails to reach unanimous agreement (Art. 133(3));
    - the inclusion/removal of SVHCs in Annex XIV (Art. 133(4)).

  The *Member State Competent Authorities* may:

  – prepare an Annex XV dossier for the identification of SVHCs and handle the comments received after consultation (Art. 59(3));

  – comment on the identification of substances with identified properties of very high concern.

  – comment on draft entries for substances recommended for inclusion in Annex XIV

- The *Commission* shall:
  – organise and manage the meetings of the Regulatory Committees (Art. 133(3) and Art. 133(4) procedures)

  – adopt final decisions in accordance with the comitology procedure referred to in Art. 133(3) on the identification of substances with identified properties of very high concern in cases where no unanimous agreement could be reached by the Member State Committee, and in Art. 133(4) on inclusion/removal of these substances in/from Annex XIV.

[9] ECHA will develop the prioritisation method while gaining experience during the development of the draft recommendations of priority substances to be included in the List of Substances subject to Authorisation.

[10] In accordance with Article 202 of the Treaty establishing the European Community (ECT), it is the task of the Commission to implement legislation at the Community-level. In practice, each legislative instrument specifies the scope of the implementing powers conferred on the Commission by the Council of the European Union. In this context, the Treaty provides for the Commission to be assisted by a committee, in line with the procedure known as "comitology" (cfr. Article 59(9)). Further details can be found at: http://europa.eu/scadplus/glossary/comitology_en.htm. More specifically, a decision under Article 58(1) of the REACH Regulation will be adopted in accordance with the regulatory procedure with scrutiny (Article 133(4)).

The *Commission* may:
- request the Agency to prepare an Annex XV dossier for the identification of substances of very high concern (Art 59(2));

- The *Member State Committee* shall:
  - resolve potential divergences of opinions and intent to find a unanimous agreement on proposals for identification of SVHCs;
  - Formulate and adopt an opinion on the identification of SVHCs where it fails in reaching a unanimous agreement on a proposal for identification of a SVHC;
  - Formulate and adopt an opinion on the recommendation of priority substances to be included in Annex XIV.

- *Interested parties* (e.g. industry, NGO's, general public) may:
  - comment on an Annex XV dossier for the identification of substances of very high concern (Art. 59(4));
  - comment on the proposals to include these substances in Annex XIV, in particular, on uses to exempt from the authorisation requirement (Art. 58(4)).

2.3 Relation with the restrictions process

The restrictions and authorisation processes are related and they can in practice have similar effect on the uses. However, they have different scope, the roles of actors differ and the procedures may have different cause. Authorisation can only address SVHCs as specified by Art. 57(a-f) (see section 2.4) whereas 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 (Art. 68(1)). Authorisation requirements apply to placing on the market and uses of a substance included in Annex XIV. It should be noted that while incorporation of the substance in articles is a substance use that requires an authorisation, the use of articles is not covered by the authorisation obligation. A restriction can cover also import and use of articles containing the substance. Furthermore, generic exemptions from the restriction procedure are limited[11] while generic exemptions from the authorisation procedure are somewhat wider (see chapter 2.5.2).

Prior to being placed on Annex XIV, any substance which is a potential candidate for authorisation may be subject to restrictions. 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. The Commission cannot grant an authorisation for a restricted use if that authorisation would mean relaxation of that restriction (Art. 60(6)). Once a substance is included in Annex XIV, it shall 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 (Art. 58(5)). However, as the import or use of articles *containing* the substance is not covered by the authorisation system, 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

[11] 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 (Art. 67(1) and Art. 67(2)).

needs to be addressed on a Community-wide basis. After sunset dates for a substance defined in Annex XIV, the Agency has a duty to consider whether the use of these substances in articles poses risks that are not adequately controlled and, where needed, prepare an Annex XV dossier for a restriction.

Substances for which all uses are prohibited under restriction procedure or under other Community legislation shall not be included in Annex XIV or shall be removed from it (Art. 58(7)).

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. Additionally, a restriction may also include conditions and derogations. 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[12]. Therefore, the authorisation procedure does not guarantee that a specified use stops at the sunset date while under restriction that use can be banned from a specified date throughout the Community. Otherwise either procedure could be used depending on the circumstances. 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. Authorisation requires applicants to prepare an analysis of alternatives (Art. 62(4)(e)) whereas the restrictions procedure requires authorities to provide available information on alternative substances or technologies. Informal consultation can be used to get this information. However, 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.

2.4 Substances subject to authorisation

Title VII on Authorisation sets out a framework for Community-wide general and specific risk management decisions. The authorisation system addresses SVHCs, specified by Art. 57 as follows:

(a) *substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC[13];*
(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC[10];
(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC[10];
(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII;
(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII;
(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

[12] Art. 58(1) lists the items that shall be specified. This does not include uses for which an authorisation shall not be granted.

[13] Note that Directive 67/548/EEC will be repealed by the GHS Regulation on Classification and Labelling which is currently proposed.

Substances fulfilling one of these criteria shall be included in the 'candidate list' of substances if there is an agreement on the proposal for identification of a SVHC. Substances in the 'candidate list' may be prioritised for inclusion in Annex XIV specifying substances that are subject to authorisation.

2.5 Uses subject to authorisation and exemptions

Continued use[14] of substances included in Annex XIV after the sunset date requires an authorisation unless that use is exempted. The Regulation foresees two types of exemptions from the authorisation requirement: general exemptions and use-specific exemptions. The uses of substances as clarified in Art. 2(5) and Art. 2(8)(b) are generally exempted from a number of provisions among them those of Title VII (authorisation). The exemptions under Art. 56 are specific for authorisation and also apply to all substances. Use-specific exemptions as given in accordance with Art. 58(2) only apply to a specific substance.

2.5.1 Uses subject to authorisation

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 (Art. 56(1)(a-e)):

a) an authorisation has been granted for the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which the manufacturer, importer or downstream user uses the substance himself;

b) specific uses of the substance on its own or in a preparation or the incorporation of the substance in an article which he is making or is marketing have been exempted from the authorisation requirement as given in Annex XIV itself (Art. 58 (2));

c) the sunset date (= the date from which the placing on the market and the use of the substance shall be prohibited unless authorised) has not been reached;

d) the sunset date has been reached and an application for authorisation has been received at least 18 months before the sunset date but a decision on the application has not been yet taken;

e) an authorisation for that use has been granted to the immediate downstream user of the manufacturer, importer or downstream user.

The use of a substance by a downstream user does not need to be authorised when an authorisation has already been granted for that use to his supplier or another actor up his supply chain (Art 56(2)) and he respects the conditions of that authorisation. In these cases the downstream user must notify the Agency within 3 months of the first supply of the substance (Art 66(1)).

[14] Under REACH (Definition 24 Art. 3), the "use" of a substance has been defined as "*Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;"*. Thus "use" has a very broad meaning of utilisation of a substance. The term "categories of uses" aims at more than one use. The Guidance on information requirements and chemical safety assessment gives guidance on how to describe the use of a substance in a structured way using a use descriptor system.

2.5.2 General exemptions

Some substances are generally exempted from a number of provisions, among them the provisions of authorisation. The provisions of authorisation shall not apply to the extent that a substance is used in:

(a) medicinal products for human or veterinary use within the scope of the respective Community Regulation (EC) N° 726/2004, Directive 2001/82/EC relating to the veterinary medicinal products[15] and Directive 2001/83/EC relating to medicinal products for human use[16] (Art 2(5)(a));

(b) food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use (Art 2(5)(b)):

(i) as a food additive in foodstuffs intended for human consumption[17];

(ii) as a flavouring in foodstuffs[18];

(iii) as an additive in feedingstuffs for use in animal nutrition[19];

(iv) in animal nutrition[20].

Substances manufactured or imported solely for any of the above mentioned uses are exempted from authorisation requirements. However if a substance is manufactured or imported for the above mentioned uses as well as other uses, then those other uses of the substance are not exempted and have to fulfil the authorisation provisions.

On-site isolated intermediates and transported isolated intermediates are exempted from authorisation (Art. 2(8)(b)).

There is a general exemption for the use of substances for scientific research and development (Art 56(3)).

The following uses of substances as specified in Art. 56(4) and Art. 56(5) are generally exempted from the authorisation requirement only:

- uses in plant protection products[21;]
- uses in biocidal products[22];
- use as motor fuels[23];

15 OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC of the European Parliament and of the Council (OJ L 136, 30.4.2004, p. 58).

16 OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC of the European Parliament and of the Council (OJ L 136, 30.4.2004, p. 34).

17 OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.

18 OJ L 84, 27.3.1999, p. 1. Decision as last amended by Decision 2004/357/EC (OJ L 113, 20.4.2004, p. 28).

19 OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

20 OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

21 within the scope of Council Directive 91/414/EEC , OJ L 230, 19.08.1991, p.1

22 within the scope of Directive 98/8/EC of the European Parliament and of the Council OJ L 123, 24.04.1998, p. 1

- uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems;
- uses in cosmetic products[24] and in food contact materials[25] for CMR substances or substances of equivalent concern for human health hazards, if they have only been subjected to authorisation because of these CMR properties, as the risks to human health are already regulated under sector specific Community legislation. However, if a PBT or vPvB substance for reasons other than human health hazards is included in Annex XIV, its use in cosmetic products or in food contact material still needs to be authorised as the risks to the environment are not regulated in the specific legislation. If a substance of equivalent concern is included in Annex XIV, this use still needs to be authorised if environmental considerations motivate the inclusion. If on the other hand only human health motivates the inclusion, then this use is exempted.

The use of substances in preparations (Art. 56(6)) is also exempted, if they are present in the preparation:

- below the lowest of the concentration limits in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC, so that the preparation would not have to be classified as dangerous; and
- below 0,1 % weight by weight for PBTs, vPvBs and substances of equivalent concern for which classification rules do not apply.

2.5.3 Specific exemptions

Uses or categories of uses may be exempted from the authorisation requirement on the condition that the risk is properly controlled on the basis of the existing specific Community legislation imposing minimum requirements on the use of the substance related to the protection of human health or the environment. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of the risk to human health and the environment related to the nature of the substance, such as where the risk is modified through the physical form (Art. 58(2)). This is further elaborated in section 4.5.

The use of the substance for product and process-orientated research and development may be exempted (Art. 56(3)): Annex XIV will specify this including the maximum quantity exempted.

[23] covered by Directive 98/70/EC
[24] Directive 67/768/EEC
[25] Regulation (EC) No 1935/2004

3 PROCEDURE TO INCLUDE SUBSTANCES INTO THE AUTHORISATION SYSTEM

The procedure to include substances into the authorisation system starts with the preparation of an Annex XV dossier aiming at the identification of a SVHC on the initiative of the Commission or a Member State. Three steps are to be distinguished:

- Establishment of the 'candidate list': the identification of SVHCs referred to in Art. 57;
- Prioritisation of substances on the 'candidate list': substances on the 'candidate list' will normally be prioritised according to predefined criteria (Art. 58(3));
- Inclusion of substances in Annex XIV: the inclusion of these substances into Annex XIV based on the priority setting of the substances on the 'candidate list' (Art. 58(1)).

The first step is the identification process which leads to the establishment of the 'candidate list'. Once the 'candidate list' is established, some substances will be prioritised. A number of these substances will be taken up in the Agency's work programme. Substances recommended for inclusion in Annex XIV by the Agency may after a Commission decision end up in Annex XIV. Member State Committee and other stakeholders are involved in this process. Further elaboration on these processes and their relationships is given in the subsequent sections. An overview of these processes is shown in Figure 2 and the deadlines to be respected are given in Table 1. Figure 3 starts with a Member State or the Agency on behalf of the Commission identifying an SVHC and gathering all the available information in order to prepare an Annex XV dossier and ends with the inclusion of SVHCs into the candidate list. Figure 4 starts with the prioritisation of substances on the 'candidate list' and ends with the final decision by the Commission on the inclusion of SVHCs into Annex XIV. Note that the chronological order of the diagram is from left to right.

3.1 Establishment of the 'candidate list'

This identification procedure starts with the preparation of an Annex XV dossier for the identification of a SVHC (category 1 or 2 CMRs, PBTs, vPvBs and substances of an equivalent concern) on initiative of the Commission or a Member State and it ends with the publication on the Agency's website of such a substance on the candidate list (see also Figure 3). This procedure consists of the following steps (Art. 59(1)):

1. The Commission or a Member State considers the need for developing an Annex XV dossier (see Guidance on identification of SVHC for more details). After submission of the Annex XV dossier by the Member States or after preparation of its own dossier, the Agency uploads the Annex XV dossier into the central REACH-IT. Interested parties will have the opportunity to subscribe to a mailing list. Interested parties on this mailing list will be informed automatically on any update of the list of Annex XV dossiers.

