# Guidance for the preparation of an Annex XV dossier for restrictions

## June 2007

**Guidance for the implementation of REACH**

## 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.

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# PREFACE

This document describes how the authorities (Member States Competent Authorities or the Agency on request from the Commission) can prepare an Annex XV dossier to propose a restriction under REACH. 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) lead by the European Commission services, involving all stakeholders: 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.

The legal reference for the document is the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

1 Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006)

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# 1 INTRODUCTION

## 1.1 Overview

This document provides draft guidance to the Member States and the European Chemicals Agency in preparing an Annex XV dossier to propose and justify a restriction on the manufacturing, marketing and use under REACH (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)).

Annex XV of the REACH lays down general principles for preparing dossiers to propose and justify restrictions on the manufacture, placin on the market or use of substances within the Community. Agreement on proposed restrictions (Commission comitology decision) will lead to the addition of any agreed restrictions to Annex XVII. Any subsequent manufacture, placing on the market or use of the substance has to comply with the conditions of the restrictions.

This guidance is intended for use by those within the Member State competent authorities and the Agency responsible for the production of Annex XV dossiers to suggest a restriction. The guidance will also facilitate industry and other stakeholders interested in following up and contributing to the development of an Annex XV dossier.

The guidance lists and elaborates the different elements that should be considered when developing a restrictions dossier. The guidance is intended to assist Authorities developing a restrictions proposal to check which of the elements are relevant to the specific case and to provide relevant considerations when elaborating those elements in the proposal. The guidance thus assists in fulfilling the principles laid down in Annex XV of REACH.

In this document the term ‘Authority’ is used to refer to the Agency or any Member State authority undertaking work on substance evaluation or developing an Annex XV dossier.

## 1.2 Links to other REACH guidance and processes

This guidance is not intended to be used as stand alone guidance. Much of the guidance needed for carrying out hazard and exposure assessment and risk characterisation for the purpose of restriction proposal is covered in the CSA guidance being developed in RIP 3.2. The same approaches should be used in most cases and so these are not repeated here. Instead, this guidance indicates when to refer to the CSA guidance, and identifies areas where the approaches in that guidance need to be adapted for the purpose of the Annex XV dossier.

The compliance check under the dossier evaluation may also provide further information where this should have been provided in the registration(s). Substance evaluation is likely to be a part of the process of producing an Annex XV dossier in cases where further information is needed. As such there is a clear link between the two activities. Some of the guidance for Annex XV dossiers may be useful for carrying out parts of the substance evaluation, in terms of justifying a request for further information based on review of the available data and on risk assessment. Guidance for the evaluation procedures can be found in the Guidance on evaluation.

A restriction proposal needs to include available information on alternatives for the substance. The Guidance on Socio Economic Analysis and the Guidance on authorisation application will also contain guidance on gathering and analysing information on alternatives.

In producing a restrictions dossier under Annex XV, the Authority may carry out a socio-economic analysis (SEA). This is briefly described in section 5.6 of this guidance.

The relevant links to these other REACH guidance documents will be introduced when the documents are available. Where necessary overlapping parts are replaced by appropriate references.

### 1.3 Structure of this guidance

This introductory section contains background information. It first starts by explaining the legal basis of the procedure and what may prompt a Member State and/or the Agency (through the Commission's request) into taking action by developing an Annex XV dossier. The actual guidance sections provide an indication of what are the information sources which will serve as the basis for the Annex XV dossier, and then provide guidance on how to use such information in order to justify and formulate the most suitable restriction proposal (and on how to use the template for the Annex XV dossier). The document also provides guidance on how to decide whether a restriction it is the most suitable process to tackle the concern. Furthermore, guidance is given on how to proceed when, based on the preparatory work for the Annex XV dossier, it is concluded that an Annex XV dossier is not the appropriate way forward. It is also the aim of this guidance to provide information on the interconnections between the different processes deriving from REACH and the preparation of an Annex XV dossier. A part in the development of the restriction proposal is the use and documentation of the available information on alternatives and the voluntary evaluation of socio-economic implications of the restriction, and this is tackled further on in the text.

