ECHA

http://echa.europa.eu

# Guidance on the preparation of an application for authorisation

Version 1

January 2011

INFORMATION NOTICE
Please note that this is the only authentic version of the guidance and takes precedence over the draft version of this guidance that has been published in the Official Journal of the European Union.

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.

***Guidance on the preparation of an application for authorisation***

**Reference:** ECHA-11-G-01-EN
**Publ.date:** January 2011
**Language:** EN

© European Chemicals Agency, 2011.
Cover page © European Chemicals Agency

Reproduction is authorised provided the source is fully acknowledged in the form “Source: European Chemicals Agency, http://echa.europa.eu/”, and provided written notification is given to the ECHA Communication Unit (publications@echa.europa.eu).

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers to) using the Guidance feedback form. The feedback form can be accessed via the ECHA Guidance website or directly via the following link:
https://comments.echa.europa.eu/Comments/FeedbackGuidance.aspx

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

# PREFACE

This document describes the REACH procedure on applications for authorisation. 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] 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, corrected version in OJ L136, 29.5.2007, p.3).

# CONTENTS

ABBREVIATIONS ..... viii

GLOSSARY OF TERMS ..... ix

1. GENERAL INTRODUCTION AND OVERVIEW OF THE AUTHORISATION PROCESS ..... 1

1.1. About this guidance ..... 1

1.2. Structure of the guidance ..... 1

1.3. Who is the guidance for? ..... 1

1.4. Links to other REACH guidance ..... 1

1.5. General overview of the authorisation procedure ..... 2

1.5.1. How substances get included in Annex XIV ..... 3

1.5.2. Annex XIV entries ..... 4

1.5.3. Application for an authorisation ..... 7

1.5.4. What happens after an application for an authorisation has been submitted ..... 14

1.5.5. Factors that are taken into account in granting or refusing an authorisation ..... 16

1.5.6. Requirements following granting or refusal of an authorisation ..... 19

1.5.7. Review of authorisations ..... 20

1.6. Summary of important deadlines for applicants and interested third parties in the authorisation process ..... 22

2. HOW TO MAKE AN APPLICATION FOR AN AUTHORISATION ..... 24

2.1. Introduction ..... 24

2.1.1. Main elements of an application for authorisation ..... 24

2.1.2. Application content ..... 26

2.1.2.1. Adequate control route ..... 26

2.1.2.2. Socio-economic assessment (SEA) route ..... 27

2.2. Compiling an application for an authorisation ..... 30

2.2.1. Substance identity ..... 30

2.2.2. Applicants ..... 30

2.2.3. Request for authorisation for specific use(s) ..... 31

2.2.3.1. Use(s) covered in an application ..... 31

2.2.3.2. Describing use(s) in the application ..... 32

2.2.3.3. Uses for which authorisation application is not required.....33
2.2.3.4. Request for authorisation for several uses .....33
2.2.4. Documentation in support of the application for authorisation .....33
2.2.4.1. Chemical Safety Report .....33
2.2.4.2. Analysis of alternatives.....35
2.2.4.3. Substitution plan .....36
2.2.4.4. Socio-economic analysis.....36
2.2.4.5. Justification for not considering certain risks .....37
2.3. Subsequent Applications.....37
2.4. Submitting the application for authorisation.....38
2.4.1. Deadlines for submitting applications for authorisation .....38
2.4.2. How to submit an application .....38
2.4.3. Fees .....38
2.5. Review reports .....38
3. PLANNING FOR SUBSTITUTION: GUIDANCE ON ANALYSIS OF ALTERNATIVES .....40
3.1. Introduction.....40
3.2. What is an alternative?.....41
3.3. The focus and scope of the analysis of alternatives.....42
3.4. Overview of how an analysis of alternatives is undertaken.....44
3.5. How to identify possible alternatives.....46
3.5.1. How to identify the Annex XIV substance functions .....46
3.5.1.1. Information on use and function of the Annex XIV substance in the CSR.....50
3.5.1.2. Other sources for information on use and function of the Annex XIV substance .....51
3.5.2. Identifying and gathering information on possible alternatives .....51
3.5.2.1. Communication within the supply chain .....52
3.5.2.2. Communication outside the supply chain.....55
3.6. How to determine the technical feasibility of alternatives.....56
3.6.1. Technical feasibility criteria .....56
3.6.2. Consideration of process adaptation and changes .....57
3.6.3. Uncertainties in determining technical feasibility .....60

3.7. How to compare the risks of the alternative and the Annex XIV substance .....61
3.7.1. General considerations on assessing and comparing the risks.....61
3.7.2. Collecting hazard and risk information on alternatives .....62
3.7.3. Assessing and comparing with the risks of possible alternative substances .....65
3.7.4. Assessing and comparing with the risks of possible alternative technologies .....69
3.7.4.1. Comparing with risks of alternative technologies: Human Health.....71
3.7.4.2. Comparing with risks of alternative technologies: Environment.....72
3.7.5. Uncertainties in evaluating risks.....73
3.8. How to determine the economic feasibility of alternatives .....74
3.8.1. Uncertainties in determining economic feasibility .....78
3.9. Research and development that is relevant and appropriate.....79
3.9.1. Circumstances that might prompt the inclusion of R&D in the analysis of alternatives.....79
3.9.2. Documenting R&D in the application .....81
3.10. Concluding on the suitability and availability of alternatives .....81
3.11. Actions needed to make possible alternatives suitable and available.....84
3.12. Considerations for documenting the analysis of alternatives .....88
3.13. Links to other parts of the application .....92
3.13.1. Substitution plan .....92
3.13.2. A socio-economic analysis (SEA) .....93
3.14. Presenting the documentation of the analysis of alternatives to the Agency.....93
4. PLANNING FOR SUBSTITUTION: GUIDANCE ON SUBSTITUTION PLANS .....94
4.1. Introduction.....94
4.2. Scope and contents of a substitution plan.....96
4.3. Preparing a substitution plan.....96
4.3.1. Factors affecting the transfer to the substitute(s).....96
4.3.2. Defining the actions .....97
4.3.3. Identifying and setting progress markers.....98
4.3.4. Defining the timing of the plan.....98
4.3.5. Communication with the supply chain and customers .....99
4.4. Documenting the plan.....99

4.4.1. Presenting the documentation of the substitution plan to the Agency .....102

5. GUIDANCE FOR THIRD PARTIES ON SUBMITTING INFORMATION ON ALTERNATIVE SUBSTANCES OR TECHNOLOGIES .....103

5.1. Circumstances leading to third party submission of information .....104

5.2. Timing of third party submissions .....104

5.3. Preparation of a third party submission .....106

5.4. Confidentiality .....109

REFERENCES .....111

APPENDIX 1 CONSIDERATIONS FOR GROUPING OF SUBSTANCES .....114

APPENDIX 2 APPLICATIONS BY SEVERAL LEGAL ENTITIES .....117

APPENDIX 3 CHECKLIST FOR ANALYSIS OF ALTERNATIVES .....120

APPENDIX 4 CHECKLIST FOR ANNEX XIV SUBSTANCE FUNCTION .....121

APPENDIX 5 BRIEF EXAMPLE OF POSSIBLE METHOD FOR PROFILING ENVIRONMENTAL RISK .....123

APPENDIX 6 CHECKLIST FOR SUBSTITUTION PLAN .....124

# TABLES

Table 1.Uses exempted from authorisation .....6

Table 2. Procedure following submission of an application.....14

Table 3. Information specified in an authorisation .....19

Table 4. Requirements following granting of an authorisation .....20

Table 5. Summary of key deadlines.....23

Table 6. Basic information that shall be included in an application for an authorisation.....24

Table 7. Other information that may be included in an application for an authorisation .....26

Table 8. Hypothetical examples of summaries of actions needed to address the suitability and availability of possible alternatives.....86

# FIGURES

Figure 1 Simplified description of the identification of substances of very high concern and the authorisation procedure.....3

Figure 2 Simplified description for granting of authorisations.....8

Figure 3 Granting of authorisations part 1 .....9

Figure 4 Granting of authorisations part 2 .....10

Figure 5 Granting of authorisations part 3 .....11

Figure 6 Timeline for granting of an authorisation. See also Table 2. .....12

Figure 7 Application content (based on Art. 60) .....29

Figure 8. Flow diagram for the analysis of alternatives.....45

Figure 9 Flow diagram for the assessment of and comparison to risks of alternatives .....66

Figure 10 Flow diagram for preparing and implementing a substitution plan .....95

Figure 11 Illustration of timeline for substitution plan.....102

# EXAMPLES

Example 1 Considerations for substance function ..... 48

Example 2 Illustration of supply chain communication ..... 53

Example 3 Considerations for technical feasibility ..... 59

## ABBREVIATIONS

| | |
|---|---|
| BREF | Best Available Technology Reference Document (guidance under IPPC directive) |
| CAS | Chemical Abstracts Service |
| CBI | Confidential Business Information |
| CMR | Carcinogenic, Mutagenic or toxic to Reproduction |
| CSA | Chemical Safety Assessment |
| CSR | Chemical Safety Report |
| DNEL | Derived No-Effect Level |
| DU | Downstream User |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| ES | Exposure Scenario |
| GD | Guidance Document under REACH |
| IPPC | Integrated Pollution Prevention and Control (Directive 2008/1/EC) |
| IUCLID | International Uniform Chemical Information Database |
| MS | Member State |
| M/I | Manufacturer/Importer |
| OC | Operational Conditions |
| PBT | Persistent, Bioaccumulative and Toxic |
| PNEC | Predicted No Effect Concentration |
| POP | Persistent Organic Pollutants (Regulation (EC) No 850/2004) |
| QSAR | Quantitative Structure Activity Relationship |
| REACH | Registration, Evaluation, Authorisation and restriction of Chemicals |
| R&D | Research and Development |
| RMM | Risk Management Measure |
| SEA | Socio-Economic Analysis |
| SDS | Safety Data Sheet |
| SIEF | Substance Information Exchange Forum |
| SVHC | Substance of Very High Concern |
| vPvB | Very Persistent and very Bioaccumulative |
| WFD | Water Framework Directive (Directive 2000/60/EC) |

## GLOSSARY OF TERMS

A glossary of technical terms used within this guidance document is provided below. The European Chemicals Agency (ECHA) also has a general glossary of terms relevant to REACH which can be found using the following link: REACH Navigator - Glossary

**Adequate control route (for authorisation):** An authorisation shall be granted if it is demonstrated that the risk to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)}, taking into account Article 60(3).

**Agency**: The European Chemicals Agency (ECHA) as established by the REACH Regulation.

**Annex XIV:** Annex XIV of REACH lists all substances which are subject to authorisation under REACH. The use and placing on the market for a use of substances listed on Annex XIV, either on its own, in a mixture or for incorporating into an article, is prohibited from the "sunset" date unless an authorisation has been granted for that use or unless an exemption applies.

**Annex XIV substance**: The substance listed on Annex XIV that is the subject of the authorisation procedure.

**Annex XV**: Annex XV of the REACH regulation lays down general principles for preparing Annex XV dossiers to propose and justify

(a) harmonised classification and labelling of CMRs, respiratory sensitisers and other effects

(b) the identification of a substance as a CMR, PBT, vPvB or a substance of equivalent concern in accordance with Article 59

(c) restrictions of the manufacture, placing on the market or use of a substance within the Community.

Proposals for restrictions and identification of substances of very high concern can be prepared by a Member State or by the Agency on a request from the Commission. Proposals for harmonised classification and labelling can be prepared by a Member State.

**Annex XV dossier**: A dossier produced in accordance with Annex XV. The dossier consists of two parts, the Annex XV report and the Annex XV technical dossier supporting the Annex XV report.

**Applicant**: The legal entity or group of legal entities submitting the authorisation application.

**Authorisation**: The REACH Regulation sets up a system under which the use of substances with properties of very high concern and their placing on the market can be made subject to an authorisation requirement. Such substances are included in Annex XIV of the Regulation, and may not be placed on the market or used without an authorisation after the sunset date. This authorisation requirement ensures that risks from the use of such substances are either adequately controlled or outweighed by socio-economic benefits. An analysis of alternative substances or technologies will be a fundamental component of the authorisation process.

**Authorisation application**: The documentation submitted to the Agency applying for authorisation in order to (continue to) use of substances included in Annex XIV.

**Authorisation review**: Authorisations granted will be subject to a review period.

**Candidate List**: The candidate list refers to the list of substances of very high concern (SVHC) from which the substances to be included in Annex XIV (list of substances subject to authorisation) are selected. The candidate list is established in accordance with Article 59.

**Carcinogenic, mutagenic or toxic to reproduction (CMR)**: Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1 or 2, in accordance with Directive 67/548/EEC, are substances of very high concern[2]. They may be included in Annex XIV and by that made subject to authorisation requirement. CMRs may be non-threshold (i.e. it is not possible to define a Derived No-Effect Level (DNEL)) or threshold (i.e. it is possible to define a DNEL)

**Chemical Safety Assessment (CSA):** Chemical Safety Assessment is the process aimed at determining the risk posed by a substance and, as part of the exposure assessment, develop exposure scenarios including risk management measures to control the risks. Annex I contains general provisions for performing a CSA. The CSA consists of the following steps:

- Human health hazard assessment
- Human health hazard assessment of physicochemical properties
- Environmental hazard assessment
- PBT and vPvB assessment

If, as a result of this hazard assessment, the registrant concludes that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC (for substances)[3] or has PBT/vPvB properties, this triggers further steps in the chemical safety assessment:

- Exposure assessment
- Risk characterization.

**Chemical Safety Report (CSR**): The chemical safety report documents the chemical safety assessment for a substance on its own, in a mixture or in an article or a group of substances.

---

2 From 1 December 2010, this should read: "Substances meeting the criteria for classification in the hazard classes carcinogenicity, gem cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1212/2008".

3 From 1 December 2010, ths should read: "If, as a result of this hazard assessment, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1,"

In other words the chemical safety report (CSR) is a document, which details the process and the results of a chemical safety assessment (CSA). Annex I of the REACH Regulation contains general provisions for performing CSAs and preparing CSRs.

**Committee for Risk Assessment (RAC):** is an Agency committee that is responsible for preparing the opinion of the Agency on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling under the classification and labelling inventory task and any other questions that arise from the operation of the REACH Regulation relating to risks to human health or the environment. The RAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three years. The Committee members may be accompanied by advisers on scientific, technical or regulatory matters.

**Committee for Socio-economic Analysis (SEAC):** is an Agency committee that is responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the REACH Regulation relating to the socio economic impact of possible legislative action on substances. The SEAC consists of at least one but no more than two members from the nominees of each Member State appointed by the Management Board for a renewable term of three year. The Committee members may be accompanied by advisers on scientific, technical or regulatory matters.

**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 mixture, 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.

**Exposure scenario**: Set of conditions including operational conditions and risk management measures 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. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

**Gross profit** of a substance or a product is the difference between the sales revenue and the variable and fixed costs of producing the product. Fixed and variable costs (also known as “cost of goods sold”) include e.g. materials and labour. Gross Profit = Revenue − variable costs − fixed costs

**Importer**: Any natural or legal person established within the Community who is responsible for import.

**Interested Third Party**: Any organisation, individual, authority or company other than the applicant or the Agency/Commission with a potential interest in submitting information on alternatives for the consideration of the Agency Committees in forming their opinions on the application for authorisation.

**Joint application**: An application for authorisation made by a number of legal entities forming a group of applicants consisting of manufacturer(s) and/or importer(s) and/or downstream user(s) of the Annex XIV substance.

**Latest application date**: Annex XIV (list of substances subject to Authorisation) will specify for each substance included in that Annex a date or dates, at least 18 months before the sunset date(s), by which applications for authorisation must be submitted if the applicant wishes to

continue to use the substance or place it on the market for certain uses after the sunset date(s) until a decision on the application for authorisation is taken.

**Legal entity**: Any natural or legal person established within the Community.

**Manufacturer**: Any natural or legal person established within the Community who manufactures a substance within the Community

**Operational Conditions (OC):** All conditions which have a quantitative impact on exposure, e.g. product specifications, duration and frequency of exposure, applied amount of substance per use or capacity of surroundings (e.g. room size, receiving environmental compartment)

**Persistent, Bioaccumulative and Toxic (PBT):** Annex XIII of the REACH Regulation defines criteria for the identification of substances that are Persistent, Bio-accumulative and Toxic (PBTs) and Annex I lays down general provisions for PBT assessment. PBTs are substances of very high concern (SVHC) and may be included in Annex XIV and by that be made subject to authorisation.

**Regulatory procedure:** procedure for the adoption of implementing legislation that involves a vote by a Committee composed of the representatives of the Member States. The Council and the European Parliament have a role to play in accordance with Article 5 of Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC. Authorisation proposals under REACH will be adopted in accordance with this regulatory procedure.

**Regulatory procedure with scrutiny**: procedure for the adoption of implementing legislation that involves a vote by a Committee composed of the representatives of the Member States and foresees a role for the Council and the European Parliament in accordance with Article 5a of Council Decision 1999/468/EC as amended by Council Decision 2006/512/EC. Decisions on the inclusion of substances in Annex XIV will be taken in accordance with the regulatory procedure with scrutiny.

**Review report:** In order to continue placing on the market or using a substance, the holder of the authorisation must submit a review report at least 18 months before the expiry date of the time-limited review period.

**Risk Management Measures (RMM):** Measures in the control strategy for a substance that reduce the emission and exposure to a substance, thereby reducing the risk to human health or the environment.

**Socio-economic analysis (SEA):** The socio-economic analysis (SEA) is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented. Although according to Article 62(5) the inclusion of a SEA is optional it should be included as part of an application for authorisation whenever the risks to human health or the environment from the use of an Annex XIV substance are not adequately controlled. Also when adequate control can be shown, an SEA may be produced by the applicant in support to his application. An SEA may also be produced by any third party in support to information on alternatives.

**Socio-economic route (for authorisation):** An authorisation may be granted if it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and if there are no suitable alternative substances or technologies {Art. 60(4)}.

**Substance function**: The function of the Annex XIV substance for the use/s being applied for is the task or job that the Annex XIV substance is performing.

**Substances of very high concern (SVHC)**: SVHC in the context of the REACH Regulation are:

1. CMRs category 1 or 2 in accordance with Directive 67/548/EEC[4].

2. PBTs and vPvBs meeting the criteria of Annex XIII and

3. 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 Annex XIII - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points 1 and 2 and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

**Substitution plan**: Is a commitment to take the actions needed to substitute the Annex XIV substance with an alternative substance or technology within a specified timetable.

**Sunset date**: Annex XIV (list of substances subject to Authorisation) will specify for each substance included in that Annex the date (called 'the sunset date") from which the placing on the market and the use of that substance shall be prohibited. That is unless an exemption applies or an authorisation is granted or an authorisation application has been submitted before the latest application date also specified in Annex XIV, but the Commission decision on the application for authorisation has not yet been taken.

**Supply chain**: Is the system of organisations, people, activities, information and resources involved in moving a substance from (supplier to customer) i.e. manufacture/importers to downstream users and end users.

**Very Persistent and very Bioacccumulative (vPvB):** Substances of very high concern, which are very persistent (very difficult to break down) and very bio-accumulative in living organisms. Annex XIII of the REACH Regulation defines criteria for the identification of vPvBs and Annex I lays down general provisions for their assessment. vPvBs may be included in Annex XIV and by that be made subject to authorisation.

[4] As from 1 December 2010 this should read: "substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1272/2008"

# 1. GENERAL INTRODUCTION AND OVERVIEW OF THE AUTHORISATION PROCESS

## 1.1. About this guidance

This document provides technical guidance on how to apply for an authorisation for the use of substances included in Annex XIV 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). In particular it includes guidance on the mixture of an analysis of alternatives, a substitution plan and how interested third parties can contribute to the authorisation process.

## 1.2. Structure of the guidance

The introductory sections (Chapter 1) contain a general overview of the authorisation process, including links to other REACH guidance. Chapter 2 provides more detailed guidance how to put together an application for an authorisation, and on the specific information and considerations needed for an application. Chapter 3 considers what is needed when carrying out an analysis of alternatives; Chapter 4 describes the production of a substitution plan; and Chapter 5 deals with the submission of information by third parties.

## 1.3. Who is the guidance for?

This guidance is primarily intended for use by manufacturers, importers and downstream users placing on the market or using a substance included in Annex XIV of REACH (List of substances subject to authorisation). The guidance is also intended to be used by third parties that may have information on alternative substances or alternative technologies in relation to a substance included in Annex XIV. In general, the user is assumed to have suitable experience for the part of the guidance they are using.

The guidance may also be useful for those within the Member State Competent Authorities and the Agency involved in the authorisation 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 relevant for preparing an authorisation application. The intention of this guidance is not to repeat guidance that is available elsewhere, and the relevant sources of further guidance are referenced as appropriate. The most relevant other parts of the REACH guidance are as follows.

- **Guidance on information requirements and chemical safety assessment (CSA).** This provides further guidance on carrying out a Chemical Safety Assessment and documenting it in a Chemical Safety Report. This guidance also includes advice, for instance, on identification/description of uses and on grouping of substances.

- **Guidance on data sharing**. This provides guidance on data sharing mechanisms under REACH, and includes the communication within SIEF and cost sharing guidance.
- **Guidance for Downstream Users**. This provides further guidance on the obligations of downstream users in relation to substances listed in Annex XIV.
- **Guidance on Socio Economic Analysis – Authorisation**. This provides detailed guidance for carrying out a socio-economic analysis.

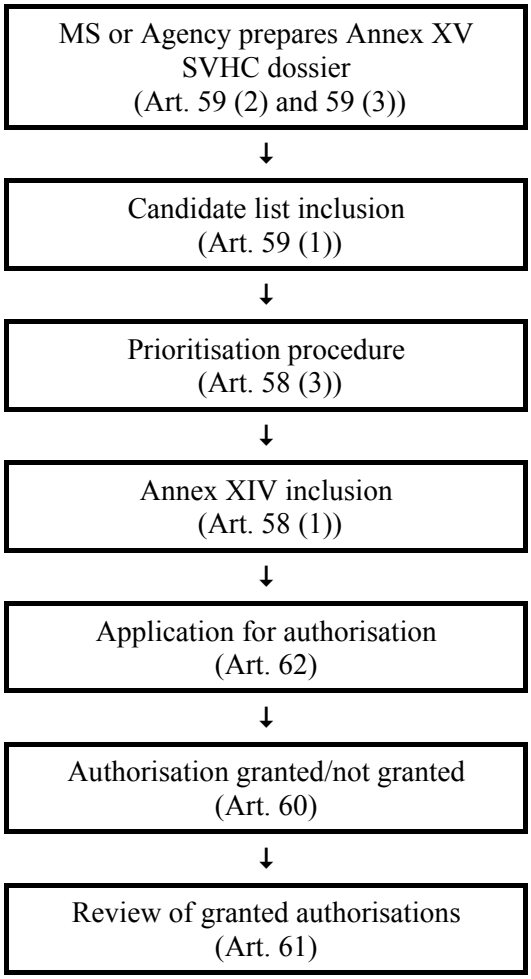
In addition, separate guidance documents are available for authorities concerning the identification of substances of very high concern, priority setting and the inclusion of a substance on Annex XIV, and so these stages of the overall process are not considered in detail in this guidance. However it is essential for a potential applicant for an authorisation and other interested third parties to understand the process that leads to inclusion of a substance on Annex XIV, as there are a number of formal opportunities for commenting and submitting information prior to the substance being included on Annex XIV. Early involvement of potential applicants and interested third parties in the process is encouraged in order to improve the quality of decision making. Therefore a brief overview of the overall authorisation process is given here. The guidance documents on identification of substances of very high concern and inclusion of a substance on Annex XIV should be consulted for more details on the authorisation procedure concerning inclusion of a substance on Annex XIV.

### 1.5. General overview of the authorisation procedure

*The aim of this Title* (VII, authorisation) *is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern 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 authorisation shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution* {Art. 55}.

Authorisations apply to substances of very high concern (SVHC) that are included in Annex XIV of REACH. There is no tonnage limit for the authorisation requirement. The overall authorisation process involves several steps including identification of substances of very high concern, prioritisation of these substances for inclusion in Annex XIV, the listing of these substances on Annex XIV, application for authorisations, granting or refusing of authorisations and reviewing of granted authorisations. A simplified description of the overall process is shown in Figure 1. The process up to inclusion of the substances on Annex XIV is described in detail in the Guidance on inclusion of substances in Annex XIV, but some background is included in Sections 1.5.1 and 1.5.2 of this guidance. The rest of this guidance relates to the steps following inclusion on Annex XIV.

**Figure 1 Simplified description of the identification of substances of very high concern and the authorisation procedure**




### *1.5.1. How substances get included in Annex XIV*

The process is started by a Member State or, on request from the Commission, by the Agency, when they produce Annex XV dossiers for identification of substances of very high concern in accordance with the procedure laid down in Article 59. Only substances with the following properties can be included in Annex XIV and therefore, be subject to authorisation {Art. 57}.

a) *Substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Council Directive 67/548/EEC.* [5]

b) *Substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Council Directive 67/548/EEC.*

[5] The references to Directive 67/548/EEC will be replaced from 1 December 2010 by references to Regulation 1272/2008 (CLP Regulation).

c) *Substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Council Directive 67/548/EEC.*

d) *Substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of the Regulation.*

e) *Substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of the Regulation.*

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 human health 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.*

The Annex XV dossier should outline the scientific evidence for identifying the substance as a substance of very high concern and candidate for eventual inclusion on Annex XIV. Direction on preparing an Annex XV SVHC dossier is included in the Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern. Comments on the Annex XV dossier are invited from the Member States, the Agency and interested parties (stakeholders), in the latter case via a notice published on the Agency's website with a deadline set by the Agency {Art. 59(4)}. These notices include, e.g., information from the Annex XV dossiers on substance identity (name, EC and/or CAS numbers), the reason why the substance is believed to meet one or more of the criteria set out in Article 57 and the deadline for comments. Guidance on how to submit comments is provided in the Guidance on inclusion of substances in Annex XIV.

Once an agreement has been reached that the substance meets one or more of the intrinsic properties outlined in Article 57 (see above), the substance will be placed on the candidate list. The main implication of placing a substance on the candidate list is that it then becomes eligible for eventual inclusion in Annex XIV. The Agency, taking into account the opinion of the Member State Committee, recommends priority substances to be included on Annex XIV. Priority will normally be given to substances with PBT or vPvB properties, or wide dispersive uses, or high volumes {Art. 58(3)}.The Agency will submit a recommendation for substances to be included in Annex XIV to the Commission at least every second year {Art. 58(3)}.

Before the Agency sends a new recommendation to the Commission, the recommendation is made public via the Agency's website, and all interested parties are invited to submit comments within three months of the date of publication. In particular, comments on uses which should be exempted from the authorisation requirement are requested. The recommendation may then be updated to take account of the comments received {Art. 58(4)}. For consultation purposes, a template for provision of comments is made available on the Agency's website. Guidance on how to submit comments is provided in the Guidance on inclusion of substances in Annex XIV. The Commission takes the decision on the inclusion of substances in Annex XIV in accordance with the Regulatory procedure with scrutiny referred to in Article 133(4) {Art. 58(1)}.

### *1.5.2. Annex XIV entries*

The Annex XIV entry for each substance will specify the following {Art. 58(1)}.

- *The identity of the substance as specified in Section 2 of Annex VI;*

- *the intrinsic property (or properties) of the substance referred to in Article 57* (i.e. properties leading to the inclusion in Annex XIV);
- *transitional arrangements:*
    - *the date(s) from which placing on the market and use of the substance is prohibited unless an authorisation is granted (hereafter referred to as the sunset date) which should take into account, where relevant, the production cycle specified for that use;*
    - *a date or dates, at least 18 months before the sunset date(s) by which applications for authorisation must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;*
- *review periods for certain uses if appropriate;*
- *uses or categories of uses that are exempted from the authorisation process, if any, and conditions for such exemptions, if any.*

After the sunset date, substances that are included in Annex XIV cannot be used by a manufacturer, importer or a downstream user, or be placed on the market by a manufacturer, importer or a downstream user for a use unless an authorisation has been granted for that use (or where an application for an authorisation has been submitted to the Agency before the deadline specified in Annex XIV but no decision has yet been reached) or the use is exempt from authorisation. The process for setting sunset dates takes into account, where appropriate, the production cycle specified for the use under consideration. Therefore it is important for the potential applicant(s) to be involved at an early stage in the process and provide information that is relevant for setting sunset dates. The Guidance on inclusion of substances in Annex XIV should be consulted for further details of the process for setting sunset dates.

Certain uses of substances are exempted from the authorisation process. These general exemptions are listed in Table 1.. In addition, the Annex XIV entry may include substance specific exemptions for uses or categories of uses, along with any conditions that apply to such exemptions. Such exemptions may be included provided that, on the basis of 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 Guidance on inclusion of substances in Annex XIV gives further examples of existing specific Community legislation that could be considered in this respect. The ultimate responsibility for deciding on which uses should be exempted lies with the Commission in accordance with the Regulatory procedure with scrutiny. In establishing 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.

**Table 1.Uses exempted from authorisation**

| |
|---|
| On-site isolated intermediates and transported isolated intermediates {Art. 2(8b)}. |
| Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2(5a)}. |
| Use in food or feedingstuffs according to Regulation (EC) No 178/2002 including use as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC, as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC or on foodstuffs drawn up in application of Regulation (EC) No 2232/96, as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 and in animal nutrition within the scope of Council Directive 82/471/EEC {Art. 2(5b)}. |
| Use in scientific research and development {Art. 56(3)} (Annex XIV shall specify if the authorisation requirement applies to product and process research and development) {Art. 56(3}. |
| Use on plant protection products within the scope of Council Directive 91/414/EEC {Art. 56(4a)}. |
| Use in biocidal products within the scope of Directive 98/8/EC {Art. 56(4b)}. |
| Use as motor fuels covered by Directive 98/70/EC {Art. 56(4c)}. |
| Use as fuel in mobile or fixed combustion plants of mineral oil products and use of fuels in closed systems {Art. 56(4d)}. |
| Use in cosmetic products within the scope of Council Directive 76/768/EEC (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5a)}. |
| Use in food contact materials within the scope of Regulation (EC) No 1935/2004 (this exemption applies to substances listed on Annex XIV on the basis of their hazard to human health only) {Art. 56(5b)}. |
| Use of substances when present in mixtures below a concentration limit of 0.1% by weight. This applies only to substances listed in Annex XIV on the basis of being persistent, bioaccumulative and toxic (PBT) as defined by Art. 57(d), very persistent and very bioaccumulative (vPvB) as defined by Art. 57(e), or listed in Annex XIV on the basis that there is scientific evidence of probable serious effects to human health or the environment which give an equivalent level of concern to substances with PBT or vPvB properties, or an equivalent level of concern to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 and 2 in accordance with Directive 67/548/EEC, as defined by Art. 57(f) {Art. 56(6a)}. |
| Use of substances when present in mixtures below the lowest concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which results in the classification of the mixture as dangerous. This applies only to substance listed in Annex XIV on the basis of their classification as CMR category 1 and 2 in accordance with Directive 67/548/EEC{Art. 56(6b)}. |

As noted in Section 1.5.1, there are two opportunities for formal comments from interested parties prior to the substance being included in Annex XIV, firstly a commenting period on the non-confidential content of the Annex XV dossier itself {Art. 59(4)} and secondly a commenting period on the recommendations for inclusion of the substance in Annex XIV {Art. 58(4)}. This second commenting period in particular, allows comments on uses that have been proposed by the Agency for exemption and further uses that should be exempted from the authorisation requirement, and information on the production cycle, to be put forward. Guidance on submitting information at these points in the process can be found in Guidance on inclusion of substances in Annex XIV.

If new information becomes available to show that the substance no longer meets the criteria of Article 57 then the substance shall be removed from Annex XIV {Art. 58(8)}. In addition, substances for which all uses are prohibited, either by the restrictions procedure under Title VIII of the regulation or by other Community legislation, shall not be included in Annex XIV or shall be removed from it (Art. 58(7)).

### *1.5.3. Application for an authorisation*

This section outlines the general requirements for an application. More detailed guidance on how to put together an application is given in Section 2. A simplified description of the process following listing of a substance on Annex XIV is shown in Figure 2. The detailed process is presented in Figure 3,

Figure 4 and Figure 5. Figure 6 outlines the time line for applications for authorisation. Further details of the timetable are included in Table 2.