2. The Agency shall circulate the dossier to all Member States (Art. 59(2), Art 59(3)). The deadline for this action is within 30 days of receipt in case the dossier is initiated by a Member State. There is no deadline for the distribution of an Annex XV dossier prepared by the Agency but the Agency should circulate such a dossier after completion without delay.

3. The Agency shall publish on its website a note that an Annex XV dossier has been prepared together with an invitation to all interested parties to submit comments before a

specified deadline to the Agency (Art. 59(4)). A proposed format for this note is given in Appendix 2. This note is the underlying Annex XV dossier but without the commercially sensitive information (see also Guidance on identification of SVHC with regard to guidance on confidential information for an Annex XV dossier).

4. Within 60 days (45 days as working practice[26]) of the date of circulation of the dossier the Member States can send to the Agency their comments on the identification of the substance as a substance of very high concern in the dossier. The Agency may provide comments as well (Art. 59(5)).

5. If the Agency has not commented or has not received any comments - either from the Member States or from interested parties – it shall include the substance in the 'candidate list' as mentioned in Art. 58(1) and it may include the substance in its recommendations on priority substances to the Commission for inclusion in Annex XIV under Art. 58(3) (Art. 59(6)).

6. When comments are made by the Agency or upon receipt of comments by a Member State or an interested party, the Agency shall forward the dossier to the Member State Committee within 15 days after expiry of the 60 (45 as working practice) days commenting period (Art. 59(7)).

   The Agency prepares a draft agreement provided with the supporting documentation for the Member State Committee for finding a unanimous agreement on identification of SVHC.

   In case no unanimous agreement is reached on identification of a SVHC the Member State Committee will issue an opinion including majority and minority positions with their grounds.

   The Authority (Member States or the Agency) that prepared the Annex XV dossier should within a reasonable time period (e.g. once a week) be informed on the comments when submitted and will then prepare a response on how to handle these comments[27]. It would be a good working practice if Authorities would submit their comments on the Annex XV dossier well in advance and not later than 45 days after the start of the commenting period allowing the Authority in charge of the Annex XV dossier to benefit from a period of 30 days to respond to the comments[28]. Any comments received at that stage are without prejudice to possible further comments in the official commenting period of 60 days. The commenting period for interested parties that is running in parallel and not fixed in Art. 59(4) will for that reason also be restricted as a working practice to 45 days.

   Since the Annex XV dossier and related information are uploaded into the central REACH-IT, the Committee members will be informed either automatically or via the

[26] See also paragraph 6 this section: It would be a good working practice if Authorities would submit their comments on the Annex XV dossier well in advance and not later than 45 days after the start of the commenting period in order to facilitate the work of the Authority in charge of the Annex XV dossier.

[27] The Authority that has submitted the Annex XV dossier is best placed to prepare a response to the comments received as he has the best knowledge of the dossier and has access to all the relevant information.

[28] Note this is not explicitly stated in the REACH Regulation but it is a working procedure that the committees could adopt in order to facilitate the decision-making process.

secretariat on the submission of the Annex XV dossier, the comments and the responses to these comments.

7. The Member State Committee will strive to obtain unanimous agreement provided with the supporting documentation that the substance fulfils the criteria of a SVHC as specified in Article 57. A written procedure for finding an agreement will have the preference as far as possible. If the Member State Committee reaches a unanimous agreement within 30 days, the Agency shall include the substance in the 'candidate list'.

   The Authority (Member States or Agency) that has submitted the Annex XV dossier will have to prepare the draft response to comments document and support document which would be based as much as possible on the original Annex XV dossier with, if necessary, new elements resulting from the comments received and /or the discussions during the MS Committee. Note that the support document (in Annex XV format) will provide the starting point for the applicant for an authorisation.

8. If the Member State Committee cannot find an agreement, then the Agency shall refer the issue to the Commission (Art. 59(9)).The Member State Committee would then issue an opinion including positions of members and their grounds.

9. The Commission shall prepare a draft proposal on the identification of the substance as a SVHC within three months of receiving the Member State Committee's opinion. A final decision shall be taken in the Regulatory Committee according to Art. 133(3) (Art. 59(9)).

10. The Agency shall publish the updated 'candidate list' for possible inclusion in Annex XIV without delay on its website after a decision on inclusion of the substance in the 'candidate list' has been taken (Art. 59(10)). A format for the candidate list is given in Appendix 3[29]. When a substance is put on the candidate list', all necessary information on the identity of the substance needs to be given. In particular, the reasons why it was identified as a SVHC (Art. 57(a-f)), whether it is a threshold or non-threshold CMR, the identification of the constituents and/or impurities that have properties of very high concern and their concentrations or concentration ranges and, if applicable, the "Specific Concentration Limits"[30] shall be included in the description of the composition of the substance as well. When the substance is on the 'candidate list' because it degrades or is transformed into PBT, vPvB or substance of equivalent concern, both the identity of the substance and the identity of the relevant degradation/transformation product shall be recorded with related concentrations or concentration ranges.

    The 'candidate list' will be a 'living' document. The Agency shall indicate within this 'candidate list' the substances that are on its work programme (Art. 59(1)) according to Art. 83(3)(e)[31].

[29] The format is taken from the appendices 1 to 6 of Annex XVII including the notes of Annex I to Directive 67/548/EEC. This will be replaced by Annex VI of the GHS Regulation once GHS enters into force.

[30] Concentration limits as specified in Directive 1999/45/EC or other legislation.

[31] The Executive Director shall submit a multi-annual work programme to the Management Board for approval. This multi-annual work programme contains a longer term view i.e. 3-5 years on the tasks be carried out by the Agency including the substances from the candidate list on which the Agency intends to work on.

3.2 Prioritisation of substances from the 'candidate list'

The Agency will prioritise substances from the 'candidate list' and recommend priority substances that might be included in Annex XIV (see also Figure 4) later on.

The Agency should give advice on the prioritisation of SVHC to ensure that decisions reflect the risks to human health and environment as well as scientific knowledge and developments (Recital 78). Priority for inclusion in Annex XIV shall normally be given to substances with:

a) PBT or vPvB properties; or

b) wide dispersive use; or

c) high volumes.

How these criteria will be used will be elaborated in guidance on the priority setting mechanisms[32] required in the context of SVHCs in Annex XIV. CMRs (Category 1 and 2) can be prioritised from the 'candidate list' on the condition that they fulfil at least one of the three above mentioned criteria.

This prioritisation will be the basis for the Agency to recommend priority substances for inclusion in Annex XIV as described in section 3.3.

3.3 Inclusion of substances in Annex XIV

The procedure starts with the verification that the substance is still a suitable candidate for inclusion in Annex XIV and is finished when the Commission has decided in the Regulatory Committee (regulatory procedure with scrutiny) to place this substance on Annex XIV based on the recommendation by the Agency (see also Figure 4). The inclusion of substances in Annex XIV consists of the following steps:

1. The Agency shall verify whether all uses of the substance have been prohibited by restrictions (Title VIII of the REACH Regulation) or by other Community legislation;

2. The Agency will prepare a draft Annex XIV entry for substances recommended for inclusion in Annex XIV, specifying the following information:
   a) The identity of the substance as specified in section 2 of Annex VI;
   b) The specific intrinsic properties which render the substance subject to authorisation;
   c) Transitional arrangements for substances which are already being used or placed on the market:
      - "the sunset date", i.e. the date from which the placing on the market and the uses of the substance are prohibited without an authorisation or a derogation linked to an authorisation application not yet decided upon. This should take into account, where appropriate, the production cycle specified for that use;
      - an application deadline, a date at least 18 months before the sunset date: the uses of the substances applied for, continue to be allowed until a decision will be

[32] ECHA will develop the prioritisation method while gaining experience during the development of the draft recommendations of priority substances to be included in the List of Substances subject to Authorisation.

taken, even after the sunset date. Applicants may apply after the specified application deadline date if they want to start new uses.

d) Review periods for certain uses, if appropriate;

e) Exemptions of uses or categories of uses and conditions for these exemptions as per Art. 56(3) and Art. 58(2), if necessary. Particularly, pursuant Art. 56(3) it should be specified whether Product and Process Orientated Research and Development (PPORDs) of the substance should be exempted from authorisation, and if so, whether or not a maximum quantity should be set.

4. The draft Annex XIV entry for priority substances recommended for inclusion in Annex XIV will be discussed in the Member State Committee who will issue an opinion (Art.58(3)). Taking into account the opinion of the Member States Committee, the Agency shall recommend priority substances from the 'candidate list' for inclusion in Annex XIV. The Agency shall make its first recommendation to the Commission by 1 June 2009 at the latest and further recommendations shall be made at least every second year with a view to including further substances in Annex XIV(Art 58(3)).

The number of substances to be included in Annex XIV and the dates specified under Article 58(1)[33] must also reflect the Agency's capacity to handle applications in the time provided for. The number of substances to be included in Annex XIV should therefore enable, in particular in the first years, the Agency to build up experience and capacity.

5. Before the Agency sends its draft Annex XIV entry for substances recommended for inclusion in Annex XIV to the Commission it shall make it publicly available on its website clearly indicating the date of publication and the information specified in Art. 58(1). The information made publicly available should take into account Articles 118 and 119 on access to information[34] (Art. 58(4)). These articles state:

- which information if disclosed would undermine the commercial interests of the enterprises concerned and which therefore must normally remain confidential,
- which information shall be made publicly available over the internet and
- which information shall be made publicly available over the internet except if a valid justification is given by the party submitting the information.

In addition, when making its draft Annex XIV entry for substances recommended for inclusion in Annex XIV available on its website, the Agency may have to consult the concerned registrant(s) with a view to assessing whether the information can be released according to Art. 4(4) of Regulation EC no 1049/2001[35], if it is not clear whether the information can or cannot be disclosed. This consideration is particularly valid with regard to the exemptions of uses or categories of uses and conditions for these exemptions. Art.

33 I.e., sunset dates and deadlines for applications for authorisation if applicants wish to continue marketing or use after the sunset date until a decision on their application for authorisation is taken.

34 Note that it is the Management Board of the Agency that shall adopt practical arrangements for implementing Regulation 1049/2001 on public access to information (cf. Art. 118(3)) which is part of the standard procedures of the Agency.

35 Regulation 1049/2001 regarding public access to European Parliament, Council and Commission Documents. According to Art. 4 of this Regulation the institution shall, as regards third-party documents, consult the third party with a view to assessing whether exceptions are applicable, unless it is clear that the document shall or shall not be disclosed.

119(1) lists the information that shall be made publicly available and Art. 119(2) lists the information that the Agency shall make available unless it agrees that the information should not be made available on the Internet[36]. A proposal for format for a draft Annex XIV entry for substances recommended for inclusion in Annex XIV is given in Appendix 4.

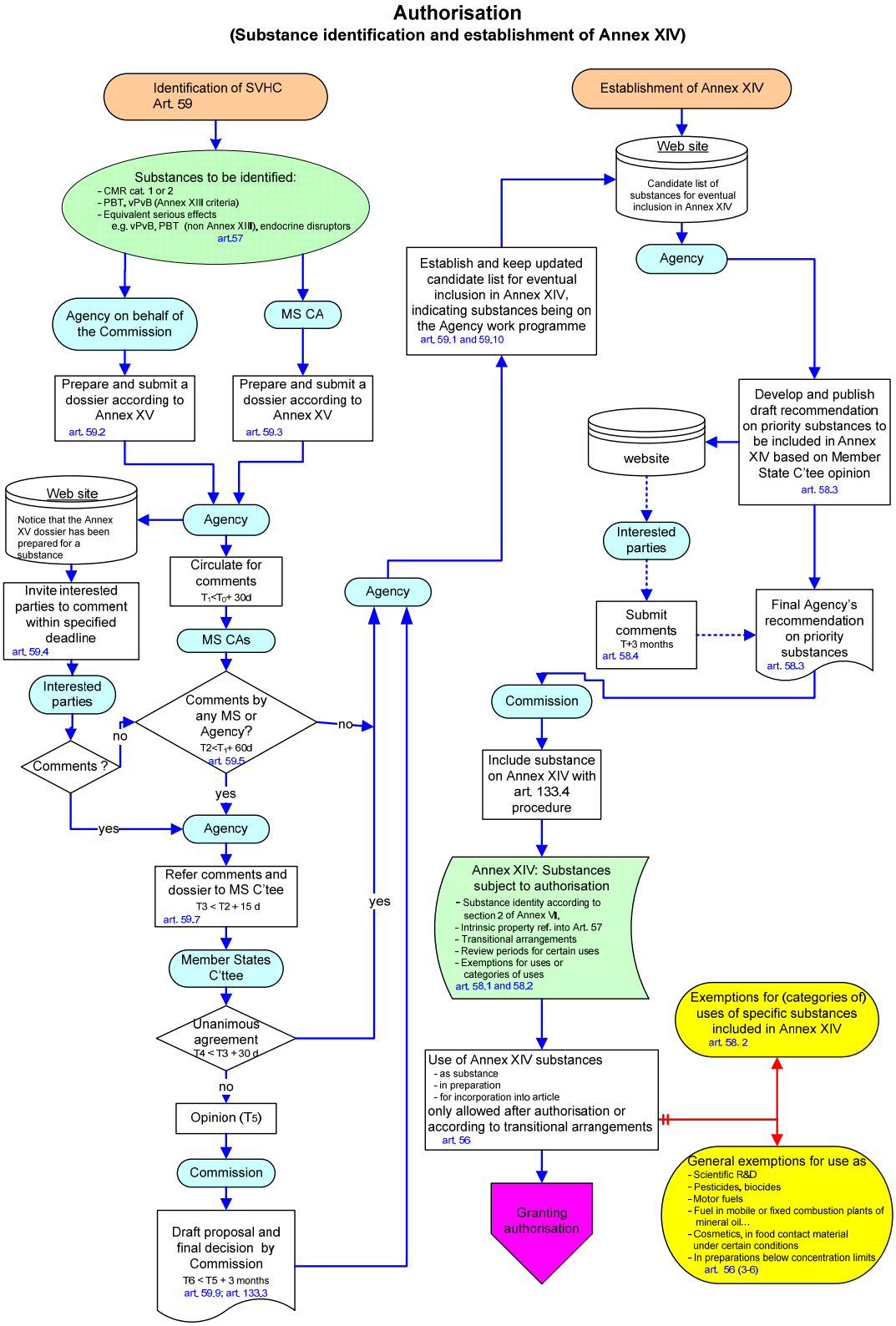
6 All interested parties shall be invited by the Agency to submit comments within 3 months from publication, in particular, on further uses which the Agency should consider for exemption from the authorisation requirement or uses which the Agency has proposed but should not be exempted. Such comments might also provide, for example, information on production cycles that may affect how the sunset date(s) are defined or on potential alternatives.