The appendices to this document provide the template of the Annex XV dossier and guidance required for the preparation of the dossier.

In addition to the main text of the guidance, the Annexes to this document contain more detailed information, and the purpose of this is to have broad guidance in the main text, and if there is the need for more detailed guidance the reader can decide to refer to the annexes.

## 2 LEGAL FRAMEWORK

The restrictions procedure is a safety net to address unacceptable risks to human health or the environment, arising from the manufacture, use or placing on the market of substances, which need to be addressed on a Community-wide basis. Restriction means any condition for or prohibition of the manufacture, use or placing on the market of substances. Any substance on its own, in a preparation or in an article may be subject, where justified, to restrictions.

All decisions on whether or not to restrict the manufacture, use or placing on the market of a substance are taken by the Commission in the regulatory comitology procedure with scrutiny. Any adopted restrictions will be included in Annex XVII to the REACH Regulation, and will thereby form part of the REACH Regulation.

There are a few exemptions from the restrictions in the REACH Regulation. They are for the manufacture, placing on the market or use of a substance (1) in scientific research and development, (2) in PPORD, if this as well as the exempted quantities are specified in the Annex, and (3) for the

use of substances in cosmetic products with regard to risks to human health within the scope of the Cosmetics Directive.

The Annex XV dossier for a restriction shall include information on hazards and risks, available information on alternatives and a justification for restrictions at Community level. In addition the Annex XV may include a socio-economic assessment. The Annex XV dossier will provide the ground for any decision taken by the Commission. If the Commission proposes restrictions to consumer use of a CMR substance on its own, in preparations or in articles, no Annex XV dossier is required, enabling a faster procedure.

An Annex XV dossier may be prepared either by a Member State or by the Agency, if the Commission asks it to do so or if the Agency considers that the use in articles of a substance subjected to the authorisation system poses unacceptable risks. Any Annex XV dossier for a restriction will be published (without prejudice to Articles 118 and 119 of the REACH Regulation) on the internet to invite interested parties' comments. The Agency's Committees for Risk Assessment and for Socio-Economic Analysis will both form an opinion on the suggested restrictions, taking into account the dossier and any interested parties' comments received.

To prevent duplication of work, any Member State is requested to notify the Agency that it proposes to prepare an Annex XV dossier for a restriction (Article 69 (4)). The Agency will maintain a list of Annex XV dossiers for restrictions that are planned or underway. For substances on this list, no other restrictions dossier shall be prepared (Article 69 (5)). The Member State that has notified the preparation of a dossier that is included on the list has to prepare the Annex XV dossier within 12 months of notification.

Therefore, when the Authority considers the need for developing an Annex XV dossier for a restriction, the first step is to check via REACH-IT the 'registry of intentions' whether another Member State or the Agency is already preparing such an Annex XV dossier on the same substance. The Agency's registry of intentions includes also information on the intentions of Authorities to prepare an Annex XV dossier for harmonised classification and labelling and for identification of SVHCs. It is recommended that the Authority checks also the stage of any such work on the same substance. If the Authority decides to proceed with the preparation of a restriction proposal although other Annex XV dossier for harmonised C&L or for the identification of SVHC is under preparation, it is recommended that he contacts the other Authorities working on the substance to ensure that work is not duplicated. The registry is accessible for the Agency, the Commission the Member States and interested parties.

Member States need also to consider carefully what the appropriate timing is for the notification of the intention to prepare a restrictions dossier under the restrictions procedure. It is recommended that a notification should only be made if there is sufficient confidence that an Annex XV dossier can be finalised within 12 months from notification and that it is likely that the dossier will conclude that a restriction is necessary to address unacceptable risks to human health or the environment at the Community level.

The main timeline of the restriction procedure is given in the figure below.

The main timeline of restriction procedure (a MS preparing the Annex XV dossier)

Durations indicated for the different tasks represent the max durations of the period within which the tasks have to be fulfilled.