**Figure 2 Simplified description for granting of authorisations**

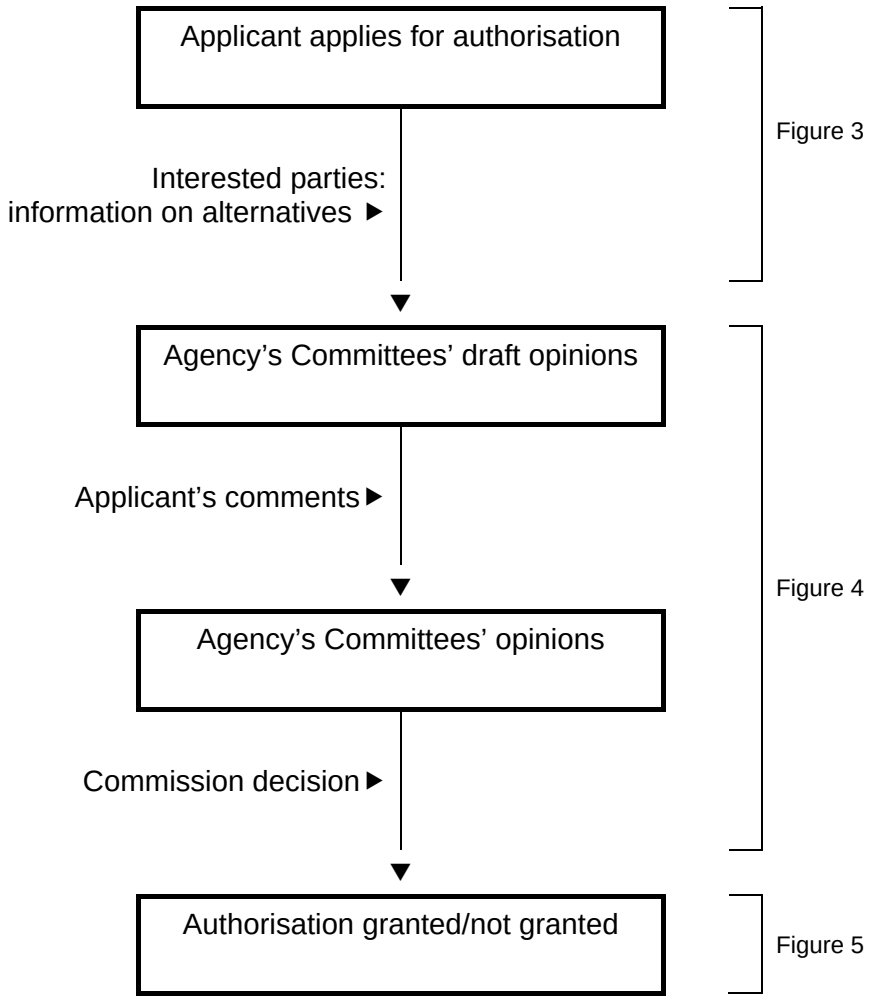


**Figure 3 Granting of authorisations part 1**

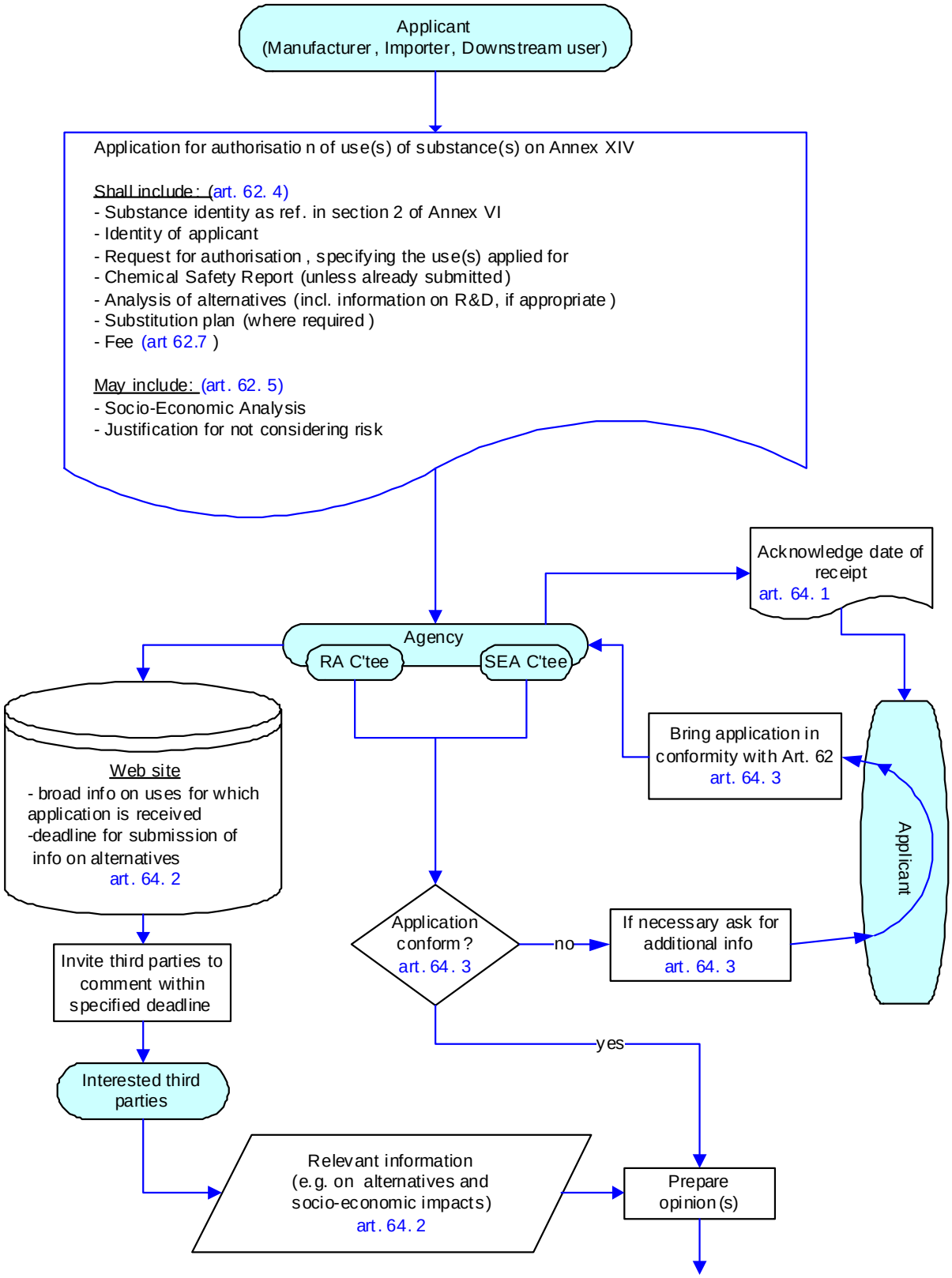


**Figure 4 Granting of authorisations part 2**

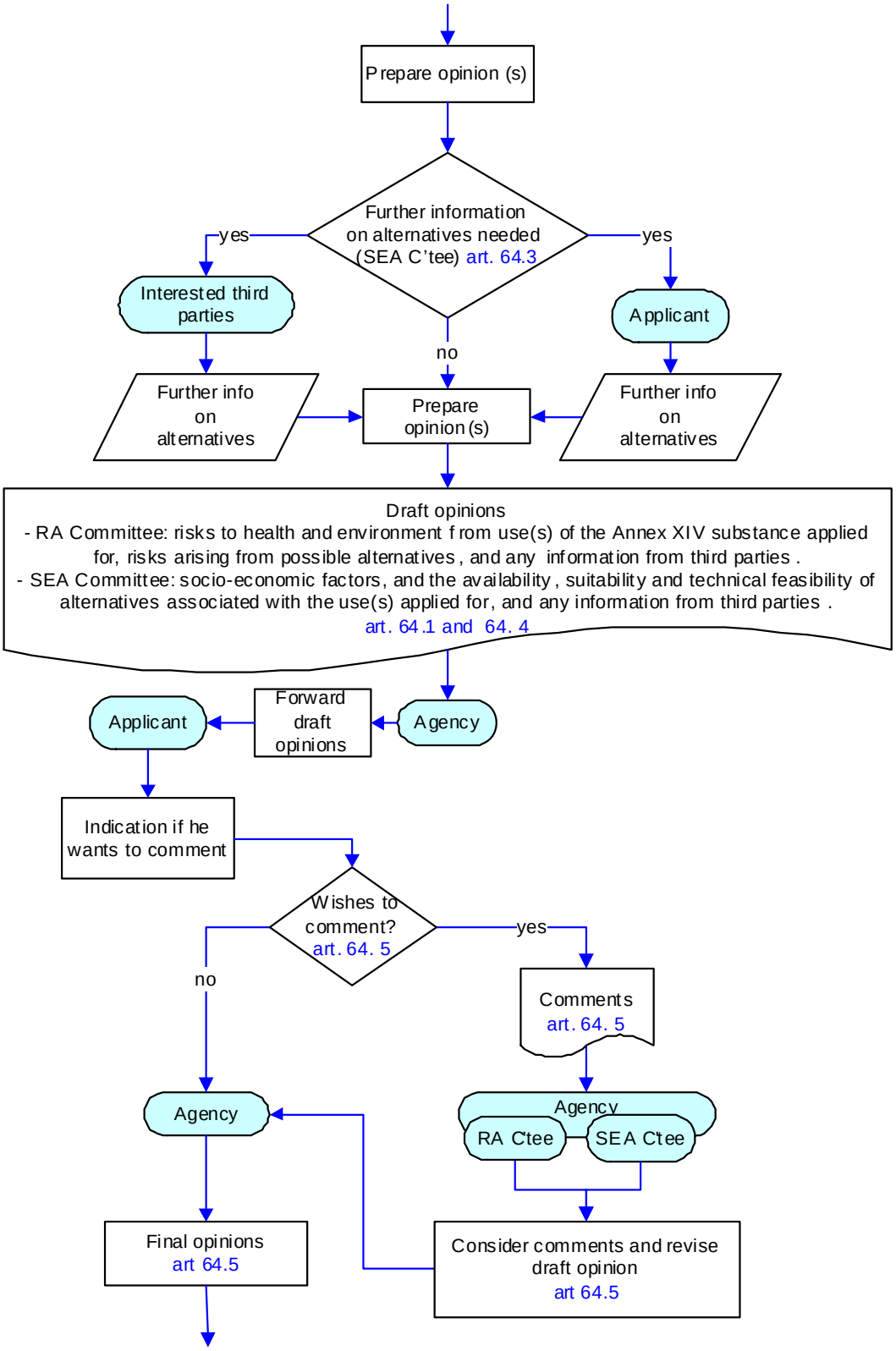


**Figure 5 Granting of authorisations part 3**

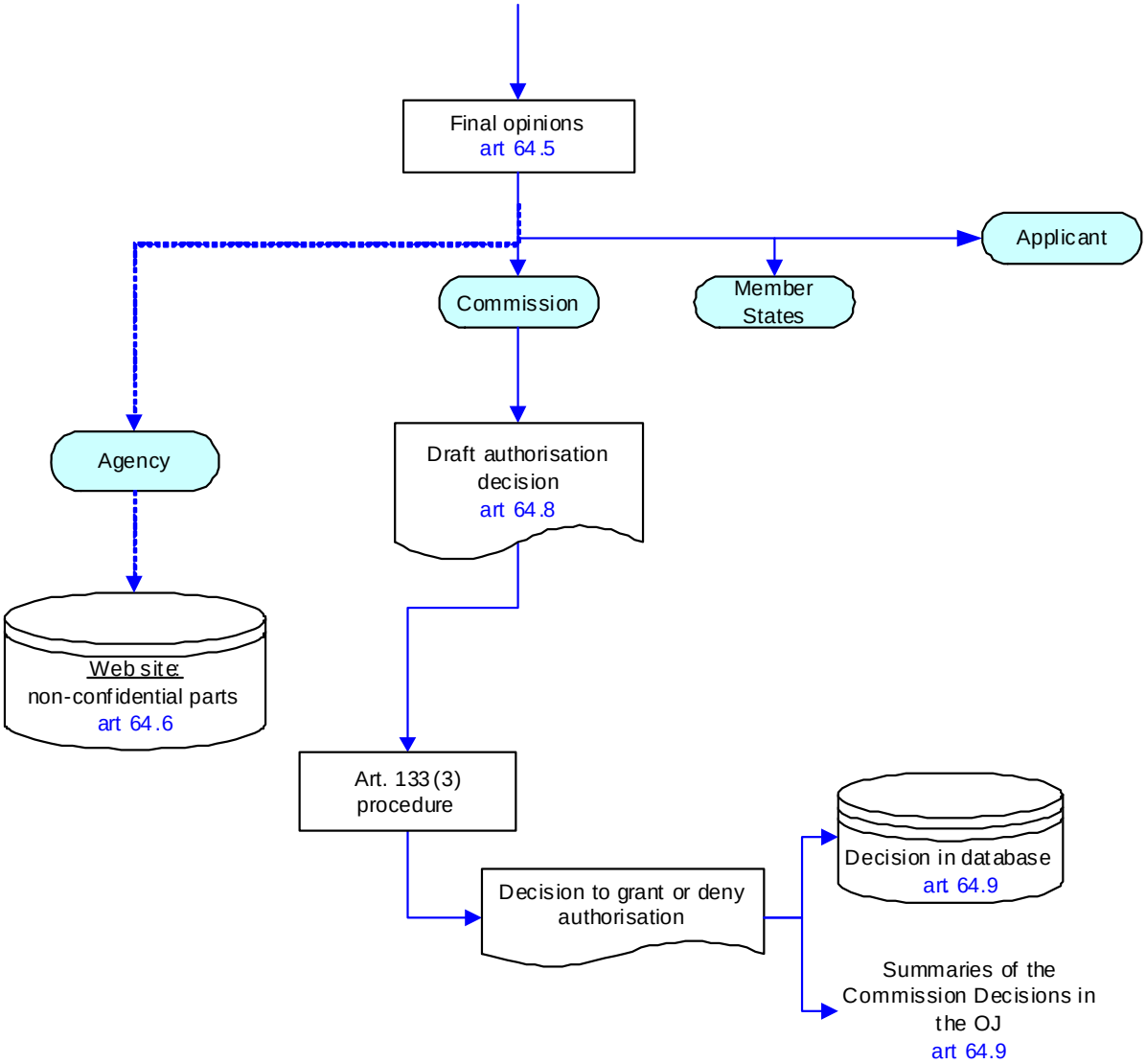
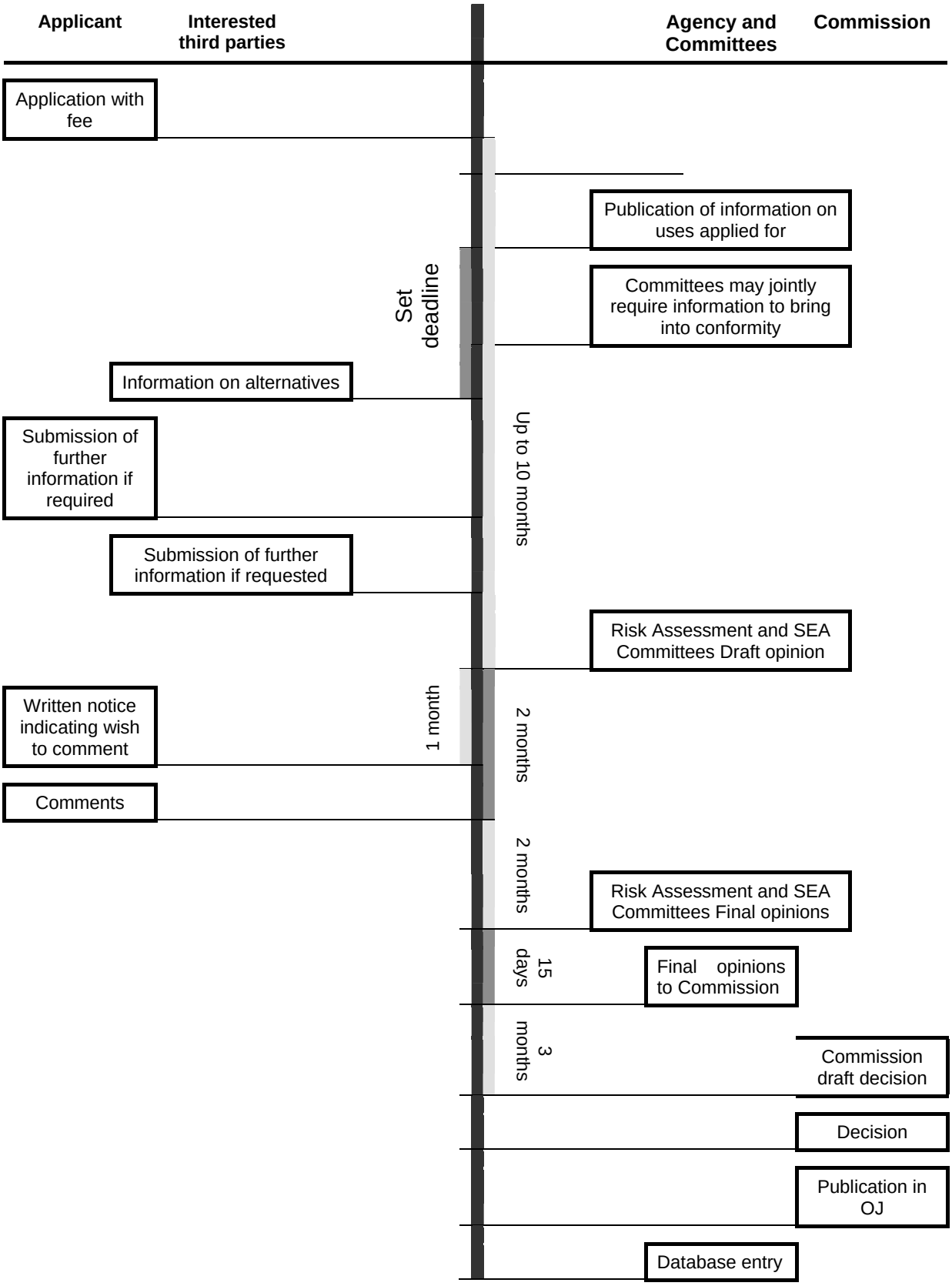


**Figure 6 Timeline for granting of an authorisation. See also Table 2.**



Applications for authorisations must conform to the requirements of Article 62 of the Regulation. These requirements are outlined below.

The applications for authorisation are made to the Agency {Art. 62(1)}. Applications can be submitted by the manufacturer(s), importer(s) and/or downstream user(s) of the substances, and one or several of these {Art. 62(2)} can make an application for authorisation for the same substance covering one or more uses {Art. 62(3)}. The uses applied for can be the applicant's own use(s) and/or uses for which the applicant intends to place the substance on the market. If an actor applies for an authorisation for a use(s) of his downstream user(s), he needs to cover all uses in the supply chain that are necessary to enable that use(s). For example, if a manufacturer or importer applies for a use of his downstream user, but there is a formulator in between him and the DU, his application has also to cover the use of the substance in formulation.

Applications can also be made for a group of substances for one or more uses {Art. 62(3)}. Grouping of substances can be made on the basis of similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity (Annex XI 1.5).

Each application should be accompanied with the fee required in accordance with Title IX {Art. 62(7)} and Commission Regulation N° EC 340/2008 on the fees and charges payable to the European Chemicals Agency (Annex VI and VII).

The information that must be included in an application for an authorisation is as follows {Art. 62(4)}:

*(a) the identity of the substance(s), as referred to in Section 2 of Annex VI;*

*(b) the name and contact details of the person or persons making the application.*

*(c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant;*

*(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;*

*(e) an analysis of alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant.*

*(f) where the analysis referred to in point (e) above shows that suitable alternatives are available, taking into accounts the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.*

The application may also include {Art. 62(5)}:

*(a) a socio-economic analysis conducted in accordance with Annex XVI;*

*(b) a justification for not considering risks to human health and the environment arising either from:*

*(i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or*

(ii) *discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.*

Article 60(7) provides that an authorisation shall be granted only if the application has been made in conformity with the requirements set out in Article 62. Since the authorisation procedure is legally subject to a time frame (provided in Article 64), it is important that the application is in conformity with these requirements at the submission stage.

Where an application for authorisation has already been made, or where an authorisation has already been granted for a use of a substance, a subsequent applicant may refer to the appropriate parts of the previous application provided that they have permission from the previous applicant. The parts of the previous application that can be referred to include the following aspects {Art. 63(1),(2)}:

- Chemical Safety Report(s),
- analysis of alternatives,
- substitution plan, and
- socio-economic analysis.

In this case the subsequent applicant shall update the information in the original application as necessary {Art. 63(3)}. Other information needed for the application shall be provided by the subsequent applicant. In cases where an application for the same substance has already been made, the Agency shall treat the applications together provided the deadlines outlined in Section 1.5.4 can be met for the first application {Art. 64(7)}.

The deadline for submission of an application for authorisation will be specified in the Annex XIV entry. Manufacturers, importers, or downstream users of a substance that is listed in Annex XIV are entitled to submit an application to the Agency after that date, but cannot place the substance on the market, or use it themselves, until they have obtained the authorisation.

### *1.5.4. What happens after an application for an authorisation has been submitted*

An overview of the processes that should be followed after submission of an application for an authorisation is outlined in Table 2.

**Table 2. Procedure following submission of an application**

| Step | Organisation responsible | Timeframe |
|---|---|---|
| Check appropriate fee paid. | Agency | |
| Acknowledgement of date of receipt of application {Art. 64(1)}. | Agency | |
| Broad (non-confidential) information on uses for which applications have been received is made available via the Agency's web-site, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties. | Agency | Deadline for information on alternative substances or technologies will be set by the Agency, within the 10 month window for the Agency's Committees draft opinions. |

| Step | | Organisation responsible | Timeframe |
|---|---|---|---|
| Check to ensure all information specified in Article 62 of the Regulation is included in the application. If necessary request further information from the applicant to bring the application into conformity {Art. 64(3)}. | | Agency's Committees for Risk Assessment and Socio-economic analysis | Deadline for further information will be set by the Agency's Committees within the 10 month window as above. |
| If it is considered necessary, require further information from the applicant or request further information from third parties on possible alternative substances or technologies {Art. 64(3)}. | | Agency's Committee for Socio-economic analysis | Deadline for further information will be set by the Agency's Committee within the 10 month window as above. |
| Draft opinions on the application are sent to the applicant {Art. 64(1, 5 and 10)}. | | Agency's Committees for Risk Assessment and Socio-economic analysis | Within ten months of the date of receipt of the application. If the application is for a use of a substance for which an authorisation has already been granted, this will be reduced to five months. |
| If the applicant wishes to comment on the draft opinion{Art. 64(5)}. | Written notice of the intention to comment shall be sent to the Agency. | Applicant | Within one month of receipt of the draft opinion. The draft opinion will be deemed to have been received seven days after the Agency has sent it. |
| | Comments/argumentation from applicant. These shall be sent in writing to the Agency. | Applicant | Within two months of receipt of the draft opinion |
| | Finalisation of opinion on the application taking into account the written comments/argumentation from applicant. | Agency's Committees for Risk Assessment and Socio-economic analysis | The final opinion will be adopted within two months of receipt of the written comments/argumentation. The final opinion along with the written comments/ argumentation will be sent to the Commission, Member States and the applicant within a further 15 days. |
| If the applicant does not wish to comment on the draft opinion, the draft opinion is sent to the Commission, the Member States and the applicant {Art. 64(5)}. | | Agency | Within 15 days of the end of the period within which the applicant may comment, or within 15 days of receipt of notice from the applicant that they do not intend to comment. |
| Non-confidential parts of the opinions and any associated documentation made publicly available on the website {Art. 64(6)}. | | Agency | |
| Draft authorisation decision {Art. 64(8)}. | | Commission | Within three months of receipt of the opinion from the Agency. |
| Final decision granting or refusing authorisation {Art. 64(8)}. | | Commission in accordance with comitology procedure in Article 133(3) | |
| Summaries of the Commission decisions, including the authorisation number and the reason for the decision, published in the Official Journal of the European Union, and made publicly available in the Agency database {Art. 64(9)}. | | Commission | |

Opinions on the applications will be drafted by the Committee for Risk Assessment and the Committee for Socio-economic analysis as appropriate. The Committees will take into account the information submitted in the application, any information submitted by third parties and any other

relevant information available to the Committees. The draft opinions will be given within ten months of the date of receipt of the application and will contain the following elements {Art. 64(4)}.

*Committee for Risk Assessment*

- *An assessment of the risk to human health and/or the environment from the use(s) of the substance including the appropriateness and effectiveness of the risk management measures as described in the application.*
- *If relevant, an assessment of the risks arising from possible alternatives.*

*Committee for Socio-economic Analysis*

- *An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when the application is made in accordance with Article 62.*
- *Any third party contributions submitted under Article 64 (2).*

Once the draft opinions of the Committees are available there will be an opportunity for the applicant to comment on the opinions before the opinions are finalised and sent to the Commission, Member States and the applicant. If the draft opinion is to grant an authorisation, the applicant may wish to comment on the proposed conditions, the length of the time-limited review period or monitoring arrangements. If the draft opinion is to reject the application, then the applicant will need to look at the reasons given for rejecting the application. They will have to consider whether further information or argumentation can be provided, to give further support to the application and to argue against the reasons given for the rejection. This will need to be clearly focussed on the specific reasons given.

If the applicant wishes to comment on the draft {Art 64 (5)}, written notice of the intention to comment shall be sent to the Agency within one month of receipt of the draft opinion. The actual comments/argumentation should be sent to the Agency within two months of receipt of the draft opinion. Within two months of the receipt of the applicant's comments or 15 days if the applicant does not wish to comment, the Committees will adopt their final opinion on the application taking into account the written argumentation from the applicant. The opinion will be sent to the Commission, which will, in accordance with the comitology procedure, decide whether or not to grant the authorisation. A summary of the decision will then be published in the Official Journal and made publicly available in the Agency database.

### *1.5.5. Factors that are taken into account in granting or refusing an authorisation*

In order to decide whether or not to proceed with an application for an authorisation, it is important to understand the factors that will be taken into account in granting an authorisation. This is elaborated further later in the guidance (Section 2). The responsibility for granting an authorisation lies with the Commission {Art. 60(1)}.

Authorisations can be granted on two bases.

a. An authorisation shall be granted if it is demonstrated that the risk to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)}

and taking into account Article 60(3). In this guidance this is referred to as the adequate control route.

b. Otherwise, an authorisation may only be granted if it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and if there are no suitable alternative substances or technologies {Art. 60(4)}. In this guidance this is referred to as the SEA route. This is the only possible basis to get an authorisation in the following cases.
    - Where adequate control of the use of a substance according to a) cannot be shown.
    - For substances included in Annex XIV on the basis of meeting any of the following criteria and for which it is not possible to determine a threshold in accordance with section 6.4 of Annex 1:
        - classification as carcinogenic category 1 or 2 in accordance with Council Directive 67/548/EEC[6],
        - classification as mutagenic category 1 or 2 in accordance with Council Directive 67/548/EEC[7],
        - classification as toxic for reproduction category 1 or 2 in accordance with Council Directive 67/548/EEC[8],
        - substances identified under Art. 57(f) with the exception of substances having PBT or vPvB properties (see below).
    - For substances included in Annex XIV on the basis of meeting the criteria in Annex XIII for persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances.
    - For substances included in Annex XIV on the basis of having PBT or vPvB properties giving rise to an equivalent level of concern (identified under Art. 57(f)).

For substances to be authorised through the adequate control route the Commission's decision will be taken based on the evidence presented in the Chemical Safety Report (CSR), taking into account the opinion of the Committee for Risk Assessment. Guidance for this process is available elsewhere (Guidance on information requirements and CSA).

---

[6] From 1 December 2010, it should read:

- substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008

[7] From 1 December 2010, it should read:

- substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/20082

[8] From 1 December 2010, it should read:

- substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008

In granting the authorisation and setting any conditions the Commission will take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision. The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC {Art. 60(2)}.For substances to be authorised through the SEA route, in cases where adequate control cannot be demonstrated or Article 60(3) applies, the Commission's decision will take into account the opinions of both the Committee for Risk Assessment and the Committee for Socio-economic Analysis and the following {Art. 60(4a to d)}.

- *The risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed.*
- *The socio-economic benefits arising from the use of the substance, and the socio-economic implications of a refusal to authorise the substance as demonstrated by the applicant or other interested parties.*
- *The analysis of the alternatives submitted by the applicant under Article 62 (4e) or any substitution plan submitted by the applicant under Article 62 (4f) and any third party contributions submitted under Article 64 (2).*
- *Available information on the risks to human health or the environment from any alternative substances or technologies.*

Planning for substitution: One of the fundamental aims of authorisation is the progressive replacement of the substances listed in Annex XIV by suitable alternative substances or techniques which are economically and technically viable. To this end, the applicant's planned activities with a view to switching to economically and technically feasible alternatives is a crucial factor in the decision to grant an authorisation. The applicant's planning for substitution is mainly reflected in the following elements of the application:

1. An analysis of alternatives: this is a required element in all applications for authorisation, and provides (together with information eventually supplied by third parties) the basis to assess whether alternative substances or techniques are available.

   When assessing whether suitable alternative substances or technologies are available, the Commission shall take all relevant aspects into account {Art. 60(5)}, including:

   - *whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;*
   - *the technical and economic feasibility of alternatives for the applicant.*

2. A substitution plan: where the analysis of alternatives shows that suitable alternatives are available, taking into account the above mentioned elements in Art. 60(5), the applicant must submit a substitution plan, including a timetable for proposed actions. It is noted that this element will only be required in those cases where an alternative substance or technique is available for the applicant, which by definition is only possible in applications under the adequate control route.

Where a restriction exists for a use of a substance, an authorisation will not be granted if this would result in a relaxation of the existing restriction {Art. 60(6)}.

All authorisations granted will be subject to a time-limited review {Art. 60(8)}. The duration of this review period will be determined on a case-by-case basis. The decision over this review period will

consider all relevant information, including the elements listed in Article 60 (4a to d) as outlined above.

In particular it is noted that the credibility of the substitution plan and the expected time-frame for the replacement of the substance submitted by the applicant under the adequate control route will determine the length of the review period. In cases where no suitable alternatives have been identified by the applicant, the information provided in the analysis of alternatives and the information submitted by third parties under Article 64(2) will be crucial to determine the length of the review period.

Likewise, under the socio-economic route, the length of the review period will be determined by the information on analysis of alternatives as well as on information submitted by third parties. Specifically, applicants should explain as part of the analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technology. This should apply in particular in cases where there is an alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") by the applicant, or another operator in the same market is already or will switch in the near future to alternatives. Having a robust analysis of the alternatives is critical for the application under the socio-economic route to be considered favourably and the absence of a justification as to the existence and suitability of alternatives may lead to a negative decision, particularly if third parties (who may provide information under Art. 64(2)) or other applicants have already switched. Absence of research and development activities should lead to fixing shorter review periods.

The information that will be specified in the authorisation when granted {Art. 60(9)} is summarised in Table 3.

**Table 3. Information specified in an authorisation**

| Information specified |
|---|
| The natural or legal person(s) to whom the authorisation is granted. |
| The identity of the substance(s). |
| The use(s) for which the authorisation is granted. |
| Any conditions under which the authorisation is granted. |
| The time-limited review period. |
| Any monitoring arrangements. |

### *1.5.6. Requirements following granting or refusal of an authorisation*

Once the authorisation number has been published in the Official Journal, the holder of the authorisation is required to include without delay the authorisation number on the label before placing the substance, or a mixture containing the substance, on the market for the authorised use. The same applies to downstream users using an authorisation granted to an actor up his supply chain for that use {Art. 65}.

The Safety Data Sheet shall also be updated without delay following granting (or refusal) of an authorisation {Art. 31(9b)}. If a Safety Data Sheet is not required, the downstream users and/or

distributors shall otherwise be informed of the details of any authorisation granted or denied {Art. 32(1b)}.

In cases where a downstream user uses the substance on the basis of the authorisation granted to his supplier, the downstream user shall notify the Agency within three months of the first supply of the substance {Art. 66(1)}. Such notifications will be kept in a register maintained by the Agency that will be made available to the Competent Authorities of the Member States on request {Art. 66(2)}.

The requirements following granting of an authorisation are summarised in Table 4.

**Table 4. Requirements following granting of an authorisation**

| Requirement | Organisation responsible | Timeframe |
|---|---|---|
| Update the registration to take account of the granted authorisation {Art. 22(2)}. | Holder of authorisation. | Within the deadline specified in the decision. |
| Update the Safety Data Sheet or provide downstream users and/or distributors with details of the authorisation {Art. 31(9b) and Art. 32(1b)}. | Holder of authorisation. | Without delay following publication of the authorisation number in the Official Journal. |
| Inclusion of authorisation number on relevant label for substance and/or mixtures containing the substance {Art. 65}. | Holder of authorisation and downstream users using the substance in accordance with Art. 56 (2). | Without delay following publication of the authorisation number in the Official Journal. |
| Notify the use of a substance on the basis of an authorisation granted to the supplier of the substance {Art. 66(1)}. | Downstream users using the substance in accordance with Art. 56(2). | Within three months of first supply for the Authorised use. |
| Maintenance of a register of downstream users who have made a notification of supply of a substance for an Authorised use {Art. 66(2)}. | Agency. | Continuous. |

In addition to any conditions of use specified in the authorisation, there also is an obligation on the holder of the authorisation to ensure that exposure is reduced to as low a level as is technically and practically possible {Art. 60(10)}.

If an authorisation request is refused, the applicant needs to update the registration taking into account the decision {Art. 22(2)} within the deadline specified in the decision. Article 22(1) sets out the areas of the registration which may need to be updated.

### *1.5.7. Review of authorisations*

As indicated in Section 1.5.5 authorisations granted for certain uses will be subject to a review period. Further details on how these review periods are determined can be found in the Guidance on inclusion of substances in Annex XIV. During such a review the Commission may decide to amend or withdraw the authorisation {Art. 61(3)} if circumstances have changed including situations where suitable alternatives have now been identified. This latter point applies to both routes of

authorisation. In order to continue to benefit from an authorisation the holder must submit a review report at least 18 months before the expiry of the time-limited review period. The review report should cover only those parts of the original application that have now changed and should contain the following elements {Art. 61(1)}.

- Number of current authorisation.
- An update of the analysis of alternatives, including information about any relevant research and development activities by the applicant, if appropriate.
- An update of any substitution plan included in the original application.
- If the update of the analysis of alternatives shows that there is a suitable alternative available, then a substitution plan, including a timetable for proposed actions by the applicant, should be included.
- If the holder cannot demonstrate that the risk is adequately controlled, then an update of the SEA included in the original application is required.
- If the holder can now demonstrate that the risk is adequately controlled, then an update of the CSR is required.
- Updates of any other elements from the original application that have now changed.

In addition to the review period specified in the authorisation, the authorisation can be reviewed by the Commission at any time in light of {Art. 61(2), (4), (5) and (6)}

- a change in circumstance of the original authorisation so as to affect the risk to human health or the environment, or the socio-economic impact, or
- new information on possible substitutes that becomes available, or
- failure to meet an environmental quality standard referred to in the IPPC Directive (Directive 2008/1/EC), or
- failure to meet the environmental objectives referred to in Article 4(1) of the Water Framework Directive (Directive 2000/60/EC) in a river basin relevant to the authorised use, or
- if the use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 on Persistent Organic Pollutants (in this situation the Commission will withdraw the authorisation for that use).

In these cases, the Commission will set a reasonable deadline for the holder(s) of the authorisation to submit further information necessary for the review.

In the review, the Commission will, taking into account the principle of proportionality[9], decide if there is a need to amend the authorisation or withdraw the authorisation, if under the changed circumstances the original authorisation would not have been granted, or if suitable alternatives become available. If suitable alternatives become available to the applicant, then the Commission shall require the holder of the authorisation to present a substitution plan if it was not already done

[9] In accordance with the principle of proportionality, as set out in Article 5 of the Treaty on European Union, the REACH regulation does not go beyond what is necessary in order to achieve its objectives.

as part of the application or update {Art. 61(3)}. In the case of an authorisation under the SEA route, if suitable alternatives become available to the applicant, the Commission will have to withdraw authorisation, taking into account the proportionality principle (Article 60(4) makes the granting of an authorisation under the SEA route conditional upon the non-existence of suitable alternatives). Should suitable alternatives become available on the market but not yet ready for an immediate substitution or has another operator in the same market switched or will switch in the short future to alternatives, the applicants should explain as part of the updated analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technique.

In cases where there is a serious and immediate risk for human health or the environment, the Commission may decide to suspend the authorisation pending the review, taking into account the principle of proportionality {Art. 61(3)}.

At the start of the review process, the Agency will make available via the web-site broad (non-confidential) information on uses covered by the application, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties {Art. 64(2)}.

### 1.6. Summary of important deadlines for applicants and interested third parties in the authorisation process

The key deadlines for applicants and interested third parties in the authorisation process are summarised in Table 5. The various deadlines in the process for any given substance up to granting of the authorisation will be made available via the Agency's website.

**Table 5. Summary of key deadlines**

| Task | Deadline | Stakeholders |
|---|---|---|
| Comment on Annex XV dossier proposing identification of SVHC. | To be set by the Agency, within 60 days of circulation of dossier to Member States. | (potential) Applicant.<br>Interested third parties. |
| Comment on recommendation for inclusion in Annex XIV (Substances subject to authorisation). | Within three months of the date of publication. | (potential) Applicant.<br>Interested third parties. |
| Submission of application for an authorisation. | To be set by the Agency (a minimum of 18 months prior to the sunset date). | Applicant. |
| Submission of information on alternative substances or technologies and socio-economic impacts. | To be set by the Agency. | Interested third parties. |
| Notify Agency of intention to comment on the draft opinion of the Agency's Committees for Risk Assessment and Socio-economic analysis. | Within one month of receipt of the draft opinion. | Applicant. |
| Comment on draft opinion of the Agency's Committees for Risk Assessment and Socio-economic analysis. | Within two months of receipt of the draft opinion. | Applicant. |
| Update the Safety Data Sheet or provide downstream users and/or distributors otherwise with details of the authorisation. | Without delay following granting of an authorisation. | Holder of authorisation. |
| Include the authorisation number on relevant label for substance and/or mixtures containing the substance. | Without delay following publication in the Official Journal. | Holder of authorisation and downstream users using the substance in accordance with Art. 56(2). |
| Notify the use of a substance on the basis of an authorisation granted to a supplier. | Within three months of first supply. | Downstream users using the substance in accordance with Art. 56(2). |

It should also be taken into account that the time needed to put together an authorisation application could be considerable. The Guidance on inclusion of substances in Annex XIV estimates that around 12 months may be needed to prepare a new application, but this could be as long as 24 months for applicants with less experience of the process. The time needed to prepare a review report is estimated at between 6 and 12 months. However, it should be noted that these estimates are made on the basis of other procedures under other legislation and need to be revisited when there is practical experience from the authorisation procedure.

# 2. HOW TO MAKE AN APPLICATION FOR AN AUTHORISATION

## 2.1. Introduction

Authorisation is required for placing on the market and use(s) of a substance listed in Annex XIV after the sunset date. Applications for authorisation can be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance, covering one or more uses and/or one substance or a group of substances. In addition applications can be made by separate legal entities or group of legal entities.

This Chapter provides detailed guidance on how to put together an application for an authorisation, and on the specific information and considerations needed for the application.