7 The Agency shall update its draft Annex XIV entry for substances recommended for inclusion in Annex XIV taking into account the comments and then send this recommendation, after consultation of the Member State Committee, to the Commission.

8 The decision to include substances in Annex XIV is taken by the Commission via the regulatory procedure with scrutiny under Article 133(4). It should be noted that the Commission is not bound by the prioritisation given in the Agency's recommendation. This decision will be in the form of a Commission Regulation.

[36] The brief general description of the identified use(s) is not on the list in Article 119 of information to be automatically published on the internet. According to Article 118(2) (b) the information on the precise use, function or application of a substance or preparation shall normally be deemed to undermine the protection of commercial interests of the person concerned. Consequently, there might be circumstances where the applicant has to decide whether he would like to keep his use confidential and as a consequence of that has to apply for an authorisation or brings forward information on a use that might be taken up by the Agency in the list of uses or categories of uses exempted from the authorisation requirement and by that enter the public domain.

Figure 2: Workflows[37] for the identification of substances with identified properties of very high concern and inclusion of these substances in Annex XIV



37 NB: in work practice there will be 45 days for commenting on Annex XV dossier by MS or the Agency. By analogy the response to comments period will be 30 days in working practice.

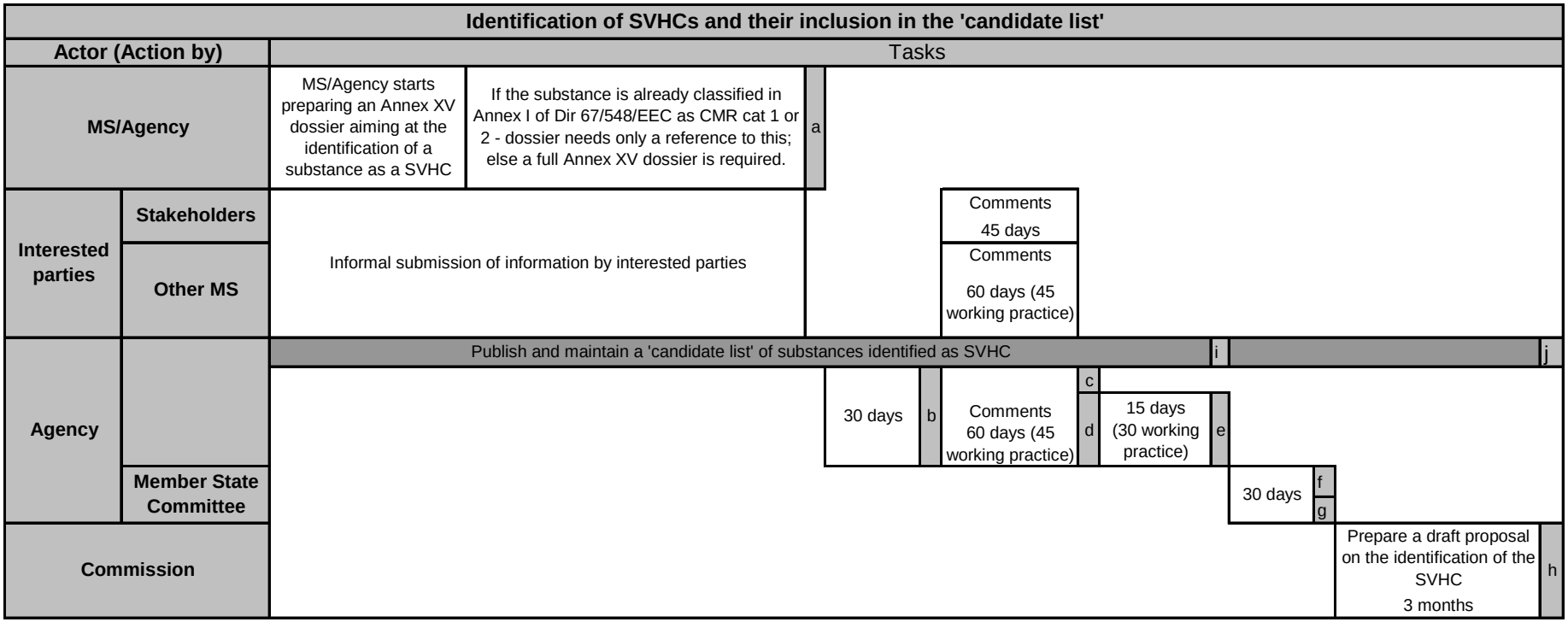
Table 1: Time line and tasks of the different actors for the identification of substances with identified properties of very high concern and inclusion of these substances in Annex XIV

Time	Process	Actor	Period	Cumulated time
	Establishment of the 'candidate list'			
T_0	Circulate an Annex XV dossier to the (other) Member State Competent Authorities for comments (Art. 59(2), Art 59(3)*)	Agency		start
T_1	Comment on the identification of substances referred to in Art. 57 (Art. 59(4), Art 59(5))	Interested parties** Member State Competent Authority/Agency	45 days 60 days (45 days working practice)	<60 days (45 days)
$T_{1'}$	Publish and update without delay the 'candidate list' (Art. 59(10))	Agency	Not precisely specified <75 days	
T_2	Refer the dossier to the Member State Committee (Art. 59(7))	Agency	15 days (30 days working practice)	<75 days
T_3	Unanimous agreement on the identification of substances referred to in Art. 57 (Art 59(8))	Member State Committee	30 days	<105 days
$T_{3'}$	Publish and update without delay the 'candidate list' (Art. 59(10))	Agency	Not precisely specified <195 days	
T_4	Upon receipt of an opinion on the identification of substances referred to in Art. 57 prepare a draft proposal (Art 59(9))	Commission	Not specified (time a) time for Member State Committee to forward opinion, 3 months	<195 days + a
T_5	Opinion on the identification of substances referred to in Article 57: no unanimous agreement, final decision (Art. 59(9), Art. 133(3))	Commission/Member State Competent Authorities	Not specified (time b) time for 133(3) procedure	<195 days + b
$T_{5'}$	Publish and update without delay the 'candidate list' (Art. 59(10))	Agency	Not precisely specified >195 days + b but before the publication of the draft priority list	
T_6	Indicate the substances that are on the Agency's work programme (Art. 59(1))	Agency	Not precisely specified >195 days + b but before the publication of the draft priority list	
	Prioritisation of substances on the 'candidate list'			
T_7	Recommend priority substances (Art. 58(3))	Agency/Member State Committee	Not precisely specified >195 days + b but before the publication of the draft priority list	
	Inclusion of substances in Annex XIV			
T_8	Publish the draft Priority List for inclusion in Annex XIV on the Agency's website and invite comments (Art 58(4))	Agency		start
T_9	Comment (Art. 58(4))	Interested parties	3 months + not specified time c	<3 months
T_{10}	Inclusion of a substance referred to in Art. 57 in Annex XIV (Art. 58(1), Art. 133(4)).	Commission/Member State Competent Authorities	Not specified (time d) time for 133(4) procedure	< 3 months +c
T_{11}	Removal of a substance from Annex XIV (Art. 58(8), Art. 133(4))	Commission/ Member State Competent Authorities	Not specified (time e) time for new information coming available and for the 133(4) procedure	< 3 months +c +d

* within 30 days of receipt of the Annex XV dossier if the process is initiated by a MSCA.

** T_0 for interested parties is the date of publication on the Agency's website of the notice that an Annex XV dossier has been prepared. Nevertheless the comments made by the Member State Competent Authorities and the third parties have to be received within the same timeframe since the Agency needs to decide on this information basis. Art 59(6) clearly states: "If the Agency does not receive **any comments**, it shall include this substance on the list referred…"

Figure 3: Overview of important milestones aiming at the identification of substances with properties of very high concern and their inclusion in the 'candidate list'.



Key Processes and Decisions

a - The dossier is submitted to the Agency; the Agency publishes a notice on the internet that an Annex XV dossier for a substance meeting the criteria in Art. 57 has been submitted

b - Circulation of the dossier to the other MS

c - No comments have been received; go to i

d - Comments are submitted

e - Dossier is referred to the Member State Committee

f Member State Committee reaches an unanimous agreement; go to i

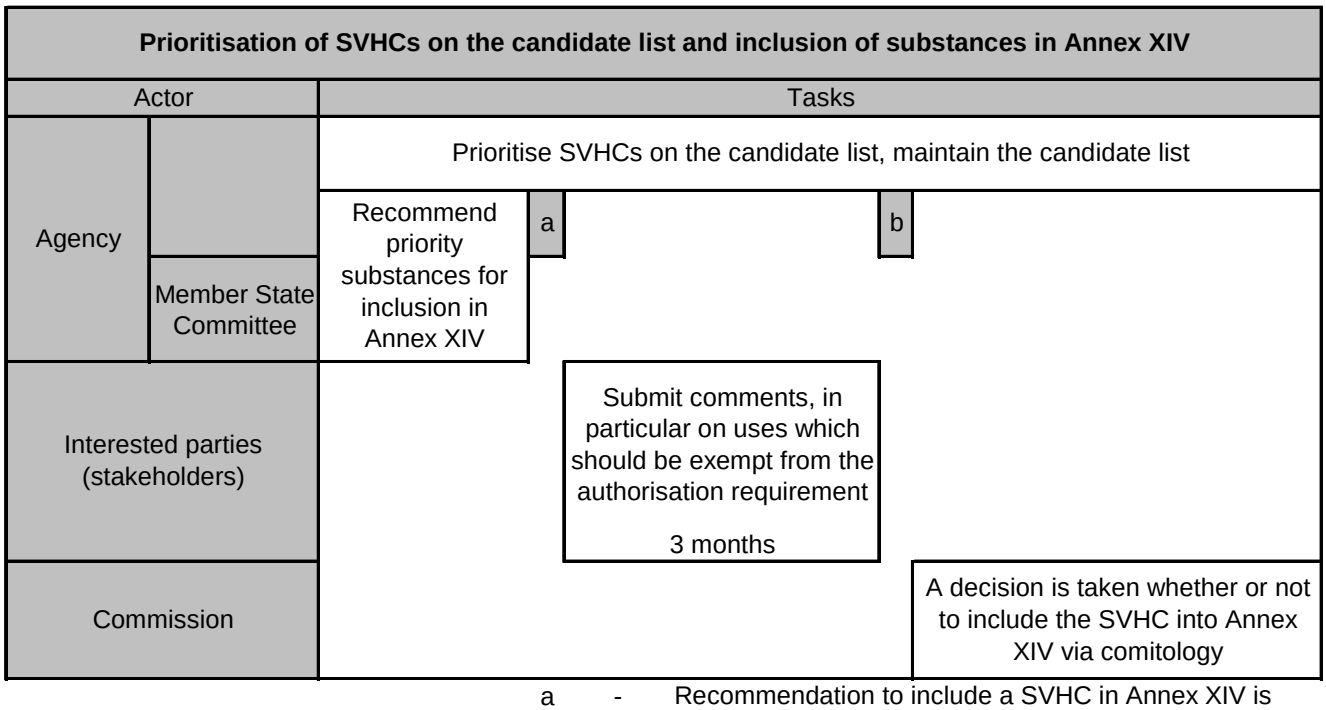
g Member State Committee fails to reach a unanimous agreement and sends an opinion to the Commission

h Decision taken via comitology

i Include the substance in the 'candidate list' and publish on the Agency's website

j Include the substance in the Work Programme

Figure 4: Overview of important milestones for the prioritisation of substances on the 'candidate list' and inclusion of substances in Annex XIV



a - Recommendation to include a SVHC in Annex XIV is published on the internet

b - Update the recommendation and submit it to the Commission after consultation of the Member State Committee

4 PREPARATION OF THE DRAFT ANNEX XIV ENTRY FOR SUBSTANCES RECOMMENDED FOR INCLUSION IN ANNEX XIV

The Agency shall in line with Article 58(1) assist in the preparation of a decision by the Commission to include a substance in Annex XIV via its draft Annex XIV entry specifying the substance identity, the intrinsic properties of the SVHC referred to in Art. 57, the transitional arrangements, review periods for certain uses, uses or categories of uses exempted from the authorisation requirement and conditions for such exemptions. Guidance on each of these items is given below.