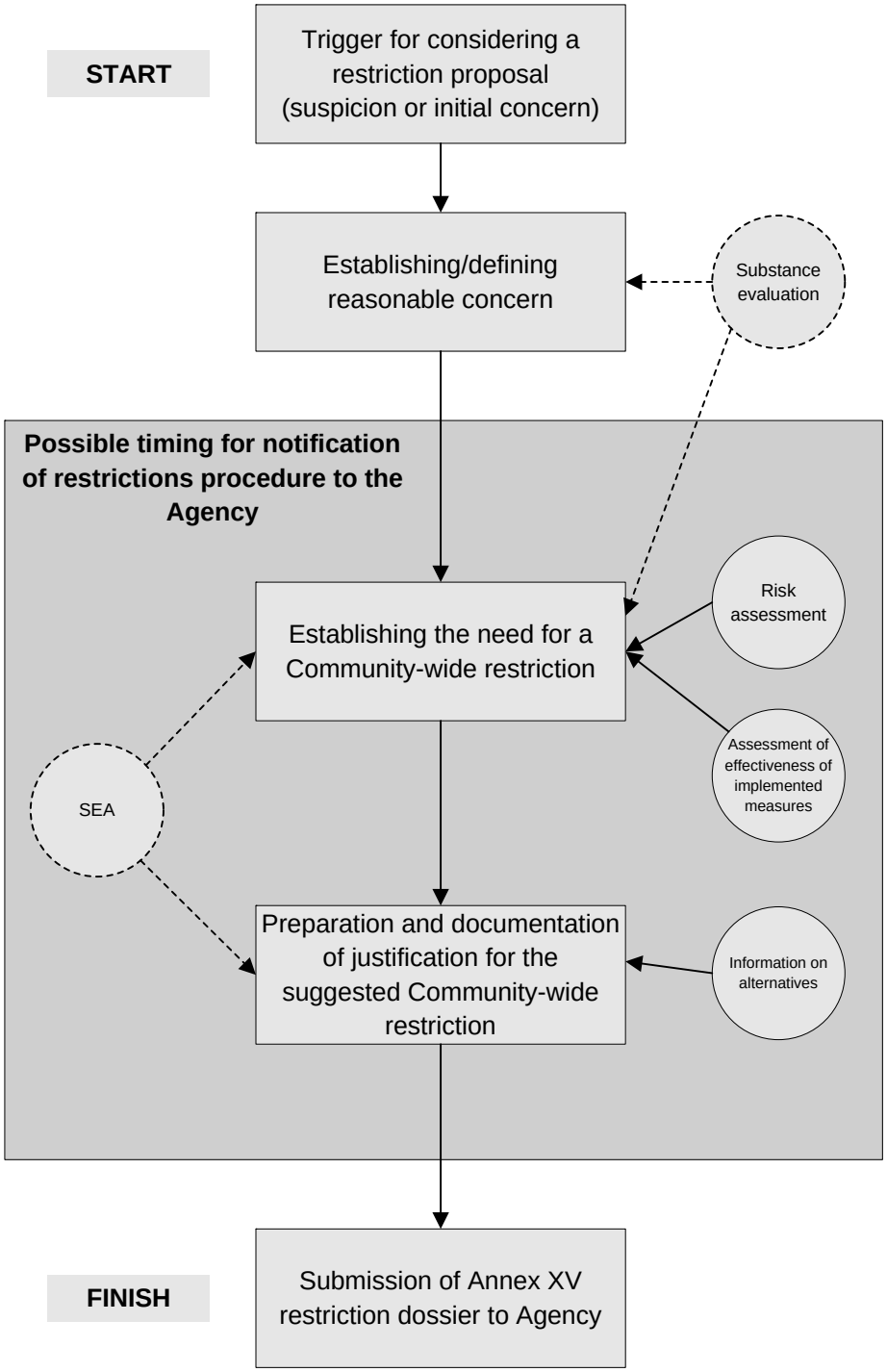
| Interested Parties | | Tasks | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Actions by MS[1] | | MS starts work related to a restriction program | a | Period for preparing the Restrictions Dossier<br>12 months | b | | | | | | | |
| Actions by 3rd parties (Industry, NGOs, other MS) | | Informal submission of information by 3rd parties | | | | Comments on dossier and suggested restrictions; SEA or input to one<br>6 months | | Comment on draft opinion of SEA<br>60 days | | | | |
| Actions by the Agency | | Maintain list of notified substances | | | | | | | | | | |
| | RA Committee | | | | | Prepare an opinion based on the dossier prepared by the Agency/MS and take into account the comments submitted by interested parties<br>9 months | | | d | | | |
| | SEA Committee | | | | | Prepare an opinion based on consideration of the relevant parts of the dossier and on the socio-economic impact<br>12 months | | | | | | |
| | | | | | | | c | | d | | | |
| Actions by the Commission | | | | | | | | | | Prepare a draft amendment to Annex XVII<br>3 months | f | at least 45 days | g |