### *2.1.1. Main elements of an application for authorisation*

As described in Section 1.5.3, Article 62(4) and (5) define the content of an application. Tables 6 and 7 provide a brief description of the content of the application, and also indicate where guidance on each item can be found.

**Table 6. Basic information that shall be included in an application for an authorisation**

| Information | | Guidance that is available |
|---|---|---|
| Identity of substance or substances covered by the application. | Specifying:<br>• reference to Annex XIV entry<br>• other information based on Section 2 of Annex VI of the Regulation which can be deemed sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear to be scientifically justified to give information on one or more of the items, the reasons shall be stated. | Guidance on substance identification.<br>Guidance on registration. |
| Name and contact details of the person or persons making the application. | | |
| Request for authorisation(s) for specific use(s) | Specifying,<br>• the use(s) for which authorisation is sought<br>• covering the use(s) of the substance(s) on its own, in mixtures and/or the incorporation of the substance(s) in articles, where this is relevant. | This guidance<br>Guidance on information requirements and CSA, Chapter R.12: Use descriptor system |
| Chemical Safety Report(s) (CSR(s)) | This is required if it has not already been submitted as part of a registration (although in some cases it may be necessary to update the existing CSR(s) so as to provide more detailed | Guidance on information requirements and CSA. |

| Information | | Guidance that is available |
|---|---|---|
| | information).<br><br>The CSR(s) shall cover all uses applied for. It shall cover the risks to human health and/or the environment from the use(s) of the substance(s) arising from the intrinsic properties of the substance(s) specified in Annex XIV of the Regulation. | |
| An analysis of the alternatives | The analysis of alternative substances and techniques shall cover all uses applied for and should consider:<br><br>• the risks from the alternatives,<br><br>• the technical and economic feasibility of substitution,<br><br>• if appropriate, information on any relevant research and development activities by the applicant, and<br><br>• if there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") or another operator in the same market has already or will switch in the short future to alternatives, the applicants should explain as part of analysis of the alternatives the actions that would be required, as well as the time-lines, to switch to an alternative substance/technique. | This guidance. |
| Substitution plan | Where the analysis of alternatives shows that suitable alternatives are available for specific use(s), taking into account elements in Article 60(5), the applicant shall also include a substitution plan, including a timetable for proposed actions. | This guidance. |

**Table 7. Other information that may be included in an application for an authorisation**

| Information | | Guidance that is available |
|---|---|---|
| A socio-economic analysis (SEA). | This is needed in cases where the applicant cannot show adequate control of risks in accordance with section 6.4 of Annex I (taking into account article 60(3)) and the authorisation is applied for on the basis that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and there are no suitable alternatives. | Guidance on Socio-Economic Analysis – Authorisation. |
| A justification for not considering the risks to human health or environment. | This is applicable to the following situations.<br>• Emissions of a substance from an installation for which a permit has been granted in accordance with the IPPC Directive (Council Directive 2008/1/EC).<br>• Discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive. | This guidance. |

### *2.1.2. Application content*

As stated in section 1.5.5, an authorisation can be granted on the basis of two different lines of argumentation, i.e., adequate control or socio-economic reasons. Therefore, this guidance refers to two routes:

- the adequate control route {Art. 60(2)}; or
- the socio-economic (SEA) route {Art. 60(4)}.

#### 2.1.2.1. Adequate control route

The 'adequate control route' applies when it can be demonstrated that the risk to human health or the environment from the use of the substance is adequately controlled in accordance with section 6.4 of Annex I {Art. 60(2)}.

If the application is based on the adequate control of risks, it must include:

- a CSR (if not already submitted as part of the registration);
- an analysis of alternatives; and
- where the analysis of alternatives shows that suitable alternatives are available, taking into account elements in Article 60(5), a substitution plan.

The basis for demonstrating adequate control of risk arising from the intrinsic properties of the substance specified in Annex XIV is a chemical safety assessment (CSA) which is recorded in a

CSR. The Guidance on information requirements and CSA provides direction on carrying out the assessment.

The evidence whether suitable alternatives are available is presented in an analysis of alternatives. The analysis must take into account the reduction in overall risks and technical and economic feasibility of the alternatives for the applicant. It must be noted that having a robust analysis of alternatives is critical for the application to be considered favourably and that absence of appropriate justification as to the existence of alternatives may lead to a negative decision, particularly if third parties under Article 64(2)} or other applicants have submitted information on the existence of alternative substances or techniques. In addition, the content and robustness of the analysis of alternatives will be a critical element to set the review period.

Where suitable alternatives are available, a substitution plan must be included in the application outlining the applicant's commitment to take actions in a specified timetable to replace the Annex XIV substance with the suitable alternative(s).

It should be kept in mind that the Committee for Risk Assessment may in its opinion disagree with the applicant's demonstration of adequate control which can lead to a decision to refuse the authorisation. Therefore, the applicant may consider to also include a socio-economic assessment to provide evidence to the Committees that the socio-economic benefits outweigh the risks arising from the use of the substance {as per Art. 60(4)}. This applies in cases where the analysis of alternatives demonstrates that there are no suitable alternatives available because then, the authorisation may still be granted on the basis of the SEA consideration. This, however, requires that the application includes all necessary information in support of the SEA argumentation.

Although not strictly required by REACH, a socio-economic analysis can also bring valuable information for defining the length of the review period and/or authorisation conditions for applications demonstrating adequate control. Guidance for carrying out a socio-economic analysis is available (Guidance on Socio- Economic Analysis – Authorisation).

The applications may also include a justification for not considering the risks to human health or environment for the use(s), as set out in Article 62(5), if applicable.

#### 2.1.2.2. Socio-economic assessment (SEA) route

The 'SEA route' applies where it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and there are no suitable alternative substances or techniques {Art. 60(4)}. It applies in circumstances when adequate control has not been demonstrated and/or for substances meeting the criteria of Article 60(3). The latter include:

- CMR category 1 and 2 substances defined under Article 57 (a), (b) or (c)[10], or substances listed in Annex XIV as being of equivalent concern defined under article 57 (f), and for which it is not possible to determine a threshold;

[10] Article 57 (a), (b) and (c) will be amended from 1 December 2010, and from that date this sentence should read: "substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity category 1A or 1B in accordance with Annex I to Regulation (EC) No 1272/2008 defined under Article 57 (a), (b) or (c),(…)".

- PBT or vPvB substances meeting the criteria in Annex XIII (article 57 (d) and (e));
- substances which are listed in Annex XIV as being of an equivalent level of concern to PBT or vPvB substances defined under article 57 (f). (See section 1.5.5 of this guidance for further detail.)

The application under the SEA route should include:

- a CSR;
- an analysis of alternatives; and
- a SEA.

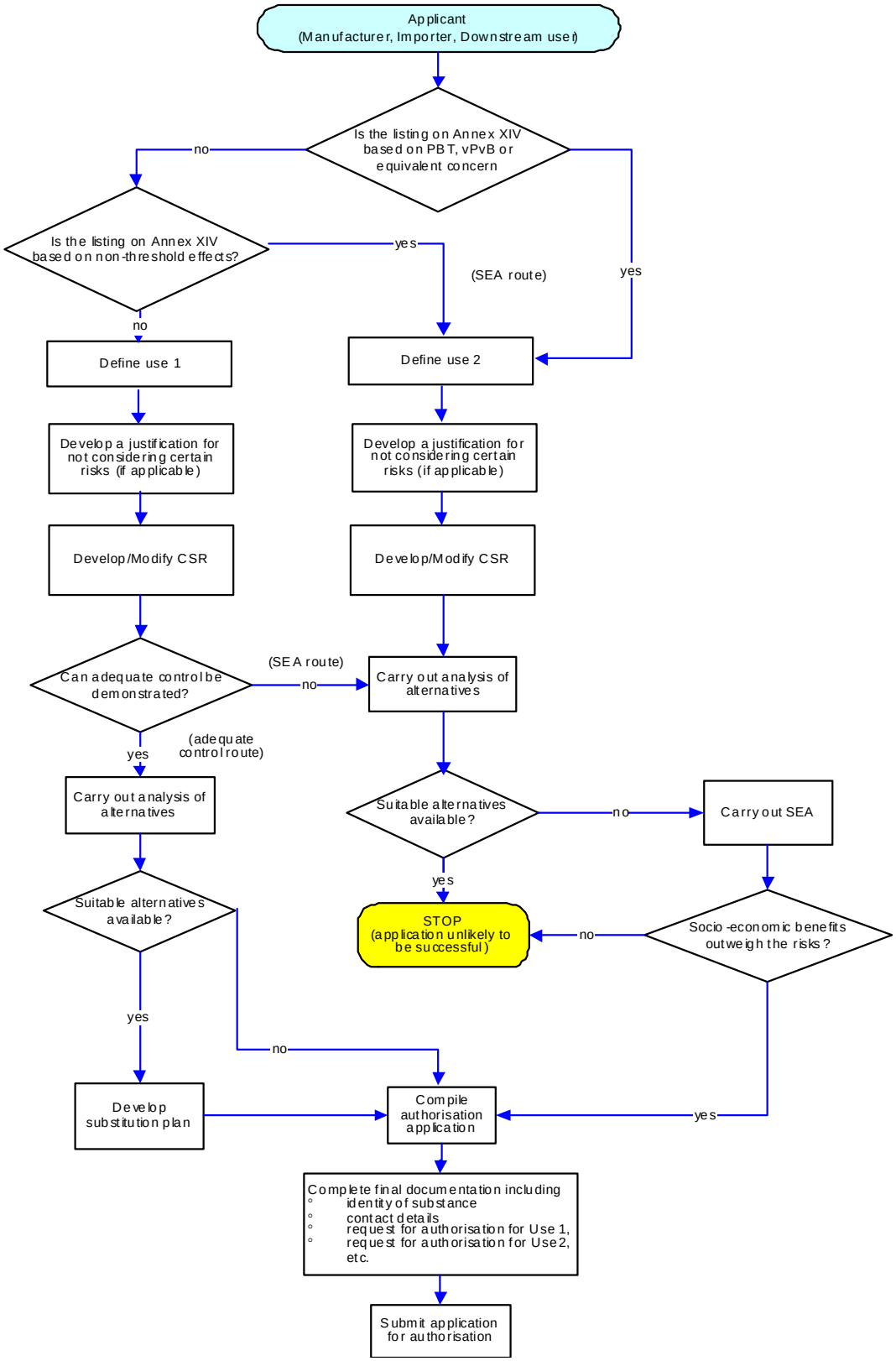
Although according to Article 62(5) the inclusion of a SEA is optional in all applications, it should be stressed that for applications under the SEA route (that is, for the substances referred to in Article 60(3) as well as for substances where adequate control has not been demonstrated) a SEA should always be included to provide evidence that the socio-economic benefits outweigh the risks arising from the use of the substance {as per Art. 60(4)}. Otherwise the granting of authorisation on socio-economic grounds is very unlikely.

If the application is made under the SEA route it should be noted that the authorisation may not be granted when suitable alternatives are available for the applicant. In the application the applicant must explain why he considers that there are no suitable alternatives and list the actions, including timelines that would be required to transfer to alternative substance or techniques, should suitable alternatives be available on the market but not yet ready for an immediate substitution.

Similar to the adequate control route, the applications may also include a justification for not considering the risks to human health or environment for the use(s), as set out in Article 62(5), if applicable.

Figure 7 outlines the information that should be included in the application.

**Figure 7 Application content (based on Art. 60)**



## 2.2. Compiling an application for an authorisation

The following sections go through each section of the application, indicating the information that should be provided. Specific technical guidance on how to compile the application for authorisation is contained in user manual(s) available on the Agency's website.

Further guidance on specific aspects of the authorisation application, for example analysis of alternatives and substitution plans, is given in Chapter 3 and Chapter 4. Appendix 1 provides guidance for substance grouping in the context of authorisation applications. Appendix 2 gives specific guidance for groups of applicants wishing to file jointly an application for an authorisation. More detailed guidance on carrying out a socio-economic analysis is given in the Guidance on Socio- Economic Analysis – Authorisation.

### *2.2.1. Substance identity*

Basic information on the identity of the substance is needed for the application for an authorisation. The information on substance identity should be based on the Annex XIV entry and on Section 2 of Annex VI of REACH.

Substance identity information should be available as part of the registration dossier for the substance or the group of substances considered in the application. In cases where no registration is available the information should be collated following the Guidance on substance identification.

A single application can be made covering several substances that meet the definition of a group of substances in section 1.5 of Annex XI of the REACH Regulation. In this case the required information on identity will be extracted for each member of the group (see Appendix 1). An argumentation for substance grouping should be included in the application in cases where the substances are not grouped in Annex XIV but have similar physicochemical, toxicological and ecotoxicological properties or where these follow a regular pattern as a result of structural similarity. Appendix 1 gives further guidance for substance grouping.

### *2.2.2. Applicants*

Applications for authorisation can be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance(s). In addition applications can be made by either separate legal entities or a group of legal entities {Art. 62(2)}.

Information for each legal or natural person submitting an application should be provided, including:

- name, address, telephone number, fax number and email address;
- contact person;
- financial and legal identifiers; and
- other relevant contact information.

In this guidance no distinction is made between situations where the applicant is a manufacturer or importer and where the applicant is a downstream user, as the main elements that need to be included in the application are broadly the same. However, the considerations when deciding

whether or not to make an application may be different for manufacturers and importers compared to downstream users. It is important to note that an authorisation granted to a downstream user also covers the supply of the substance to the downstream user holding the authorisation {Art. 56(1a)} irrespective of whether or not the manufacturer(s) or importer(s) have or have not made an application for an authorisation for that particular use.

In order to ensure that the process is effective, it is important that, where the potential applicant is not (or does not include) a downstream user, he keeps his downstream users of the substance informed of what will and will not be covered in the application. Similarly, it would be important for downstream users to provide information on their specific uses back to the applicant. Given the length of time it may take to put together an application (see Section 2.4.1) it is important that such dialogue starts at an early stage in the process.

As mentioned earlier, applications can be made by several legal entities. It will be up to each potential applicant (whether a manufacturer, importer or downstream user) to decide on a case-by-case basis whether he wishes to make an application, either as individual or as part of a group of applicants. Appendix 2 discusses further the reasons and approach for filing joint applications for an authorisation by several legal entities.

### *2.2.3. Request for authorisation for specific use(s)*

#### 2.2.3.1. Use(s) covered in an application

Each applicant can apply for an authorisation for his own use(s) of the substance and/or uses for which the applicant intends to place the substance on the market. If manufacturers and importers wish to prepare applications covering both their own use(s) and any use(s) for which they wish to place the substance on the market, the application would need to cover the downstream uses of the substance. In this situation, the downstream users themselves would not necessarily need to submit an application as long as their uses were covered by the application from the manufacturer or importer. However, it is important to note that such an application from the manufacturer or importer does not preclude the downstream user from making his own application if desired.

As it is up to each actor to decide, on a case-by case basis, whether or not he wishes to cover his downstream users' use(s) in his authorisation application, it is possible that a potential applicant may not wish to apply for an authorisation for a specific use he currently supplies for. Examples (non-exhaustive) of some of the many possible situations where this could arise include:

- the applicant does not wish to continue supply for economic reasons (e.g. the costs of preparing an application are high compared to the value of the product),
- the applicant cannot demonstrate safe use and there appear to be suitable alternatives available, or
- the applicant cannot demonstrate safe use and the risks to human health or the environment from the use of the substance appear likely to outweigh the socio-economic benefit of continued use of the substance.

In these cases the downstream users of the substance for the specific use may wish to consider developing their own application for their specific use(s). When deciding to do this, they would

need to consider their own specific case carefully. Non-exhaustive examples of some situations where this could arise include:

- the actual use or process used by the downstream user is confidential,
- adequate control can be demonstrated at the downstream user site as a result of specific risk management measures and operational conditions in place, or
- the downstream user can demonstrate that socio-economic benefits outweigh the risks for the specific use employed by him in cases where no suitable alternatives are available for him for this specific use.

In such cases it would be advisable for the downstream user to inform their supplier(s) and, if relevant, their downstream users (customers) of the substance that they intend to make an application for authorisation.

#### 2.2.3.2. Describing use(s) in the application

The use or uses should be described in the authorisation application in accordance with user manual(s) for authorisation applications made available on the Agency's website. This section should be completed for all applications, irrespective of the basis on which the application is made. This should also cover any use(s) of the substance(s) in mixtures and/or incorporation of the substance into articles, where this is relevant. For applications for a group of substances it is important that the uses being applied for are clearly identified for each member of the group.

It should be remembered that an authorisation is granted for the use(s) described in the exposure scenario(s) and documented in the CSR (see Section 2.2.4.4). The key point is therefore that the description has to relate to the exposure scenario(s) for the use(s) for which authorisation is being requested, as included in the CSR, the analysis of alternatives, and SEA, when available. The development of the description of the use is an iterative process and it should therefore be finalised after the work on the CSR, analysis of alternatives and SEA has been carried out. Guidance on information requirements and CSA (Chapter R.12: Use descriptor system) has guidance on developing descriptions of uses and this should be consulted, but it may in many cases be necessary and useful for the applicants to develop the description further to specify more precisely what use is applied for.

Note that the CSR and in particular the exposure scenario(s) needs to cover all of the relevant life cycle steps of the substance associated with the use applied for. For example, if the end use applied for is part of a mixture, the step formulating the mixture will need to be included. The service life of articles containing the substance may also need to be considered.

Where the substance forms part of a mixture, the use descriptor system in Guidance on information requirements and CSA (Chapter R.12: Use descriptor system) characterises the use of the substance by the type of end-use product in which the substance is known to be used. Hence the use of a mixture is described in a similar way to the use of a substance. Further information on the specific purpose of the substance in the mixture can be added if needed. Where the substance is used in production of articles, the use descriptor system will include the category of article into which the substance is incorporated (it should be noted that the use of the articles themselves is not subject to authorisation).

2.2.3.3. Uses for which authorisation application is not required

The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC {Art. 62(6)}.

In addition, Table 1 in section 1.5.2 includes other exempted uses from applications for authorisation. Further to these general exemptions, the Annex XIV entry for each substance may list substance specific exempted uses, or categories of uses, along with any conditions that apply to such exemptions.

2.2.3.4. Request for authorisation for several uses

As mentioned earlier the application can cover several uses. Some of the possible advantages of an application considering more than one use are to avoid repetitions and to include a more integrated picture of the use of the substance. A main disadvantage is having to produce a complex application where there are a high number of uses, or where the application requires both the adequate control and SEA routes in order to cover all the uses.

The applicant should decide on a case-by-case basis if the advantages of combining several uses in one application outweigh the drawbacks. Some of the disadvantages of combining several uses in one request for authorisation can be addressed through methodical organisation of the application. This could be achieved by either the development of separate reports (i.e., the CSR, the analysis of alternatives, the substitution plan, and the SEA, where appropriate) or the development of distinctly defined sections in each of these reports. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

### *2.2.4. Documentation in support of the application for authorisation*

As discussed in Section 2.1.2, the information contained in the application may be different depending on the basis for the argumentation in the application, i.e. adequate control or socio-economic benefits. Figure 7 presents in a graphical form the information that should be included in the application for each route. The sections below outline the specific information that will need to be provided in support of the application.

2.2.4.1. Chemical Safety Report

All authorisation applications need to include a CSR or refer to one submitted as a part of a registration dossier substances manufactured in quantities of 10 tonnes or more per year per registrant must include a CSR as a part of a registration dossier). The CSR(s) should cover the risks to human health and/or the environment (as appropriate) from the use or uses of the substance applied for arising from the intrinsic properties specified in Annex XIV of the Regulation.

a) Development and submission

Where a CSR has been submitted already as part of the registration, and no changes have been made for the authorisation application, there is no need to resubmit a copy.

However, the applicants may need to update their original (registration) CSR as part of their authorisation application. This may be required for instance where the applicant wishes to provide a

more precise exposure scenario and/or refine the exposure assessment. It may be advisable to submit a revised CSR where the original CSR covers several uses of the substance but the applicant only wishes to apply for an authorisation for some of these uses. This may be particularly important where some of the uses not applied for lead to high emissions that dominate the total emissions of the substance. Here, the update to the CSR could consider the effect of the change in the applicant's use pattern on the overall emissions and risk characterisation from the remaining uses.

If a CSR is not available, then it will be necessary to carry out a Chemical Safety Assessment (CSA), record the assessment in a CSR, and submit it as part of the application. In these cases and where a CSR is updated for the purposes of an application for authorisation, it only needs to cover the identified uses applied for and can be limited to the risks to human health and/or the environment arising from the intrinsic properties specified in Annex XIV. The hazard assessment part of the applicant's CSR needs to be based on the Annex XV dossier that led the substance to be included in Annex XIV. The remainder of the CSR has to be developed in accordance with Annex I for which the standard guidance on CSA/CSR can be used (see Guidance on information requirements and CSA[11]). Depending on the substance properties this includes a quantitative or a qualitative risk characterisation, in accordance with either Section 6.4 or 6.5 of Annex I and following the general CSA guidance.

The content of the CSA varies depending on the basis of the authorisation application. If an authorisation is applied for via the adequate control route, the CSR needs to demonstrate that for the uses(s) of the substance(s) concerned, the risks are adequately controlled in accordance with section 6.4 of Annex I. Therefore, iteration of the exposure scenario or the assessment is needed until adequate control can be demonstrated. This may include:

- refinement of exposure estimates to better reflect the implemented or recommended conditions of use, e.g. by
    - collecting further information on conditions of use,
    - use of measured data,
    - use of better models, or
- modification of risk management measures or operational conditions, or
- narrowing down the areas of use for which authorisation is applied for.

If an authorisation is applied for via the SEA route, possibilities to improve control of risks via iteration of the exposure scenario or the assessment need to be considered with a view to demonstrate minimisation of emissions and exposures as far as possible, and to show that the likelihood of adverse effects is reduced. This may include the same actions as listed under the adequate control route. Section A.4.3 of the Guidance on information requirements and CSA outlines further the steps in the CSA for the purpose of an authorisation application.

[11] The following sections of the Guidance on information requirements and CSA are of particular relevance: Parts A, C, D and E of the Concise Guidance and from the In Depth Guidance Chapter R.11.2 on emission and risk characterisation for PBT/vPvB substances and Chapters R14 – R18 on exposure estimation.

In cases where a new CSR has been generated for the application, or where an existing CSR has been modified, a copy of the new or revised CSR should be appended to the application as an assessment report.

b) CSR for several uses

In circumstances where one application covers several uses, it is important to clearly set out the exposure scenarios for each use. This can be achieved by developing distinctly defined sections for each use in the CSR. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

c) CSR for a group of substances

In the event the application for authorisation is for a group of substances, CSR(s) needs to cover all substances in the group for which authorisation is sought. Although in principle it is possible to generate one CSR covering the grouped substances and all their uses, this may not be practical in case of applications for many substances with many different uses as documentation of all the many different combinations (of substances/uses) could result in a poor analysis that lacks transparency and consistency. In such situations a CSR for each member of a group may be more appropriate. Appendix 1 provides additional information for substance grouping.

2.2.4.2.Analysis of alternatives

All applications must include an analysis of alternatives. The purpose of this analysis is to determine if there are any suitable alternative substances or alternative techniques. There are three main aspects that at least should be considered, these are:

- risks from alternatives,
- technical feasibility of substitution, and
- economic feasibility of substitution.

It is important to stress the need for a robust analysis of alternatives. Applicants should explain as part of the analysis of the alternatives the actions and timelines required to transfer to an alternative substance or technique, in particular in cases where there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") or other operators in the same market are already using or will transfer in the near future to alternatives.

Furthermore, if appropriate, the analysis of alternatives should include information on any relevant research and development activities by the applicant. In particular, applicants should include information about research and development that is considered appropriate for the understanding of the present or future availability of suitable alternatives to the Annex XIV substance. Future plans for research and development may also be documented in the application. This may be appropriate when no suitable alternatives have been identified.. The information on research and development will be taken into consideration in the determination of the review period. In the absence of any relevant programme by the applicant intended to allow him to transfer to an alternative, the review period will tend to be shorter than in cases where serious actions are taken. In the latter case the review period would normally take into consideration the timelines identified by the applicant to accomplish the programme.

It should be noted that in order for an authorisation to be granted under the SEA route, the analysis of alternatives must show that there are no suitable alternative substances or techniques taking into account elements mentioned in Article 60(5) (in addition to the demonstration that the socio-economic benefits outweigh the risks {Art. 60(4)}).

Detailed guidance on how to carry out an analysis of alternatives is given in Chapter 3. The analysis of alternatives should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

In circumstances where one application covers several uses, it is important to clearly set out the alternatives for each use. This can be achieved by developing a separate analysis of alternatives report for each use or by developing distinctly defined sections for each use in one report. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

For applications covering a group of substances, it would need to be considered on a case-by-case basis whether the analysis of alternatives should cover the group or whether individual reports should be generated for each member of the group.

#### 2.2.4.3. Substitution plan

The application must include a substitution plan if the analysis of alternatives shows that suitable alternatives are available, taking into account reduction of overall risks and technical and economic feasibility of alternatives for the applicant.

Detailed guidance on preparing a substitution plan is given in Chapter 4 of this guidance. The substitution plan should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

In circumstances where one application covers several uses, it is important to clearly set out a substitution plan for each use. This can be achieved by developing a separate substitution plan for each use or by developing distinctly defined sections for each use in one report. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

For applications covering a group of substances, it would need to be considered on a case-by-case basis whether the substitution plan should cover the group or whether individual substitution plans should be generated for each member of the group.

#### 2.2.4.4. Socio-economic analysis

SEA is an approach used to analyse and describe all relevant impacts of granting (or refusing) an authorisation. Although not strictly required by the Regulation, an SEA is particularly important in circumstances where adequate control of risks cannot be documented (see section 2.1.2.2), and the applicant will need to demonstrate that the risk to human health or the environment from the use of the substance or substances is outweighed by the socio-economic benefits {Art. 60 (3 and 4)}.

SEA can also be beneficial in adequate control route applications. For example, applicants can use socio-economic analysis to give the basis for defining the length of the review period or any conditions in the authorisation decision.

Annex XVI of REACH outlines the information that may be included in an SEA and more detailed guidance for carrying out a socio-economic analysis is given in the Guidance on Socio Economic

Analysis – Authorisation. The detailed report and supporting information should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

In case one application covers several uses, it is important to clearly set out the socio-economic impacts for each use. This can be achieved by developing a separate SEA report for each use or by developing distinctly defined sections for each use in one report. This will facilitate the preparation of the application and its processing by the Agency and the Commission.

Where a socio-economic analysis is needed for the application for authorisation for a group of substances, it will need to be considered on a case-by-case basis whether a single socio-economic analysis covering the whole group, or individual socio-economic analyses for each member of the group should be prepared.

2.2.4.5. Justification for not considering certain risks

All applications may include a justification for not considering the risks to human health or environment {Art. 62(5b)}. This applies to uses in installations where emissions of the substances are controlled by a permit granted in accordance with the IPPC Directive (European Parliament and Council Directive 2008/1/EC) or to point sources governed by the requirements of prior regulation referred to in Article 11(3)g of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive.

For a group of substances it would be possible to develop a justification for not considering certain risks provided that all substances in the group are used in installations where emissions of substances are controlled by permit in accordance with the IPPC Directive (European Parliament and Council Directive 2008/1/EC) or to point sources governed by the requirements of prior regulation referred to in Article 11(3)g of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive.

The justification should be submitted as part of the application as indicated in the user manual(s) made available on the Agency's website.

## 2.3. Subsequent Applications

It is possible for an application for authorisation to refer to previous applications for authorisation for the same substance(s) and use(s). Two possible situations exist {Art 63 (1) and (2)}:

a. Where an application has been made by other applicants for the same substance(s) and use(s).

b. Where an authorisation has been granted for the same substance(s) and use(s).

In both of these cases, a subsequent applicant can refer to the following parts of the previous application, provided they have permission from the previous applicant or authorisation holder:

- Chemical Safety Report(s).
- Analysis of alternatives.
- Substitution plan.

- Socio-economic analysis.

In this case the subsequent applicant should update the information in these parts of the original application as necessary {Art. 63(3)}, and complete the following parts of the application.

- General applicant information (see Section 2.2.2).
- Substance identity (see Section 2.2.1 – this should relate to the substance used by the subsequent applicant), including a description for substance grouping (if applicable – see Appendix 1)
- Request for authorisation for specific uses(s) (see Section 2.2.3 – this can refer to the previous applicant's CSR, SEA or analysis of alternatives and substitution plan as appropriate)
- Other information (if appropriate).

## 2.4. Submitting the application for authorisation

### *2.4.1. Deadlines for submitting applications for authorisation*

The deadlines for applications for authorisation will be set by the Commission for each substance when it is listed in Annex XIV. Applications for authorisation will be made to the Agency {Art. 62(1)}.

The time needed to put together an application for authorisation should not be underestimated. The Guidance on inclusion of substances in Annex XIV estimates that around 12 months may be needed to prepare a new application, but this may be as long as 24 months for applicants with less experience of the process. This should be born in mind when planning an application for authorisation.

### *2.4.2. How to submit an application*

Applications should be submitted to ECHA, via its website, in accordance with user manual(s) on how to submit an application made available on the Agency's website.

### *2.4.3. Fees*

The applicant(s) must pay the required fee in accordance with Title IX {Art. 62(7)} and Commission Regulation N° EC 340/2008 on the fees and charges payable to the European Chemicals Agency (Annex VI and VII).

## 2.5. Review reports

Authorisations will be subject to a time-limited review period. The review period will be specified in the granted authorisation. In order to continue placing on the market or using a substance, the

holder of the authorisation must submit a review report at least 18 months before the expiry date of the time-limited review period.

The review report should address only the parts of the original application that have now changed but should contain the following elements {Art. 61(1)}.

- Number of current authorisation.
- An update of the analysis of alternatives, including information about any relevant research and development activities by the applicant, if appropriate.
- An update of any substitution plan included in the original application if appropriate.
- If the update of the analysis of alternatives shows that there is a suitable alternative available, then a substitution plan, including a timetable for proposed actions by the applicant, is required. It is noted that under the SEA route, when suitable alternatives become available for the applicant, the authorisation must be withdrawn, taking into account the proportionality principle.
- If the holder cannot demonstrate that the risk is adequately controlled, then an update of the SEA included in the original application is required.
- If the holder can now demonstrate that that the risk is adequately controlled, then an update of the CSR is required.
- Updates of any other elements from the original application that have now changed.

Review report can be created using the Agency recommended software as indicated in the user manual(s) made available on the Agency's website. Only the parts that have changed need to be completed. Any more detailed reports and information (e.g. updated CSRs, SEAs etc.) can be appended to the review report.

The review report will be assessed through the same process as used for the original authorisation request (see Section 1.5.7).

In addition, an authorisation may be reviewed at any time if circumstances change so that the risks to human health or environment considered in the original authorisation are affected, or the socio-economic impact is affected. A review can also be triggered by new information on possible substitutes becoming available. Under these circumstances, the holder of the authorisation will be invited by the Commission to submit any information necessary for the review within a deadline set by the Commission. The holder will need to address any specific aspects requested by the Commission, and may also wish to consider the impact of the new information on their CSR and SEA. The new information triggering the review and information provided by the holder will be considered according to the same procedure as for the original request (see Section 1.5.7).

# 3. PLANNING FOR SUBSTITUTION: GUIDANCE ON ANALYSIS OF ALTERNATIVES

## 3.1. Introduction

The progressive replacement of SVHCs by suitable alternatives is one of the fundamental aims of authorisation and is mainly translated into two elements of an application for authorisation: the analysis of alternatives and the substitution plan. The analysis of alternatives is the first step in the process of planning for substitution, where an assessment is made on the availability of suitable alternative substances or techniques, their risks for human health and the environment, and their economic and technical feasibility for the applicant. The analysis of alternatives may also include information about relevant R&D activities by the applicant. While such information is not mandatory, it will be a critical factor for fixing the review period, in particular in cases where the analysis of alternatives concludes that there are no suitable alternatives. Where the analysis of alternatives leads to the conclusion that a feasible alternative is available for the applicant, the latter must also provide a substitution plan, including a timetable for proposed actions.

This chapter provides guidance primarily directed to the applicant for authorisation on the analysis of alternative substances or alternative technologies to the Annex XIV substance. The chapter sets out:

- What is an alternative;
- What should be the focus and scope of an analysis of alternatives;
- How to conduct an analysis to identify and assess possible alternatives; and
- How to document the analysis in the application.

An analysis of alternatives is required in all applications for authorisation according to article 62(4)(e) of REACH. Therefore, the applicant for authorisation must document an analysis of alternatives in his application. Whilst this guidance focuses on the applicant, who may be a M/I or a DU or indeed a group including different legal entities, it is intended to describe a process by which a reasonable and logical analysis of alternatives may be approached, conducted and documented. Therefore, it may also help third parties to submit well documented information on alternatives[12] under the provisions in Articles 64(2) and 64(3).

The guidance is intended to provide considerations for the analysis of alternatives so that users of the guidance may provide information that documents their analysis in the best possible light for consideration by the Agency and ultimately by the Commission in the decision whether or not to grant an authorisation.

This chapter also addresses how, and under what circumstances, the analysis of alternatives links with a substitution plan and a socio-economic analysis (SEA). As described in previous sections (1.5.5, 2.2 and 2.4.4.2) authorisations can be granted on the basis of two principally different lines of argumentation, i.e. on the basis of adequate control or for socio-economic reasons, leading to

[12] The presentation of an analysis of alternatives by a third party may help to support the case that the alternative is suitable and available for the uses set out on the Agency web site. Guidance for third parties is at Chapter 5 of this GD.

applications via either of two routes, the so called adequate control route or the SEA route. The route for application influences the requirements for a substitution plan and the applicability of SEA.

**Substitution plan**: If an application under the adequate control route concludes in the analysis of alternatives that a suitable alternative(s) is available, then the applicant must prepare a substitution plan that sets out his commitment to transfer to that substitute(s), setting out the timing and other considerations for transferral. The detail of how to conduct and document a substitution plan is set out in Chapter 4 of this guidance document, but the links between the analysis of alternatives and the substitution plan are also highlighted in this chapter. It is noted that an authorisation under the SEA route may not be granted if there are suitable alternatives for the applicant.

**Socio-Economic Analysis (SEA)**: Although according to Article 62(5) the inclusion of a SEA is optional in all applications, for applications under the SEA route it should be included and can also be submitted in the case of applications under the adequate control route on a voluntary basis. See section 1.5.5 for further details on which types of substances or situations that are applicable for the SEA route to authorisation. Guidance for compiling an SEA in support of an authorisation application and submission of an SEA or input to one from a third party as part of the authorisation process is set out in a separate document Guidance on Socio Economic Analysis – Authorisation. Key phases of the analysis of alternatives where links to the SEA are important are indicated in this guidance, e.g. in section 3.3 on the scope of the analysis of alternatives, in section 3.5 on how to identify possible alternatives, and in section 3.7 on comparing the risks of the alternative with the Annex XIV substance. Where an SEA is developed an assessment of human health and environment impacts will be a necessary part of the SEA. This assessment could be used in the analysis of alternatives to assist in the decision regarding comparison of risks for substances following the SEA route (see section 3.7.1).

## 3.2. What is an alternative?

An alternative is a possible replacement for the Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs. The alternative could be another substance or it could be a technique (e.g. a process, procedure, device, or modification in end product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance function altogether.

Article 60(5) provides that when assessing the availability of suitable alternative substances or techniques, *all relevant aspects must be taken into account*, including:

a) whether the transfer to the alternative would result in *reduced overall risks* to human health and the environment (as compared to the Annex XIV substance) taking into account risk management measures,

b) the *technical* and *economic feasibility* of alternatives for the applicant for replacement of the Annex XIV substance.

The alternative must also be *available* for the applicant (i.e. can be accessed in sufficient quantity and quality) for transferral. As an application may be for a number of uses of the Annex XIV

substance, it may be that there will be different alternatives that are *suitable* and *available* for each different use of the Annex XIV substance that has been applied for.