4.1 The identity of the substance as specified in section 2 of Annex VI

The identity of the substance recommended for inclusion in Annex XIV should be obtained from the Annex XV dossier as amended during the inclusion of the substance in the 'candidate list' (see Guidance on identification of SVHC). This should contain details of the identity of the substance (substance name, CAS/EC number(s), registration number(s) (if available), molecular formula, structural formula, purity and impurities) in accordance with the guidance developed under the Guidance on substance identification.

4.2 The intrinsic property (properties) of the substance referred to in Article 57

Information on the intrinsic properties of the substance referred to in Art. 57 should be obtained from the Annex XV dossier. The first part of the Annex XV report contains a summary of the proposal for identification of the substance as a CMR substance, a PBT substance, a vPvB substance or a substance of equivalent concern. This summary should be taken over in this part of the draft Annex XIV entry for substances recommended for inclusion in Annex XIV.

The summary of the proposal for an Annex XV dossier should also contain a summary of the properties of very high concern of the substance. This should include one of the following statements:

- It is proposed to identify the substance as a CMR (cat 1 or 2) according to Article 57 (a), (b) and/or (c).
- It is proposed to identify the substance as a PBT according to Article 57 (d).
- It is proposed to identify the substance as a vPvB according to Article 57 (e).
- It is proposed to identify the substance as a substance of equivalent concern according to Article 57 (f).

This should be followed by a short paragraph outlining the main reasons for this statement (Art. 57(a-f)), whether it is a threshold or a non-threshold CMR, the identification of the constituents and/or impurities that have properties of very high concern and their concentrations or concentration ranges. If applicable the "Specific Concentration Limits" [38] shall be included in the description of the composition of the substance as well. If the proposal for an Annex XV dossier is based on the fact that the substance degrades or is transformed into PBT, vPvB or substance of equivalent concern, both the identity of the substance and the identity of the relevant degradation/transformation product shall be recorded with concentrations or concentration ranges.

[38] Concentration limits as specified in Directive 1999/45/EC or other legislation.

4.3 Transitional arrangements

The aim of authorisation is, besides ensuring the functioning of the internal market, to ensure that risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. The transitional arrangements should be set in a way so that they help to achieve this objective. Two types of dates will be fixed with regard to the transitional arrangements (Art. 58(1)(c)):

- the sunset date(s). Different sunset dates might be set: for placing on the market of the substance as well as for each of the uses of that substance (different sunset dates for different uses);
- a date or dates at least 18 months before the sunset date(s) by which the Agency must receive application(s) if the applicant wishes to continue to use the substance or place it on the market for certain uses.

Both dates are linked and should therefore be considered together when setting the transitional arrangements.

The legal text clearly states that the sunset date(s) should take into account the production cycle specified for that use where appropriate (Art. 58(1)(c)(i)). In view of workability and practicality considerations as regards applicants who have to prepare applications and as regards the authorities who have to process authorisation applications realistic deadlines should be set (Recital 77). In this perspective a number of criteria (see section 4.3.1) were developed.

4.3.1 Criteria for setting the sunset date

The following criteria for setting the sunset date could be considered: hazard(s) identified including exposure considerations (from the Annex XV dossier), production cycle specified for that use, the deadline to apply for an authorisation if the manufacturer/importer/downstream user wishes to continue to use the substance or place it on the market for certain uses, a reasonable time-frame for the applicant to prepare an authorisation dossier and the workload of the Agency that has to process authorisation applications. These criteria are discussed below. As with all the criteria for setting the sunset date, the underlying rationale must be to ensure a high level of health and environmental protection whilst ensuring cost-efficiency as far as possible, namely, costs that can easily be avoided with more adaptation time, without compromising the reasons (risks for man and environment) to impose a sunset date in the first place.

Hazard or exposure considerations

The sunset date could reflect the nature and the extent of the hazards identified in combination with the use and exposure information available (from the Annex XV dossier) without ignoring socio-economic considerations. The use and exposure information may indicate the extent of possible exposure of humans and the environment to the substance of very high concern, which can be taken into account in setting the sunset date. Uses resulting in a relatively high (e.g. as a consequence of high bioavailability) or prolonged exposure (e.g. as a consequence of a long service life of an article and/or as a consequence of the waste stage after a long service life) should have a sunset date earlier in time compared to uses resulting in a relatively low exposure.

The main information sources on exposure may be the Annex XV dossier produced by the authorities and the technical dossier laid down by the registrant although this is for the individual registrants rather than the substance as a whole. Other information sources for exposure could be the result of follow-up activities like enforcement.

When no specific information on exposure is available, it will not be appropriate to use this criterion.

Production cycle specified for a use

The legal text states that the sunset date(s) should take into account, where appropriate, the production cycle specified for that use. Elements that need consideration are the requirements under other legislation in relation to the use of substances, or customer requirements related to quality and test trials. Information on these aspects can come from the Annex XV dossier, comments and considerations when including the substance in the 'candidate list'. It should be noted that industry can come forward with information since all interested parties are invited by the Agency to submit comments within three months of the date of publication of the draft Annex XIV entry for substances recommended for inclusion in Annex XIV by the Agency (Article 58 (4)).

For the purpose of this guidance, the 'production cycle specified for a use' is defined as the period in which it is technically and economically feasible to remove the substance from its use. Thus, in practice this period amounts averagely to 60 months but can be for specific cases substantially shorter or longer.

It is unlikely that the registration dossier, the CSR or the Annex XV dossier contains sufficient information, if any, on the 'production cycle' to determine its duration for the various uses of the substance in question. Although there is a need for relevant information on the specific characteristics of the manufacture, supply chains and the uses, such information may only become available in the later stage of the authorisation procedure, namely via the authorisation application for (a) particular (group of) use(s) when it is no longer useful for setting the sunset date.

In the worst case, it may be impossible to define a uniform time period which aptly captures all the 'production cycles' in a precise and well-founded manner. It should be strived to make the sunset date generic for all uses of the substance, while recognising that there can be specific uses for which the setting of a different sunset date for that specific use may be appropriate. However this will not always be the case. The use-by-use approach may make an industrial activity uneconomic (and force closure) well before the sunset date. The impact on downstream users of a substance with later sunset dates should also be considered when taking a decision. Such an approach is also feasible as all interested parties are invited by the Agency to submit comments within three months of the publication date of the draft Annex XIV entry for substances recommended for inclusion in Annex XIV containing the proposed sunset date(s). Thereby, industry and other parties can come forward with relevant information. Where appropriate, the Agency may request additional information from the concerned industries on an informal basis.

The deadline to apply for an authorisation

The sunset date should take account of a time period of at least 18 months before it, since this is the required minimum period for the Agency to process applications 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).

Time required by the potential applicant to prepare an authorisation dossier

The time needed for the preparation of a new application for authorisation will probably vary from case to case depending on, e.g., how complicated supply chain (up and down from the applicant) is

related to the use(s) applied for, how specific are the use conditions, what is the status of the development of alternatives, how straightforward or complicated are the considerations related to the alternatives and who possesses the relevant information on alternatives. The Commission Services estimated that the average time needed amounts to roughly 12 months. With time, experience on the preparation of an authorisation application will become available enabling more appropriate estimates. Furthermore, an applicant may not be able to consult the expertise required for certain issues of the application in a short time frame. Therefore a time period of 18 months (an additional time buffer of 6 months on top of the 12 months required for the preparation itself), should be given to prepare a well documented application for authorisation (see also the Guidance on authorisation application).

Workload of the Agency

The time needed to process an application for authorisation starting from the submission of the application until the preparation of a draft authorisation decision on the granting amounts roughly to 18 months. Every application for an authorisation generates a substantial workload for the Agency, particularly for the Committees for Risk Assessment and Socio-economic analysis (Art. 64). The workload for the Agency arising from each substance included in Annex XIV will be estimated from the number of registration dossiers (depending on factors such as the number of registrations, the number of joint registrations, the number of downstream users for each registration). Possibly, further fine-tuning could be done based on specific information available in these registration dossiers (such as uses, other specific Community legislation, identified downstream users, etc.). Different sunset dates will be set for different substances included in Annex XIV taking into account the capacity of the Agency in such a way that the workload for the Committees for Risk Assessment and Socio-economic Analysis can be balanced over time by taking account of the number of applications to be expected and by setting appropriate application dates.

4.3.2 Proposal for appropriate transitional arrangements (Art. 58(1)(c)(i) and (ii))

With regard to the transitional arrangements the sunset date(s) should be set taking into account the aforementioned criteria of section 4.3.1. As explained in the previous section, a generic approach is foreseen, allowing for use-specific dates where required.

The sunset date(s) should not be set within the period of 36 to 42 months after the decision to include a substance in Annex XIV. Normally this time period should be longer, since this is the minimal time the applicant for an authorisation needs for fulfilling his legal obligations. This figure takes account of the deadline to apply for an authorisation (at least 18 months before the sunset date) and the time required by the applicant to prepare an authorisation dossier (12 months for preparing the dossier and another 6 months for consulting the required expertise). These aforementioned factors should be considered in parallel to the duration of the production cycles for the involved uses and the workload of the Agency. The Agency needs some flexibility in order to be able to set up an appropriate planning of the required resources, in particular for the Committee work, whereas 60 months is as explained an average time for the ‘production cycle specified for a use’.

The time period by which applications must be received should be set at least 18 months before the sunset date. The possibility requiring the applicant to submit his dossier more than 18 months before the sunset date should be left open for substances for which complex applications are anticipated and which have the sunset date considerably later than 60 months from the date of the inclusion decision.

The transitional arrangements for the involved uses should take account of the draft Annex XIV entries for substances recommended for inclusion in Annex XIV made in the past and distribute the transitional arrangements over time in order not to overload the Agency by a huge inflow of application dossiers.

4.4 Review periods for certain uses, if appropriate

Article 58(1)(d) allows for 'review period for certain uses, if appropriate'. The review periods mentioned in Art. 58(1)(d) deal with the same type of review periods as for individual decisions on authorisation applications falling under Art. 61, but in this case a generic review period that applies to all future authorisation decisions related to that specified use is set already when a substance is included in Annex XIV, whereas Art. 64 deals with a case-by-case decision after submission of individual authorisation applications. In setting a review period upfront the authorisation process requires that the Agency has access to adequate information to propose such a generic review period on the basis of which the Commission can take the decision. If necessary information is not available preference should be given to set the review period for the individual authorisation decision based on information in the authorisation application. It is suggested to set the review period on the basis of the authorisation decision (the same length for all authorisation holders, slightly different dates to submit review reports) and not on the basis of the sunset date (same date for all authorisation holders) so that all applicants will face a reasonable review period and in order to be able to balance the workload of the Agency.

The length of the review period can only be decided at inclusion in Annex XIV, if sufficient information, i.e., on uses and alternatives is already available at the stage of developing the Annex XV dossier, in the registration dossiers, or if such information is provided by interested parties (in particular, potential applicants) during the 3-months consultation period. However, in most cases such information is expected only to become available in the later stage of the authorisation procedure, namely through the authorisation application. After evaluation of the information it might be considered to set a review period for certain uses and possibly to update the inclusion of the substance in Annex XIV via a decision through the regulatory procedure with scrutiny, taken by the Regulatory Committee according to Art. 133(4).