Key Deadlines

| | | |
|---|---|---|
| a | - | Notification to the agency |
| b | - | Submission and publication of the restriction proposal [2] |
| c | - | SEA publishes the draft opinion |
| d | - | Submit opinion of the Committee to the Commission and publish on the website |
| f | - | Draft amendment submitted to the Member States |
| g | - | Commission decision via Comitology procedure |

An overview of the compilation of an Annex XV report proposing a restriction is described in chapter 5.1 and more detailed guidance is given in chapters 5.2 to 5.6. Figure 1 below shows the main tasks to be taken by Authorities when preparing a restriction proposal.

**Figure 1** Overview of Authorities' actions throughout the preparation of a restriction proposal




Dotted shapes or lines represent non-compulsory actions or sources of information that may not always be available.

# 3 WHAT PROMPTS A RESTRICTION DOSSIER?

This section presents some examples of situations which may prompt a Member State or the Commission to consider a restrictions proposal.

Some of these triggers in the first group may lead a Member State to propose the substance for substance evaluation in order to request the data required for the restriction proposal. The Agency may then include such a substance on the Community rolling action plan for substance evaluation. The result of the substance evaluation may then trigger a restriction proposal.

The examples are not intended to be exhaustive since the motivation for initiating the restrictions process may depend on several different factors, including specific characteristics of the substance of concern.

*Examples of triggers for initiating the restrictions process*

- Where there are a number of available Chemical Safety Reports (CSRs) for one substance, even if each CSR demonstrates that the risks related to the activities covered by each registration are adequately controlled, the aggregation of the exposure related to all of the activities covered by the CSRs may lead to risks which may not be adequately controlled. For example, this could be through **multiple human exposures** from different sources including exposure via the environment, e.g. simultaneous exposure via inhalation of air, water intake, food consumption, handling of preparations and/or articles releasing the substance, where different components of the exposure arise from activities covered by different CSRs. Alternatively, it may be that the **total environmental exposure from aggregated sources** is considered likely to cause an unacceptable risk at regional level. This may be shown by combination of the largest regional concentrations from a single CSR with the local concentrations from others, or the sum of the individual regional PECs, for example.
- There may be combined exposure due to the formation of the substance of concern through degradation of another substance(s). Two examples where several/many substances were found to have the potential to break down to produce the same substance are presented in the box below.

**Example 1** Examples of substances identified as posing a risk and produced by the breakdown of other substances

***Nonylphenol*** - the ethoxylate derivatives of nonylphenol break down under some circumstances to form nonylphenol. Production of the ethoxylates is the production of another substance, or rather a range of substances, which might not be considered together as a group. These substances act as a further source of the original substance over and above what is released from direct use.

***PFOS*** - a range of related substances could break down to give PFOS. In this case, most of the parent compounds are not made directly from PFOS itself, but involved several steps in-between. To produce an Annex XV dossier, one would need to identify (as far as possible) the possible parent compounds that could degrade into the substance. Where they exist, CSRs for the parent compounds could be used. Calculations would need to look at the contributions made by each product (or groups of products) to the overall emissions or levels of the substance of concern.