### 3.3. The focus and scope of the analysis of alternatives

The analysis of alternatives may be relatively simple.For example, where an application is being compiled for a single use that is being applied for, the applicant may know of one or a few alternatives. In this case, a simple analysis may be able to fairly rapidly identify their capability to reduce the overall risk and whether they are technically and economically feasible. In addition, some of the work might have already been done in relation to requirements of other legislation, e.g. Directive 2004/37/EC ('the carcinogens Directive') requires employers to consider the substitution of the use of a carcinogen or mutagen as the first level of the risk management hierarchy.

However, the analysis may require a more detailed assessment. For example, the application may start from a position in which no alternatives are known, where the function is complex and where there are a number of constraints on the function (including, e.g., strict customer requirements for the use of specific substances) as well as the supply chain being complex.

The focus of the analysis of alternatives is to identify possible alternatives to the Annex XIV substance and to assess, on the basis of reduction in overall risks, economic and technical feasibility of substitution and availability whether they can be used in place of the Annex XIV substance. The documentation of that analysis needs to be presented in the application for authorisation and can be referred to as the analysis of alternatives report.

The applicant's analysis of alternatives will conclude that there is a suitable alternative available when an alternative substance(s) or technology/ies or their combination:

- provide an equivalent function to that provided by the substance or makes the substance' use redundant (note that a single alternative may not be suitable for all different processes or uses for which the original substance was suitable, thus the original substance could be substituted by more than one suitable alternative);
- will result in reduced overall risks to human health and the environment, taking into account appropriateness and effectiveness of risk management measures;
- are technically and economically feasible (for substitution in the uses applied for) and available, for the applicant.

The applicant should demonstrate whether the above criteria are satisfied or not by possible alternatives. It is in the interest of the applicant to be specific in the assessment of the suitability and availability of alternatives and to document the results of the assessment in a transparent way. It is also strongly recommended that the applicant demonstrates that a comprehensive and adequate assessment of alternatives has been done. This is because the Agency in its opinions and the Commission in its assessment of whether suitable alternatives are available will take "all relevant aspects" into account {Art. 60(5)}, including information submitted by interested third parties.

This means that in practice the applicant may be well advised to consider including in the scope of his analysis all possible alternatives, considering both substances and technologies. This applies also to cases where the applicant is a M/I and the alternatives may not be products from his own portfolio. An incomplete analysis of alternatives by an applicant may lead the Agency to question the accuracy of such an analysis and why some possible alternatives have not been assessed if the Agency has received well-documented information that suitable alternatives exist. It is also

advisable for the applicant to detail for example relevant research and development that he has carried out, with specific emphasis as to why a certain alternative substance or technology was not technically or economically feasible.

If the analysis of alternatives demonstrates that currently there is/are no suitable alternative(s) available for the applicant, the latter should provide information on what would be required to make possible alternatives suitable and available within an estimated timescale (further guidance is given in section 3.10). This information will be key to set the review periods. In particular, if no information is provided, the review period would be short, as it would be necessary to assess whether there have been any changes.

The applicant will be a manufacturer/importer (M/I) or downstream user (DU) of the Annex XIV substance. Joint applications may also be made (see Chapter 2 on who can make an application).

The focus and scope of the analysis of alternatives may be influenced by who makes the application for authorisation. Box 1 considers the perspective of the M/I and DU in the analysis of alternatives.

In order for the applicant to best understand what alternatives may be available and what the scope of the analysis of alternatives will be, it is recommended that consultation within the supply chain is begun at an early stage. This is so that applicants are in the best position to understand what information is available on use of the Annex XIV substance and on possible alternatives to the Annex XIV substance. Consultation within and outside the supply chain is considered in section 3.5.2 and issues relating to competition law and confidential business information (CBI) in Box 2.

**Box 1 Perspective of the analysis of alternatives for different actors**

A M/I may find it difficult to have full information on how possible alternatives may fulfil substance function for downstream uses and he may have to work with DUs to understand this fully if the M/I intends to cover downstream uses in his application.

A DU may wish to make an application because he does not wish to share information on exact use with his supplier for reasons of commercial confidentiality. Or he may need to apply because he finds that his use will not be supported in an application by his supplier (i.e. the M/I).

It may of course be an option for M/I and DU to make a joint application or share information through an independent party to ensure that confidential information is not shared within the supply chain.

Third parties may submit information on alternatives, which will be taken into consideration by the Agency and the Commission when assessing whether suitable alternatives exist

Annex XIV will set a deadline for submitting an authorisation application (see Chapter 2), so the amount of work that can be conducted in the analysis of alternatives will be limited by time and resource. In practice, it will make sense to undertake some of the tasks of the analysis of alternatives at the same time; as information from one part of the analysis may inform other parts. For example, gathering initial information to ‘screen’ the possible technical feasibility of an alternative may be combined with screening of alternatives on the basis of risks.

Where an application is via the SEA route the applicant may also wish to consider the information needs of the SEA when considering the analysis of alternatives. Consideration of the information needs of the SEA may prompt the applicant to collect information on the possible responses of the supply chain to not being able to use the Annex XIV substance, at the same time as gathering

information on possible alternatives. This is considered in section 3.5. Guidance on Socio Economic Analysis – Authorisation is provided in a separate guidance document.

A suggested check-list for the inclusion of information in the analysis of alternatives is given in Appendix 3. Guidance on what to document in the analysis of alternatives and a possible outline for the analysis of alternatives report is given in section 3.12.

### 3.4. Overview of how an analysis of alternatives is undertaken

This guidance chapter sets out how an applicant:

- may conduct an analysis of alternatives; and
- can document this in the analysis of alternatives report.

The process involves:

- identifying possible alternatives for each use applied for on the basis of the functional requirements (section 3.5);
- assessing the technical feasibility of possible alternatives identified (section 3.6);
- assessing possible alternatives for their potential risks to the environment and to human health. For this purpose the applicant should assess whether the alternatives represent a reduction in overall risk compared to the Annex XIV substance, taking into account risk management measures and operational conditions implemented and recommended (section 3.7);
- assessing the economic feasibility of possible alternatives identified (section 3.8);
- identifying relevant R&D that is appropriate to the analysis (section 3.9);
- assessing the suitability and availability of possible alternatives, on the basis of their technical and economic feasibility for the applicant, reduction in risk and accessibility (section 3.10); and
- determining the actions and timescales that may be required to make possible alternatives suitable and available for the applicant, taking into account relevant R&D where appropriate (section 3.11).

The process for undertaking an analysis of alternatives is illustrated in Figure 8. This diagram outlines the possible steps in an analysis of alternatives and the possible outcomes depending upon the status of the Annex XIV substance and the identification of available alternatives.

Clearly, in order to identify possible alternatives to the Annex XIV substance, the function of the Annex XIV substance needs to be identified first. However, the further analysis of technical and economic feasibility, the comparative safety of the alternatives and availability need not be addressed in the order set out in this guidance. The applicant should show and document analysis of these aspects, but the importance of different aspects of the analysis will be different in each case. For example, it may be clear to the applicant in his analysis of alternatives that all possible technically feasible alternatives do not represent a reduction in risk as compared to the Annex XIV substance. In this case there would be little merit in detailed analysis of the economic feasibility of these alternatives, once it is known that none of them is suitable on the basis of the risks.

**Figure 8. Flow diagram for the analysis of alternatives**

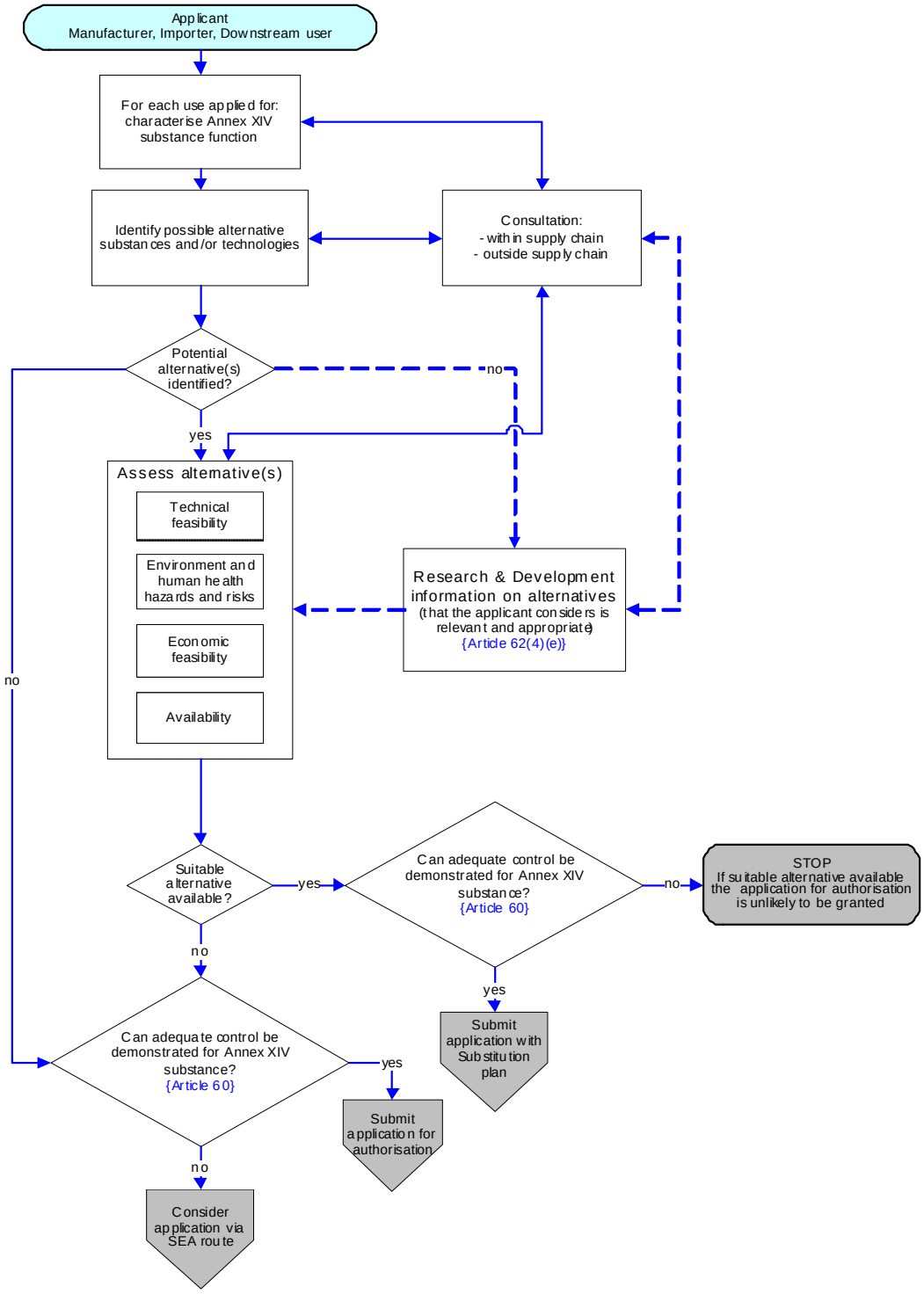


Figure 8 illustrates that to properly assess possible alternatives, consultation within and outside the supply chain is recommended. This is so that the applicants can:

- Fully understand the exact uses that are being applied for and therefore understand the function of the Annex XIV substance;
- Ensure that they are aware of the technical and economic feasibility of possible alternatives for the uses of the Annex XIV substance for which they are applying;
- Decide if past, ongoing or planned R&D is relevant and appropriate for the analysis;
- Decide if the alternative/s is/are suitable and available in order to enable a transfer to the alternative/s to take place; and
- Determine what actions and timescale would be required to make possible alternatives suitable and available.

Figure 8 includes consideration of relevant and appropriate R&D. As it is not obligatory to conduct R&D within the analysis of alternatives, this is indicated by a broken line in the figure. Applicants may have done or be aware of research and development (R&D) on possible alternatives. Such R&D may have highlighted the possibilities and difficulties for using particular alternatives. Therefore, it may help in the analysis of alternatives to refer to and explain R&D that is relevant to showing how alternatives may or may not be feasible. In addition, this information will be taken into account to fix the review periods. The absence of R&D activities should lead to fixing shorter review periods.

## 3.5. How to identify possible alternatives

### *3.5.1. How to identify the Annex XIV substance functions*

The function of the Annex XIV substance for the use/s being applied for is the task or job that the Annex XIV substance is performing.

The process of identification of alternatives normally begins with the consideration of the function of the Annex XIV substance. A detailed and specific knowledge of the exact function that the Annex XIV substance is doing (and where and how, i.e. under what conditions, that function must be performed) for a particular use, will allow the applicant to look for other ways of performing that function. This may be by using another substance or technology or by changing the process or end product. In the latter cases it is possible that the original function of the substance may become redundant.

Knowledge of the precise function of the Annex XIV substance assists in consultation on alternatives within and outside the supply chain by setting out the technical requirements that any possible alternatives must meet. This allows users, suppliers and technologists to assess whether there may be possible alternatives and also what actions are needed to make them technically feasible (technical feasibility is considered in section 3.6). The users, through co-operation with suppliers, may have conducted possible research and development on existing alternatives, for example trials of alternative substances and technologies, and this may be helpful in identifying and assessing possible alternatives (R&D is considered in section 3.9).

The function of a substance could be related to its physical or chemical properties as well as the form it is used in (for example, for a solid this may be as a powder, pellets or granules), the physical state may also be dependent upon process conditions. Key questions to be considered for each use when determining the functions of a substance can be divided into two main groups:

1. **Task** that the substance performs: This will require an understanding of the exact use of the substance including a description and outcome of the process where the use is applied. Key questions addressing the task performed by the substance include:

   - What is the exact use of the Annex XIV substance and what task does it perform?

     This will need to be as specific as possible and the exact function will determine within which limits possible alternatives can be identified. For example, a substance that functions as a solvent to degrease metal may be replaced by a number of possible substance and technical alternatives. However, if the specific function is to degrease fine-bore metal tubes to a particular standard of cleanliness, then this will narrow down the possible alternatives that can perform this function.

   - What are the critical properties of the substance for this use?

     The function will depend upon key properties of the Annex XIV substance. For example this could be its persistence (e.g. a flame retardant or plasticiser; both of which need to have longevity in the final product in order to continue to impart their function for the lifetime of the product), or a physical property such as its viscosity or vapour pressure. The key properties could be a critical combination of properties that make the function possible.

2. The **conditions** under which the substance is used: This will require an understanding of the specific process conditions for using the substance and of any conditions or requirements on possible end-products resulting from the process. These may impose constraints under which the desired function must be performed and thereby influence which alternatives that may be used. Key questions addressing the process **conditions** where the use is applied include**:**

   - What are the physical and chemical (process/operational) conditions under which the function must be performed?

     Physical conditions will include, for example, temperature and pressure of the process. Also there may be considerations of increased or decreased electromagnetic radiation (e.g. photosensitivity). Chemical conditions may include; the presence or absence of other chemicals (introducing issues of chemical compatibility such as reactivity and flammability), the process pH, and the gaseous atmosphere (for example increased or decreased oxygen partial pressure or other gases including potentially explosive atmospheres), amongst numerous others.

   - Are there any specific timing conditions for the substance function?

     There may be constraints on the timing for technical delivery of the function – i.e. the function may be delivered in a particular part of a process that is time-critical and dependent on the properties of the substance; or the function may need to continue for a minimum or maximum time period. Note that for some functions the performance cannot be judged in the short-term (e.g. coatings and lubricants) because the function is based on the longevity of the function and this can only be evaluated over time.

- How could the quality of the final product be affected if the substance/process is altered?

  This requires consideration of how the use of an alternative may affect the end products in terms of final function. Qualities of the final product may need to be considered over a longer timescale. For example, some coatings may need to provide resistance to weathering over a specific product lifetime. This may also include consideration for the final disposal of the product and/or its potential recycling.

- Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated?

  For example the Annex XIV substance may be used to control emissions of another substance or produce another substance. If the need for control is removed or the end product is altered so that the second substance is no longer needed then the Annex XIV substance may be more easily substituted or not required at all.

- Are there features of the end product that determine the requirement for use of the substance?

  For example the specific use of the substance may be required because it imparts certain characteristics to an end product (e.g. due to customer or legal requirements). Using a different end product that performs the same function may enable an alternative to be used or may mean the substance is no longer required for the use.

Appendix 4 presents a check-list for determining the functional requirements for possible alternatives (it is not exhaustive) based on functional aspects of the Annex XIV substance. While the check list is not mandatory, it gives an indicative list of aspects that should be considered when identifying the substance function.

Example 1 illustrates how substance function might be considered for a particular situation. Available information has been used to simulate the possible answers to the questions posed in Appendix 4. The functional aspects numbered 1 to 2 in the example and the checklist in Appendix 4 address the function of the Annex XIV substance (i.e. the task it performs), aspects 3 to 7 address the process conditions for the Annex XIV substance (i.e. what process requirements must be fulfilled, including possible legal requirements).

**Example 1.** Considerations for substance function

Defining substance function is an essential step in understanding the exact use of the Annex XIV substance. Clear definition of function and tolerances allow possible alternatives to be assessed on the basis that it may be possible to use them to perform the function of the Annex XIV substance. The example below illustrates a possible process for determining substance function for the uses that are to be applied for and how this can be documented for presentation in the analysis of alternatives report.

Substance A is an organic solvent with a strong solvent action, a medium boiling point and high vapour density. It is used as an industrial solvent, primarily for vapour degreasing and cleaning of metal parts. More specifically, it is used for the removal of substances such as oils, greases, waxes and buffering compounds, or soils. The specific use for this example is:

Degreasing and cleaning of components that have a complex construction including details that have complex construction.

Components must be free from grease and dirt and dried quickly; corrosion, staining and remaining oil/grease deposits are not acceptable. For intricate articles the low surface tension of Substance A allows the cleaning of folds, double folds and fine tubes.

In terms of defining substance function the checklist set out in Appendix 4 is used:

1 *Task performed by Annex XIV substance*:

What is the task that must be performed by the substance?

The substance is used for degreasing very fine seamless stainless steel tubes (e.g. internal diameter ranging from 1 to 5 mm, straight lengths and coils) in particular for use in the aviation industry and for medical devices. The function is the rapid removal of grease leaving no residue and no oxidation or staining. See table below for further description of applicable criteria.

2. *What critical properties and quality criteria must the substance fulfil?*

Production of clean and dry metallic parts; where the metallic part needs to be dry for the treatment following (e.g. coating). The cleaned item must be grease/oil free and free of any staining/oxidation (e.g. from contact with water/aqueous solutions.)

3. *Function conditions*:

Task timing and through-put required are indicated in table below. The use of solvent in vapour degreasing baths is efficient because solvent is recycled. Primary and secondary cooling coil systems reduce vapour and hence solvent loss and use of covers that seal the degreasing bath work chamber from the atmosphere virtually eliminate evaporative losses during downtime.

4. *Process and performance constraints*

To produce clean and dry metallic parts, where the metallic part needs to be dry for the following treatment (e.g. coating), a solvent cleaning should be used. Intricate parts and fine tubes limit access for mechanical cleaning means.

5. *Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated?*

Eliminating any oil or grease on the surface of metal tubing components would negate the need for vapour degreasing. However, metal parts would need to be grease/oil/dirt free to the standards required. No staining or oxidation is acceptable. Currently tubing production methods require the use of oils to ensure that components remain free of oxidation.

Although aqueous-based cleaning systems are effective in many applications, some aspects of aqueous-based cleaning can make it impractical or unusable for certain types of work pieces. Solvent degreasers must be used for the removal of oil, flux, grease wax and other stubborn solvent-soluble soils from the metal surface. Intricate metal tubes and parts for aerospace and medical instruments are routinely cleaned in vapour degreasers prior to assembly, inspection, or further processing. Because no water is used in the process, nearly any part can be cleaned in a solvent degreaser without concern for quality control issues like the effects of part oxidation, soap residue, water stains, and ineffective drying.

Possible alternatives include other hydrocarbon solvents, aqueous formulations and water blasting or soft blasting (shot blasting using a relatively soft medium such as limestone). Continuing improvements in solvent recovery technology on hot vapour degreasing baths has reduced the amount of substance A used for hot vapour degreasing. These reductions are as a result of better working practices and the use of newer technology. Some companies are also attempting to find other hydrocarbon solvents or water-based cleaning agents as alternatives.

6. *What customer requirements affect the use of the substance in this use?*

Customers (including the aerospace industry) require (through operating procedures that must be used) the use of solvents for cleaning. Any process change requires customer approval; the time taken and technical and cost justification for product change in these sectors are considerable. Quality control inspection criteria demand the components be grease/oil stain and oxidation free (non destructive testing applied).

*7. Are there particular industry sector requirements or legal requirements for technical acceptability that must be met and that the function must deliver?*

Medical device and aerospace industries are required to use solvents for cleaning. There may be implications for fulfilling legal requirements for product safety in these two product areas such as stringent airworthiness and

safety requirements (e.g. European Aviation Safety Agency (EASA) Airworthiness Directives) and the Medical Devices Directive (93/42/EEC). These need to be assessed to estimate the minimum time needed for changes.

**The Table below provides an example of how to summarise and document functional aspects and/or criteria for determining substance function based on the solvent example in this box**:

| Functional aspect | Considerations | Criterion | Tolerance | Testing | Quality control | Consequence |
|---|---|---|---|---|---|---|
| Grease/oil removal | Necessary degree of cleanliness | No oil grease residue staining of tubes upon heating to 200°C | None | Part of non destructive testing prior to use/fitting | Quality system ensures inspection according to testing schedule that parts are grease free.<br><br>Criteria are set out in customer specific requirements. | Residual grease could cause malfunction of instrumentation. Therefore, if testing reveals residual grease parts are rejected and cannot be fitted. |
| Limitation of oxidation | Necessary degree of cleanliness<br><br>Requirements from further processing (gluing, electroplating, painting or coating) | No oxidation or staining as result of contact with water or moisture | <60% humidity | Part of non destructive testing prior to use/fitting – inspection for oxidation | As above | As above |
| Drying time | Acceptable or necessary duration of the cleaning process<br><br>Requirements from further processing (gluing, electroplating, painting or coating<br><br>Quantity of parts to be cleaned per hour/per day; | Must be < 1 minute to ensure no staining prior to application of other coatings | + 15 seconds | None | As above for application of coatings | As above for effect on application of coatings. |
| Task timing | Quantity of parts to be cleaned per hour/per day<br><br>Acceptable or necessary duration of the cleaning process | Degreasing and drying must be completed in 7 minutes | + 1 minute | N/A | N/A | Increase in degreasing time would significantly decrease the output of components and affect the efficiency of the process. This affects downstream processes such as coating of tubes. |

### 3.5.1.1. Information on use and function of the Annex XIV substance in the CSR

Information on the use of the Annex XIV substance will be documented in the CSR (see Guidance on information requirements and CSA). This can either be parts of the CSR from substance registration or a CSR for authorisation; in the latter case the CSR has only to focus on the properties of the substances that have caused it to be listed on Annex XIV {Article 62(4)(d)}. The key part of the CSR in this context will be the exposure scenarios (ES) for the uses applied for, as the authorisation will be possibly granted on the basis of those exposure scenarios. It should be noted that use descriptions developed according to guidance for preparing the CSR may not be sufficient

on their own to describe the use in sufficient detail to determine exact use function[13]. Some suppliers may have used questionnaires to request information from DUs on uses in order to prepare the CSA and CSR. These may be a useful source of information on use.

The applicant will need to elaborate upon the information set out in the CSR based on his knowledge of the specific uses being applied for and the function that the substance must perform for each use. This can be used to determine the function for each use and will include information on the substance's physicochemical properties, biological properties and operational conditions as well as its functionality.

3.5.1.2.Other sources for information on use and function of the Annex XIV substance

Information specifying the exact function of the Annex XIV substance can be found, for example in company records (e.g. operating procedures, customer specifications for substance use and product specifications) and the wider literature (e.g. industry technical literature describing specific uses, standard operating procedures and technical research papers). Communication with the supply chain can be useful to further define function and use conditions and to ensure that all functions for uses applied for in the authorisation have been identified (see chapter 3.5.2.1). It is important to determine all the functions of a substance for each use, so that possible alternatives that may deliver or replace the equivalent function can be identified. The determination of a specific function and use conditions allows clearer communication and consultation within and outside the supply chain as it describes exactly what is required. Suppliers of alternative substances and alternative technologies can then try to match the function performed with possible alternatives.

### *3.5.2. Identifying and gathering information on possible alternatives*

As described above the understanding of the exact tasks the Annex XIV substance performs and the conditions under which it has to be able to perform these tasks is the starting point for the identification of alternative substances or technologies.

On the basis of the substance function it is useful to identify possible alternatives and at the same time gather the information needed to establish their technical and economical feasibility, capability to reduce the overall risk and availability. Recommendations and considerations for identifying alternatives and gathering information are given in the sections below. Further guidance on gathering information on hazards and risks to health and environment is given in section 3.7. The applicant is advised to consider what he will need to consider in his SEA at the stage where he is gathering and analysing information for the analysis of alternatives.

[13] The Chemical Safety Report (CSR) is a mandatory part of an authorisation application. The CSR must assess the exposure scenarios for those uses that are applied for. Authorisations may be granted for uses within the conditions specified in such exposure scenarios as amended by the conditions of the authorisation decision if any. The exposure scenarios for authorisation applications therefore need to be sufficiently specific and precise. Guidance for the preparation of the CSR contains advices on the development of the CSR including the specific circumstances for authorisation.

It is advisable to also list possible alternatives which are easily shown not to be suitable. This is to document that the applicant has considered the possible alternatives broadly. However, the information gathering and analysis of such clearly non-suitable alternatives can be kept limited as long as it meets its purpose of showing whether they are suitable or not.

3.5.2.1. Communication within the supply chain

Consultation with the supply chain with regard to the uses of the Annex XIV substance to be applied for will be important at an early stage. This will help to ensure that consideration has been given to the exact use of the substance and for supply of information on alternatives that may possibly fulfil an equivalent function to the uses applied for. Consultation may also address any necessary changes in equipment, the form of the substance and the waste and re-use of the substance (these may also have economic consequences). The aim of communication with the supply chain is to identify for each use, what the possible alternatives are, and to understand how they perform in relation to the required equivalent function.

Possible sources for the applicant to initially find possible alternatives within the supply chain include (the list is not exhaustive):

- Applicant's own knowledge (including industry employees/in-house knowledge)
- Downstream users
- Suppliers
- Trade/sector organisations

Communication with the supply chain will help to:

- Gain precise knowledge of specific function;
- Identify possible alternatives (substances and technologies);
- Provide an understanding of the technical and economic feasibility, safety and availability of alternatives;
- Identify information on existing, on-going and planned future research and development on alternatives; and
- Identify possible responses of the supply chain to not being able to use the Annex XIV substance (for the uses applied for).

Alternatives can be identified that seem feasible for a particular use; but there may be some factors that could make the transfer to such alternatives difficult. For example, a downstream user relying on their supplier's (e.g. M/I) authorisation[14] may have the use of a particular substance imposed on

[14] Note that an applicant can be a manufacturer/importer or a downstream user, or a joint application may be made in involving a number of legal entities.

them through the use of operating procedures that are set out by legislation or their customers (sometimes in countries outside the EU) and therefore substitution can only be made with prior consent. In some cases this may lead to loss of contract work, which may have economic consequences (economic feasibility of alternatives is considered in section 3.8).

On the last bullet point above, this information will be useful to gather for applicants preparing application under the SEA route. Information in the SEA on what downstream users may do if they cannot use the Annex XIV substance (i.e. if an authorisation was refused), may be needed to analyse if the socio-economic benefits of continued use of the Annex XIV substance (for the uses applied for) outweigh the risks to human health and the environment. Gathering this information from the supply chain at the same time as information on alternatives will optimize the applicant's data gathering and give a better understanding of what possible alternatives might be used. Guidance on Socio Economic Analysis – Authorisation is set out in a separate guidance document (this includes guidance on developing a consultation plan in Appendix A of the guidance).

Supply chain communication is an interactive process and can involve all relevant parts of the supply chain from downstream users to suppliers, involving the appropriate experts. This is important for identifying possible alternatives for all uses applied for. Suppliers may have identified a possible alternative that the downstream users are unaware of and *vice versa*. Downstream users usually have a clear understanding of the functions required by a substance/product/process, whilst suppliers, manufacturers and importers may have a more informed view on possible alternatives. Contact with trade associations could also prove useful in this regard.

Consultation with the supply chain is an interactive process, so when possible alternatives have been identified, the supply chain may have to be consulted further on technical and economic feasibility; environmental and human health hazards and risks; as well as availability of alternatives. Guidance for Downstream Users sets out guidance on aspects of communication with the supply chain from the DU's point of view. Example 2 illustrates the process of supply chain communication for a substance.

**Example 2.** Illustration of supply chain communication

Substance B is used as a coolant and a lubricant for metal-working. When coolants/lubricants containing substance B are used, the substance has potential emissions and risks for the environment. Workers are potentially exposed to the substance through skin contact or inhalation of dust or mist and there are risks for workers through use of the substance.

The initial view of the supplier (here M/I as applicant) was that it would be difficult to find a suitable substitute. The supplier had contacted relevant downstream users in order to gather information to develop the CSR for substance B. During this process information on possible alternatives and process changes required to accommodate possible alternatives were gathered.

As a result of the collected information, the supplier contacted users, to identify possible alternative for the substance in the metal working fluid.

Possible alternatives identified through communication with the supply chain DUs were:

| **Possible alternative** | **Identified problems** | **Possible solutions** | **Comments** |
|---|---|---|---|
| Sulphur based oils | Production of $SO_2$ during use and risk to workers also problem for waste and disposal of substance after use – environmental risk and | Control of sulphur release and emission. | Expensive to fit and require very large investment in equipment disproportional to benefits |

| | | | |
|---|---|---|---|
| | cost implications. | | |
| Animal fat oil | Problems with use at high temperature – inadequate cooling. | Addition of additives to increase high temperature resistant properties | No such additives available |
| Vegetable fat oil | As above | As above | As above |
| Zinc-based compound | Increase of environmental risk | Control of metal in waste – emissions treatment. | Very difficult to remove metal component from waste stream. |
| Process optimisation | Requires different formulations to be used according to the material (i.e. type of metal) that is being processed. | Testing required to identify possible reformulation of products in order to reduce and eliminate use. | Requires drawing on R&D and possible technical testing programme. Business risks as programme has costs and may not be possible at busy times. |

For the options above the details of the relevant R&D may be appropriate to set out in the analysis of alternatives, in particular where the supplier and user identified that testing would be required in order to understand better if the alternative was a technically and economically feasible option (consideration of R&D is in section 3.9).

This process of collecting information from the supply chain was repeated for each use that is to be applied for by the applicant. Information on alternatives can be summarised as in the table above.

It may also be useful for the applicant to consider the possible barriers to information gathering on the substance and possible alternatives. For example, effective communication within the supply chain may be hindered by aspects of confidential business information (CBI), which may prevent some parts of the supply chain giving full and precise information on specific uses and possibly on possible alternatives. In this case, the downstream user would need to consider the possibility to supply that information under a confidentiality agreement with his supplier or to make his own application for the authorisation of that use. Box 2 sets out CBI and competition law in this context.

## Box 2. Competition Law and confidential business information (CBI)

**Competition Law**

EU Competition law is not intended to inhibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between companies or decisions by associations or concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are prohibited (Article 81 of the EC Treaty).

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

not give rise to antitrust concerns.

Further information and considerations can be found in the Guidance on data sharing.

**Confidential business information (CBI)**

Some information or data may be considered by companies to be confidential business information (CBI) that they consider important to protect. Whether certain information is CBI, needs to be determined on a case-by-case basis. CBI issues must not be confused with competition law which refers to situations where the sharing of information is likely to lead to distortion of competition (see above). The Guidance on data sharing is also considering CBI in detail, including useful options identified to circumvent problems with CBI (e.g. using third party experts to assess information which companies do not want to exchange).

3.5.2.2.Communication outside the supply chain

For information on possible alternatives, it may be useful to contact other manufacturers, research organisations, environmental or consumer groups, academic institutions, industry experts or other third parties. This is particularly important when a possible alternative is not produced by manufacturers/suppliers within the supply chain.

It will be possible to search within the REACH IT system i.e. IUCLID 5, for substances within the same broad category of use, and this may act as a starting point for identifying possible alternative substances. There may be difficulties associated with this approach, for example where possible alternatives are not part of the applicant's portfolio of products or where another company holds a patent on an alternative technology.

External sources to be consulted will vary depending on the substance under consideration. It may prove useful to consult:

- Key suppliers/manufacturer/importers not within the substance supply chain
- Key process/technology developers/producers not within the substance supply chain
- Leading academic and research institutions on chemicals and processes
- Publicly available tools and databases

Possible sources for the applicant to initially find possible alternatives outside the supply chain include (the list is not exhaustive):

- Academic/trade journals
- Trade/labour unions
- EU and non-EU programmes on chemical safety
- REACH-IT system
- Non-confidential Annex XV dossier information; comments from public consultation and response to comment
- Patents databases

## 3.6. How to determine the technical feasibility of alternatives

Technical feasibility of an alternative is based on the alternative fulfilling or replacing the function of the Annex XIV substance. It is therefore closely linked to the function that the Annex XIV substance performs, i.e. the specific task that the Annex XIV substance performs and under what conditions the function must be performed as discussed in Section 3.5.1. Therefore, the function of the Annex XIV substance in the uses applied for must be clearly defined before considering the technical performance and feasibility of the alternative(s).

In principle, the assessment of technical feasibility may be straight forward as it may be a case of selecting an alternative that meets specific functional requirements in order to replace the Annex XIV substance. However, the process changes that may be needed in order to accommodate the alternative have to be considered in all cases. On the other hand, the determination of technical feasibility may require a more detailed analysis and may include research in order to identify whether the alternative can perform or replace the function of the Annex XIV substance as well as possible trials to verify performance.

### *3.6.1. Technical feasibility criteria*

It may be possible to develop technical feasibility criteria (i.e. a list of technical requirements on function that must be fulfilled for an alternative to be technically feasible, see Box 3). A good understanding of the substance function is the basis for the development of these criteria. This list of criteria may include the tolerances of these requirements (i.e. an acceptable range) and may also include consideration of the constraints on functionality. For example, for replacing one substance with another the criteria may include a criterion on the minimum purity required or minimum physical or chemical properties that must be imparted to the end product. For the process changes needed to allow the use of an alternative, criteria may include the range of conditions that can be achieved with available technology and evaluation of whether these enable the alternative to be used for the desired function.

**Box 3. Technical feasibility criteria and performance analysis**

The development of criteria for evaluating technical feasibility could include a series of steps, as set out below (a screen-printing ink cleaner is used as the example*):

1) Review the functional requirements of the use. For example, for a printing ink cleaner a minimal amount of residual ink on the screen after cleaning may be a specified requirement. A performance criterion may be that the screen must be cleaned until no visible ink residue remains on the screen surface.

2) Identify relevant performance characteristics that could be qualitatively or quantitatively evaluated. For example these might include the ease of use (e.g. the physical effort required to clean the screens), the time required to accomplish the desired function (e.g. cleaning), the effectiveness of the alternative in achieving the function, or the effect of the alternative on the quality of the finished product (e.g. will use of the cleaner reduce the life of the screen).

3) Establish a performance scale for each of the performance measures to facilitate evaluation of the alternative/s. The scale should consider both subjective and objective characteristics. (For example, visual inspection could be used to assign a high, medium or low level of cleanliness. A quantitative test, such as light transmission through cleaned screens, could be used to quantitatively measure the amount of residual ink left on a screen after cleaning). Some objective characteristics can be evaluated using standard product specifications, such as military specifications.

The technical criteria against which possible alternatives can be appraised for feasibility will depend upon the

consideration of the function as well as other concerns such as customer requirements. The approach to technical feasibility set out here relies upon setting a basis for technical feasibility that is determined by the functioning of the Annex XIV substance (the assumption here is that the Annex XIV substance performs the function adequately, otherwise the applicant would not be considering applying for continued use of the substance). However, this does not disregard the possibility that an alternative may out-perform the original substance in terms of technical functionality.