It should be noted that an authorisation may be reviewed at any time if there are changes in circumstances that affect the risk related to the authorised use or to the socio-economic impacts, if new information on substitutes becomes available or if environmental quality standards under the water framework directive or the IPPC-directive are not met. The need to withdraw an authorisation could for example arise as a consequence of a cause-effect relationship between the exceedance of the standard and the use of the substance for which an authorisation has been granted.

4.4.1 Criteria for review periods for certain uses

In line with the philosophy applied in section 4.3 on the transitional arrangements of Article 58(1)(c), the review period should be set to ensure a high level of health and environmental protection whilst attempting to avoid costs that could be easily avoided with more adaptation time. The review period should therefore take account of realistic deadlines to submit a review report, the time required by the potential holder of the authorisation to prepare a review report and a reasonable workload for the Agency. Other elements to be considered are the extent of the risks identified and the time required for identifying and making available suitable alternatives that are technically and economically feasible. These criteria are discussed below.

Hazard or exposure considerations

The length of the review period should reflect the nature and the extent of the hazards identified in combination with the use and exposure information available (from the Annex XV dossier). The use and exposure information may indicate the extent of possible exposure of humans and the environment to the substance of very high concern, which can be taken into account in setting the review period. Uses resulting in a relatively high (e.g. as a consequence of high bioavailability) or prolonged exposure as a consequence of a long service life of an article and/or as a consequence of the waste stage after a long service life should be reviewed more often compared to uses resulting in a relatively low exposure.

The main information sources on exposure may be the Annex XV dossier produced by the authorities and the technical dossier laid down by the registrant although this is for the individual registrants rather than the substance as a whole. Other information sources for exposure could be the result of follow-up activities like enforcement.

When no specific information on exposure is available, it might not be appropriate to define a review period already at inclusion of a substance in Annex XIV. Instead a review period should be defined based on information in the application and any other information obtained through the public consultation period.

The deadline to submit a review report

The holder of an authorisation should submit a review report at least 18 months before expiry of the time-limited review period and consequently at least 18 months should be taken into account in setting the review period.

Time required by the potential applicant to prepare a review report

It is estimated that the preparation of a review report requires on average the same work by the applicant than a new application for authorisation. The time needed also depends on the conditions set by the Commission for granting the authorisation. It is estimated that the preparation of a review report will take about 12 months. With time, experience on the preparation of an authorisation application will become available enabling more appropriate estimates. Furthermore, an applicant may not be able to consult the expertise required for certain issues of the application in a short time frame (see also the Guidance on authorisation application).

Workload of the Agency

The time needed to process a review report starting from the submission of the application until the preparation of a decision on amending or withdrawing the authorisation, is considered to be comparable to a new application and amounts to about 18 months.

Every submission of a review report results in a substantial workload for the Agency on top of the workload arising from new applications for authorisation. The workload arising from applications for a renewal of authorisation should be organised so that a balanced workload for the Committees for Risk Assessment and Socio-Economic analysis is achieved. This could be done by taking account of the number of review applications for each substance included in Annex XIV and setting appropriate review periods spread over time.

Time required for having alternatives available

It can take several years before alternatives are available for the applicant. Subsequently, sufficient time should be given enabling industry to adapt. A short review period e.g., 3 to 5 years could have a negative impact on the relevant companies since time to adapt to reformulation and process changes might be too short. Three to five years is also a very short time period for most Research and Development projects[39]. Evidence collected in the various REACH Impact Assessment exercises suggest that even with the alternative substances and/or technologies already known, it may easily take more than 3 years to carry out the quality and performance tests. In other cases the alternatives might be already available but the approval procedure takes a long time[40]. On top of these considerations several additional time consuming actions are required to substitute a substance or to use alternative technologies including investments, and adaptation of the equipment and training, making often a case-by-case approach more suitable instead of defining a review period in Annex XIV.

Available information on alternative substances and techniques, including: (a) information on the risks to human health and the environment related to the manufacture or use of the alternatives; (b) availability, including the time scale; and (c) technical and economical feasibility, may be provided in the Annex XV dossier and it is good practice to do so. This information, where available, can be used for setting generic review periods in Annex XIV entries. However such information on alternatives produced through REACH might be scarce, particularly in the early years when most of the phase-in substances have not yet been registered[41].

4.4.2 Proposal for an appropriate review period (Art. 58(1)(d))

Setting a review period upfront in the authorisation process should only be done in the case where adequate information is available. Otherwise preference should be given to set the review period later on in the process when an individual decision on an authorisation needs to be taken at a stage that adequate information might be available from the authorisation applications.

In case adequate information would be available all criteria mentioned under section 4.4.1 should be taken into account in order to set an appropriate review period. Factors to be considered in setting a review period are the deadline for submitting a review report (at least 18 months before expiry of the time-limited review period) and the time required by the applicant to prepare the review report (about 12 months) in order to fulfil his legal obligations. These factors should be considered in parallel to other criteria, particularly the extent of the risks identified and the time required for having alternatives implemented (at least 5 years) could have a substantial impact on setting the review period. Additionally, some flexibility in order to be able to set up an appropriate planning of the required resources, in particular for the Committee work, might be suitable for the Agency.

In the draft Annex XIV entry for substances recommended for inclusion in Annex XIV, the review periods of the respective substances should take account of draft Annex XIV entries for substances recommended for inclusion in Annex XIV made in the past and distribute the review periods for different substances over time in order not the overload the Agency with peak workloads.

---

39 The fact that no alternatives for aviation hydraulic fluids are available at present and that according to industry sources, there have been attempts over the last 30 years to find alternatives illustrates this.

40 For example in the case of Penta-Brominated Diphenyl Ether in emergency escape slides approval was calculated to require 2-3 years.

41 This is one of the reasons why there will be a public consultation (Art. 64(2)), in addition to the one on inclusion in Annex XIV, (Art 58(4)).

4.5 Uses or categories of uses which may be exempted from the authorisation requirement and conditions for such exemptions

Under the authorisation regime of REACH, continued use of a substance included in Annex XIV needs to be authorised unless they are already exempted from the authorisation requirement in the inclusion decision or by the provisions of the REACH Regulation itself.

Uses or categories of uses[42] *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* (Art. 58(2)). The Agency may include in its draft Annex XIV entry for substances recommended for inclusion in Annex XIV such exemptions for a substance on a case by case basis. These specific exemptions apply only to the substance they concern.

In addition the draft Annex XIV entry for substances recommended for inclusion in Annex XIV (and the decision) may include a specific exemption of the use of the substance in product and process oriented research (PPORD) up to defined quantity (Art 56(3)).

When considering the needs and possibilities to exempt uses or categories of uses from authorisation requirements, attention should be paid as to whether or not a specific existing Community legislation

- addresses the substance in question either by naming the substance specifically or by addressing the group the substance belongs to in an adequate manner (e.g. by referring to the classification criteria for CMR category 1 or 2);
- covers the considered use or categories of use, taking into account exemptions;
- imposes minimum requirements for the control of risks; in other words the Member States may adopt more but not less stringent measures when implementing the Community rules;
- covers those properties that led to inclusion of the substance in Annex XIV.

An example that could qualify for an exemption under this article is (are) the use(s) of 4-nitrodiphenyl. This substance is prohibited according to the directive 98/24/CE and may be subjected to an individual authorisation by the Member States. The specified uses of this particular substance could therefore be exempted for occupational uses from the REACH authorisation procedure.

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 (Art. 58(2)). This situation could, for example, arise from inclusion of a substance into a matrix, evaporation from an article, degradation/evaporation in the atmosphere, or waste water degradation after disposal. Other examples are substances where hazard and risk characteristics depend on the particle size (e.g. massive form versus powder).

[42] Under REACH (Definition 24 Art. 3), the "use" of a substance has been defined as "*Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;".* Thus "use" has a very broad meaning of utilisation of a substance. The term "categories of uses" aims at more than one use. The Guidance on information requirements and chemical safety assessment gives guidance on how to describe the use of a substance in a structured way using a use descriptor system.

These exemptions allow 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. If as a result of information gathered under REACH or from developing other Community legislation, further uses are justified to be exempt from the authorisation requirement, such exempted uses can be added to Annex XIV at a later stage following the regulatory procedure with scrutiny according to Art. 133 (4) of the Regulation.

5 CONSULTATION OF THE MEMBER STATE COMMITTEE AND INTERESTED PARTIES

Consultation of the Member State Committee and other interested parties by the Agency in the process of establishment of the 'candidate list' and in the inclusion of substances in Annex XIV is built into the authorisation process in a formal way. It is important for improvement of the quality of decision making and may help to avoid time-consuming confrontations in the decision making process under Art. 133(4). For this reason, the Member State Committee and interested parties should be involved from the early stages of the process. The key element for a successful consultation in this perspective is early planning and a good communication of the different steps in the process.

5.1 Consultation of the Member State Committee

If the Agency does not receive or make any comments on an Annex XV dossier for a SVHC, it shall include the substance on the 'candidate list'. When comments are made or received, the Agency shall consult the Member State Committee in the process of the establishment of the 'candidate list'. Consultation on the draft Annex XIV entry for substances recommended for inclusion in Annex XIV is, however, always obligatory.

5.1.1 Establishment of the 'candidate list'

Within 60 days (45 days)[43] of circulation of an Annex XV dossier, the Member States may in the process of the establishment of the 'candidate list', comment to the Agency (Art. 59(5)) on the identification of the substance in relation to the criteria in Art. 57. This can be done simply by including annotations or comments in the dossier. Upon receipt of comments by a Member State or interested party the Member State Committee needs to be consulted automatically (see section 3.1).

5.1.2 Draft Annex XIV entry for substances recommended for inclusion in Annex XIV

The Member State Committee may give its opinion on each of the issues specified for the substance proposed for inclusion in Annex XIV as listed in Art. 58(1). Comments on the substance identity and the intrinsic property (properties) of the SVHC are not expected since this should already have been commented on before in the process of setting up the 'candidate list'. It would be of particular importance to have the views of the Member State Committee on the priority given to a particular substance, the transitional arrangements, review periods for certain uses, uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions.

The Agency shall take into account the opinion of the Member State Committee in its draft Annex XIV entry for substances recommended for inclusion in Annex XIV to the Commission (Art. 58(3)). A deadline for submission of an opinion by the Member State Committee is not foreseen by the legislation. It would be good practice if this would not interfere with or delay further steps in the process. The timing needs to fit with the overall timeframe provided for this process. **Therefore as a rule of thumb and in line with the deadline for submitting comments by other interested parties, the Member State Committee should deliver its opinion within an indicative timeline of 3 months if possible.**

[43] See also paragraph 6 section 3.1: It would be a good working practice if Authorities would submit their comments on the Annex XV dossier well in advance and not later than 45 days after the start of the commenting period in order to facilitate the work of the Authority in charge of the Annex XV dossier.

5.2 Consultation of interested parties

Interested parties shall be invited to submit comments on the Annex XV dossier that has been prepared for a candidate substance to be included in the 'candidate list' (Art 59(4)) and on the draft Annex XIV entry for substances recommended for inclusion of a substance in Annex XIV (Art 58(4)). Since interested parties might be less familiar with the process of inclusion of SVHCs in Annex XIV, they should be informed on the Agency's website of the whole decision-making process including the deadlines for commenting. Interested parties that have subscribed for the mailing list dealing with Annex XIV will be informed automatically on any update of the list of Annex XV dossiers.

5.2.1 Establishment of the 'candidate list'

All interested parties may submit comments before a specified deadline to the Agency (Art. 59(4)) once a note that an Annex XV dossier (in practice the non-confidential parts of the underlying Annex XV dossier) has been prepared and is published on the Agency's website. Although an exact deadline is not specified in the legal text, this deadline should not disturb the normal continuation of the procedure. **For practical reasons, it seems most appropriate to consult stakeholders at the same time as Member States, with a maximum deadline of 45 days.**

An appropriate format for submission of comments should also be provided on the Agency's website. A proposal for a template is given in **Appendix 5.** Interested parties submitting comments should identify themselves, insert the date the note was published on the Agency's website and the identity of the substance they are commenting on. Additionally and as far as relevant for their comments on the identification of a SVHC, they should provide the underlying evidence for their statements. This could be done, for example, by including references to the scientific literature or data which support or call into question the identification of the SVHC. The Agency shall make the comments available to the Member State Committee. Interested parties have the possibility to remain anonymous and on the condition that a justification is given, the information provided may be kept confidential.

5.2.2 Draft Annex XIV entry for substances recommended for inclusion in Annex XIV

After consultation of the Member States Committee and before sending the recommendation to the Commission, the Agency shall make its draft Annex XIV entry for substances recommended for inclusion in Annex XIV publicly available on its website[44]. The date of publication shall clearly be indicated. Additionally, the draft Annex XIV entry for substances recommended for inclusion in Annex XIV shall specify for each substance the items mentioned under Article 58(1) (the substance identity, the intrinsic properties of the SVHC, the transitional arrangements, review periods for certain uses, uses or categories of uses exempted from the authorisation requirement and conditions for such exemptions).

An appropriate format for submission of comments should also be provided on the Agency's website. A proposal for a template is given in Appendix 6. The design of the template is targeted to the items listed under Art. 58(1) in order to facilitate the submission of comments by interested

[44] Taking into account Art. 118 and Art 119 on access to information and electronic public access respectively. Note that it is the Management Board of the Agency that shall adopt practical arrangements for implementing the Regulation on public access to information (cf. Art. 118(3)) and is part of the operational procedures of the Agency.

parties in a clear structure that assists Agency staff in quickly recognising the issues brought forward and dealing with the comments appropriately.

Interested parties submitting comments should identify themselves, insert the date of publication on the Agency's website and the identity of the substance they are commenting on. Interested parties can provide comments on the draft Annex XIV entry for substances recommended for inclusion in Annex XIV under the relevant heading of the proposed template. The comments should focus on the issues listed under Art. 58(1), particularly the exemptions of use and should be received by the Agency within 3 months of the date of publication. As far as relevant for their comments they should provide the underlying evidence for their statements (e.g. scientific literature). The Agency shall update its draft Annex XIV entry for substances recommended for inclusion in Annex XIV taking into account the comments received.

6 REFERENCES AND OTHER BACKGROUND INFORMATION

- European Commission. The Technical Guidance Document (TGD) on development of risk reduction strategies. Office for Official Publications of the European Communities, 1998, Luxembourg. ISBN 92-828-3296-1.

- Flow Charts for the New Chemicals Legislation REACH (can be downloaded from the ECB web-site: http://ecb.jrc.it/REACH/), Ispra, Italy, 14/02/2007.

- Experiences from EU business impact assessment studies of new legislation (http://europa.eu.int/comm/enterprise/regulation/better_regulation/impact_assessment/index.htm).

APPENDIX 1: OVERVIEW OF THE ROLES, OBLIGATIONS AND RIGHTS OF THE ACTORS

Table 2: Tasks and responsibilities of the Agency

Tasks and responsibilities of the Agency	
Establishment of the 'candidate list'	***REACH text***
Prepare a dossier in accordance with relevant sections of Annex XV for substances which meet the criteria set out in Art. 57 (Commission initiative)	Art. 59(2)
Make the dossier available to the Member States	Art. 59(2)
Receive an Annex XV dossier prepared by Member States (Member State initiative)	Art. 59(3)
Make a dossier in accordance with Annex XV for substances which meet the criteria set out in Art. 57 available within 30 days of receipt to the other Member States (Member State initiative)	Art. 59(3)
Publish on the Agency's website a notice that an Annex XV dossier has been prepared and start the Agency consultation process	Art. 59(4)
Invite interested parties to submit comments on a dossier in accordance with Annex XV for substances which meet the criteria set out in Art. 57 within a set deadline	Art. 59(4)
Submit comments within 60 days of circulation on the identification of the substance in relation to the criteria in Art. 57 in the dossier	Art. 59(5)
If no comments received, include the substance in the 'candidate list' for eventual inclusion in Annex XIV	Art. 59(6)
Include the substance in its recommendations under Art. 58(3)	Art. 59(6), Art. 59(9)
Upon receipt of comments from MS or third parties or on its own initiative refer the dossier to the Member State Committee for an opinion within 15 days of the end of the 60-day period	Art. 59(7)
If within 30 days of the referral the Member State Committee reaches unanimous agreement on the identification include the substance in the 'candidate list' for eventual inclusion in Annex XIV	Art. 59(8)
Publish and update the 'candidate list' for eventual inclusion in Annex XIV without delay after a decision on inclusion of a substance has been taken	Art. 59(9)
Indicate which substances on the 'candidate list' are on its work programme according to Art. 83(3)(e)	Art. 59(1)
Prioritisation of substances on the 'candidate list'	
Place substances on the draft Priority List to be included in Annex XIV. Priority shall be given to substances with PBT, vPvB properties, wide dispersive use or high volumes Make its first recommendation of priority substances to be included in Annex XIV by June 2009 and any further recommendations follow at least every second year.	Art. 58(3)
Inclusion of substances in Annex XIV (or removal)	
Verify if all uses have been prohibited under Title VIII or by other Community legislation for any substance on the candidate list for eventual inclusion in Annex XIV and update the candidate list for eventual inclusion in Annex XIV if necessary.	Art. 58(7)
Verify if the substance is subjected to new restrictions under procedure of Title VIII (Restrictions)	Art. 58(5), Art. 58(6)
Verify if the substance is still fulfilling Art 57 (a-f) based on new information and inform the Commission in case the substance does not longer meet the criteria of Art. 57.	Art. 58(8)
Publish the draft Priority List for inclusion in Annex XIV on the Agency's website and invite all interested parties to submit comments within 3 months of the date of publication in particular on uses which should be exempt from the authorisation requirement	Art. 58(4)
Update the draft Priority List of substances to be included in Annex XIV according to the comments received	Art. 58(4)
Send recommendation for inclusion in or removal of a substance from Annex XIV to the Commission	Art. 58(4)

Table 3: Tasks and responsibilities of the Member State Competent Authorities

Tasks and responsibilities of the Member State Competent Authorities	
Establishment of the 'candidate list'	***REACH text***
Prepare an Annex XV dossier for substances that meet the criteria set out in Art. 57	Art. 59(3)
Submit comments within 60 days of circulation on the identification of the substance in relation to the criteria in Art. 57 in the dossier	Art. 59(5)
Participate in the Regulatory Committee (Art. 133(4)) on the identification of the substance in relation to the criteria in Art. 57	Art. 59(9)

Inclusion of substances in Annex XIV (or removal)	
Participate in the Regulatory Committee (Art. 133(4)) on the inclusion of a substance in Annex XIV	Art. 58(1)
Submit comments on the identification of substances with identified properties of very high concern	Art. 58(4)

Table 4: Tasks and responsibilities of the Commission

Tasks and responsibilities of the Commission	
Establishment of the 'candidate list'	***REACH text***
Ask the Agency to prepare an Annex XV dossier for substances that meet the criteria set out in Art. 57	Art. 59(2)
Prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee if the Member State Committee fails to reach a unanimous agreement	Art. 59(9)
Takes a decision on the identification of the substance in relation to the criteria in Art. 57 in the Regulatory Committee (Art. 133(4))	Art. 59(9)
Inclusion of substances in Annex XIV (or removal)	
Upon receipt of a recommendation from the Agency to include a substance referred to in Art. 57 in Annex XIV decide on the inclusion in the regulatory Committee (Art. 133(4)).	Art. 58(1)
If as a consequence of new information a substance does not longer meet the criteria of Art. 57 remove the substance from Annex XIV in the Regulatory Committee (Art. 133(4))	Art. 58(8)

Table 5: Tasks and responsibilities of the Member State Committee

Tasks and responsibilities of the Member State Committee	
Establishment of the 'candidate list'	***REACH text***
Adopts an opinion on the identification of a candidate substance for inclusion in the 'authorisation list'	Art. 59(8) Art. 59(9)
Forwards opinion to the Commission in case of failure to reach unanimous agreement	Art. 59(9)
Prioritisation of substances on the 'candidate list'	
Adopts an opinion on the recommendation of priority substances to be included in Annex XIV	Art 58(3)

Table 6: Tasks and responsibilities of interested parties

Tasks and responsibilities of interested parties	
Establishment of the' candidate list'	***REACH text***
Submit comments on a dossier in accordance with Annex XV for substances which meet the criteria set out in Art. 57 within a set deadline	Art. 59(4)
Inclusion of substances in Annex XIV (or removal)	
Submit comments within three months of the date of publication on draft Priority List for inclusion in Annex XIV in particular on uses which should be exempt from the authorisation requirement	Art. 58(4)

APPENDIX 2: FORMAT FOR A NOTICE THAT AN ANNEX XV DOSSIER FOR THE IDENTIFICATION OF A SUBSTANCE AS A CMR, PBT, VPVB OR A SUBSTANCE OF EQUIVALENT CONCERN ACCORDING TO ART. 59 HAS BEEN PREPARED

Notice for an Annex XV dossier for the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern

dd/mm/yy

The date of publication on the Agency's website should be given here

Revised Draft report format

NOTICE FOR AN ANNEX XV DOSSIER FOR THE IDENTIFICATION OF A SUBSTANCE AS A CMR, PBT, VPVB OR A SUBSTANCE OF EQUIVALENT CONCERN[45]

Substance name:
EC number:
CAS number:
Molecular formula:
Structural formula:

Summary of how the substance meets the CMR, PBT or vPvB criteria, or is considered to be a substance of equivalent concern

[45] A registrant may identify certain information in their registration as commercially sensitive. If the justification with regard to information listed in Article 119 (2) is accepted as valid by the Agency, then this information will be marked as commercially sensitive in REACH–IT. Such information can be used in the preparation of an Annex XV dossier for discussion with the Agency and Member States, as such discussions can be confidential. However, such information must not be included in any documents to be used for public consultation. The Authority therefore has to consider this when preparing an Annex XV dossier. It is recommended to include or mark confidential information in such a way (e.g. in separate annexes) that it can easily be left out when the Agency publishes a notice and the non-confidential parts of an Annex XV dossier for commenting in accordance with Art 59(4).

Authorities need to pay attention also to information listed in Article 118 (2). Information to which access cannot be granted under Article 118 must not be published on the internet because the Agency would already have to deny access to such information on request in a single case on the basis of Regulation 1049/2001.
The general provisions on access to information are twofold:
- Some pieces of information will be made available over the internet in accordance with Article 119 (1).
- Access to other pieces of information will be granted by the Agency on request on a case by case basis in accordance with Regulation 1049/2001, as per Article 118 (1). Regulation 1049/2001 defines cases in which access to information has to be denied e.g. for reasons related to the protection of commercial interests which are further explained in Article 118 (2). It also requires the Agency to check with companies that have submitted information to it whether the company claims that the information asked for is confidential. The Agency then has to take a decision.

1 IDENTIFICATION OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

Section 1.1 should be used to outline the purity of the substance and any impurities and additives present in the substance. This is particularly important in relation to complex substances. Where possible the impurities and additives should be identified by chemical name and CAS Number, and the level of such impurities/additives present in the substance should be given. The outcome from the Guidance on substance identification will provide further guidance in relation to defining the substance identity in terms of composition and purity. For the physicochemical properties, it is not necessary to complete the table for all of the properties. The most useful physico-chemical properties in relation to PBT considerations are likely to be melting point, boiling point, vapour pressure, water solubility, n-octanol/water partition coefficient and dissociation constant (if relevant) and it is recommended that at least these data be included.

Name:
EC Number:
CAS Number:
IUPAC Name:
Molecular Formula:
Structural Formula:
Molecular Weight:
Synonyms:

1.1 Purity/Impurities/Additives

1.2 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

REACH ref Annex, §	Property	Value	[enter comment/reference or delete column]
V, 5.1	Physical state at 20 C and 101.3 KPa		
V, 5.2	Melting / freezing point		
V, 5.3	Boiling point		
V, 5.5	Vapour pressure		
V, 5.7	Water solubility		
V, 5.8	Partition coefficient n-octanol/water (log value)		
VII, 5.19	Dissociation constant		
	[enter other property or delete row]		

2 MANUFACTURE AND USE

Not relevant for this type of dossier.

Information on uses may be useful for prioritisation for inclusion in Annex XIV but this should be

summarised under the heading 'Information on use, exposure, alternatives and risks'

3 CLASSIFICATION AND LABELLING

This could be any current classification, for example

- *the classification listed in Annex I of Directive 67/548/EEC*
- *the classification given in the publicly available classification and labelling inventory (containing Industry self classifications as well as Annex I classifications when relevant).*

The source of the classification should be stated.

4 ENVIRONMENTAL FATE PROPERTIES

This outlines the environmental fate properties of the substance.

4.1 Degradation

This section should summarise all of the relevant abiotic and biotic degradation data for the substance. A summary of the key studies should be included in Section 4.1.1 (in the case of abiotic studies) or Section 4.1.2 (in the case of biotic studies). Any supporting information, such as information from field studies, monitoring data or results from multimedia modelling should be included in Section 4.1.3 (other information). A key part of this section is the summary and discussion of persistence (Section 4.1.4). Here the available data should be discussed and the actual derived half-life or half-lives of the substance in the various environmental media considered should be summarised. In the case of equivalent concern, a summary of the main discussions related to persistence should be given if appropriate.