Evaluation against technical criteria measures how well an alternative performs to meet the functional requirements of the use. Technical performance data can be collected for both current use and the alternative processes and used as a basis for an evaluation. The effort required to perform a useful assessment of technical feasibility may vary depending on the thoroughness of the study and the specific nature of the process under consideration. In the first instance the evaluation would rely on the compiling of performance information from literature sources and from consultation rather than the design of an actual operating trial. The focus for the user will be on the:

- Design of accurate and reliable performance measures.
- Collection of required data from suppliers.
- Evaluation of relative performance of the alternative.

** Based on the US EPA document: US Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543*

### *3.6.2. Consideration of process adaptation and changes*

The selection of possible alternatives to the Annex XIV substance can be done based on consideration of the replacement of substance function with another substance or with a technical alternative or perhaps by eliminating the need for the Annex XIV substance through process change or changing the end-product. How to use substance function to identify possible alternatives is considered in the previous section (section 3.5). The determination of what process adaptations or changes may be needed to replace or remove the need for the Annex XIV substance and whether these are technically feasible are considered below.

The technical feasibility of an alternative will be highly dependent on the possibility of the process adaptations and changes that may need to be put in place in order for the alternative to perform the desired function. Therefore, the consideration of the questions below for each type of alternative is recommended in order to address the technical feasibility of a possible alternative (i.e. substance or, technical alternative or process redundancy) [15]:

1. Is it possible to replace the Annex XIV substance with an alternative substance?
    a. If yes, what adaptations to the process are needed?
    b. Are these adaptations technically feasible for the applicant?
2. Is it possible to replace the Annex XIV substance with an alternative technology?

[15] Considerations on the economic feasibility of replacement of the Annex XIV substances are set out in section 3.8. Considerations for the documenting past or future R&D are set out in section 3.9.

   a. If yes, what adaptations to the process are needed in addition to applying the technology for replacing the substance?
   b. Are these adaptations technically feasible for the applicant?
3. Is it possible to make redundant the process or a part of the process in which the Annex XIV substance is used?
   a. If so, what changes are needed?
   b. Are these changes technically feasible for the applicant?

Consideration of process conditions influencing the functional requirements have also been given in section 3.5.1 The alternative may not need to be used under the same process conditions as the Annex XIV substance in order to fulfil the same function. For example, it may be possible that the constraints imposed by the use of other chemicals or processes could be adapted or changed to accommodate an alternative. However, the constraint may be imposed by the conditions under which the function must be performed.

Process change is normally required to accommodate an alternative and technical feasibility should not be discounted on the basis that an alternative cannot be simply substituted without any process change. For example:

- Changing one chlorinated solvent for another with a higher boiling point in vapour degreasing baths may mean increased use of energy to produce the necessary vapour.
- The design and use of spraying nozzles for the use of biodegradable mould releases; the nozzles for the current substance in use are not effective with the alternative substance. Adaptation of the design of the nozzles allows the alternative to be used.
- In offset printing, certain rubber mixtures for the rollers could not be used, as they tended to swell with alternative substance. Using different material for the rollers allowed the use of the alternatives. This however required tests to determine the technical feasibility of the new roller types (with time implications).

An alternative substance or technology may also require investment in equipment for it to become technically feasible. Therefore, what process changes and investments in equipment and training are required should be identified and described. These may include:

- Determining what equipment and worker training will be needed for changes in the process required in order to accommodate the use of an alternative substance or technique.
- Assessing the requirements associated with installation of equipment e.g. space (housing) considerations, health and safety requirements (for installation and operations of equipment) and maintenance and repair of equipment.
- Calculating the cost of equipment and training requirements[16].

Based on consideration of the constraints, an assessment can be made of whether it is possible for the applicant to replace the Annex XIV substance through changes and adaptation to accommodate the alternative or remove the need for the Annex XIV substance function altogether. However, the technical feasibility of these adaptation or changes will also be dependent on further factors.

[16] The analysis of economical feasibility is addressed in section 3.8.

Therefore the assessment will also comprise consideration of requirements which may include one or more of the following:

- Legal requirements: for example relating to product safety.
- Customer requirements: for example changes that require customer approval.
- Testing or research requirements: for example the process change may need to be tested to ensure that it is compatible (this may have fit in alongside normal production processes), or research may be needed to analyse the effects of the process change.

The outcome of the assessment of the technical feasibility of process adaptation or change has to be documented in the application. The assessment of technical feasibility of alternatives may clarify actions needed to make an alternative technically feasible or reveal need for research and development to develop or ensure the technical feasibility of an alternative. In such case relevant action, together with a timetable, and/or R&D should be documented in the application. How to do this is set out in further sections of this guidance:

- Circumstances that might prompt the inclusion of R&D in the analysis of alternatives is considered in section 3.9.1; and
- The listing and documentation of the actions that are needed in order to make an alternative suitable and available are set out in section 3.11.

Example 3 is intended to give an illustration of the consideration of the technical feasibility of alternatives.

**Example 3. Considerations for technical feasibility**

Substance C is used in plating of metals and plastics; it is used to lower the surface tension of metal plating solutions to prevent the formation of mists containing potentially harmful components from the baths. The substance is used specifically in this application for hard metal and plastic plating and decorative metal plating.

The importance of the substance for metal plating is that it is stable in 'hostile' environments, such as hot metal acid, where it can form a foam blanket on the surface of the treatment bath, thereby preventing the release of acid mists by acting as a barrier. The substance is considered to be vital to operations of this type ensuring the health and safety of workers and reducing the risks of health impacts (including lung cancer and metal exposure ulcers) associated with metal plating. Prior to the introduction of the substance, control of metal ion emissions was by local extraction – substance C is considered to have made the control of mists more efficient and a considerable help to meet Workplace Exposure Limits.

Suppliers purchase aqueous solutions of the substance C, which they may dilute further and then sell to their customers. Typically 10% solutions are used.

R&D suggests that the substitution of the metal ion with a less hazardous ion of the same metal in some plating applications (use 1) would eliminate the need to use any substance for prevention of mist formation. This option is not available for use 2 – alternatives for this use are subject to industry research.

**Difficulties with technical feasibility**

<u>Substance alternatives</u>

There are currently no known alternative chemical mist suppressants to the substance for metal and plastic plating. Testing* has shown that substitute mist suppressants, such as substances D and E are not technically feasible because of excessive pitting of coatings and rapid breakdown during the process (electrolysis). [*Reference to relevant R&D reports or findings supports this]

**Possible technically feasible alternatives**

Technical alternatives

A number of options for mechanical mist suppression and improved ventilation have been identified.

For use 2, the longer time periods of immersion in the electrolyte required to obtain the necessary thickness of coating provides the opportunity for greater tank enclosure (compared with use 1 where immersion times are measured in minutes rather than hours/days). Whilst causing some interruption to the process of immersing and taking out articles, this would eliminate the need for chemical mist suppression to meet occupational exposure level when combined with suitably adjusted ventilation extraction (the use of the metal ion is already limited in the automotive electric and electronics industries).

For use 2 applications the use of greater physical tank enclosures presents some operational disadvantages over the use of chemical mist suppressants. These include the need to remove and replace the enclosure between operations; the advantage of chemical mist suppressants being that they effectively provide a floating chemical enclosure through which articles can be raised and lowered. Such disadvantages do not occur with the use of improved ventilation extraction alone. However, while these may present operational disadvantages over chemical mist suppressants there are no technical disadvantages from the perspective of product quality /production standards.

Process changes making the Annex XIV substance function redundant

For use 1, the indication from R&D is that the use of the less toxic ion of the metal would eliminate the need for substance C (or any other substance for the prevention of mist formation) in this use and would not result in any significant technical difficulties and may have a number of technical advantages including:

- production of fewer rejects and freedom from burning
- better metal distribution and good covering resulting in better corrosion production
- easier draining because of the lower viscosity and lower chemical concentration of metal ion electrolytes resulting in less staining of the work.
- uniform coverage without build up on high current density areas
- maintained plating and deposit appearance over a very wide current density range

### *3.6.3. Uncertainties in determining technical feasibility*

It is important to clearly set out what the uncertainties are in the documentation of the analysis of alternatives and determine how they may affect the outcome of the assessment of the analysis. Setting out the actions required to make an alternative suitable and available (see section 3.11) will therefore be a critical part of the analysis of alternatives and this will include the consideration of what needs to be done to make an alternative technically feasible. The uncertainties, for example the possible outcome of research, product safety[17] and technical test-trials will need to be part of the documentation.

[17] Product safety referred to here relates to the possible legal requirements, such as for fire safety as distinct from the analysis of safety of chemical within REACH (i.e. in the CSA).

## 3.7. How to compare the risks of the alternative and the Annex XIV substance

### *3.7.1. General considerations on assessing and comparing the risks*

The use of a suitable alternative must lead to a reduction in overall risks to human health and the environment compared to the Annex XIV substance. Therefore, in the analysis of alternatives it is essential to compare the potential risks of possible alternatives to the Annex XIV substance for the uses that are being applied for. This should also include the consideration of the appropriateness and effectiveness of risk management measures that control risks.

Note that for substances included in Annex XIV and following the SEA route to authorisation (based on the provisions in Article 60(4), see section 1.5.5. for further details on applicability), an SEA report, which may include an assessment of health and environment impacts made according to the Guidance on Socio-Economic Analysis - Authorisation will be available. This assessment could be used to support the decision making on whether the possible alternatives will lead to a reduction in overall risks or not.

The assessment of risks related to the alternatives has a comparative nature. It should document whether or not the transfer to the alternative would result in reduced overall risks to human health and the environment. It is therefore important not only to consider the risks that resulted in the requirement for authorisation (based on the substance properties listed in art. 57), but also all other possible risks resulting from the Annex XIV substance and the alternative. The aim is to assess the effects of the transferral to the alternative in reducing the identified risk of the Annex XIV substance while not causing other risks that cannot be controlled.

For example, in relation to alternative substances, the work involved may include:

- collecting data on the properties of alternative substances from manufacturers and importers or other sources (e.g. registration dossiers on alternatives when these have been registered, or from other sources when registration has not yet taken place);
- examining the hazard profiles of the alternative substances and comparing them to the hazard profile of the Annex XIV substance to assess whether it is possible to determine with sufficient certainty that the alternative would result in a lower level of risk;
- examining the exposure levels of the alternative substance, e.g.,
    - examining information on emissions to the environment and/or environmental concentrations of the alternatives and data on current levels of exposure of workers or consumers from publicly available sources or impacts associated with alternative options;
    - using exposure modelling
- where necessary, combining the hazard and exposure data for alternatives to determine whether they would result in a lower level of risk
- if appropriate, quantifying and valuing the change in risk following the approach set out for the Annex XIV substance.

The applicant is not required to generate new hazard data or provide a chemical safety assessment for each of the alternatives. Nor is it required that the risks associated with alternative substances or

technologies are assessed in the same detail as the risks associated with the Annex XIV substance. The level of effort that needs to be put into this assessment above the documentation of available information will be a matter of judgment for the applicant. For example, the comparison of hazard profiles may indicate that the alternatives present a clearly lower level of risk. In these cases, no additional assessment may be necessary. When a comparison of hazard profiles or a lack of data raises concern, then there may be a need for more detailed assessment of any changes in risk following as appropriate the approaches described in the guidance on preparing chemical safety assessment.

For the purpose of the analysis of alternatives, when the applicant can show that an alternative that could be assumed to entail lower risks is not technically or economically feasible for him, it would not be necessary to continue with further assessment of the risks of the alternative. However, if the applicant considers inclusion of a SEA in his application, it may be useful for the applicant to provide information comparing the risks of alternatives to those of his application (even if the alternatives are not feasible for the applicant) to be used as a basis for the assessment of health and environment impacts within his SEA.

### *3.7.2. Collecting hazard and risk information on alternatives*

This section addresses primarily how to collect information on alternatives that are substances, but to some extent also provide information relevant for alternative technologies (e.g. see box 4).

As already mentioned it should be noted that the applicant is not required to generate new hazard data or perform and submit a chemical safety assessment in order to determine the safety of possible alternatives. However, the applicant should use all information available for him, including public information generated by possible registrants of the alternative substances.

The guidance for preparing the CSA will be useful for collecting and generating easily available information on hazards and risk and control of risks in order to compare the safety of the alternatives with the Annex XIV substance. For example, the applicant can use the same basic information strategies in assessing the risks of alternative substances as set out in the Guidance on information requirements and CSA. These approaches consider what the applicant might do in cases where information on hazard and exposure of the alternative substance is scarce or are not available, for example because the alternative substance is not registered under REACH[18]. Where there is insufficient information on hazards for the purpose of concluding whether the overall risks are reduced by a transfer to an alternative substance, the applicant may for example use methods like quantitative structure activity relationships ((Q)SARS) and 'read-across' from similar substances.

The CSA guidance also includes detailed information on data search strategies and databases for collection of available data using publicly available data sources to assist with gathering information on possible alternatives. Box 4 gives some further examples of internet based information tools that have been developed to assist with comparing safety of alternatives. The

[18] Availability of data via REACH-IT will be dependent on whether substances have been registered (above 1 tonne per annum). Note that the registration timetable depends on the tonnage band therefore this will determine whether and when information is available on possible substance alternatives within the REACH system. It should also be noted that the whole registration dossier is not publicly available.

examples in Box 4 are only examples of the type of information that is freely available and are not recommendations. Note that none of the databases is designed specifically for REACH.

**Box 4. Examples of databases and tools to assist with hazard and exposure information on possible alternatives**

There are a number of publicly available databases that have been set up aimed at assisting the substitution of dangerous substances. Some allow hazardous properties of substances to be searched, while others provide examples of how hazardous substances have been substituted (i.e. case studies). Some of these databases are listed and commented upon below (these are examples and there are other databases available):

**Examples of alternative comparison tools:**

*Tool: P2Oasys Tool to Compare Materials*

Developed by: TURI - Toxics Use Reduction Institute (University of Massachusetts Lowell USA)

Web reference: http://www.turi.org/

Description/comments: The aim of P2OASys is to allow companies to assess the potential environmental, worker, and public health impacts of alternative technologies aimed at reducing 'toxics' use. The tool is supposed to assist companies in two ways: 1) Examine the potential environmental and worker impacts of 'TUR' options in a comprehensive manner, examining the total impacts of process changes, rather than simply those of chemical changes. 2) To compare TUR options with the company's current process based on quantitative and qualitative factors.

Input of data can be quantitative and/or qualitative data on the chemical toxicity, ecological effects, physical properties, and changes in work organisation as a result of the proposed option.

*Tool: Column Model*

Developed by: Berufsgenossenschaftliches Institut für Arbeitsschutz - BGIA

Web reference: http://www.hvbg.de/e/bia/

Description/comments: Various types of hazard (health, environmental, fire and explosion, potential emission and procedural) are grouped in columns and the attributes of a possible alternative could be compared (with the Annex XIV substance) within a group/column. This allows the user to focus on the hazards and exposure potential that is most significant for the use of the alternative.

Because of data uncertainties, data quality and the mix of quantitative, semi-empirical and qualitative data used to complete the matrix; a risk index of this type can be subjective.

**Example of hazardous substances database:**

*Database: PRIO*

Developed by: KEMI (Swedish Chemicals Agency)

Web reference: http://www.kemi.se/

Description/comments: The aim of PRIO is to facilitate in the assessment of health and environmental risks of chemicals so that environmental managers, purchasers and product developers can identify the need for risk reduction. To achieve this PRIO provides a guide for decision-making that can be used in setting risk reduction priorities.

The PRIO database is most useful for users identifying the hazardous properties of the substances they use in order to help them in priority setting for action on the substance, rather than identify possible ('safer') alternatives to a substance. Listing of alternatives is not currently available, but may be considered in the future.

**Example of substitution experience database:**

*Database: CatSub*

Developed by: European Agency of Occupational Safety and Health, Danish Working Environment Authority

and Danish Environmental Protection Agency

Web reference: http://www.catsub.dk

Description/comments: Catsub is a database of examples of the substitution of hazardous substances. The data base is populated with some 200 examples which can be viewed. The process of substitution difficulties and how these were overcome is provided in the commentary from industry and authorities.

The database does not provide information 'look-up' on hazardous properties of substances or have possible alternatives for dangerous substances other than those in the database examples. The examples are in the Danish language (apart from eight examples in English). There are plans to develop Catsub into an international tool for substitution.

It should be noted that the information on the comparison on the risks of the Annex XIV substance and alternative(s) may be of use in an SEA, if such an analysis is to be performed for the application. As noted in sections 3.2 and 3.4.2, key information collected and analysed in the analysis of alternatives may be used in the SEA. Conversely, the assessment of health and environment impacts that may be carried out as part of the SEA could be used in the analysis of alternatives to support the decision making on whether the possible alternatives will lead to a reduction in overall risks or not. Box 5 sets out the links between the comparison of risks in the analysis of alternatives and the assessment of impacts in the SEA.

**Box 5. Comparison of risks: links to the SEA**

The aim of the SEA as part of an authorisation application is to assess whether the socio-economic benefits of the use of the Annex XIV substance (for the uses applied for) outweigh the risks to human health and the environment (see Guidance on Socio-Economic Analysis - Authorisation). To do this two scenarios are compared:

1. The use of the Annex XIV substance for the uses applied for (this is called the 'applied-for use' scenario); and

2. Not using the Annex XIV substance for the uses applied for (this includes what the response to the 'non-use' (i.e. removal) of the Annex XIV substance would be – this is called the 'non-use scenario'.

In order to compare the two scenarios, there is a need to understand what the impacts of the two scenarios are, and to assess what the difference is (i.e. the net impact). When assessing the health and environmental impacts, a stepwise approach is proposed, whereby the assessment focuses on those impacts that are considered to be significant outcomes of the authorisation, with the level of detail and quantification applied determined by the extent to which further information will be needed in presenting a robust SEA. Throughout the process, judgements will need to be made on what impacts are likely to be significant and how these can best be assessed.

The basis for the identification and assessment of health and environmental impacts is a proper understanding of the changes that granting or not granting an authorisation causes on step 1-3 below:

1. The use of the Annex XIV substance or the use of any alternative substance or technology.

2. The resulting emissions and exposures,

3. The subsequent impacts to health and environment,

4. If possible, valuation of these changes in impacts can be applied as a last step.

The stepwise assessment of changes induced needs to be done for the Annex XIV substance as the 'applied-for use' scenario and any alternative substance or technology identified for under the 'non-use scenario'. Respectively, any other affected process upstream or downstream in relation to the Annex XIV substance or to alternative(s) will be analysed.

The above outline is used as the conceptual framework for identifying, assessing and, if possible, quantifying, and ultimately valuating health and environmental impacts in the SEA.

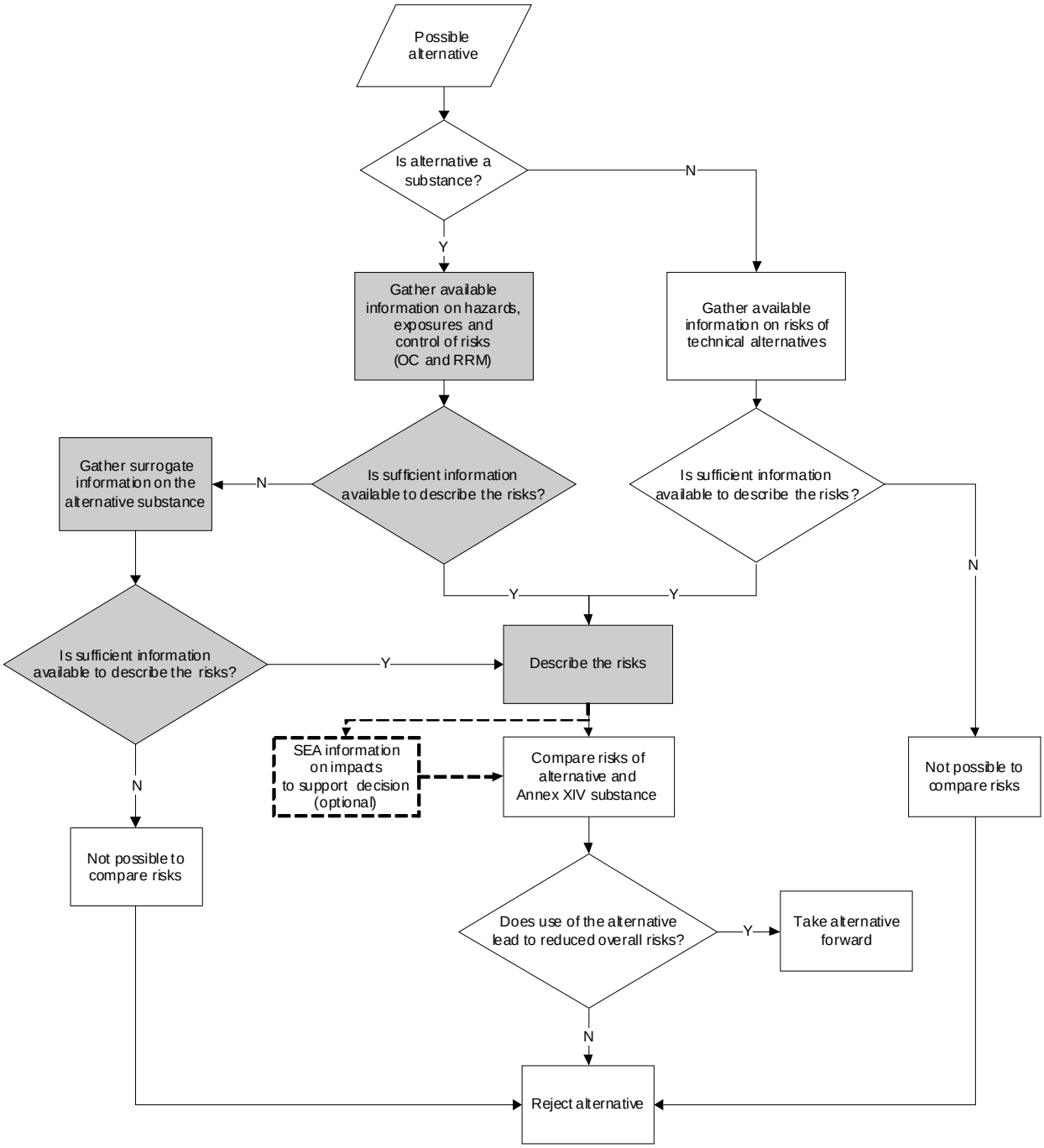
The analysis of alternatives may have considered replacement or adaptation of the end product that would lead to removal of the need for the Annex XIV substance altogether. However, the extent/scope of the analysis of alternatives may not have covered the extent of the non-use scenario in the SEA (e.g. use of a non-suitable alternative which may be applied in case the Annex XIV substance is not granted authorisation). This may require the gathering of further information for the impact assessment of the SEA as mentioned in sections 3.3 and 3.5.2 above.

### *3.7.3. Assessing and comparing with the risks of possible alternative substances*

In principle the assessment of human health and environmental risks for an alternative substance can be conducted using the same approaches as for the Annex XIV substance for which a CSR is developed as a part of the application. However, the Guidance on information requirements and CSA does not consider the comparison of risks between substances (i.e. comparing the risk of the alternative with the Annex XIV substance).

In order to be able to compare the risks arising from the available alternatives one needs to take a flexible approach towards the assessment of such alternatives, as well as the Annex XIV substance. Ideally the assessment should address all possible risks throughout the entire lifecycle of the substances including all relevant compartments and populations, even those not originally associated with the identified risk. The reason for this is that, while an alternative may reduce the specific identified risks of the Annex XIV substance, it may pose other risks at different points in its lifecycle or may shift the risks to other compartments/populations when it replaces the substance of concern. In other cases, the use of alternatives may have secondary adverse effects that may not be immediately recognisable, for example, an increase in the production of hazardous waste at the end of the lifecycle or increased energy consumption.

It is recommended that the assessment of the risks of possible alternatives is approached in a step-wise manner, considering whether there is sufficient information on hazard, exposure, risk and risk control in order to make an assessment of the risks of the alternative and compare this to the Annex XIV substance. Figure 9 illustrates in a general flow diagram how one might address the risks of alternatives.




Note: Solid grey boxes indicate where guidance on gathering hazard and exposure information and chemical safety assessment of substances is set out in Guidance on information requirements and CSA (including where surrogate information on hazards may be derived such as (Q)SAR and read-across); the dashed box indicates a link to Guidance on Socio-Economic Analysis - Authorisation.

**Figure 9 Flow diagram for the assessment of and comparison to risks of alternatives**

The assessment of alternatives should be based primarily on risk rather than hazard. However, risk-based replacement of the original substance or process may not always be simple or indeed feasible. Therefore, assessing the risks of alternatives substances may be conducted using a tiered approach starting from a comparison of the hazardous properties and, if necessary, possibly ending in a full assessment of the risks arising from the alternatives.

A detailed tiered approach is described in Box 6. Each tier increases the level of data required and complexity of the assessment. However, the complexity of the assessment is highly dependent on the properties of the alternative substance or technology. For example, if a clearly less hazardous substance is available then a comparison of the hazardous properties could be enough, or in the case where an alternative technique results in the elimination of emissions of the substance of concern, then a description of the resulting emissions could be suitable. Nevertheless, care should be taken to assess other possible secondary effects of the alternative, such as possible increases in the production of hazardous waste or increased energy consumption.

**Box 6. A tiered approach for assessing the risks of alternative substances**

For alternative substances the tiered approach set out below may be appropriate. Such an approach may include the following levels of increasing complexity:

- **Tier 1:** Comparison of the hazards of the alternative substance to those of the substance of concern.

  Part A: Collection of available hazard information for the alternatives. Where registration dossiers and other REACH-related information (Articles 31 and 32) are available, these may be reviewed. If such sources are not available, other sources should be considered (see section 3.5). Where vital information is missing, consideration may be given to generating this, for example, by use of (Q)SARs. Uncertainty on the validity of such results should be acknowledged and documented in the analysis.

  Part B: Comparison of the hazard information of alternatives to that of the Annex XIV substance. This assessment should be used as a screening process to rank alternatives based on their hazard profile in order to help on whether to consider such alternatives as potentially suitable. This comparison should first look at those hazard properties of highest concern such as PBT/vPvB, and CMR characteristics. If both the Annex XIV substance and the alternative substances have similar properties of concern or when all potential alternatives have PBT/vPvB/CMR properties, the applicant should take into consideration information on the potential exposure and any possibilities to better control the exposure[19]. Furthermore, for applications via the SEA route a health and environment impacts assessment may form part of an SEA. This assessment can provide further information for the decision on whether the alternative would lead to a reduction in overall risks or not. The same principles apply when comparing less severe hazard properties. If the alternatives have been registered and have been assessed for risks, PNEC and DNEL values for them may be available and these may be compared to those for the Annex XIV substance. Also, the collection and comparison of information on physico-chemical properties of the alternatives may be pursued if it is of particular relevance to the identified risks.

- **Tier 2:** This would involve the use of information on the alternative substance (properties and hazards) within the Chemical Safety Assessment for the Annex XIV substance to perform a quick revised exposure assessment and risk characterisation for the alternative for the applications associated with the identified

[19] If an alternative substance is already on Annex XIV, it will normally not make sense to transfer to it. If the substance is on the candidate list, then a very close consideration on the overall risks should be given before transferring to it. If the alternative substance seems to fulfil article 57 criteria but it is not yet on the candidate list or registry of intentions, the applicant should document his reasons for suspecting the substance to be a SVHC and such hazard profile could be seen as an argument that the transfer to this substance may not reduce the overall risks.

risk; there may be three possible situations of increasing complexity:

1) If the exposure assessment for the Annex XIV substance shows that the release estimates do not depend on the substance properties, then the existing emission estimates for the original substance may be used.

1a) When the alternative has similar physico-chemical and environmental fate properties to the Annex XIV substance, it may be sufficient to use the existing PEC values for the comparison of the PNEC or DNEL values of the substance of concern and the alternative; or

1b) When the alternative does not have similar physico-chemical and environmental fate properties to the Annex XIV substance, the emission estimates may be used in conjunction with environmental fate data on the alternative to calculate its PEC values. These should then be used to revise the risk characterisation.

2) If the emission estimates in the chemical safety assessment depend on the substance properties, it may be possible to estimate whether the alternative would have lower or higher emissions than the Annex XIV substance by simple consideration of the properties. However, it is possible that emissions to one compartment may increase while those to another decrease, and it will be difficult to make a simple judgement on how this would affect the PECs (for regional concentrations at least). In such cases, it may be necessary to estimate the emissions of the alternative substance and then carry out similar calculations as those for the substance of concern to generate PEC values. It may also be necessary to consider the effect of replacing the substance with the alternative in terms of the tonnage of the alternative that would be required. For example, the registration dossier for the alternative will be based on the current tonnage and uses and is unlikely to consider an increase in use or a new use as a result of replacement (see also Appendix 5 on 'risk profiling' for environmental risks of substance alternatives).

- **Tier 3:** use of exposure scenarios specific to the alternative substance (rather than those for the Annex XIV substance) to perform an assessment of risks for the alternative for the applied for uses across all compartments/populations at risk. This will effectively be similar to Tier 2 only that the Exposure Scenarios will be specific to the alternative substance for the applications associated with the identified risk, if available for example from an annex to the SDS or from a registration dossier for the alternative.

  Note: This approach has been adapted from an approach set out in Guidance for the preparation of an Annex XV dossier for restrictions

It may also be the case that the Annex XIV substance would have to be replaced not by a single substance but rather a combination of substances or a complete reformulation of products containing the substance or even by alternative substances used within an alternative processes. In such cases, the combined effects of such changes may be difficult to assess. Therefore, the analysis may include an assessment of the potential effects of each alternative used in isolation and some discussion of the envisaged implications of combined effects may be provided.

For hazard data, the key health and environmental effects of alternatives should be identified where this is possible. For alternative substances particular attention should be focussed on carcinogenic, mutagenic or reproductive effects and PBT and vPvB properties. These comparisons of similar properties and effects between substances are not necessarily straightforward or simple. The classification and labelling of possible alternative substances can be consulted in the list of harmonised classifications (Part 3 of Annex VI to Regulation (EC) No 1272/2008 (if available[20])

[20] The Classification and Labelling Inventory (database) is available at the ECHA website.

and the hazard statements applied to substances may be useful in the assessment of the comparative hazard[21].

The comparison of different hazards and their magnitudes may require value judgments about the acceptability of different risks to different endpoints. For example, such judgements may involve comparing different types of health impacts (e.g. liver toxicity versus neurological effects) or different effects to the environment. Simultaneously ranking health, safety and environmental risk may require the applicant to be involved in trade-offs which are not always straightforward. Risks of the alternative may also be difficult to compare to those of the Annex XIV substance because they may be of a radically different nature. For example, a substance of low toxicity could have an adverse effect on the earth's ozone layer. Alternatives may be more benign with regard to such effects but they could be, for instance, flammable, toxic or may pose other hazards to the environment. In these cases, the applicant should assess the relative importance, gravity, imminence and implications of the different types of risk and decide whether the risks introduced by the alternatives are acceptable and why.

The applicant may also need to consider the wider implications of the risk and impacts in order to further inform and support the decision on whether the use of the alternative would represent a reduction in risk. This may include addressing risks of various other substances from other processes, i.e. upstream or downstream processes related to the manufacture or use of the Annex XIV substance and alternative substances. This may also include external impacts or substances created unintentionally, e.g. emissions from energy generation as well as consumption/production of other things such as waste production and water use.

It may not, however, be necessary to conduct a full comparison of risks on all possible alternatives. This could be very resource intensive, especially if new information needed to be collected on a number of possible alternatives in order to compare risks. For alternative substances it may be possible to conduct an initial comparison of risks by focusing on the specific use pattern, tonnage used and predicted emissions. With key (but limited) information on the physico-chemical, eco-toxicological and biodegradation properties, alternatives may be compared in terms of their predicted risk. Such a process of so-called risk profiling[22] may enable short listing of alternatives that may be of lower environmental risk.

### *3.7.4. Assessing and comparing with the risks of possible alternative technologies*

There are difficulties in comparing the risks of a substance and the risks of a technical alternative. For example, there may be risks associated with alternative technologies but these may not be of the same nature that the Annex XIV substance risks present to human health and the environment However, for it to be suitable, the alternative must represent a reduction in the overall risks to human health and the environment as compared to the Annex XIV substance. Therefore, a comparison of risks must be conducted and the applicant will need to consider how these different

[21] For example the COSHH Essentials published by the UK HSE provides a scheme by which substances can be grouped by relative hazard on the basis on risk phrases.

[22] An approach developed by the Environment Agency of England and Wales for compiling generic risk assessment from detailed knowledge of likely release patterns and the influence of key environmental properties of those substances used in a particular industry. A brief description is presented in Appendix 4.

risks might be compared in terms of risks to human health and the environment. Note that the introduction of an alternative technology to replace the Annex XIV substance may also involve a change in the use of other substances in the relevant processes. Possible risks of these substances will also need to be considered in the assessment following, as far as possible, Guidance on information requirements and CSA and section 3.7.3.

The comparison with technological alternatives can normally not be fully quantitative (i.e. with directly comparable numeric values) as the risks will not be expressed in similar terms, but will in most cases be qualitative or semi-quantitative. Nevertheless, a clear and transparent description can give a good basis for the applicant to conclude whether overall risks are reduced (and for the Agency Committee to give its opinion on that).

Especially in the case where the analysis requires the comparison of the risks of technical or process alternatives with the Annex XIV substance[23] the applicant may also need to consider the wider implications of the risk and impacts in order to further inform and support the decision on whether the use of the alternative would represent a reduction in risk. For alternative technologies consideration should for example be given to environmental controls, working practices and legislation controlling other risks (e.g., fire and explosion, confined spaces and extreme temperature and pressure). Care should be taken to assess other possible secondary effects of the alternative, such as possible increases in the production of hazardous waste or increased energy consumption (see also Box 7).

There are systems that have been developed for the qualitative, semi-quantitative and quantitative comparison of risks. These range from simple comparisons of hazard information such as the 'column model' from Germany's Berufsgenossenschaftliches Institut für Arbeitsschutz – BGIA (see also Box 4), to more complex systems that consider more far-reaching impacts from the whole life cycle of products such a life cycle analysis (LCA) and related methodologies. With LCA methodologies, however, it may be difficult to focus only on the impacts from the alternative since the LCA is concerned with all impacts from the final end product. These methodologies are designed more for selection of the sustainable manufacture and use of products than selecting lower risk alternatives for hazardous chemicals for particular uses. But the same basic methods and approaches used in LCA to describe the effects could be used.

Some consideration of the possible difficulties in comparing substances risks and risks from technical alternatives is given in the example in Box 7.

### Box 7. Comparing risks from substances and technical alternatives

**Cleaning of facades – halogenated solvents vs. high pressurised water**

The cleaning of building facades can use a number of hazardous chemicals. In this example the focus is on the use of a chlorinated solvent (that is assumed to be the Annex XIV substance). An alternative cleaning method (i.e. technical alternative) for this use is high pressure water systems. The alternative technique has risks associated with its use but these are not toxic risks but are due to the physical working environment, waste and energy use created by the use of the alternative. The risks of the solvent and the use of high-pressure water are summarised below:

[23] The socio-economic impacts of the possible wider risks of the use of alternatives may be one of the aspects considered within an SEA (see Guidance on Socio-Economic Analysis - Authorisation).

Risks of halogenated solvents:

- Exposure of workers with a toxic or carcinogenic substance (risk to workers health)
- Contaminated soil (risk to environment)
- Dangerous waste (risk to health and environment)

The identification of risks takes into account risk management measures and operational conditions related to the control of exposures. It is of importance to consider the actual effectiveness of the measures. For the purposes of this example, it is assumed that the effectiveness of risk management measures to control emission to soil is limited due to problems in putting them in place as the work moves from site to site. Similarly, occupational controls are not fully implemented in practise because the use is not in one place and some items of personal equipment (e.g. respirator) are found to be physically restrictive for the operator when using the substance in particular situations.

Risks of high pressure water:

- Accident risk due to high pressure (risk to workers' health), also for pedestrians (risk to public health)
- Noise and vibration (risk to workers' health)
- Technical Risks: Risk of damages of the façade: mechanical, wetness, oxidation, freezing (technical risk)
- Waste water (risk to health and environment)
- Energy consumption (risk to environment)

As for the substance, the risks are considered with possible risk controls in place. As with the use of the substance, some measures are not fully implemented because of the non-stationary nature of the use scenario. When assessing these (non-toxic) risks any obligations under other Community legislation setting requirement on the implementation of RMMs and OC has to be taken into account. As above, the actual effectiveness and the possibilities to implement these requirements have to be considered.

#### 3.7.4.1. Comparing with risks of alternative technologies: Human Health

Physical hazards to human health arising from the use of alternative technologies such as potential exposure to extreme temperatures, raised levels of noise and vibration or increased risk of fire and explosion are likely to be particularly relevant in the workplace. Comparison of the risks associated with use of the Annex XIV substance and those associated with other possible alternatives should include these physical risks. However, comparing different types of risks (i.e. toxic with non-toxic) is also difficult (see Box 7).

Although the guidance on the evaluation of human health risks within the Guidance on information requirements and CSA is not directly applicable to the consideration of alternative technologies and does not address all the different kinds of physical hazards that could be posed by technologies, it provides a framework for an assessment that may be applied to the assessment of these risks (i.e. comparing hazards with exposure).

Where hazards have threshold effects; no-effect 'safe' levels could be determined. These levels can be compared to the predicted worker exposure level. The implementation of control measures to mitigate risk should be included in the assessment. The safety of an alternative technique may be assessed by comparing residual exposure (i.e. after the implementation of control measures) to effect levels.

Member State Competent Authorities for the protection of worker health will often have information available on the assessment and control of non-toxic hazards. It is recommended that

such guidance is consulted to determine the relevant risks (and control measures) from alternative techniques.

3.7.4.2.Comparing with risks of alternative technologies: Environment

The comparison with risks to the environment from alternative technologies replacing the Annex XIV substance will probably in many cases primarily address changes in the use of other substances in the relevant processes caused by the introduction of the alternative technology. The risks of these substances will need to be included in the assessment and should as far as possible be assessed following the Guidance on information requirements and CSA and section 3.7.3.

A potential difficulty with comparing environmental risks of alternative technologies to those of the Annex XIV substance is that the risk of toxicity and or risk of persistence in the environment may need to be compared with other kinds of risks. For example such as the risk presented by the generation of greenhouse gases from increased use of energy or risks by increased production of waste etc. However, it should be noted that these risks could also be caused by the release of chemical substances and this difficulty is not confined to comparison of substances and technologies.

Some guidance on determining best available techniques (BAT) has been developed in the framework of Integrated Pollution Prevention and Control directive (see Box 8). This offers a methodology to allow a comparison of different options in terms of their potential environmental effects considering seven broadly defined so called environmental themes. The concept takes into account the likely cost and benefits of measures as well as aiming to protect the environment taken as a whole to avoid creating a new and more serious environmental problem when solving another.

**Box 8 Alternative techniques and comparing environmental risks: 'cross media effects' guidance from IPPC**

Choosing between different options for the control of emissions to the environment has been considered under Integrated Pollution Prevention and Control (IPPC). A Reference Document ('BREF') on Economics and Cross-Media Effects has been developed and published[1].

In the BREF document the term 'cross-media effects' is used to describe the environmental effects of the options under consideration. Choosing between alternative options might require a choice to be made between releasing different pollutants in the same environmental medium (e.g. different technology options might release different air pollutants). In other cases, the choice might be between releasing to different media (e.g. using water to scrub an air emission thereby producing waste water or filtering a water discharge to produce a solid waste). The BREF also provides guidance on comparing the costs of different abatement measures (including investment costs, operating and maintenance costs, revenues and avoided costs) the possible use of this methodology is considered later in section 3.8 on economic feasibility.

The BREF is focused comparing alternative options for determining what represents the best available technology (BAT) for controlling emissions from industrial processes in order to achieve a high level of protection for the environment as a whole. It is not specifically intended to allow a comparison between the specific use of a substance and a possible alternative. The BREF does however offer a methodology to allow a comparison of different options in terms of their potential environmental impact, taking into account different environmental media, different environmental impacts and the costs of each option.

The cross-media methodology consists of four steps. However, the first two steps (called 'guidelines' in the BREF) describe the process for identification of abatement technology and compiling an inventory of emissions for each option. Whilst this is not so relevant for identification of alternatives under the REACH authorisation process, it presents a framework for the selection of techniques that may be helpful. Steps (guidelines) 3 and 4 in which the possible effects and risks from different techniques are compared and interpreted are of more direct

use. The BREF also describes how the economic viability of different options can be evaluated.

Where the BREF may be helpful is where it considers effects other than toxic effects on humans and the environment (such as ozone depletion, climate change, eutrophication and acidification etc.). The BREF does set out assessing toxic effects, but the methodology is based on toxicity factors that have been derived from a number of air pollutants for human health and the derivation of PNECs (based on the TGD for new and existing substances). For assessing the risks of the Annex XIV substance and alternative substances the guidance within REACH, i.e. Guidance on information requirements and CSA should be used where relevant.

The BREF guidelines are summarised below:

Guideline 1 - Scope and identify the alternative options: the initial step in the process is to scope and identify the alternative options that are available and that could be implemented. The boundaries of the assessment need to be set at this stage, with the normal expectation being that the assessment will be restricted to the boundary of the IPPC process.

If at this stage there is sufficient justification to come to a conclusion, the user should stop and set out the justification for the decision.

Guideline 2 - Inventory of emissions: this step requires the user to establish an inventory of emissions for each of the alternative options under consideration.

If at this stage there is sufficient justification to come to a conclusion, the user should stop and set out the justification for the decision.

Guideline 3 - Calculate the cross-media effects: this step allows the user to express the potential environmental effects anticipated from each of the pollutants within seven environmental themes (e.g. human toxicity, global warming, aquatic toxicity, etc.). This is so that a wide range of pollutants can either be compared directly or aggregated and expressed as a total effect.

Two approaches are described which allow the mass emissions of an individual pollutant to be expressed as an equivalent effect (e.g. the Global Warming Potential of a wide range of greenhouse gases can be expressed as kg of CO2 equivalents). These allow individual pollutants to be summed and expressed as a total potential effect within each of the seven environmental themes2. The user may then be able to compare the alternatives to estimate which option has the lowest potential effect in each theme.

If at this stage there is sufficient justification to come to a conclusion, the user should stop and set out the justification for the decision.

Guideline 4 - Interpret the cross-media effects: this final step in the cross-media guidelines discusses how the user can interpret which of the alternative options offers the highest level of protection for the environment. Different approaches for comparing the result of the cross-media assessment are discussed.

The degree of uncertainty in the basic data collected for Guidelines 1 and 2 is relatively low compared to the uncertainty after subsequent manipulation when guidelines 3 and 4 are applied.

[1] *European Commission (July 2006) Integrated Pollution Prevention and Control Reference Document on Economics and Cross-Media Effects*

[2] *Environmental themes/cross media effects are: human toxicity, global warming, aquatic toxicity, acidification, eutrophication, ozone depletion and photochemical ozone creation.*

### *3.7.5. Uncertainties in evaluating risks*

The uncertainties in determining chemical safety are set out in the Guidance on information requirements and CSA. However, that guidance does not consider the uncertainties associated with determining risks that are wider than toxicity or physico/chemical effects when considering substances and in particular technical alternatives.

The quality of the data that is used to assess the risks of alternatives is important. This is because a decision on the relative risks of the alternative (i.e. as compared to the Annex XIV substance) may be based on these data. The applicant may need to evaluate the quality of the data available and to compare data from different sources where necessary. There may be quantitative measures available regarding the uncertainty that can be attributed to data. For example, reported output of emissions may be measured or estimated based on a range (e.g. ± 5 %). Using such data it may be possible to consider the upper and lower ranges to allow a sensitivity analysis.

It may also be possible to give a qualitative indication of the data reliability using a rating score. This may help to give a guide to the confidence the applicant has in the data and may help to indicate the depth of a sensitivity analysis. See the Guidance on information requirements and CSA for further guidance on evaluating data quality and reliability.

It is important that data of 'inferior' quality are not suppressed nor excluded from the assessment by considering only data of highest quality. Otherwise, if less reliable data are excluded, then applying the methodology might become a barrier to considering alternatives. New and innovative alternative techniques will often not have as much data available as established techniques. If only data of inferior quality are available, then conclusions should be drawn cautiously. However, conclusions can still be drawn and can form the basis for further discussion or to identify where more reliable data needs to be obtained.

Uncertainties will apply to the risk assessments for the Annex XIV substance and to the alternatives, but may not apply equally. This needs to be considered in drawing the conclusions.

### 3.8. How to determine the economic feasibility of alternatives

The economic feasibility of an alternative is to be addressed within the analysis of alternatives and is focused on the economic viability of the use of the alternative in the uses applied for. It focuses on the changes in applicant's costs and revenues including possible pass-through of cost to customers if he was to transfer to an alternative substance or technique.The assessment will not regard the wider impact on society or the wider economy.

The assessment may consider the economic impacts of the transferral to an alternative and the use of an alternative within the supply chain. The assessment may include:

- The investment and recurrent costs of the alternative substance or technology including how they may change over time.
- Other costs of transferral to the alternative – including equipment, training, energy use, regulatory costs, potential down-time and handling to the extent these are not covered under recurrent costs.
- The cost of R&D – including trials[24].
- The time spent and other costs by downstream users in re-specifying alternative products.
- Potential market distortions: For example if an alternative is produced by only a single company (monopoly) or a very limited number of companies (oligopoly). However, one

[24] This should be documented along other aspects of R&D, see section 3.9 on research and development.

should note that if a producer of an alternative would abuse its dominant market position, competition authorities of Member States should be notified.

One criterion for an alternative to be economically feasible is whether the net present value of the revenues minus costs is positive. In other words, the issue is that using the alternative should result in generating gross profit.

**Box 9. Economic feasibility: links to socio-economic analysis**

While the assessment of economic feasibility focuses on the economic viability of the possible alternative for the applicant; SEA addresses the wider social and economic benefits of the continued use of the Annex XIV substance (granted authorisation) and compares this to possible the social and economic impacts of the withdrawal of the Annex XIV substance from the market (refused authorisation).

Applications for authorisation for Annex XIV substances that cannot be adequately controlled can only be granted if it is shown that the socio-economic benefits outweigh the risks to human health and the environment and there are no suitable alternatives to the Annex XIV substance. The way to assess the socio-economic benefits is by conducting a socio-economic analysis (SEA) and guidance on how to conduct and document an SEA supporting an authorisation application is in a separate Guidance on Socio-Economic Analysis – Authorisation. The entry point to the SEA is that the analysis of alternatives has concluded that there are no suitable alternatives. (SEA may also be used to support authorisation application for Annex XIV substances which can be adequately controlled.)

Some of the same techniques that are used and explained in the guidance for SEA may be used in the assessment of economic feasibility and where relevant reference is made to the separate Guidance on Socio-Economic Analysis – Authorisation, including:

- Consistency in cost analysis;
- Discounting;
- Relevant product/substance life-times

These techniques are set out and explained in the technical guidance for SEA because that guidance includes the consideration of economic methodologies and is a good reference if the applicant chooses to use and apply such techniques to his assessment of economic feasibility. Since applications under the SEA route will have to include documentation of an SEA, the applicant will need to refer to that guidance in this case anyway.

The basis of determining the economic feasibility of alternatives can be called a cost analysis. This identifies the costs associated with the Annex XIV substance and compares this to possible alternatives, calculating the comparative costs between them. The analysis should also include possible changes in revenues due to substitution. Such revenues would be deducted from the costs.

The costs and revenues identified should reflect only the uses applied for and take account of economic consequences of any related changes in the production volume. It is recommended that, as a minimum, the cost analysis identifies and compares the direct and indirect costs and revenues

of the use of the Annex XIV substance and the use of alternative(s). Data may also be collected on future liability costs[25] and indirect benefits[26] that occur due to the transferral to an alternative.

Appendix I of the Guidance on Socio-Economic Analysis – Authorisation provides practical information and further guidance on how to estimate economic feasibility in the analysis of alternatives. The appendix builds on this section as well as Chapters 3.4 (Economic impacts), to some extent 3.5 (Social impacts) and Appendices B, C, D, E and F of the Guidance on Socio-Economic Analysis - Authorisation.

The process can be summarised as:

- Categorise and determine the costs and revenues that are incurred by producing or using the Annex XIV substance and the alternative(s).
- Identify possible liability issues and less-tangible benefits that can result from the transferral to the alternative.
- Perform a comparative cost analysis of current use of the Annex XIV substance versus the alternative/s.

A stepwise process for considerations in determining economic feasibility is set out below[27]:

1) Determine the data requirements for the cost analysis, including data showing if the revenues of the applicant would be affected as a result of producing or using the alternative substance or technology. It is advisable that these data are collected at the same time as data on the technical feasibility of alternatives (see section 3.5.2). Data should be collected on a "per unit production basis", or some other basis that allows a comparative evaluation of the trade-off issues (for example human health and environmental risks and energy use). Obtain these data and additional relevant cost-related data for example on energy use, risk management measures, regulatory status, process safety and market information. Determine whether resource consumption rates, waste generation rates, and worker activities data for the Annex XIV substance and alternatives are consistent. If the data are not consistent, it may be necessary to have knowledgeable industry personnel review and resolve any inconsistencies[28].
2) Estimate the direct costs associated with the operation of the Annex XIV substance and the alternatives using the data gathered in and checked in Step 1. Direct costs include capital expenditure, operating costs, and maintenance costs. Waste management costs are also examples of direct costs (but many businesses allocate these costs to overhead). The costs

[25] It can be difficult to quantify costs that are incurred as a consequence of uncertain future liability for clean-up of hazardous substance releases or for liabilities from personal injury claims stemming from environmental releases or product use.

[26] These are benefits that may occur but cannot be readily quantified (e.g. reduced health maintenance costs because of a safer work environment, or increased product sales as a result of better product performance).

[27] Based on US Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543

[28] To ensure that the cost analyses for alternatives are comparable, these data should be used in actual cost calculations only if the data are available for all of the alternatives being evaluated. There may not be sufficient data contain on new or novel alternatives that are not widely used.

relating to the application procedure (fees, personal costs for drafting and updating authorization dossier) should also be included. Estimate the revenues from the sales of the Annex XIV substance (or the product using the substance) as well as the revenues for the alternative.

3) Estimate possible indirect costs, indirect benefits and possible liability issues for the Annex XIV substance and alternatives:
    a. If there is a reasonable indication of possible liability in connection with the use of the Annex XIV substance or the alternatives, this should be considered. In most instances, the estimation of future liability cost is subject to a high degree of uncertainty. Therefore, the need to quantify the future liability may be less important than assessing how likely it is that the risk of liability could materialise in future.
    b. If possible, identify any less-tangible benefits that could result from the transferral to an alternative. The benefits of a cleaner product, process, or technology can be substantial and should not be overlooked when performing a cost analysis.
4) Perform cost analysis of the Annex XIV substance and alternative(s) using the data on costs and revenues collected in Step 1 and possibly in Step 3. (Further guidance on how to ensure the consistency of the cost analysis can be found in Appendix I and Chapter 3 of the Guidance on Socio-Economic Analysis – Authorisation. This provides guidance on dealing with; exchange rates, inflation, double counting and discounting. These are crucial aspects to any robust cost analysis.)

The above points present a generic approach for considerations to asses the economic feasibility of alternatives. In addition, it may be possible to support the cost analysis using financial ratios that may be available as these are the figures that are routinely reported for financial performance of companies (such as for reporting to shareholders or for internal financial reporting). However, in many cases these financial ratios are company wide figures rather than product specific, and furthermore, such figures are not available for the future. Therefore their use is likely to be limited. (Possible financial ratios which can be used for assessing economic feasibility are set out in chapter 3 of the Guidance on Socio-Economic Analysis – Authorisation.)

Apart from analysing if the net present value of the revenues minus costs is positive aplicants may use other methods to document whether an alternative is economically feasible for them, but it is recommended that any such explanation is sufficiently detailed, particularly if the applicant concludes that the alternative is not economically feasible for them. A simple conclusion that the alternative is not economically feasible for the applicant that is not supported by sufficient justification could be considered insufficient by the Agency, particularly if other applicants have identified that alternative as being suitable for them.

The example presented in Box 10 illustrates simple supporting arguments for non-feasibility of an alternative on an economic basis (based on the example above). Note that these are descriptive examples and use in an application would have to be supported by evidence (i.e. data) and/or references.

**Box 10. Simple example of supporting information**

If the alternative had a negative NPV it could be argued that the alternative was not economically feasible. This may be based on the assumption that the price of the product is unchanged. A qualitative assessment of the market provides some supporting evidence for this assumption that the price will not increase (although references and data where possible should be used for an actual authorisation application).

Current market synopsis of the applicant's product:

- The market for the product produced with the use of Annex XIV substance is price driven by a highly competitive international market (i.e. the use can take place either within or outside EU where no authorisation is needed). There are approximately 60 producing companies, with no single producer having a dominant share of the market. Any increase in the price of the product will mean a substantial loss in demand for the applicant's product. This is because the costs of transporting rival imported products accounts for only a very small fraction of the product price. The threat of imports and competition from rival products ensures the applicant product price does not increase (in order to some on pass on some of the capital costs required to use the alternative) with the overall price remaining sufficiently low to make competing products less attractive than the applicant's product.
- Due to low product prices combined with low entry costs for new entrants to the market, current profitability is kept low by market forces. If sufficient profits were made in the industry then new entrants would have the incentive to enter the market (i.e. enter the market with a lower price to gain market share at the cost of a small reduction in profitability). Therefore if it is not possible to pass on some of the capital costs of the alternative, it is not economically feasible to invest and raise the capital required to use the alternative, even though there will be some savings in operating costs.

The qualitative analysis above only considers the implications of using the alternative to the applicant. Impacts such as unemployment and health benefits are not included because they are not part of the economic feasibility analysis. Guidance on Socio-Economic Analysis – Authorisation is provided in separate document and chapter 3 of that guidance provides further details on how to analyse the market for a substance.

### *3.8.1. Uncertainties in determining economic feasibility*

The evaluation of economic feasibility may be based on the average cost of a substitute at a "typical" or "model" facility. Neither the cost analysis nor the assessment of technical performance are intended to give absolute cost or performance information, but they may result in comparative information on the relative cost or performance of the Annex XIV substance and alternatives. This analysis together with the information on the impact of the substitution costs on the operating margin and on their possible pass over of the costs, would give the basis upon which the applicant can demonstrate whether an alternative is economically feasible for him. However, the uncertainties in the assessment of economic feasibility should be clearly stated in the documentation of the analysis of alternatives. Chapter 4 of the Guidance on Socio-Economic Analysis – Authorisation can be used for guidance on how to carry out uncertainty analysis and Appendix F of the SEA guidance contains several uncertainty techniques which may be relevant when determining if an alternative is economically feasible.

## 3.9. Research and development that is relevant and appropriate

Article 62(4)(e) states that the application shall include: *an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate, information about any relevant research and development activities by the applicant*;

This means that the applicant should document in the analysis of alternatives of his application any relevant information on research and development that is considered appropriate for the understanding of the Agency and the Commission of the present or future availability of suitable alternatives to the Annex XIV substance. Although not mandatory, it is noted that it is strongly advisable to provide this information if available, in order to strengthen his analysis of alternatives, particularly when it is concluded that there are no suitable alternatives available. Also, the applicant may plan to initiate new R&D and may decide to document this in the application. These plans will play a critical role in fixing the review period. This may be appropriate when no suitable alternatives have been identified. The Commission, when deciding on the duration of the time-limited review, would take this information into account.

This section addresses the consideration of R&D in the analysis of alternatives, it includes consideration of:

- Under what circumstances it would be appropriate to report (document) R&D that the applicant considers to be relevant to the analysis of alternatives;
    - Examples of relevant types of R&D and what they may involve;
    - The costs of R&D; and
- Documenting R&D in the application (see also section 3.12).

### *3.9.1. Circumstances that might prompt the inclusion of R&D in the analysis of alternatives*

The applicant should consider that past, current (on-going) or planned research and development activities are appropriate for inclusion in the analysis of alternatives for example in the following situations:

- The results of past or current R&D activities can be used to support the documentation that sufficient analysis of identified possible alternatives has been made. This is particularly relevant when suitable alternatives have not been identified or have been identified on the market but are not available for the applicant for an immediate substitution..
- R&D related to generating information on risks, economic or technical feasibility of the identified possible alternatives, in order to support the arguments made in the analysis of alternatives.
- When R&D is needed because transferring to the alternative would require major changes in the production processes or in the supply chain; or because the transfer include fulfilling legal product safety or other requirements that may take many years. This may include test trials by the applicant, his suppliers or downstream users, that are necessary to ensure functioning and acceptability of the alternative. While R&D is not mandatory, it should be noted that the finding that no suitable alternatives exist and no plans for R&D are indicated will lead to short review periods. It may also undermine the credibility of the applicant,

particularly if third parties have submitted information about alternatives or other operators in the sector have transferred to an alternative.

- The lack of any possible alternatives may prompt the initiation of R&D on novel substances and/or techniques. Although there is no obligation for the applicant to initiate such research and development, it may be very valuable to show such research has, is being, or is planned to be conducted to support the analysis of alternatives.

In summary, as mentioned above information from any relevant research and development activities by the applicant should be considered appropriate to include in the analysis of alternatives whenever this information can be used to increase the understanding of the Agency and the Commission regarding the reasons for present alternatives being non-suitable and prospects for future availability of suitable alternatives in the uses applied for. The information on research and development will also be taken into account by the Commission when deciding on the duration of the time limited review period.

Below some **examples** are given showing different reasons for presenting R&D on the basis of past, current and future activities:

- Past R&D may be demonstrating why a certain alternative is not technically feasible, or that processes are unable to be adapted to accommodate an alternative. This R&D may take the form of test trails for example. Test trials may also be related to the manufacturing of the alternative. For example, where the R&D has focused on the possibility to achieve the required purity of an alternative substance. Test trials with end products may have focused on the quality of the end product manufactured using the alternative. (For example, in the production of paper, by investigating the possibility of coating drying cylinders without using the Annex XIV substance or with an alternative and testing the quality of paper produced against customer quality requirements.) Past R&D may also demonstrate that possible alternatives are not technically feasible on the basis that they have not been demonstrated to meet legal standards for product safety.
- Ongoing R&D may be able to show that there are efforts being made to search for alternatives, or that currently technically unfeasible or unavailable alternatives are being subject to research on what would be required to make them feasible. For example, what needs to be done to make an alternative available and/or feasible? This may relate to sourcing or production of the alternative or industry and legal requirements that must be satisfied before products can be accepted. This R&D may have addressed what testing must be done and what criteria need to be satisfied before an alternative can be used for a particular function. It should also clearly set out the timing for such product testing and research. In some industry sectors the timing for such product safety development and testing can take many years.
- Future (planned) R&D will have a similar role to ongoing R&D and may be able to show a planned commitment to continued investigation of alternatives that have been shown to be currently not technical feasible or available and investigating what will be needed to make them suitable. R&D could also focus on the continued search for replacements for the Annex XIV substance such as molecular or product design. It may address known, possible or anticipated changes in product design and consumer need. For example, there could be indications of further technological changes that reduce the need for the Annex XIV substance or will make use of the substance redundancy due to trends in industry design or new technology in the longer term.

The applicant may also identify research and development undertaken by suppliers, industry, regulators, universities, research institutes and others by using in-house information, publicly available information and/or by communicating within and outside the supply chain.

**The costs of R&D** can be considerable and vary widely from sector to sector. Expenditure on R&D may also be the subject of commercial confidentiality. However, the cost of R&D should be considered and may help to show, in cases where there are no suitable and available alternatives, a commitment to replace the Annex XIV substance when that becomes a possibility. The cost of further R&D needed should also be considered within the assessment of the economic feasibility of an alternative.

#### *3.9.2. Documenting R&D in the application*

The applicant may wish to consider supporting an application by including details of:

- Results of past relevant research and development activities;
- The current status of relevant research and development activities regarding alternative(s) for the applicant and for other users;
- Planned future relevant research and development for identification of possible alternatives to the Annex XIV substance.

Further recommendations on what to consider in documenting relevant research and development activities is given in section 3.12.

### 3.10. Concluding on the suitability and availability of alternatives

The analysis of alternatives is the process of determining the suitability of the alternative and consideration of its availability. There are three main aspects that the applicant should assess in relation to the suitability of the alternative for each use applied for:

- reduction of overall risks to the environment and to human health (taking into account the appropriateness and effectiveness of risk management measures);
- technical feasibility for the applicant (based on the alternative fulfilling the specific function); and
- economic feasibility for the applicant (based on the assessment of the economic consequences of transferral to the alternative).

The guidance here is intended to show how the applicant can draw together his analysis and conclude on the suitability and the availability of alternatives. This process focuses on the three main aspects mentioned above. However, it should be borne in mind that according to Article 60(5) not only these but all relevant aspects shall be taken into account by the Commission in assessing whether an alternative is suitable and available. Consequently, the applicant may also decide to include other relevant aspects in his assessment.

The flow diagram in Figure 8 illustrates a process for the analysis of alternatives that may be considered to be step-wise, considering different aspects of an alternative's feasibility, risks and availability separately and bringing these together in a final decision. However, in reality although this may be possible, it is more likely that all these aspects will be considered simultaneously.

Further to this, consultation within and outside the supply chain on alternatives will not be a single process in advance of selecting possible alternatives for further investigation; but rather it will be iterative, with continued consultation and information gathering at each stage of the process.

The alternative must represent a reduction in risk compared to the Annex XIV substance. The alternative must also be technically and economically feasible. For risk, the evaluation is one of comparing the alternative with the Annex XIV substance. In terms of technical and economic feasibility, the evaluations are whether the alternative is viable for the applicant, including if relevant his downstream users in the uses applied for. The applicant can refer to any of these aspects or combination thereof when demonstrating that an alternative is not suitable.

The applicant should show and document analysis of these aspects, but the extent of the different parts of the justifications that should be provided by the applicant will depend on the specific circumstances of the case. If the applicant concludes that there are no suitable alternatives, then the analysis of alternatives should clearly document the reason why no such alternatives exist. For example, the applicant should document in as much detail as possible why identified alternatives resulting in an overall reduction of risks were not technically or economically viable for him. In addition, in this case the applicant is encouraged to provide information on planned or ongoing R&D activities concerning potential alternative substances or technologies. In these cases it is not necessary to explain in full length the examination of the risks of such potential alternatives.

The level of detail will of course depend on the relative importance of each aspect in determining the alternative as not suitable. For example, it may be clear to the applicant that all technically feasible alternatives do not represent a reduction in risk as compared to the Annex XIV substance. In this case there would of course be little merit in detailed analysis of the economic feasibility of those alternatives that are not suitable on the basis of the risks.

The focus of the analysis will be the compilation of the information from the assessments of the various aspects of the alternatives and weighing them together and considering any possible trade-offs between them in order to draw a conclusion on the suitability and availability:

- Compilation of the results of the assessments of technical feasibility, economic feasibility and risk; comparing the Annex XIV substance and the alternatives;
- Compilation of information on the uncertainties in the data that should be considered in the decision-making process;
- Identification of the possible ‘trade-offs’ between technical feasibility, economic feasibility and risk; comparing the original substance and possible alternatives. For example, some reduction in end product performance resulting from the use of an alternative could be acceptable (subject to, for example, product safety approval) on the basis of the reduction in risk and the decreased costs in exposure control; and
- Consideration of the availability of suitable alternatives: e.g. whether there is enough of the alternative available at a certain point in time and if it is accessible to the applicant.

Alternative techniques can be regarded as available when they are developed enough to allow implementation in the relevant industrial sector and they are reasonably accessible without undue delay to the operator. Alternative substances can be regarded as available when they are reasonably accessible without undue delay to the operator in the required quantity (i.e. the global production capacity should not be severely constrained due to the new demand). To be considered available, both techniques and substances have to fulfil the relevant legal requirements (e.g. a substance may need to be registered in accordance with REACH before it can be manufactured, imported, placed

on the market or used; or the change of the substance used in production may require approval under other legislation; a major change to the production facility may require a permit in accordance with the IPPC-directive.)

An important issue in identifying the availability of alternatives is also timing: alternative substances may not be available immediately or they may not be available in the required tonnages but could become available in the market at some point in the future. To assess this, knowledge of the quantities, relevant markets and the current trends and research within them would be useful. On alternative techniques the same basic consideration applies: is the necessary equipment or technology already available in the market in sufficient quantities? The time needed to invest, install and make alternative techniques operational should be considered. This applies also to alternative substances that need changes in processes or equipment. In both cases fulfilling the legal requirements may require time.

When assessing the time constrains the applicant will have to consider the sunset date, i.e. the date from which the placing on the market and the use of the substance is prohibited unless an authorisation is granted. The sunset date will take into account, where appropriate, the production cycle specified for that use (Article 58.1(c)(i)) and will be at least 18 months after the deadline for receiving the authorisation applications (Article 58.1(c)(ii)). Should the substitution be possible before the sunset date, the alternative will be considered available from this perspective.

For the reviews of authorisations the holder of an authorisation will have to submit an update of the analysis of alternatives taking into account any new possible substitutes. He should verify the grounds for concluding on availability (or non-availability) of suitable alternatives referring also to the list of recommended actions to make possible alternatives suitable and available (see section 3.11), contained in his original application. It should be noted that under the SEA route authorisations will have to be withdrawn when suitable alternatives exist for the holder of the authorisation, having due regard to the proportionality principle.

Box 11 sets out some considerations on suitability and availability of alternatives for different types of applicants and for a third party.

**Box 11. Availability of suitable alternatives for different actors**

The consideration of whether an alternative is *available* will depend upon the perspective of different actors in the authorisation process. For example:

Manufacturer/importer (M/I) as the applicant: The M/I should not *a priori* take the view that any alternative that is not or cannot be part of his product portfolio is not an alternative that is *available* to him. He will need to consider what alternatives may be *suitable* on the basis of technical and economic feasibility, considering possible alternatives from outside of his portfolio and even from outside of his sector (for example, possible alternatives for one or more uses that he may be applying for may be a change in process or a technical alternative rather than a substance). He may also wish to consider the suitability of the alternative for other parts of the supply chain.

Downstream user (DU) as applicant or contributor to an application: The DU, who is in perhaps the best position to understand his use most fully, may not be familiar with the supplier's portfolio, and be only aware of what alternative(s) is(are) technically and economically feasible for his use(s).

Third party, contributing information on alternatives: The third party may have less resource for investing in research to understand all the possible alternatives but may have experience of what may be suitable or available for broad uses. Note, however, that third parties could be suppliers of alternatives. In this case they may have the full technical knowledge of the alternative. However, they have to submit information on alternatives on the basis of 'broad information on uses' on the Annex XIV substance published on the Agency's website. Therefore, the information may not be able to be tailored to the specific uses that are the subject of the application.

As set out in Figure 8 in section 3.4, if the applicant's analysis of alternatives concludes that suitable alternatives are available, an authorisation cannot be granted in accordance with Article 60(4) ('socio-economic route').

### 3.11. Actions needed to make possible alternatives suitable and available

If the analysis of alternatives demonstrates that currently there are no alternatives or the possible alternative(s) is/are not suitable or available, the applicant should provide the following additional information:

- a list of actions that are needed to make a possible alternative(s) technically or economically feasible for the applicant and a timetable in which these actions can be implemented taking into account investment and operating costs required; and
- research and development activities needed, e.g.:
    - What research and development activities are needed and/or planned to develop an alternative substance(s) or technology(ies), or develop equipment or processes enabling the use of alternative(s); and
    - What testing must be done and what criteria need to be satisfied before an alternative can be used for a particular function – including clearly setting out the timing for such product testing and research.

The inclusion of the additional information listed above would support the applicant's assessment that the alternatives are not available for the applied-for uses within the given timetable. It will also be taken into account when fixing the review period of the authorisation. The actions needed for

making a non-suitable and/or non-available alternative into a substitute will most likely have been considered by the applicant in determining the various parts of the analysis of alternatives. For example, in the consideration of technical feasibility the applicant will have determined why the possible alternative is not technically feasible for him and on what basis. It may be that the alternative is not technically feasible because it has not yet satisfied the legal safety or performance criteria that are required for the end product. Here the list of actions would include what needs to be done for the alternative to be allowed to be used and the timetable necessary for these actions. Furthermore, the possible costs of such actions may well have been considered in the assessment of the economic feasibility of the alternative, or may be available in an SEA.

In the list below some examples are given of situations where the applicant should include information on actions needed to make the alternative suitable and available (this list is not exhaustive):

- The transfer to the alternative requires investments that take considerable time (time needed to plan the necessary changes, to purchase the equipment needed, to build any constructions, to install, to train the personnel, etc.);
- The transfer to an alternative substance requires regulatory approval (e.g. production of aircraft or medical equipment), or change to an alternative technique requires a review of a permit (e.g. under the IPPC Directive);
- The transfer to an alternative requires customer approval (e.g. for use in products that must be tested for technical performance over long time periods, or where the transfer to an alternative up in the supply chain may affect the quality of the end products and testing by several downstream user levels is required );
- An alternative substance is currently not produced in sufficient quantity ; and
- Costs related to investment in new equipment/techniques may depend on other planned investments, age of the current equipment, etc.

Example 4 illustrates, for a hypothetical substance and situation, how the applicant identified the actions that may be needed to make a possible alternative suitable and available.

### Example 4. Actions needed to make a possible alternative suitable and available

**Scenario description**

Substance H (a vPvB substance) is an active ingredient in coatings that are used to prevent corrosion in commercial/industrial machinery. The coatings are used in production of the machinery and also for professional maintenance and repair of machines. Substance H is only used professionally by trained technicians and exposure of workers and the environment to substance H is well controlled both during machine manufacture and repair and maintenance. The CSR details the operational conditions and risk reduction measures in place. The applicant is the downstream user of the substance.

There are very prescriptive legal safety requirements that mean that any change in manufacture, maintenance or repair of the machines is subject to considerable safety criteria and legal requirements. Addressing the safety criteria and legal requirements takes a minimum of five years.

The machines have a long service life (30+ years, if well maintained). The continued use of the Annex XIV substance is required to maintain and repair machines during their service life. As there is no available alternative that is technically feasible, a refused application would mean that machines would be manufactured outside the EU and existing machines could not be repaired and maintained and therefore would not be available for use.

**Alternative that is not technically feasible for the applicant**

There is a possible substance alternative that may be used to replace the function of the Annex XIV substance. However this alternative has not been subject to any safety testing, so it is not yet shown to be technically feasible or available for the applicant (or anyone) to use for the desired function.

**The identification of actions needed to transfer from the Annex XIV substance to the possible substance alternative**

This includes what testing has currently been done on product safety and what further work is required for it to satisfy product safety legislation (noting that the alternative may fail to fulfil the product safety requirements). It also includes a description of the time required for product safety testing. To document this, the applicant sets out (in the analysis of alternatives report in the application):

- The safety requirements that must be met;
- What product safety testing has been done and what the results were for the possible alternative;
- What further testing needs to be completed for the legal requirements to be met; and
- The time-line for the completion of the testing programme for the possible alternative.

The task here is bringing together of all the aspects of the alternative that lead to it being concluded as not suitable and not available and assessing what would have to be done to make it a suitable and available substitute. The applicant will have concluded that these actions are not currently possible; otherwise he would not have concluded that there are no suitable and available alternatives. Therefore, for each aspect of the evaluation of alternatives (i.e. technical and economic feasibility, reduction in risk and availability of the alternatives) the applicant can consider the actions and timescale required to make the alternative suitable and available. Table 8 illustrates hypothetical examples of how the information may be summarised.