4.1.1 Abiotic degradation

4.1.2 Biotic degradation

4.1.3 Other information [46]

4.2 Environmental distribution

This section is concerned with the environmental distribution. This section is of relevance to a PBT or vPvB report as information on the environmental distribution can be useful for identifying the relevant environmental compartment(s) for consideration of the persistence of the substance. In addition considerations of environmental distribution may also be relevant for equivalent concern, particularly in relation to transportation over long distances (for example consideration of the adsorptive properties and/or volatility of the substance may be relevant). In these cases a summary of the relevant information should be added to the appropriate section.

4.2.1 Adsorption

[46] e.g half life from field studies or monitoring data

4.2.2 Volatilisation

4.2.3 Elimination in wastewater treatment plants

4.3 Bioaccumulation

This section is concerned with the bioaccumulative properties of the substance. For a PBT or vPvB report the most relevant data are likely to be the results from actual bioconcentration studies with aquatic organisms and so most attention should be focussed on including a summary of the key study (or studies) under Section 4.3.2 (Measured bioaccumulation data). In this case, screening data (for example log Kow values or predicted BCFs) or monitoring data are likely to be used only as supporting information (if at all) and so only a very brief summary of these data would generally be needed in Section 4.3.1 and Section 4.3.3, and in some cases
there will be no need to complete these sections at all. The summary and discussion of bioaccumulation data (Section 4.3.4) should clearly outline the key findings and values for the bioconcentration or bioaccumulation factors if relevant.

4.3.1 Screening data[47]

4.3.2 Measured bioaccumulation data[48]

4.3.3 Other supporting information[49]

4.3.4 Summary and discussion of bioaccumulation

4.4 Secondary poisoning

This section concerns any information relevant to secondary poisoning. Here any relevant information on accumulation through the food chain could be summarised. This type of information is likely to be most useful in relation to equivalent concern. In relation to equivalent concern, a wider range of information may be required, ranging from screening information (e.g. log Kow or predicted BCFs), to uptake and accumulation studies with non-aquatic species, to other supporting data such as monitoring data. Therefore it may be that more information may be needed in Section 4.3 and Section 4.4 than may be required for a PBT or a vPvB report. This information should be added to the appropriate subsection(s) of the report.

5 HUMAN HEALTH HAZARD ASSESSMENT

Section 5 outlines the mammalian toxicity data. The criteria for T in Annex XIII are based on the classification and labelling of the substance. In cases where an agreed appropriate classification exists there is no need to report the underlying toxicity data that leads to the classification in this section. However, in some cases it may be necessary to complete at least some of this section in detail for a PBT assessment, for example where there is no CSR or technical dossier or if there is a disagreement over the actual classification and labelling presented in the CSR or technical dossier. The aim should be to demonstrate that the substance meets the relevant classification criteria and hence the T criteria for PBT. Evidence of uptake in mammals from toxicity studies may also be useful in relation to the B or vB criteria. For an equivalent concern report (and in some cases a

[47] For example, log K_{ow} values, predicted BCFs
[48] For example, fish bioconcentration factor
[49] For example, measured concentrations in biota

PBT or vPvB report), there are a number of other areas that may need to be considered. For example, information on the toxicokinetics (Section 5.1) may be relevant to the discussion of the bioaccumulation potential of the substance. Similarly it may be necessary to consider the acute toxicity (Section 5.2), repeated dose toxicity (Section 5.6), mutagenicity (Section 5.7), carcinogenicity (Section 5.8) and toxicity to reproduction (Section 5.9). The other sub-sections are likely to be less relevant for an equivalent concern dossier and would generally not need to be completed. For each relevant endpoint, a summary of the key studies should be added under the appropriate heading, and an overall summary of the key findings should be completed at the end of each sub-section.

5.1 Toxicokinetics (absorption,metabolism,distribution and elimination)

5.2 Acute toxicity

5.2.1 Acute toxicity: oral

5.2.2 Acute toxicity: dermal

5.2.3 Acute toxicity: inhalation

5.2.4 Acute toxicity: other routes

5.3 Repeated dose toxicity

5.3.1 Oral studies

5.3.2 Dermal studies

5.3.3 Inhalation studies

5.3.4 Other relevant information

5.3.5 Summary and discussion of repeated dose toxicity

5.4 Mutagenicity

5.4.1 In vitro data

5.4.2 In vivo data

5.4.3 Human data

5.4.4 Other relevant information

5.4.5 Summary and discussion of mutagenicity

5.5 Carcinogenicity

5.5.1 Oral studies

5.5.2 Dermal studies

5.5.3 Inhalation studies

5.5.4 Human data

5.5.5 Other relevant information

5.5.6 Summary and discussion of carcinogenicity

5.6 Toxicity for reproduction

5.6.1 Effects on fertility

5.6.2 Developmental toxicity

5.6.3 Human data

5.6.4 Other relevant information

5.6.5 Summary and discussion of reproductive toxicity

5.6.6 Other effects

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

This section relates to the human health hazard assessment of physicochemical properties not relevant for this type of dossier.

7 ENVIRONMENTAL HAZARD ASSESSMENT

This section considers the available ecotoxicity data for the substance. For a vPvB substance, this section need not be completed. For a PBT substance, the most relevant data are the long-term toxicity data with aquatic organisms. Therefore details of the key studies should be added to the appropriate sections for fish (Section 7.1.1.1), aquatic invertebrates (Section 7.1.1.2) and algae (Section 7.1.1.3). Only those values used for demonstrating that the T-criterion is met need be added, and so it is possible that not all of these Sections will need to be completed. Summaries of the key studies can be taken directly from the registration dossier if available. For an equivalent concern report, it may be necessary to consider ecotoxicity data other than long-term toxicity data for aquatic organisms. Thus it is possible that information on the acute toxicity to fish (Section 7.1.1.1), aquatic invertebrates (Section 7.1.1.2) or alga (Section 7.1.1.3) may need to be considered, or indeed toxicity data on sediment organisms (Section 7.1.2), other aquatic organisms (e.g. amphibians (Section 7.1.3), terrestrial organisms (Section 7.2.1), the atmospheric compartment (Section 7.3) or birds (Section 7.5.1)) may need to be considered. Again summaries of only the key studies relevant to the discussions over equivalent concern should be added to the relevant sections (the other Sections need not be completed).

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity test results

7.1.1.1 Fish

Acute toxicity

Long-term toxicity

7.1.1.2 Aquatic invertebrates

Acute toxicity

Long-term toxicity

7.1.1.3 Algae and aquatic plants

7.1.2 Sediment organisms

7.1.3 Other aquatic organisms

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.2 Terrestrial plants

Acute toxicity

Long-term toxicity

7.2.2.1 Soil macroorganisms

Acute toxicity

Long-term toxicity

7.2.2.2 Soil microorganisms

7.2.2.3 Other terrestrial organisms

Acute toxicity

Long-term toxicity

7.3 Atmospheric compartment

7.4 Microbiological activity in sewage treatment systems

7.5 Indirect exposure via the food chain

7.5.1 Effect data

8 PBT, VPVB AND EQUIVALENT CONCERN ASSESSMENT

This concerns the PBT, vPvB and equivalent concern assessment. If a PBT or vPvB assessment has already been completed, for example, as part of the CSR, the key findings can be taken directly from the CSR and used as the basis for the assessment here.

8.1 PBT, vPvB assessment

Section 8.1 relates to the PBT and vPvB assessment. This section should summarise why the substance is considered to meet the PBT or vPvB criteria. Thus it should take each criteria in turn and discuss, by reference to the available persistence, bioaccumulation and toxicity (in the case of a PBT report) data summarised elsewhere in the dossier, why each of the criteria is met. No new data should be introduced in this section. Any information used (either data relating directly to the criteria or supporting information) should be summarised in the appropriate part of the report. Thus this section should be seen as a summary section whereby all the findings related to persistence, bioaccumulation and toxicity (in the case of a PBT dossier) are drawn together. For a PBT or vPvB report there is no need to complete Section 8.2. For an equivalent concern report, Section 8.1 should not be completed, and all the discussion should be added to Section 8.2.

8.2 Assessment of substances of equivalent concern

This section should summarise why the substance is considered to be a substance of equivalent concern. Again any information used should be summarised in the appropriate part of the report. The summary should clearly outline what the equivalent concern relates to, for example if it is related to a concern equivalent to CMR, a concern equivalent to PBT or other equivalent concerns such as endocrine disruption, and summarise the main data that lead to this conclusion.

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON EXPOSURE

The available exposure-related information should be summarised in this section. The main purpose of the exposure- related information is to identify if significant exposure of man or the environment can occur from the production and/or use of the substance. General information on the amounts produced, imported and/or used, along with a description of the uses of the substance could be given. For chemicals where multiple registrations exist these data from the individual registrations should be combined where possible. Exposure information may be useful for priority setting for Annex XIV inclusion.

2 INFORMATION ON ALTERNATIVES

This section is divided into two parts, one dealing with alternative substances and the other with alternative techniques. If there is no information relevant to one or either section then a note to say this should be included in the report. Where the information on the alternative(s) is limited it can be presented in this section of the report. Where the Authority wants to present more extensive information on alternatives, it is suggested that they make use of the PBT report format to provide a suitable framework for this. Clearly not all sections need to be completed, only those which are considered significant. The two sub-sections on alternatives should be used as appropriate.

2.1 Alternative substances

This section deals with alternative substances. Registration dossiers will be a major source of information on alternative substances, although other readily available sources could be used where appropriate. The information to be included should show that the alternative substance(s) are less hazardous. Hence information on the classification and labelling, and PBT characteristics of the alternative substance should be included, together with information on use and potential for exposure. It should be made clear as far as possible for which uses the alternative substance is a replacement for the subject of the proposal. If available, information on the functionality of any alternatives should also be included.

2.2 Alternative techniques

This section should be used for information on alternative techniques which could be applied to reduce or eliminate releases of the substance.

3 RISK-RELATED INFORMATION

This section can be used for other information relating to risks of the substance and alternatives which may be useful for the prioritisation process. This could include DNEL and PNEC values. Information such as PNECs and DNELs may be useful priority setting for Annex XIV inclusion.

OTHER INFORMATION

It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g. Technical Dossiers, CSRs, other published sources) used for the dossier could also be indicated here. However, this section should not contain any new technical information.

APPENDIX 3: FORMAT FOR THE 'CANDIDATE LIST'

'Candidate List' of Substances of Very High Concern[50]

Substances	Index number	EC number	CAS number	Main reason[51]	Uses in articles known to ECHA[52]	Agency's Work Programme	Notes[53]
IUPAC-name substance X	xxx-xxx-xx-x	xxx-xxx-x	xx-xx-x			yes/no	

[50] The name is the same as that used for the substance in Annex I to Directive 67/548/EEC. Whenever possible dangerous substances are designated by their EINECS (European Inventory of Existing Commercial Chemical Substances) or ELINCS (European List of Notified Chemical Substances) names. These are referred to as EC numbers in the table. Other entries not listed in EINECS or ELINCS are designated using an internationally recognised chemical name (e.g. ISO, IUPAC). An additional common name is included in some cases. The index number is the identification code given to the substance in Annex I of Directive 67/548/EEC. Substances are listed in the Appendix according to this index number.

[51] The main reasons should explain why the substance is on the candidate list:
- Art 57(a), Art 57(b), Art. 57(c), Art. 57(d), Art. 57(e) or Art 57(f).
- Threshold or non-threshold CMR
- Concentration range if determining the hazardous properties of the substance

[52] This will help focussing work according to Articles 7.2 and 33.

[53] The full text of the notes can be found in the Foreword of Annex I to Directive 67/548/EEC which will be repealed by the GHS Regulation on Classification and Labelling which is currently proposed and which will take over these notes.

APPENDIX 4: FORMAT FOR A DRAFT ANNEX XIV ENTRY FOR SUBSTANCES RECOMMENDED FOR INCLUSION IN ANNEX XIV

Draft Annex XIV entry for substances recommended for inclusion in Annex XIV

Revised Draft report format

DRAFT ENTRY OF A SVHC FOR INCLUSION IN ANNEX XIV

Substance name:
EC number:
CAS number:
Molecular formula:
Structural formula:

Summary of the draft Annex XIV entry for substances recommended for inclusion in Annex XIV

1 DATE OF PUBLICATION ON THE AGENCY'S WEBSITE

The date of publication on the Agency's website should be given here.

2 INFORMATION ON THE IDENTITY OF THE SUBSTANCE

The information given in this section shall be sufficient to enable identification of the substance. 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. Detailed information on the substance identity is required in order to avoid that by mistake a substance that is not of very high concern will appear on the Agency's website. This could for example happen in case substances share the same main identifiers but have a different toxicological profile due to different impurities or different composition.