### Table 8. Hypothetical examples of summaries of actions needed to address the suitability and availability of possible alternatives

| Aspect of | Outcome of analysis of | Action to address suitability/availability |
|---|---|---|

| analysis | alternatives | |
|---|---|---|
| Technical feasibility | Not feasible on the basis that the required purity of the substance cannot be achieved (see: ref to reported R&D and assessment of technical feasibility). | R&D is addressing the possible methods that may be able to provide the required purity (99.9%) at the volumes needed. These include:<br>• 'Method 1'<br>• 'Method 2'<br>• 'Method 3'<br>The method that indicates that the required purity can be achieved will be subject to R&D to investigate the possibility to scale the production to deliver the required volume. Actions required with indicative timescales are:<br>• Completion of lab scale R&D to determine which method can be used to deliver the required purity: x to y months.<br>• Confirmation of lab scale results on purity: x to y months.<br>• Planning of pilot plant for initial production: x to y months.<br>• Pilot scale production on-line and conformation of purity: x to y months.<br>• Product testing and customer approval: x to y months.<br>• Commercial scale production initiation to x% of required tonnage: x to y months.<br>• Scale up to full commercial production: x to y months.<br>Total timescale required x to y months/years.<br>Details of the proposed R&D programme are at (ref). |
| Economic feasibility | Not feasible because introduction of the technical alternative would mean that no currently used equipment could be used (i.e. this would mean that the current assets would be zero as sale value of equipment would be very limited). The replacement would mean re-housing and relocation of all users. The investment in capital and operational costs are too large to be borne by any users. This prevents the possibility of costs being passed onto the customer, because the economic barrier is the investment costs to accommodate the alternative. Phase out/phase in is not possible as the systems are so different (see economic feasibility analysis - ref) | The capital and operational costs could only be overcome by very large financial investment in the industry, which is currently not possible (as essentially this would mean firms changing the business they are in). This would require considerable financial assistance for phase out of the Annex XIV substance and phase in of the alternative over at least an x year period.<br>Actions required (with indicative timescales) to overcome the financial barriers to substitution for each of estimated 200 users are:<br>• Identify possibilities for re-housing/relocation possibilities required to house and operate new equipment (approx. cost to each user firm depending on location € x to y): Possible timescale: x to y months.<br>• Investment in new equipment required to accommodate alternative (approx. cost to each user firm € x) – action to find funds or investor: Possible timescale: x to y months.<br>• Set up and testing of equipment and facility (including, relocation, recruitment, training/retraining, detailing and documentation of new operating procedures, health and safety and other legal requirements). Approx. cost to each user firm depending on location € x to y). Timescale: x to y months.<br>• Customer approval for use of alternative, including product testing. Approx. cost to each user firm € x. Timescale: x to y months.<br>Estimated cost per user facility ranges from € x to y M per user firm (total estimated cost (i.e. for 200 firms) ranges from € x to y billion).<br>Estimated timescale ranges from x to y years for each user. |

| | | |
|---|---|---|
| | | (Details of the financial analysis are presented in the analysis of alternatives under the assessment of economic feasibility) |
| Risks to human health and the environment | The alternative has not been demonstrated to represent an overall reduction in the risk to human health and the environment as compared to the Annex XIV substance. This is because the alternative is a nanoparticle for which the possible risks to human health and the environment have not yet been fully understood. There is evidence to suggest that release to the environment and exposure to workers could cause risks. However, the control of risks is still uncertain since the hazards are not well understood and the operational conditions and risk reduction measures are not yet developed (see consideration of risks of the alternative - ref) | Understanding of the hazards and exposure presented by the alternative is required before appropriate control measures can be developed to ensure that the possible risks from the alternative are adequately controlled. This is possible but is dependent on further research and development of appropriate tests to determine the hazards of such materials and development of appropriate exposure control measures.<br>Actions required to determine the human health and environmental safety of the alternative are:<br>• Completing of documentation of the test methodologies for determining the environmental hazard of nanoparticles. This is being completed by an international initiative. Timescale for completion of ring-test for aquatic toxicity testing: x year/s.<br>• Publishing of test guidelines that can be used by industry: x years.<br>• Development of test programme to determine the environmental (aquatic toxicity) hazard – x year/s.<br>• Completion of test programme for human health hazard: x year/s*.<br>• Development of risk reduction measures for the effective control of emissions to the environment: x years<br>• Development of occupational control measures for workplace exposure: x year/s*.<br>(*Human health testing programme and development of controls could be planned and conducted at the same time as the environmental testing.)<br>Total time required to be able to assess the risks and develop effective control measures – x years. |

**Note:** Entries in the table are summaries for different hypothetical alternatives and situations. Each aspect is considered individually. However, the total actions and time required to make a possible alternative suitable and available should include consideration of all the aspects that have been identified leading to the conclusion that the alternative is not suitable or available. Some actions may be conducted at the same time.

## 3.12. Considerations for documenting the analysis of alternatives

REACH does not specifically describe the minimum documentation required for the analysis of alternatives. However, Article 62(4)(e) sets out the information on alternatives that shall be part of the analysis. This includes consideration of the risks of alternatives and the technical and economic feasibility of substitution and, if appropriate, information on any relevant research and development activities by the applicant. Furthermore, the applicant should note that according to Article 60(5) the Agency's opinions and the Commission's assessment of the application with regard to the suitability and availability of alternatives is not limited to reduction in overall risks or technical and economic feasibility of the alternative, but will take all relevant aspects into account. This could for example include information on alternatives from interested third parties. Therefore, in order to demonstrate that adequate steps have been taken to identify possible alternatives or to demonstrate whether or not possible alternatives are suitable and available the applicant would be well advised to document a comprehensive analysis of all possible alternatives and take all relevant aspects into account.

It is important that the documentation is clear and transparent. This means that for each part of the analysis the applicant should try to present the information in a logical way that describes how they came to their conclusion on each aspect of the analysis. It should present the information used to come to decisions, including data/information gaps and assumptions made, as well as provide explanations and justifications for the conclusion made addressing the uncertainties, and reference the material that has been used. In this way the Agency can see what is being presented, what assumptions have been made, what conclusions are drawn and how those conclusions were drawn.

Information on appropriate research and development activities could be included under the most relevant heading for each separate case. For example it could be addressed under section 2 on the analysis of substance function or under section 4.1 on the assessment of technical feasibility of alternatives. The applicant may also consider adding a separate heading for research and development, e.g. under section 4 on the assessment of suitability and availability.

The guidance below is intended to be an indication of what could be documented for each aspect of the analysis of alternatives following the structure of the analysis of alternatives format published on the Agency's website. Under these headings the applicant should document the results of his analysis for each use applied for (noting that he may indicate which data he regards as confidential).

**Summary of the analysis of alternatives**

This section could present a summary of the findings and conclusions of the analysis regarding the identification of possible alternatives and the suitability and availability of alternatives for each use applied for. Furthermore, any findings on actions needed to make possible alternatives suitable and available and the timescales for these actions should also be included.

**Introduction**

The applicant could use this introduction to describe any appropriate background information for the analysis of alternatives.

**Analysis of substance function**

Detailed information should be presented on the precise functions or tasks performed by the Annex XIV substance for each of the uses applied for. This should also include a description and outcome of the process where the use is applied and under what process conditions the function must be performed. Examples of functional requirements to take into consideration may include: critical substance properties related to the desired equivalent function, quality criteria, process and performance constraints, customer requirements or legal requirements for technical acceptability.

For all functions the applicant may wish to report any obstacles or difficulties identified or expected in relation to finding possible alternatives and their consideration as substitutes.

**Identification of possible alternatives**

The possible alternatives identified for each use should be presented and described in detail in this section. For substance alternatives this would include the identity and a summary table of relevant properties. For technical alternatives a description should be given of the technology to be

introduced in order to achieve the same function as the Annex XIV substance, or to possibly remove the need for the Annex XIV substance function altogether by other changes to the process.

A description of the data searches and consultations that have been made should be included. In particular in cases where no possible alternatives have been identified this documentation needs to be detailed and thorough. In such cases also including information on research and development activities supporting the lack of possible alternatives would be appropriate.

Data searches

The extent and results of searches for data and information on possible alternatives should be detailed and in particular how these were incorporated into the analysis of alternatives.

Consultation

The applicant may wish to document consultation undertaken during the analysis. Such documentation should be transparent and auditable. When documenting the communication to support an application the applicant may wish to include:

- Details on which parts of the supply chain have been consulted;
- Details on other organisations that have been contacted;
- Details on the possible alternatives that have been identified through this process and evidence of (non)availability of (suitable) alternatives.

**Technical feasibility**

Technical feasibility is a key aspect for determining the suitability of alternatives. Here the applicant needs to present a transparent analysis of technical feasibility of alternatives in terms of the possible provision of equivalent function. There may be a number of alternatives for different uses, therefore the applicant must clearly document the consideration of the technical feasibility for each use that is being applied for and consider each alternative for that use in turn.

If an approach developing technical feasibility criteria has been taken (see Box 3 section 3.6), the applicant should clearly document how the criteria for equivalent function were applied to possible alternatives to determine technical feasibility. For example, which data were used (citing the sources) and how they were used including any assumptions made, i.e. what was the process by which criteria were developed and applied.

The applicant should also document the process changes required for possible transfer to the alternative as well as the requirements for equipment, risk management measures, energy, personnel changes and training needs (amongst others) and how these affect the technical feasibility of the alternatives.

The analysis will be different depending on who the applicant is. For example, the technical feasibility of an alternative may depend upon process changes, use of equipment or risk reduction measures that are available to the manufacturer but not to downstream users for technical or economic reasons. An important consideration will be the uncertainties in data evaluation and how these have been dealt with. The applicant should clearly indicate the effect that these uncertainties may have on the assessment of technical feasibility.

**Reduction in overall risks to human health and the environment**

An important consideration for documenting the assessment of the reduction of overall risks to human health and the environment by use of possible alternatives will be what data have been used to compare the risks of the Annex XIV substance and the alternative. For example as mentioned in section 3.7, there is likely to be less information available on alternatives than there is for the Annex XIV substance (but noting that if the alternative has been registered and a CSR has been carried out, there may actually be a similar amount of information on the risks as for the Annex XIV substance). Therefore, the documentation will need to set out how the assessments have been conducted, what data were used and what assumptions have been made (for example the use of assessment factors for hazard data and conservative emissions for exposure scenarios).

Further to this, how any comparison between risks of different types has been dealt with will need to be described and clearly documented. For example how have different health effects or different environmental effects been compared and weighed against each other? For alternative technologies, where the risks may be physical such as temperature or vibration, how have these risks been compared to toxic risks of the Annex XIV substance? The conclusions drawn on the possible reduction in risk to human health and the environment will need to be supported by the data used; highlighting the uncertainties within those data and how they have been addressed.

**Economic feasibility**

As with technical feasibility the evaluation of economic feasibility is from the applicant's perspective. It will be important, for each use, to set out how the analysis has been conducted detailing the data and the methodology used for analysis. It will also be important to set out the perspective of the analysis, as the economic feasibility of an alternative may be different for a downstream user compared to a supplier. For example, a downstream user may be able to easily consider the economic feasibility of an alternative (provided it is technically feasible and reasonably accessible) by assessment of the direct cost of possible transfer. However, for a supplier this could mean having to implement changes in production process and the loss of customers for the product related to the Annex XIV substance that cannot switch to the alternative and, as such, the analysis would be more complex. The analysis will therefore be different depending on who the applicant is. As such, the documentation of the assessment of economic feasibility will need to clearly set out the boundaries of the assessment and show the reasoning for the setting of these boundaries.

The documentation of the assessment of economic feasibility will need to set out the sources of data and importantly the uncertainties in the data sources used and how these have been dealt with (i.e. what the assumptions are).

**Research and development activities**

When documenting any relevant research and development activities, for example the following issues should be considered:

- What is the purpose of documenting the R&D?
    - Demonstrating that a possible alternative is not technically feasible for an applied use.
    - Demonstrating that the alternative does not satisfy product safety legislation or rules.

  - Demonstrating research and development on novel substances and/or techniques to show that such research has, is being, or is planned to be conducted to support the analysis of alternatives.
- Who did/does/will do the R&D, who was/is/will be participating/consulted (e.g., in house, trade organisation, commissioned or from literature only)?
- What was/is/will be done?
- What were the results/findings?
- What were the changes implemented and other follow-up actions taken?

The applicant should note that he may indicate parts of the application that are confidential {Art. 118 and 119}. This may be of particular importance with regard to research and development on possible alternatives, but also other confidential information that he considers would have a detrimental affect on his business, if they were to be made public (see Box 2).

**Conclusions on suitability and availability of alternatives**

The documentation of the steps taken to identify whether alternatives are suitable and available will need to set out that a sufficient analysis of alternatives has been conducted. Clear reasoning and transparent documentation will be essential to demonstrate that a proper consideration has been made of the technical and economic feasibility, reduction in overall risks and availability of alternatives.

This is especially important in cases where the conclusion is that no suitable alternatives are identified. In these cases the applicant should also provide information in the report on what actions and time scales are needed to make the alternative a suitable replacement for the Annex XIV substance in the uses applied for.

**Actions needed to make a possible alternative suitable and available**

This section should include a presentation of a list of actions that would be needed in order to make the alternative(s) technically and/or economically feasible, and available in the uses applied for, including the time frame required for these actions to be implemented as well as potential obstacles (see section 3.11 and Table 9). This should apply in particular in cases where the conclusion is that no suitable alternative is available for the applicant but there is a suitable alternative available on the market although not yet ready for an immediate substitution (i.e. within the "sunset date") or another operator in the same market is already or will switch in the short future to alternatives. This information will be considered for determining the review period of the authorisation decision.

## 3.13. Links to other parts of the application

### *3.13.1. Substitution plan*

If an application under the adequate control route concludes in the analysis of alternatives that a suitable alternative(s) is available, then the applicant must prepare a substitution plan that sets out

his commitment to transfer to that substitute(s), setting out the timing and other considerations for transferral. Guidance for how to produce a substitution plan is set out in Chapter 4 of this guidance.

*3.13.2. A socio-economic analysis (SEA)*

An SEA is required for applications under the SEA route and can also be submitted in the case of applications under the adequate control route on a voluntary basis. Guidance for compiling an SEA in support of an authorisation application and submission of an SEA or input to one from a third party as part of the authorisation process is set out in the Guidance on Socio-Economic Analysis – Authorisation.

A key link between the analysis of alternatives and the SEA will be communication with the supply chain on the possible response to an authorisation not being granted. For example, this may lead to the use of alternatives that were found to be unsuitable. The SEA may have to consider the socio-economic impact of such a scenario. Another key area is the comparison of the safety of alternatives with the Annex XIV substance (see section 3.7, Box 5). While the analysis of alternatives is focused on the Annex XIV substance function and whether this can be replaced or made redundant; the SEA may need to consider a wider boundary. This may be considering the consequences of use of an unsuitable alternative or the wider consequences of removal of function in end-products. This would usually be beyond the scope of the analysis of alternatives. However, the SEA assessment of health and environmental impacts could be used in the analysis of alternatives to assist in the decision regarding comparison of risks for substances following the SEA route.

The applicant is advised to consider what he will need to consider in his SEA at the stage where he is gathering and analysing information for the analysis of alternatives. This will help to optimise data gathering and help the applicant to have a wider consideration of possible alternatives to the Annex XIV substance, especially where there are possibilities to make redundant the use of the substance by changes in end-product. Key phases of the analysis of alternatives where links to the SEA are particularly important are indicated in the guidance, especially in:

- section 3.3 on the focus and scope of the analysis of alternatives;
- section 3.5 on how to identify possible alternatives; and
- section 3.7 on comparing the risks of the alternative with the Annex XIV substance.

## 3.14. Presenting the documentation of the analysis of alternatives to the Agency

Applications should be made via the Agency's website. Applications can be prepared as indicated in the user manual(s) made available on the ECHA's website. Supporting documents such as the analysis of alternatives and an SEA should be appended to the application.

# 4. PLANNING FOR SUBSTITUTION: GUIDANCE ON SUBSTITUTION PLANS

## 4.1. Introduction

If the applicant has found a suitable and available alternative to the Annex XIV substance for a use(s) for which he is applying for an authorisation under the adequate control route, he must provide a substitution plan. A substitution plan is **a commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable.**

The information contained within a substitution plan will be used by the Agency Committees when forming their opinion and by the Commission when considering granting an authorisation and it will be taken into account when determining the duration of the time-limited review period of an authorisation decision[29].

This section of the guidance addresses the preparation of a substitution plan in accordance with {Art. 62(4)(f)}. It encompasses guidance on the following elements:

- Scope and contents of a substitution plan
- How to prepare and document a substitution plan:
    - Identifying the actions required for substitution.
    - Defining a timetable for those actions.
    - Documenting the plan for submission with the application.

Figure 10 illustrates the overall proposed process of developing a substitution plan; including consulting with downstream users/the supply chain, where relevant, to get necessary information and to ensure that it is workable; documenting the plan; and submitting it with the application. The figure also includes later stages (i.e. post granting of an authorisation) relating to initiating the introduction of the substitute and updating the plan as a result of authorisation conditions and for the authorisation review process. However, the guidance set out here focuses on the preparation and documentation of the substitution plan that is presented as part of the application.

[29] Various other factors are taken into account in determining the duration, as set out in Article 60(8), see Section 1.5.5. Note that the holder of an authorisation has to comply with any conditions of the authorisation. This may require him to take different actions than he had presented in his substitution plan included in the authorisation application. However, once an authorisation is granted there is no obligation to re-submit an up-date of the substitution plan, until the authorisation is due for review.

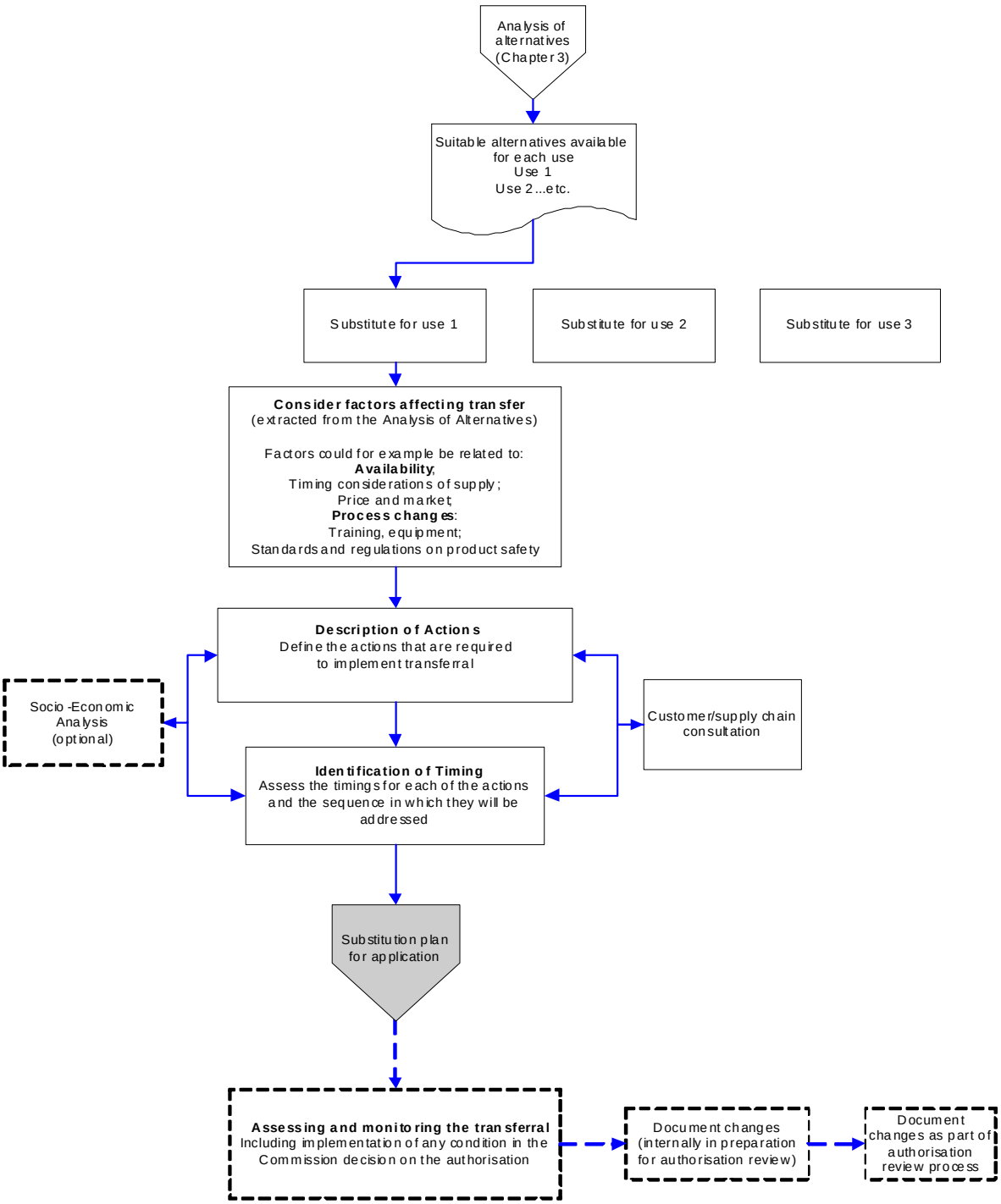



**Figure 10 Flow diagram for preparing and implementing a substitution plan**

## 4.2. Scope and contents of a substitution plan

A substitution plan can only be developed for those uses for which a suitable alternative is available to the applicant. It should be noted that different alternatives may be suitable for different uses applied for, so a number of substitution plans may need to be developed and included in the authorisation application. The overall process of preparing and submitting a substitution plan is expected to be similar amongst different types of applicants (e.g. M/I or DU).

The key elements of the substitution plan are the list of actions required for transferral to the substitute and the timing for those actions. The substitution plan therefore needs to include:

- A description of proposed actions and justifications why those actions are required;
- Who will conduct the proposed actions;
- A timetable for proposed actions that will lead to transferral to the substitute and justification why the actions require the time allocated; and
- What the uncertainties are in achieving the actions within the timescale and what possible mitigation is to be considered.

## 4.3. Preparing a substitution plan

The preparation of the substitution plan involves a number of activities summarised in the bullet list given below. It should be noted that the order of the bullets do not imply that they should be carried out following that sequence. Especially supply chain consultation will have been an important part already in the analysis of alternatives and will be crucial also in detailing the actions for the substitution plan.

- Identifying the factors affecting the transfer to the substitute(s);
- Determining the actions required for transferring to the substitute;
- Determining what time is needed for each of those actions;
- Consultation with the supply chain on actions and timings;
- Planning the management of the actions including consideration of uncertainties and mitigation; and
- Identifying how to follow up the progress of the plan.

Each of these aspects is considered in the sub-sections below. In Appendix 6 a possible check-list for a substitution plan is presented. This list is intended to assist the applicant in planning how to develop a substitution plan and identifying the essential issues to be considered.

### *4.3.1. Factors affecting the transfer to the substitute(s)*

The main factors that affect the suitability and availability of the alternative will have been addressed in the analysis of alternatives. Therefore, the substitution plan should be based on the considerations of these factors for the alternative and especially on how these different factors may

influence the actions needed and the timing for the transfer to the substitute. Some examples are given below:

- Availability (considered in the assessment of availability in the analysis of alternatives): How soon can the substitution be made based on current markets? The substitution plan will need to take account of the ability of the market to supply the substitute and within which timetable. The transferral will be dependent on continuing supply of the substitute. The possibility of the substitute being phased in could also be taken into consideration.
- Price and the market (considered in the assessment of economic feasibility in the analysis of alternatives): For example how potential changes in the market for the alternatives may change the availability of the substitute (perhaps not considered in the analysis of alternatives in the wider context of the supply chain). This may also have links to a supporting SEA that considered the wider impacts of transferral in terms of socio-economic impact and may consider more complex analysis of a justification for the timing of transferral.
- Process change (considered in the assessment of technical feasibility in the analysis of alternatives): Changes in equipment and production processes (including training and health and safety considerations) may be required to accommodate the use of the alternative. In some cases this may take considerable time and resource.
- Process change (considered in the assessment of technical feasibility in the analysis of alternatives): Regulations, standards and customer requirements may require testing and changing of operating procedures as well as product safety requirements. These factors require actions that have a considerable influence on the timing of the plan (for example legal product safety requirements can often take substantial time to complete).

The appraisal of these factors will enable actions to be defined on how these factors can be addressed so that the substitute can be transferred to, in a way that is achievable and manageable for the applicant. This appraisal can then be used for the derivation of the justification required for each action and/or the time needed for the action in the documentation of the substitution plan.

### *4.3.2. Defining the actions*

The actions are defined as individual tasks or sets of tasks that address distinct aspects of the transferral process. It is recommended that the list of actions should contain the following elements:

- A series of actions proposed by the applicant (though not necessarily always for the applicant to undertake) to carry out the substitution.
- A proposed timescale/date for the completion of each action (see section 4.3.4 below).
- A justification statement to present the rationale behind each action/timescale proposed by the applicant.
- Detail of uncertainties associated with actions and possible problems that may affect the actions or the timing of actions. This should include consideration of measures that can be put in place to mitigate any problems that may arise.

- A process for reviewing progress against the proposed timetable for the actions. This assists with investigating reasons for lack of progress and with planning and initiating corrective actions when the plan is in progress.

### *4.3.3. Identifying and setting progress markers*

The identification of critical actions or groups of actions that must be completed in order to ensure that the substitution can be carried out in practice will facilitate the development of the substitution plan and later support its implementation. Progress markers ('milestones') essentially represent the completion of key stages (e.g. groups of actions) in the plan and allow progress to be measured and assessed against the timetable of the substitution plan. It is useful to document these milestones in the substitution plan as this will help the Committees in assessing the effectiveness and practicality of the substitution plan.

It is important to bear in mind when setting milestones that, whatever milestones are chosen, they must be relevant to the analysis conducted earlier in the development of the substitution plan (i.e. to those elements to which the most significant uncertainty or highest level of risk are attached or on which the success of the overall substitution plan depends).

The next stage is determining what review criteria will be used. This can be as simple as assessing whether or not a milestone target has been achieved in line with the proposed timetable. In more complex substitutions, a broader set of review criteria may be warranted such as:

- Is the project on target with the proposed timetable?
- Are all outstanding actions from the last review complete?
- Have all high risks (to the substitution plan) been mitigated? If not how many remain?
- Are all interdependencies currently being managed?

Such criteria as given above are illustrative only and should be set in discussion with supply chain stakeholders in the substitution plan. Documenting in the substitution plan how the applicant plans to follow up and document the progress against the plan increases the credibility of the plan and will facilitate in the update of the plan for the review of the application (if and when appropriate).

### *4.3.4. Defining the timing of the plan*

The timetable for actions can be drafted using a number of methods. At its simplest it could be a short list of key actions and associated timescales.

The key element of the substitution plan timetable is the start and end dates for the identified actions. Both are critical and must be made with full and appropriate consideration of the factors affecting the transfer to the substitutes and the uncertainties that should be identified in the preparatory work to produce the substitution plan. The setting of an end date (i.e. the date at which completion of the substitution plan is made) should be guided by the development of the list or series of actions and individual dates for completion of each of these actions.

For each action that has been identified, it is required that the substitution plan contains a justification made by the applicant as to why such an action is required and a justification for the time allowed for it to be implemented. In many cases this may be obvious (for instance, the supply

of sufficient quantities of the alternative(s) may take a certain amount of time). In other cases, the justification may be more complex and draw upon information from a wide range of sources.

When setting the timetable it may be important to consider issues such as (list is not exhaustive):

- Periods of stakeholder consultation and/or information dissemination;
- Potential delays from other parties, particularly where information is being supplied by another company or person outside of direct programme/project control;
- Customer approval timescales (for example industry standards); and
- Other legislation (e.g. that affects the final product).

#### *4.3.5. Communication with the supply chain and customers*

In developing a substitution plan, good communication with key stakeholders in the supply chain is in many cases important to ensure that the plan will be practical and implementable. Supply chain communication will also be important for gathering information to identify the actions needed for substitution and timings for those actions and to understand the conditions necessary for these actions to succeed.

It will be important for all relevant parts of the supply chain to be aware of the need to replace the substance and input to the development of the plan. An applicant that is a manufacturer of the Annex XIV substance may, for example, benefit by taking into account his customers' or suppliers' needs in developing the substitution plan.

The presentation of information on communication could be used in the justifications for actions needed, where appropriate, to demonstrate that the substitution plan, and especially the timetable, has a practical basis and takes into account implications for the supply chain and end users. It can also be used to show how the applicant and downstream users intends to carry out the substitution in the uses applied for in accordance with the timetable set out.

### 4.4. Documenting the plan

The format of the substitution plan is not set out in the REACH Regulation. Due to the nature of the substitution plan the structure must be flexible to meet the requirements of the application. For the five part outline suggested below (and illustrated in a format published on the Agency's website), the applicant is prompted by questions to set out the detail of each aspect of the plan, so that a full documentation of the plan may be presented to the Agency/Commission in the authorisation application.

- Part 1) Use and substitute;
- Part 2) Analysis of factors affecting transferral;
- Part 3) Actions required for transferral with a time-plan;

- Part 4) Links to other parts of the application[30]; and
- Part 5) Internal monitoring

It may be helpful to document a summary of the justification for actions to be taken and the actions themselves in the plan. In many cases, a simple table of issues referenced to justification statements may be sufficient to demonstrate a considered approach with suitable transparency. In others, a more complex approach may be required. An example is provided in Box 12.

[30] Especially links to the analysis of alternatives, but there may be links to other parts of the application. For instance, there may be links to a voluntarily submitted SEA, as some of the reasons why the transfer to an alternative requires time may be of a complex socio-economic nature.

## Box 12 Summarising actions of the substitution plan and their justifications

Table A Example of an action list summary table

| Ref. | Factor affecting transferral | Proposed Action | Resource | Review | Timescale |
|---|---|---|---|---|---|
| | *Keep this brief and if necessary, refer back to other documents or parts of the substitution plan* | *When proposing actions, focus on succinct statements including the following:*<br>*Indication of any uncertainty/how this will be managed.*<br>*Links to any proposed mitigation measures.* | *Who is responsible for completing the action.*<br>*Availability of staff resources* | *Who is responsible for reviewing the action* | *This may be a date or a timeframe (e.g. within 6 months)* |
| A1.1 | Sufficient supply of alternative substance | Agree contracts in principle with supplier to allow sufficient quantities to be developed. Monitor progress through regular meetings. | Suppliers in place and staff availability for undertaking work confirmed | Manager/skilled person in place to review decisions | 12 months |
| A1.2 | | | | | |
| A1.3 | | | | | |

Table B Example of an action list justification statement summary table

| Ref. | Rationale/Justification | Additional Reference |
|---|---|---|
| | *When writing the justification try to consider the following elements:*<br>*Why the action is required?*<br>*What additional information supports the action?*<br>*Are there any constraints relating to the action (e.g. resources).*<br>*The rationale behind setting any dates for completion?*<br>*Estimation/quantification of the level of risk associated with completing the action.*<br>*Whether the action is on the critical path.* | *It is important that links to supporting information be made, for example arguments made within the socio-economic analysis report should be referenced.* |
| **A 1.1** | Substance Y (the replacement for substance X) has only recently become available commercially. Current production is only 25% of that needed for full replacement of substance X in this use.<br>Detailed discussions have been undertaken with the supplier of substance Y and 12 months is considered the most realistic estimate of the time required to reach the desired level of supply.<br>This is critical to achieving full substitution. If there is not full replacement of X with Y, it will no longer be possible to produce the required number of medical devices, etc. | Contact details for supplier of substance Y. |
| **A 1.2** | | |
| **A1.3** | | |

Summarising the actions against timescales and their justifications are intended as a presentation of considerations of the applicant based on a wide range of factors. Some of which are likely to be presented in further detail in other documents, such as the analysis of alternatives and the socio-economic analysis.

The actions should be set out against a timeline for achieving these actions with progress markers and key stages indicated. This can be described simply against a timescale and illustrated in a table or using a timeline illustration or project management graphic tool such as a Gantt chart. How this is done is dependent upon the complexity of the plan. A possible illustration is set out below.

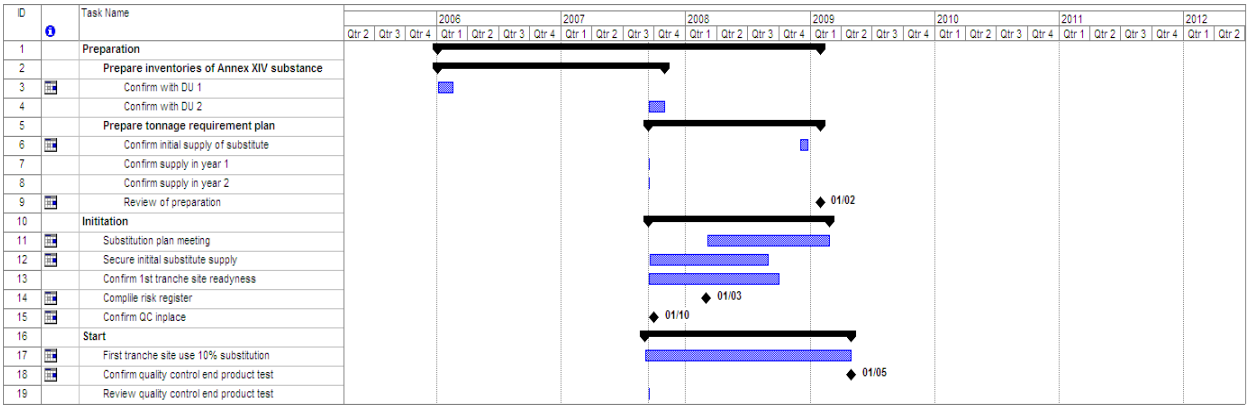



**Figure 11 Illustration of timeline for substitution plan**

In order to demonstrate transparency within the substitution plan, the sources of information used by the applicant should be clearly referenced. The most appropriate method of this may be inclusion of an appendix or a referencing system to other documents submitted as part of the authorisation application (or available elsewhere).

### *4.4.1. Presenting the documentation of the substitution plan to the Agency*

The substitution plan should be submitted as part of the application for authorisation as indicated in the user manual(s) made available on the Agency's website.

## 5. GUIDANCE FOR THIRD PARTIES ON SUBMITTING INFORMATION ON ALTERNATIVE SUBSTANCES OR TECHNOLOGIES

The guidance in this chapter has been drafted to assist third parties in their submission of information about alternative substances and technologies to the substance for which authorisation is sought or reviewed. The aim is to assist third parties in making effective submissions to the Agency. Further detailed guidance on how to perform an analysis of alternatives primarily directed to the applicant for authorisation is given in chapter 3. Interested third parties may find the guidance in that chapter useful in order to submit a well documented information on alternatives.

It should be noted that interested parties also have an opportunity to contribute further evidence to support the decision making process on the Annex XIV substance on the basis of its technical performance, on economic grounds or its environmental/human health impacts through contribution to the SEA process (guidance on this process is given in Guidance on Socio-Economic Analysis – Authorisation).

This chapter describes the overall context within which third parties may wish to provide information and the interactions between the applicant, downstream users, the Agency and third parties. The guidance chapter is intended to assist all third parties: any organisation, individual, authority or company other than the applicant or the Agency/Commission with a potential interest in submitting information on alternatives including:

- The suppliers of alternative substances or technologies;
- Academics/innovators who have developed or have knowledge of an alternative substance or technology;
- NGOs and Trade Unions;
- Governmental and intergovernmental agencies; and
- Downstream users.

Submissions from third parties may be extremely important to the Agency's Committees' considerations on authorisation applications. The applicant may not be aware of the alternative substance or technology proposed by the third party and the Agency may only become aware of the existence of alternatives through the submissions made by third parties. In addition, technical, economic and safety information provided by third parties on alternative substances or processes may influence the Committees' assessment of suitability.

The extent to which information submitted by third parties can influence the decision process will depend on the quality and clarity of information submitted and the extent to which third parties are able to help to demonstrate the technical and economic feasibility of using an alternative substance or technology as well as assessment of its capability to reduce the overall risk. In accordance with Article 64(3) any information submitted by third parties will be taken into account by the Agency when preparing an opinion. In this regard, it should be noted that, in deciding whether an alternative is suitable for the applicant, the Agency will have to consider the economic and technical feasibility for the applicant.

Third parties do not have access to the detailed information within the application for authorisation and must base their submissions on the information provided by the Agency on its website about the broad use of a substance for which authorisation is sought or being reviewed. Third parties

should pay special attention on when describing what function the alternative fulfils, for which uses their alternative is suitable and under which conditions is can be used. For example, a lubricant that is specially designed for extreme temperatures and/or use with specific material; should not be described simply as a lubricant without any accompanying information about the conditions of use.

Information must be submitted within a specified time period (see below), if it is to be considered by the Agency. It may be appropriate to submit information even before technical feasibility for a specific use has been fully established. For instance, a convincing case may be presented that the innovation is sufficiently promising to warrant further research, further research is planned and the innovation would be likely to have a major benefit for human health or the environment. This information may inform the specification of a review period for the authorisation by the Agency.

The Agency is not required to respond to submissions made by third parties but may choose to request further information.

### 5.1. Circumstances leading to third party submission of information

Third parties may wish to submit information about potentially suitable alternatives that are technically feasible and safer for human health and/or the environment. They may have a particular interest in indicating how the use of a chemical could be entirely avoided by use of an alternative technology or by optimizing the process such that the chemical is no longer required or very much less is used.

### 5.2. Timing of third party submissions

Third parties are specifically invited to submit information on alternatives when the Agency publishes information on its website about uses for which applications have been received or when the Agency indicates on its website that an authorisation is subject to review (Art. 64(2)). The Agency will indicate a deadline for the submission of information which will be within the 10-month period that the Agency's Committees for Risk Assessment and Socio Economic Analysis have to prepare a draft opinion. Article 64(3) indicates that third parties may also be invited by the Committee for Socio-economic Analysis to provide additional information on possible alternative technologies and substances.

The sunset dates[31] given in the Annex XIV list provide an indication of the likely timing of applications for authorisation. Applications for authorisation should be made before the deadline specified in the Annex XIV entry, which will be at least 18 months before the sunset date, in order that use of the substance shall be allowed after the sunset date if a decision has not been taken by that time. Once an application is submitted, the Agency's Committees for Risk Assessment and Socio Economic Analysis must issue a draft opinion within a 10-month period.

Submissions on proposed alternatives are likely to be most effective in influencing the decision process if submitted during the consultation period defined under Article 64(2) that is specifically tailored for the consideration of alternatives. There are however two earlier periods of consultation during which interested parties may wish to comment:

[31] Date from which the placing the market and use of the substance shall be prohibited unless an authorisation is granted

- Following the preparation of an Annex XV dossier[32] by the Agency/Member State, the Agency is required by Article 59(4) to place a notice on its website inviting comment from interested parties. Details of this process are provided in the Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern and Guidance on inclusion of substances in Annex XIV.
- Once the Agency has considered the Annex XV dossier, Article 58(4) requires the Agency to publish its recommendations on priority substances and uses to be included on Annex XIV on its website and to invite comments, in particular on uses which should be exempted from the authorisation requirement, from 'all interested parties'.

These earlier phases of the procedure provide an early indication of substances that may become subject to authorisation. In addition, these phases provide information about why substances have been placed on Annex XIV. This may assist third parties in the preparation of a submission that can demonstrate a suitable alternative when a certain use(s) is applied for. It should be noted that the inclusion in the candidate list does not set any presumption when the substance would be subject to authorisation.

As well as the formal opportunities for input of information and commenting, some third parties (for example users of a substance for which an application for authorisation is being made) may wish to maintain a two-way dialogue with the applicant for the authorisation to ensure that information on the actual uses, and what is and is not being covered by the application is clear to both parties, and the best available information is used to generate the application. Communication within the supply chain is addressed in more detail in Chapter 3.

Following the granting of an authorisation, third parties may still submit relevant information to the Agency. All authorisations will include a time limited review period and the holders of authorisations are required to submit a review report at least 18 months before the expiry of this period. In addition, Article 61 (2) indicates that the Agency may review authorisations at any time if circumstances change so as to affect the risk to human health or the environment or the socio-economic impact, or if new information on possible substitutes becomes available. The review process will include an invitation for third parties to submit further information within a specified time period following the publication of broad information on uses on the Agency's website.

The time line below summarises the opportunities available to third parties to comment on Annex XIV substances. The guidance in this chapter relates to the specifically to the stages after placement of a substance on Annex XIV including the granting of authorisation and the subsequent review of authorisations.

[32] Annex XV dossier proposing the identification of substances of high concern. For further information see Guidance on inclusion of substances in Annex XIV).

A time line illustrating the opportunities for third parties contribution is shown below:

| Agency actions | Third party actions |
|---|---|
| Notice that Annex XV dossier has been prepared placed on Agency website (Article 59(4)) | |
| | Comments invited from interested parties within specified time period (Article 59(4)) |
| Substance placed on candidate list, recommendations for priority substances published on Agency's website (Article 59(10)) | |
| | Comments invited from interested parties, in particular on uses that should be exempted within 3 month time period (Article 58(4)) |
| Substance placed on Annex XIV, applicant applies for authorisation, Agency publishes information on broad uses on website (Article 64(2)) | |
| | Information on alternatives invited from third parties within a specified time period (Article 64(2)) |
| Agency may request further information from third parties (Article 64(3)) | |
| Granting of authorisation (Article 60) | |
| | Interested parties may still provide information on alternatives to the Agency (Article 61(2)) |
| Review of authorisation (Article 61) | |
| | Comments invited from interested parties (Article 61, 64(2)) |

## 5.3. Preparation of a third party submission

All information submitted by third parties must be taken into account by the Agency, but submissions are most likely to be effective if information is presented in an organised logical fashion that will enable the Agency to take proper account of the arguments and information presented. Third parties may wish to state their interests in respect to the outcome of the authorisation process.

Third party submissions should be based on the information provided by the Agency on use and, if possible, include sufficient technical detail to enable the Agency to assess the availability and suitability of the proposed alternative. If possible, the extent to which the alternative can deliver an equivalent function to that provided by the substance in relation to the use(s) specified by the Agency should be clearly described.

A single alternative may not be suitable for all different processes or uses for which the original substance was suitable, thus the original substances could be substituted by more than one suitable alternative. Third parties may submit information relevant to a limited number of uses or describing several alternatives for different uses. Third parties may submit information about alternatives that are still under development, where technical feasibility and reduced risks to human health and/or the environment have still to be fully established. Although it would not be possible to immediately introduce the alternative, the Agency will take such information into account when setting of a review period for the authorisation.

Third parties may wish to take account of the information requirements placed on the applicant (Chapter 2), in setting out their submissions. The guidance provided for applicants on the analysis of alternatives may be of particular relevance (Chapter 3). Ideally, submissions would include a good description of the proposed alternative and indicate its relevance within the context of the authorisation process. A suggested format for third party submissions is provided on the Agency's website.

In making an assessment of the suitability and availability of proposed alternatives, third parties may wish to take account of the information provided by Agency on the inclusion of the substance on Annex XIV that led to the application for authorisation and on the uses for which authorisation is sought.

To the extent that it is possible (which is likely to be limited by the information available about use), third parties should provide any information that is relevant to the application and seek to demonstrate that the proposed alternative(s):

- Meet(s) technical performance specifications relevant to the uses described by the Agency;
- Are/is safer for human health and/or the environment, and/or
- Are/is economically feasible including reasonably accessible in sufficient quantities to meet the probable annual volume required for the use of interest.

An alternative should have adequate technical performance that is fit for purpose. Third parties may wish to consult with the supply chain in order to inform their submission. Although it is unlikely to be possible to fully demonstrate technical and economic feasibility for the applicant, combined with reduced risks for health/environment, third parties should include any information that is relevant to the assessment of suitability. A statement that alternative X can be used should be supported by data and information demonstrating for which use(s) and under which use conditions it is a plausible substitute.

When providing information on an alternative substance, third parties may wish to consider what data are available that can be used to demonstrate lowered risks and to provide a description of these data in their submission. For substances already registered under REACH, information may be available from within REACH IT to demonstrate lowered risks to human health or the environment. When providing information on alternative technologies third parties would ideally seek to demonstrate that their use would lead to a reduction in human or environmental risks.

Where alternative substances or technologies are readily available, it would be helpful to describe the predicted costs, if known, associated with using an alternative in relation to those associated with the substance subject to authorisation. Where alternatives are not currently readily available, the costs of making them available and predicted costs of use would be useful.

In as far as it is possible, third parties should describe as clearly as possible the extent to which an alternative is better or worse than the subject of the authorisation application for each of the three criteria: technical and economic feasibility and reduction of overall risks. When assessing whether suitable alternatives are available the Agency is required to take into account all relevant aspects concerning the alternative(s), as stated in Article 60 (5) including whether:

- the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures; and
- be technically and economically feasible for the applicant.

In considering risks to human health and the environment, a life cycle analysis approach may be taken for the specified use of the substance. Some examples of hypothetical situations are given in Box 13.

**Box 13. Examples of third party consideration of alternative substances**

| |
|---|
| **Substance**: carcinogenic organic solvent<br><br>**Specified use**: solvent used for extraction during laboratory analysis<br><br>**Proposed alternative**: organic solvent with similar chemical and physical properties but not known to be carcinogenic, mutagenic or toxic to reproduction; similar potential to persist in the environment or bioaccummulate as the original solvent.<br><br>**Functionality:** Alternative solvent is unlikely to provide same range of functionality as current solvent, but for many analytical protocols, the performance of the alternative is adequate.<br><br>**Technical feasibility**: suitably as a laboratory solvent demonstrated for 4 widely used analytical protocols. Although alternative solvent is more flammable than the original solvent and therefore may not be suitable for larger scale applications; suitability of alternative solvent not demonstrated for all potential uses and its suitability would need to be validated for each analytical protocol.<br><br>**Economic feasibility:** alternative solvent is more expensive, but as only small quantities are used, the calculated overall cost to laboratories of substitution is extremely small in comparison to the overall costs of maintaining laboratory facilities.<br><br>**Risk reduction**: levels of human exposure similar for both solvents, but alternative not associated with cancer risk; environmental risks similar for both solvents |
| **Substance**: carcinogenic organic solvent<br><br>**Specified use**: solvent used for cleaning of reaction vessels used in polymer production<br><br>**Proposed alternative**: treatment with water heated to 90$^{o}$C followed by treatment with an alternative organic solvent with similar intrinsic properties, including environmental hazards, but no proven potential to cause cancer<br><br>**Functionality:** the hot water was not capable of removing congealed fragments of part formed polymer from the reaction vessel, but the two stage process was demonstrably effective and resulting in a lower use of the alternative solvent than would have been required if the hot water step had been omitted. The water requires treatment before discharge to the environment and the use of hot water presents safety issues.<br><br>**Technical feasibility:** Alternative process was adequate for the intended purpose but introduced a requirement for facilities for wastewater treatment that had not previously existed.<br><br>**Economic feasibility**: An analysis of the cost of heating and subsequently treating the water indicated that these represent substantial additional process costs. The alternative solvent is currently more expensive than the original solvent but this is likely to change as the demand for alternative solvents increases.<br><br>**Risk reduction:** levels of human exposure lower for alternative solvent which is not associated with cancer risk, giving |

| |
|---|
| rise to an overall reduction in health risks; reduced quantities of solvent use associated with small reduction in environmental risks; introduction of new hazard in form of hot water |
| **Substance:** carcinogenic organic solvent<br>**Specified use:** solvent used for cleaning of nozzles used in polymer extrusion<br>**Proposed alternative:** organic solvent with similar chemical and physical properties, poses similar risks to environment but not known to be carcinogenic<br>**Functionality:** Solvent was demonstrated to be effective in use provided a longer washing time was allowed.<br>**Technical feasibility:** Although the alternative solvent provided an equivalent function, the longer washing time had an adverse impact on the overall production schedule.<br>**Economic feasibility:** The cost of the alternative solvent is similar to that of the original solvent. The longer washing time means that operators may need to have an increased number of spare nozzles available as the longer turnaround time means than individual nozzles are used less frequently. Over a ten year period, the calculated additional costs were small in relation to total operational costs.<br>**Risk reduction:** levels of human exposure similar for both solvents, but alternative not associated with cancer risk; environmental risks similar for both solvents |
| **Substance:** carcinogenic metal<br>**Specified use:** used with other metals in high strength alloy<br>**Proposed alternative:** reformulated alloy excluding metal carcinogens<br>**Functionality:** reformulated alloy is more brittle than original alloy and not suitable for all applications<br>**Technical feasibility:** The reformulated alloy can be produced using existing production facilities<br>**Economic feasibility:** Market demand for reformulated alloy is likely to be smaller than for the original formulation because of its lower technical performance. It is estimated that future demand will fall to 50% of current levels.<br>**Risk reduction:** Reduction in human exposure to the metal carcinogen |
| **Substance:** carcinogenic solvent<br>**Specified use:** dry degreasing of surfaces such as plate glass<br>**Proposed alternative:** specialist textile which eliminates need for solvent use<br>**Functionality:** the textile is highly effective in removing grease from smooth surfaces, but less effective on rough surfaces; textile becomes progressively less effective as it becomes saturated with grease but can be regenerated by treatment with an environmentally friendly detergent<br>**Technical feasibility:** The textile can provide a similar quality of cleansing for smooth surfaces as the solvent but requires manual cleaning to be undertaken whereas the solvent can be used within automated process<br>**Economic feasibility:** For small scale processes employing manual cleaning, there is a small long term saving in cost through discontinuation of use of the solvent, although initial investment in the textile is required. For processes that are currently automated, the transition to manual cleaning is likely to greatly increase labour costs and process time and the replacement of a solvent based process by a manual process employing the textile is likely to give rise to unacceptably high additional costs.<br>**Risk reduction:** Use of the textile eliminates the need for human exposure to the carcinogenic solvent |

## 5.4. Confidentiality

Third parties wishing to submit information on alternatives should take account of the right of access to documents of the Community institutions. Under 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 including 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.

or where disclosure would undermine the protection of:

— commercial interests of a natural or legal person, including intellectual property,

— court proceedings and legal advice, and

— the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure.

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)).

In case of a request for a third party document, according to Article 4(4) of Regulation 1049/2001, "[the Agency] shall consult [the provider of the comments] with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed."

Under Article 118 of REACH disclosure of information on the full composition of a mixture; on the precise use, function or application of a substance or mixture; 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. Thus, an exception according to Article 4(2) in the right of access of Regulation 1049/2001 will normally apply.

Third parties should clearly indicate within their submissions the information that they wish to remain confidential and the reasons for not disclosing submitted information. The Agency may grant access to documents, unless any of the above reasons applies. Therefore, if clear reasons for not disclosing information are not provided, the Agency reserves its right to decide that access can be given to your comments.

Third parties who have requested that information remains confidential 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.

## References

1999/217/EC: Commission Decision of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 (notified under number C(1999) 399). Official Journal L 084, 27.03.1999, p1-137.

Berufsgenossenschaftliches Institut für Arbeitsschutz – BGIA (2006): The column model: An Aid to substitute assessment.

Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Official Journal P 196, 16.08.1967, p1-98.

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Official Journal L 262, 27.09.1976, p169-200.

Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition. Official Journal L 213, 21.07.1982, p8-14.

Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production. Official Journal L 184, 15.07.1988, p61-66.

Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption. Official Journal L 040, 11.02.1989, p27-33.

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. Official Journal L 189, 20.7.1990, p17-36.

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Official Journal L 230, 19.08.1991, p1-32.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal L 169, 12.7.1993, p1-43.

Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control. Official Journal L 257, 10.10.96, p26-40.

Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. Official Journal L 123, 24.04.1998, p1-63.

Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC. Official Journal L 350, 28.12.1998, p58-68.

Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices. Official Journal L 331, 7.12.1998, p 1-37.

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States

relating to the classification, packaging and labelling of dangerous mixtures. Official Journal L 200, 30.07.1999, p1-68.

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 200 establishing a framework for Community action in the field of water policy. Official Journal L 327, 22.12.2000, p1-73.

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products. Official Journal L 311, 28.11.2001, p1-66.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal L 311, 28.11.2001, p67-128.

European Commission (July 2006) Integrated Pollution Prevention and Control Reference Document on Economics and Cross-Media Effects

Federal Ministry of Labour and Social Affairs (BMAS) Germany. Technical Rules for Hazardous Substances; Substitution -a general framework for the integrated assessment of the feasibility of substitution. TRGS 600, (2007).

Okopol/Kooperationsstelle (2003) Substitution of hazardous chemicals in products and processes: Report compiled for the Directorate General Environment, Nuclear Safety and Civil Protection of the Commission of the European Communities Contract No B3-4305/2000/293861/MAR/E1

Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs. Official Journal L 299, 23.11.1996, p1-4

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal L 031, 01.02.2002, p1-24.

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. Official Journal L 268, 18.10.2003, p29-43.

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Official Journal L 136, 30.4.2004, p1-33.

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC. Official Journal L 158, 30.04.2004, p7-49.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. Official Journal L 338, 13.11.2004, p4-14.

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. Official Journal L 396, 30.12.2006, p1-849.

Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control. Official Journal L 24, 29.1.2008, p8-29.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. *Official Journal L 353, 31.12.2008, p. 1–1355.*

TemaNord 97 Nordic Council of Ministers, The use of decision-aid methods in the assessment of risk reduction measures in the control of chemicals, TemaNord 1997:622

The Danish Ecological Council, "Hazardous Chemicals Can Be Substituted"; February 2006.

The Massachusetts Toxics Use Reduction Institute (2005). Alternatives Assessment for Toxics Use Reduction: A Survey of Methods and Tools. Methods and Policy Report No. 23

US Environmental Protection Agency: Cleaner Technologies Substitutes Assessment - Office of Pollution Prevention and Toxics Washington, DC 20460 EPA Grant X821-543

## Appendix 1 Considerations for grouping of substances

An application for a group of substances is only possible if it is for a group in accordance with Article 62 (3). A description of the reasons for considering the substances as a group is required. It should be submitted as part of the application, in accordance with specific instructions in user manual(s) made available on the Agency's website. It should outline the argumentation for the grouping, based for example on similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity.

The group or category is most likely to have already been created as part of the registration process or for the Annex XV dossier which lead to inclusion on Annex XIV. In such cases, the argumentation for considering the substances as a group will already have been prepared, and the benefits of an application for a group should be relatively easy to determine. The majority of the guidance in this section relates to the situation where the applicant wishes to form a new group for the application. However, some of these considerations may be useful in deciding whether to apply for an authorisation for all members of an existing group.

The definition of a group of substances is given in Section 1.5 of Annex XI of the Regulation, and according to this definition, grouping of substances can be made only on the basis of similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity. Similarities may be based on:

- a common functional group;
- the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
- a constant pattern in the changing potency of the properties across the category.

It is important to note that this definition precludes grouping of substances based on similarity of use alone. Further guidance on grouping of substances is given in the Guidance on information requirements and CSA.

### A1.1 Reasons for grouping substances

The main reason for grouping of substances for an application for authorisation is that savings in time and effort can be made in some situations, particularly where common information can be used for the application. Possible situations that are envisaged with a group of substances are outlined below. For each situation, although there is nothing to stop an applicant from submitting a single application covering the group of substances, there may be some cases where the complexity of the situation will outweigh any benefit from reduction of information and effort needed. Therefore, it is advisable that the applicant assesses the benefits from grouping on a case-by-case basis.

a) All members of the group have the same uses, and the application for authorisation is made for all of the uses of the group. Here, as the same uses are considered for all substances, the information needed for the application for all substances may be similar, or could involve consultation with the same users or industry sectors, and so could then be collected at the same time.

b) All members of the group have the same uses, but the application for authorisation is made for only some specific uses of each substance within the group. Similar to above, if the specific uses considered are common to more than one of the substances in the group, then the necessary information could be collected at the same time. If, on the other hand, the specific uses are all different for each substance in the group, there would appear to be little advantage in treating the substances as a group, as the information for each substance would probably need to be collected separately, and the application would be complex and may lack transparency and clarity.

c) Members of the group have different uses, and the application for authorisation is made for different uses for each substance. Here there would appear to be little advantage in grouping the substances.

Another consideration when grouping substances is the basis that will be used for the application, i.e., whether the "adequate control route" or the "socio-economic analysis route" can be used. Different documentation may be needed for applications by these two routes and so there would appear to be little advantage in grouping substances where different routes will be used for individual substances.

When deciding whether or not to submit an application for a group of substances, a key consideration is maintaining clarity in the applications. In complex cases, it may be preferable to submit separate applications for each member of the group. In this case it may still be possible to use some of the same supporting information for each application if this information was collected for the group as a whole.

### A1.2 Argumentation for grouping substances for authorisation

Several possibilities could be envisaged as a basis for describing the arguments for the grouping of substances. Examples are given below.

a) The substances were treated as members of a group or category in the context of registration (*i.e.* for the purpose of the CSR or use of read-across for the purpose of preparing the registration dossier). In this case an argumentation for considering the substances as a group/category would already exist in the registration dossier and the same reasons could be used as a basis for considering the substances as a group/category for authorisation, if compliant with Section 1.5 of Annex XI.

b) The Annex XV dossier(s) for inclusion of the substance in the Candidate List treated the substances as a group or category or used a read-across approach for the substances. Here, reference to the Annex XV dossier in the application for authorisations would be sufficient for considering the substances as a group/category for authorisation.

c) Grouping based on a common impurity or degradation product, or constituent of multi-constituent substance, if the impurity/degradation product/constituent is the reason why the substances were listed on Annex XIV. Again the Annex XV dossier for the substances should provide the necessary background for considering the substances as a group/category for authorisation.

d) The substances are considered as a group or category based on structural similarity. The arguments that could be used here could be structured around common structural features and/or functional groups or a constant and predictable pattern in the properties of relevance across the category. The properties of relevance here would be the properties outlined in the Annex XV dossier that lead to the substance being identified as a substance of very high concern, and so subsequently listed in Annex XIV. In this case the Guidance on information requirements and CSA (Chapter R6.2) should be used to develop the argumentation. If necessary, it is possible to draw on substances not listed in Annex XIV to strengthen the argumentation, although such substances themselves cannot be the subject of the application for authorisation.

For a review report, the argumentation for the grouping should be reconsidered in light of any new data that has become available.

## Appendix 2 Applications by several legal entities

### A2.1 Reasons for joint applications

Possible advantages for joint applications:

- Sharing of costs needed to put together the necessary documentation required.
- Broader range of experience and expertise.
- Ensuring the specific conditions of use of downstream users are covered.

Possible disadvantages for joint applications:

- Commercial and confidentiality issues relating to the use(s) of the substance.
- Not all uses of the substance may be relevant to each legal entity.
- Disagreements over the information.

Applicants who want to submit a joint application should refrain from exchanging commercial sensitive information prohibited under the competition rules (*e.g.* information about prices or customers). Exchanging information about substance identity or substance properties is permissible under the competition rules. However, exchanging detailed information about alternatives could give raise to concerns, particularly if there is a concerted action as to whether, when, and how companies switch to an alternative. Therefore, when preparing the analysis of alternatives, parties may consider the use of an independent third party.

### A2.2 Approach for joint applications by groups of applicants

The basic approach for an application by a group of applicants[33] would be to firstly identify the manufacturer(s), importers and downstream users that are involved in the supply chain for the substance.

If a SIEF has been created for the substance, the interested members of the SIEF could form a useful basis for the formation of group for the application. SIEFs have no legal status in relation to applications for authorisations, but they may be a useful platform in cases where the substance has been (pre-)registered by more than one company. However an application for an authorisation from a group of applicants need not be limited to the group of, or a subgroup of, the members of a SIEF (*e.g.* manufacturers and importers of substances that have been identified as suitable for read-across).

[33] The REACH Regulation does not specify what form of co-operation should be used for applications from more that one applicant. This could include formal consortia or other forms of cooperation. The term group of applicants is used here to cover all forms of possible cooperation between manufacturer(s); importer(s) and/or downstream user(s) acting as applicants for authorisation.

It may also be beneficial to include downstream users in the group of applicants if they are not already members of the SIEF. Such downstream users could be identified, for example, based on the known customers of the members of the SIEF etc., or through relevant trade associations etc.

The Guidance on data sharing gives detailed guidance on how to put together SIEFs and other forms of collaboration, and how to deal with issues in relation to Confidential Business Information (CBI) and competition laws. This guidance could also be useful in the case of applications for authorisations by a group of applicants, however, it will be up to the applicants themselves to decide how they share information and prepare the joint application.

Possible situations that could be envisaged when considering an application for authorisation from a group of applicants are outlined below.

- The potential group of applicants consists of actors in one supply chain (manufacturer or importer and downstream user(s)). The different actors will have knowledge on different aspects required for the application and can effectively contribute to a joint application. For example, a downstream user has detailed knowledge on actual conditions under which he uses the substance contributing to an accurate exposure scenario while the manufacture or importer may have better knowledge on how to perform an exposure assessment and develop the CSR on the basis of that exposure scenario. The downstream users have good understanding on the requirements for an suitable alternative, knowledge of all actors is relevant for a SEA, etc.

- The potential group of applicants consists of manufacturer(s) and/or importer(s), all supply the substance for the same uses, and the application is for all uses of the substance. In this case there would appear to be an advantage in developing a group for the application as the information needed for the application would be common to all members of the group.

- The potential group of applicants consists of manufacturer(s) and/or importer(s) and/or downstream user(s), and the application is for only some of the uses. Here the advantages of developing a group for the application would need to be considered on a case-by-case basis as not all information that will be needed for the application may be relevant to all members of the group.

- The potential group of applicants consists of manufacturer(s) and/or importer(s) and/or downstream user(s) that each supply the substance for different uses, and the application is for all uses of the substance. Here it could be questioned whether there is any benefit derived in developing a group for the application.

The same situations could also arise where the application is for a group/category of substances. However here, as discussed at length in the Guidance on information requirements and CSA, the formation of a group/category may also be dependent on which chemicals are of interest to the companies sponsoring the category.

Subsequent applications {Art. 63}, whereby a second legal entity wishes to make an application for authorisation when an application has already been submitted by another applicant or an authorisation has already been granted to another legal entity, are discussed in Section 2.2.5 of this guidance.

### A2.3 Completing the application

For groups of applicants the following points should be taken into account when completing the application.

- The application should identify the members of the group of applicants and also the main contact point.
- The application must have CSR(s) covering all the uses applied for by the group of applicants. In some cases it may be possible to use the existing CSRs of the group members (if available) but it is also possible that a single, consolidated CSR covering the uses for which authorisation is applied for, may need to be generated. The Guidance on information requirements and CSA should be followed in this case.
- An analysis of alternatives and where included in the application, an SEA and/or a substitution plan have to cover all uses applied for and can be submitted jointly.
- There may be issues in relation to Confidential Business Information (CBI) and competition laws in relation to an application for a group of applicants. The Guidance on data sharing gives more detailed guidance on these aspects but, if in doubt, legal advice should be sought.

How a single application from multiple applicants will be created in practice will be elaborated in a separate user manual.

## Appendix 3 Checklist for analysis of alternatives

### Analysis of Alternatives Checklist

The following checklist can be used by the applicant for cross-referencing the key components of an analysis of alternatives against their own preparatory work.

| The analysis of alternatives includes the following information: | Yes ✓ | No ✘ |
|---|---|---|
| 1. Identification of Annex XIV substance function for the uses applied for | | |
| 2. Identification of possible alternatives(s) – substances and/or technologies for the uses applied for | | |
| 3. The assessment of risks to human health and the environment of the alternatives and whether the transfer to alternatives would result in reduced overall risks; | | |
| 4. The assessment of the technical feasibility of the alternative(s) for substitution; | | |
| 5. The assessment of the economic feasibility of the alternative(s) for substitution; | | |
| 6. The assessment of availability of the alternative(s). | | |
| 7. List of actions required, as well as the time-lines, to switch to an alternative substance/technology.<br><br>*In particular in cases where there is a suitable alternative available on the market but not yet ready for an immediate substitution (i.e. within the "sunset date") or another operator in the same market is already or will switch in the short future to alternatives.* | | |
| 8. A justification for the conclusion of the analysis of alternatives if it concludes that there are no suitable alternatives available.<br>a. Reference to an SEA (if the application is for an Annex XIV substance which cannot be adequately controlled; i.e. for an application under the socio-economic route) | | |
| 9. A justification for selection of the alternative (for an application under the adequate control route)<br>a. Reference to a substitution plan (if the application is for a substance for which adequate control can be demonstrated and there is a suitable alternative available). | | |
| 10. Relevant R&D is documented and explained where appropriate | | |
| 11. References to all information sources cited | | |
| 12. Confidential data is clearly indicated as such. | | |

## Appendix 4 Checklist for Annex XIV Substance Function

The following checklist can be used to assist in determining the functional requirements of possible alternatives based on functional aspects of the Annex XIV substance (it is not exhaustive).

| Functional aspect[1] | Explanation |
|---|---|
| 1. Task performed by Annex XIV substance | What is the task that must be performed by the substance?<br>Consider in detail what is required of the specific task that must be performed by the Annex XIV substance and why and how this must be performed.<br>Sources of information:<br>Exposure scenarios in CSA/R – this will detail the operational conditions (Guidance on information requirements and CSA).<br>Supply chain: More specific information detailing exact use, quality criteria and specific product requirements will need to be gathered from downstream users (if they are not the applicant) – (see Guidance on information requirements and CSA).<br>Note: the exact description of the function may be considered to be confidential information by the user – i.e. they may not wish to impart details of the exact process for manufacture. In that case the DU can consider providing the information under a confidentiality agreement. Alternatively he can consider making his own application for that use. |
| 2. What critical properties and quality criteria must the substance fulfil? | This should include the tolerance range for acceptability, i.e. what is the acceptable range for performance (for example maximum drying time for a solvent or coating, or temperature tolerance). |
| 3. Function conditions<br>What is the frequency of performing the task (continuous or batch process)?<br>How much of the substance is used/consumed in the process. | This will give an indication of the amount of substance that is required for the function and the speed and duration of the task. |
| 4. Process and performance constraints<br>What are the process constraints of the task? Does the task have to be performed under particular conditions? | For example these could be physical and chemical constraints as well as temporal and quality constraints.<br>Consider the circumstances under which the task must be performed. How do these conditions determine the qualities of the Annex XIV substance i.e. what are the constraints? These could for example be physical (e.g. extreme pressure or temperature, or confined space), chemical (e.g. possible reaction with other chemicals in the process or pH), or biological (stability for biological systems e.g. microorganisms involved in the process e.g. a bioreactor) that may dictate how the task is performed. |
| 5. Is the function associated with another process that could be altered so that the use of the substance is limited or eliminated? | For example the Annex XIV substance may be used to control emissions of another substance or produce another substance. If the need for control is removed or the end product is altered so that the second substance is no longer needed then the Annex XIV substance may be more easily substituted or not required at all. |
| 6. What customer requirements affect the use of the substance in this use? | For example, customers may have particular operating procedures that must be followed and contractual arrangements that demand use for a certain length of time. |
| 7. Are there particular industry sector | For example some substances are long lifetime products that must |

| | |
|---|---|
| requirements or legal requirements[2] for technical acceptability that must be met and that the function must deliver? | be tested for technical performance and acceptability for use over a long period. Also the function may need to deliver a function that meets particular standards (such as fire safety requirements, product safety or component worthiness). |

*Notes:*

1. *Functional aspects suggested are not an exhaustive list, but an indication of the main considerations that may assist the applicant in determining function.*
2. *This is considered further in section 3.6 on technical feasibility.*

## Appendix 5 Brief example of possible method for profiling environmental risk

'Risk profiling' may be used for comparing environmental risks of different substances used within the same specific industry sectors (using emission scenario information) and a similar technique may be adapted for human health. An outline of the technique is set out in Box A. The technique may be helpful for assessing the comparative risk of alternative substances and for indicating the potential risk of the alterative if used in the same use pattern (i.e. assuming the same emission scenarios).

### Box A Risk profiling for environmental risks

Risk profiling[1] is a technique developed to allow the generic assessment of the environmental risks of substances that have similar function. It uses the same principles used in the risk assessment of chemicals for assessing the need to limit risks based on comparison of exposure with effects, but instead of focusing on a single substance, a range of possible substances used within a use pattern can be considered and the physical and chemical characteristics that lead to risks can be evaluated.

The prediction of emissions from the life cycle phases of substances can be determined based on the combination of the type of industry in which the substance is manufactured and uses to which the substance is put. These combinations determine the predicted emissions to environmental compartments based on the so-called A and B tables in the Guidance on information requirements and CSA and within the European Union System for the Evaluation of Substances (EUSES). Furthermore, more specific emissions from some industrial sectors have been documented in emission scenario documents. The emissions can be used to derive predicted environmental concentrations (PEC) for environmental compartments. However, certain key physico-chemical properties (biodegradability, octanol-water partition, and vapour pressure and water solubility) have the most influence on the environmental fate of a substance released into the environment. Therefore for substances with the same use pattern (i.e. releases to the environment) for the same tonnage use, risks will be determined by exposure (determined by key properties) and the toxicity of the substance (i.e. the predicted no-effect concentration - PNEC).

By using the calculations for determining the environmental fate of substances based on key properties and basic information on the aquatic toxicity of the substances, the combinations of these features and the tonnage used of substances that give rise risks can be investigated. Therefore for particular use patterns that define releases to the environment a theoretical 'profile' of the key physico-chemical properties, toxicity and tonnage use can be investigated. Combinations that lead to risks can be avoided and those that do not can be investigated further.

The utility for the analysis of alternatives is that for use patterns with known emission characteristics and for particular tonnage uses, the combinations of physico-chemical and toxicological characteristics substances that give rise to a risk can be compared to and between possible alternatives. This can be based on a small amount of information on the alternative substances (e.g. readily biodegradable, octanol-water partition and acute aquatic toxicity). The alternatives that indicate a potential risk can be avoided and those that do not can be selected for further investigation.

1. Environment Agency (2004) R&D Report: "Development and Assessment of Risk Profiles for Substances: Application to Specific Industry Sectors – Plastics Additives and Lubricant Additives

## Appendix 6 checklist for substitution plan

### Substitution Plan Checklist

The following checklist can be used by the applicant for cross-referencing the key components of a substitution plan against their own preparatory work.

| Element | Yes ✓ | No ✘ |
|---|---|---|
| **1. The substitution plan includes the following information**<br>• A list of actions detailing (as a minimum) the information presented in 2 (e-h).<br>• A timetable for implementation of actions<br>• The method used to communicate information to stakeholders and the supply chain<br>• References to supporting information or reports (e.g. SEA) | | |
| **2. The list of actions includes:**<br>• A series of actions proposed by the applicant (though not always for the applicant to undertake) to facilitate or carry out the substitution.<br>• A proposed timetable with a deadline for the completion of each action.<br>• A justification to present the rationale behind each action/timetable proposed by the applicant.<br>• A reviewing progress against proposed actions/timetable. (This may take the form of a progress chart so that progress can be tracked against the planned action (for example a Gantt chart). | | |
| **3. A substitution timetable should be presented within the plan that:**<br>• Contains a start-date for implementation of the substitution plan<br>• Contains an end-date by which substitution is anticipated to be complete<br>• Contains a timetable with a deadline for each action<br>• Is realistic given the limitations identified in the substitution plan<br>• Contains references to suitable justifications for proposed dates<br>• Highlights the milestones set within the action plan<br>• Highlights the internal progress review and internal progress reporting (i.e. by the applicant) | | |
| **4. Internal review of overall substitution position for the purpose of the review report, where relevant:**<br>• Are there any new/emerging alternatives that were not present before?<br>• Is the substitution still the best available option? | | |

**European Chemicals Agency**
P.O. Box 400, FI-00121 Helsinki
http://echa.europa.eu