2.1 Name or other identifier of each substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)
Other names (usual name, trade name, abbreviation)
EINECS or ELINCs number (if available and appropriate)
CAS name and CAS number (if available)
Other identity code (if available)

2.2 Information related to molecular and structural formula of each substance[54]

Molecular and structural formula (including Smiles notation, if available)
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
Molecular weight or molecular weight range

2.3 Composition of each substance[55]

Degree of purity (%)
Nature of impurities, including isomers and by-products
Percentage of (significant) main impurities
Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)
Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
High-pressure liquid chromatogram, gas chromatogram

[54] Taking into account Art. 118 and Art 119 on access to information and electronic public access respectively this is to be considered as confidential information and should be taken out of the recommendation when publishing on the Agency's website.

[55] Taking into account Art. 118 and Art 119 on access to information and electronic public access respectively this is to be considered as confidential information and should be taken out of the recommendation when publishing on the Agency's website.

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

3 INFORMATION ON THE INTRINSIC PROPERTIES OF THE SUBSTANCE

Summary of how the substance meets the CMR, PBT or vPvB criteria, or is considered to be a substance of equivalent concern

4 TRANSITIONAL ARRANGEMENTS

Sunset date: a documented proposal for sunset should be given here.

Deadline for submission of an application for authorisation: a documented proposal for a deadline for submission of an application for authorisation should be given here usually 18 months before the sunset date.

5 REVIEW PERIODS FOR CERTAIN USES

A documented proposal for a review period should be given here if appropriate

6 USE CATEGORIES OF USES EXEMPTED FROM AUTHORISATIONS[56]

Uses/category of uses: if relevant uses or categories of uses to exempted should be given here. It should be indicated if PPORDS are exempted from authorisation.

Conditions: as far as appropriate the conditions for these exemptions should be specified e.g. the maximum quantity exempted for PPORDs

7 OTHER INFORMATION[57]

It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g. Technical Dossiers, CSRs, other published sources) used for the dossier could also be indicated here. However, this section should not contain any new technical information.

[56] Taking into account Art. 118 and Art 119 on access to information and electronic public access respectively this could to be considered as confidential information and might be taken out (partly or completely) of the recommendation when publishing on the Agency's website.

[57] Taking into account Art. 118 and Art 119 on access to information and electronic public access respectively this could to be considered as confidential information and might be taken out (partly or completely) of the recommendation when publishing on the Agency's website.

APPENDIX 5: COMMENTING FORM ON THE IDENTIFICATION OF THE SUBSTANCE IN RELATION TO ART. 57 WITH REGARD TO THE NOTICE PUBLISHED BY THE AGENCY TO BE COMPLETED BY INTERESTED PARTIES

Format for submitting information on Annex XV dossiers for identification of SVHC:

1. Identity of the substance
    a. Substance name [*to be filled in automatically by the IT system]*
    b. CAS number [*to be filled in automatically by the IT system]*
    c. EC number [*to be filled in automatically by the IT system]*
    d. The reason why the Annex XV dossier was submitted (PBT/vPvB, CMR, equivalent concern) [*to be filled in automatically by the IT system]*

The interested party should be identified in order to submit information. The following information is required to be given before the comment can be submitted:

2. Identification of the interested party/Member State submitting information

Note that the following fields are mandatory.

Box to fill in information on the identity of the interested party:

a. First Name b. Family Name c. Email d. Country (*a pick list could give here the option to choose among the EU Member States and a non-EU country to be given in detail in a free text field)*

e. Are you submitting information on behalf of a Member State Competent Authority (*if yes it shouldn't be possible to fill f*)

If yes than the pick list of the 27 MS should be displayed and there is no need to fill f

f. Are you submitting information as *(the options below should be in a form of a pick list):*

i. An individual

ii. On behalf of an organisation or institution

iii. As an individual affiliated to an organisation or institution

If ii. and iii. are chosen, the interested party would need to fill in the fields 1., 2. and 3. below in order to be able to submit information.

1. Type of organisation/institution (e.g. company, national authority; regional or local authority; academic institution; national NGO; international NGO; industry or trade association; other contributor)

2. Name of organisation/institution

3. Country in which the organisation/institution is legally established (*a pick list could give here the option to choose among the EU Member States and a non-EU country to be given in detail in a free text field)*

g. [tickbox] I do not wish my above identity to be disclosed if the comments are made publicly available.

The interested party is requested to provide a non-confidential version of the information which ECHA may make available to the public. Confidential details to support the non-confidential information may be submitted as well (see further detailed instructions below). A justification must be given by the submitting party to explain why the information is confidential. Such confidential information will only be used by ECHA, including its Committees.

After filling in the information on his/her identity and, if relevant, the identity of the organisation/institution above, the interested party will be able to submit information in a structured commenting table + attachments as indicated below:

The information submitted should be structured as follow:

The Box for submitting information should be structured as follows or commenting table to attach

General comments (please add the page number in front of your comment e.g. p.12 *the conclusion on …..*)

Specific comments on the justification

Identity of the substance and physico-chemical properties

Classification and labelling

Environmental fate properties

Human health hazard assessment

Human health hazard assessment of physicochemical properties (if relevant)

Environmental hazard assessment

Specific comments on information on use, exposure, alternatives and risks

Information on uses

Exposure information

Information on risks related to the substance

Information on alternative substances and techniques

Information on risks related to the alternatives

ECHA may make this information publicly available. In case you wish to submit confidential supporting information, you are requested to tick the relevant boxes below and to submit the confidential information in a separate file (see instructions for submitting attachments below). If you tick in the second box, you are requested to fill in the information to justify the confidentiality in order to facilitate ECHA's work in deciding on requests for access to documents.

☐ The submitted information can be made publicly available.

☐ I have the following reasons enumerated in Article 4(1) or 4(2) of Regulation (EC) No 1049/2001 regarding public access to documents why the information submitted as confidential cannot be disclosed to persons requesting access to documents (please explain below in the commenting field those reasons; a reason could be that the protection of your commercial interests, including intellectual property, would be undermined).

Free text box where the third party would have to explain why the information submitted should not be disclosed to the public

1. *After the interested party would submit the information he/she would get an automatic reply that the information was successfully submitted.*

2. *If the user has not filled in the mandatory fields indicated above the IT system displays the user an error message stating 'Please fill in ALL mandatory fields in 'Identification of the party submitting information'. Your submission could not be retrieved due to data lacking from these fields'.*

APPENDIX 6: COMMENTING FORM[58] ON THE DRAFT ANNEX XIV ENTRY FOR SUBSTANCES RECOMMENDED FOR INCLUSION IN ANNEX XIV TO THE COMMISSION TO BE COMPLETED BY INTERESTED PARTIES

Comments shall be sent to xx.yy@zz before dd/mm/yyyy. These comments will be considered for the update of the draft Annex XIV entry for substances recommended for inclusion in Annex XIV but no responses to comments will be made.

Please note that pursuant to Art. 2(1) of Regulation 1049/2001, any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the Community institutions, except for a defined number of reasons such as commercial interests including intellectual property. The reasons enumerated in Art. 4 (1) and 4 (2) of that Regulation are outlined in the box below. Similarly, the institutions may grant access to documents to any natural or legal person not residing or not having its registered office in a Member State (Art. 2(2)) non-citizens of the Union.
Please note that according to Article 118 of REACH information on the full composition of a preparation, on the exact use, function or application of a substance or preparation, on the precise tonnage as well as on links between a manufacturer or importer and his distributor or downstream user **normally will be deemed to undermine the protection of the commercial interests** of the concerned person.

Regulation 1049/2001, Art. 4

1. The institutions shall refuse access to a document where disclosure would undermine the protection of:
(a) the public interest as regards:
— public security,
— defence and military matters,
— international relations,
— the financial, monetary or economic policy of the Community or a Member State;
(b) privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.
2. The institutions shall refuse access to a document where disclosure would undermine the protection of:
— commercial interests of a natural or legal person, including intellectual property,
— court proceedings and legal advice,
— the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure.
[…]

In case of a request for a document, Article 4(4) of Regulation 1049/2001 provides that "[the Agency] shall consult [the provider of the comments] with a view to assessing whether an exception

[58] Under revision by ECHA

in the right of access according to paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed."

In order to assess whether an exception in paragraph 1 or 2 is applicable, you are requested to verify whether any of these exceptions applies to your document. If this is the case, please indicate the reasons below.

 My comments may be made available to the public

 I have the following reasons enumerated in Art 4(1) or 4(2) of Regulation 1049/2001 why my comments cannot be disclosed to potential applicants for access to documents (please explain those reasons. A reason could be that commercial interests or intellectual property is undermined)

Please note that the Agency may not refuse access to documents, unless any of the above reasons applies. Therefore, if you do not indicate any reasons above, the Agency reserves its right to decide that access can be given to your comments.

In case you have indicated a reason why your comments cannot be disclosed, you may still decide to make available

- certain parts of the document to anyone requesting access to it or
- certain parts or all of the document to a restricted number of actors requesting access to it

To facilitate the procedure, you may hereby in advance give an approval to disclose all or part of your comments to all or a certain number of actors. Should this be the case, please mark the relevant alternative(s) below (please note that in the absence of any reasons pursuant to Art. 4(1) or 4(2) of Regulation 1049/2001 (see above), the Agency may still come to the conclusion that your comments must be disclosed to anyone requesting access to them, independently of any other option ticked below):

 My comments may be made available to the public

 My comments may be made available to the applicant(s) for authorisation

 My comments may be made available to the Member State(s) competent authorities

 Certain parts of my comments may be made available to the public (if this is the case, please indicate which parts and, if applicable, to which of the above actors):

Name[1]**:**

Organization:

Country:

Contact details[1,2]**:**
e-mail:
telephone:

Date of publication on the Agency's website[1,2]**:**

Information on the identity of the substance[1,2]**:**

Name:
EC Number:
CAS Number:
IUPAC Name:
Other identity code:
Molecular Formula:
Structural Formula:
Molecular Weight:
Synonyms:

Information on the intrinsic properties of the substance as specified in Art. 57:

CMR/PBT/vPvB/substance of equivalent concern[3]:

Please provide your comments on the draft Annex XIV entry for substances recommended for inclusion in Annex XIV under the relevant heading:

Information on the intrinsic properties of the substance as specified in Art. 57:

Transitional arrangements:

Review periods for certain uses:

Use categories of uses exempted from authorisations:

Other comments:

[1] Compulsory

[2] <dd/mm/yyyy + 3 months

[3] Indicate what is relevant/delete what is not relevant

APPENDIX 7: DEFINITIONS AND ABBREVIATIONS

Annex XIII	Criteria for the identification of PBTs and vPvBs
Annex XIV	List of Substances subject to Authorisation
Annex XV dossier	A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report.
Annex XV report	A report produced as part of the Annex XV dossier according to the guidance and format outlined in the Guidance on identification of SVHC. Unless specified otherwise, it is implicitly assumed in the text that the Annex XV dossier in this guidance relates to the identification of SVHCs.
Annex XVII	Restrictions on the manufacturing, placing on the market and use of certain dangerous substances
Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
BOEL	Binding Occupational Exposure Limit
CAD	Chemical Agents Directive
'candidate list'	Candidate list of substances for eventual inclusion in Annex XIV
CAS number	Chemical Abstracts Services registry number
CMR	Carcinogenic, mutagenic and toxic to reproduction.
CSA	Chemical safety assessment.
CSR	Chemical safety report.
Downstream User	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
EC-Inventory/EC-number	The three European lists of substances from the previous EU chemicals regulatory framework, EINECS, ELINCS and the NLP-list, in combination are called the EC Inventory. The EC Inventory is the source for the EC Number as an identifier of substances
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ELV	Emission Limit Value
EQS	Environmental Quality Standard
Exposure scenario	The set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposure of humans and the environment. Exposure scenarios may cover one specific process or several processes or uses as appropriate.
Importer	any natural or legal person established within the Community who is responsible for import
IPPC	Integrated Pollution Prevention and Control

IUCLID	The database underlying the REACH-IT system.
IUPAC	International Union of Pure and Applied Chemistry
Manufacturer	Any natural or legal person established within the Community who manufactures a substance within the Community.
MS	Member State
OEL	Occupational Exposure Limit
PBT	A persistent, bioaccumulative and toxic as defined in Annex XIII.
Phase-in substance*	A substance which meets at least one of the following criteria: (a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS); (b) It was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once before the entry into force of the REACH regulation; (c) It was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC; provided there is documentary evidence of this.
PPORD	Product and Process Orientated Research and Development
Preparation	Mixture or solution composed of two or more substances.
RA	Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	The information technology (IT) system for creating and administering documentation under REACH.
Restriction	Any condition for or prohibition of the manufacture, use or placing on the market.
RIP	REACH implementation project
Substance	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.
SVHC	Substance of Very High Concern meeting the criteria of Art. 57
SEA	Socio-Economic Analysis
Technical dossier	A dossier containing robust study summaries.
TGD	Technical Guidance Document
vPvB	Very persistent and very bioaccumulative as defined in Annex XIII.