- A further situation could be where a registered substance (or substances) breaks down to give a product which is not produced or imported (and therefore is not subject to registration) or to a product which is not yet subject to registration (due to tonnage) and which may give rise to concern.
- When a single registration is available, there may still be cases where there is a need for a Community-wide restriction. However, in these cases the preliminary work before proceeding with preparing an Annex XV dossier is important to ensure that identified risks are addressed with an appropriate action.
- A restriction under REACH may be an appropriate measure in cases where the proper implementation and enforcement of risk management measures under other REACH processes or under other legislation is not possible to achieve. Such cases may include:
    - substances having a wide range of uses associated with multiple exposures;
    - substances which may be widely used by consumers in several applications and for which the conditions of safe use cannot be ensured.

It is possible that more than one of the above may be valid for any given substance.

*Triggers resulting from enforcement*

- Substance evaluation or a compliance check of dossiers by the Agency identifies unacceptable risks that may not be dealt with appropriately by proper implementation of other REACH requirements.
- Enforcement shows that the implemented risk management measures are insufficient and that better enforcement cannot reduce the risks to acceptable levels.
- Enforcement and monitoring of other legislation provides evidence that controls set at the Community level (for instance, environmental quality standards, emission limit values or occupational exposure limits) cannot adequately manage the risk and a change of these values would not be the right measure to achieve the aim.

*Limits – when should an Annex XV dossier not be prepared?*

An Annex XV dossier may not always be the right way to address the identified risks to human health or the environment. To be aware of the limits of the restrictions procedure under REACH can save a lot of time and resources.

There are limits set out in the REACH Regulation itself:

- A substance included in Annex XIV (the list of substances subject to authorisation) may not be subjected to new restrictions addressing risks related to the intrinsic properties specified in Annex XIV apart from the risks from the presence of the substance in article(s) (Article 58 (5) and (6)). Article 69 (2) requires the Agency to consider for each substance subjected to authorisation whether there are unacceptable risks from the use of the substance in articles after the sunset date set in Annex XIV.
- For the re-examinations of existing restrictions a decision whether this should be done will have to be taken by Comitology (advisory procedure) based on evidence presented by the Member State or the Agency (Article 69 (5)).

A restriction should not be considered to be the universal solution for solving enforcement problems, as all restrictions also need to be applied, monitored and enforced. What is relevant is that all persons who have to comply with any legal obligations are aware of these

obligations and know how to define risk management measures (RMMs) and operational conditions (OCs) required for fulfilling the obligations. The REACH Regulation provides tools to identify RMMs and OCs in the chemical safety reports and communicate these in the safety data sheets or other information to downstream users.

There may also be situations where it can be recognised already at an early stage that an identified risk may not directly require the introduction of Community-wide restrictions and other action, e.g. enforcement may be considered as well. Some examples could be the following:

- The CSRs produced by manufacturers, importers and downstream users may recommend different risk management measures for the same activity and some of these are not adequate.
- The modelling or calculation methods used to estimate exposure concentrations may prove to be not suitable for the substance, resulting in the under-estimation of exposure levels. This may arise when new data on substance properties or re-interpretation of existing data may lead to higher calculated concentrations which may be of concern.
- For effects, the trigger for the Authority's interest may be new data on effects (human health effects or environmental effects), or the re-interpretation of existing data. Where exposures have already been assessed (in CSRs for example) the new effect data would presumably indicate that the exposure levels were now expected to lead to an unacceptable risk.

It is recommended that such new data, or re-interpretation of existing results, are first discussed with registrants, who should, as appropriate, revise their CSRs. If such revision results in adequate management of the risks, the Authority would generally not need to initiate the restrictions procedure (although this may depend on the severity of the effects shown by the new data).

When the risk is relevant in just one Member State, there is no basis for it to be addressed on a Community wide basis. In this case the Member State might have to consider a case under Article 95 (5) of the Treaty. In cases where one Member State identifies a risk and there is no information whether this is the case only in this Member State, it is recommended that they should inform other Member States about this concern to find out whether the concern is shared.

# 4 INFORMATION FOR THE PREPARATION OF A RESTRICTION DOSSIER

## 4.1 Information sources

For the decision on whether there is a risk to human health or the environment, all available information on the hazards and risks of the substance should be gathered and evaluated. This information may stem from registrations and evaluations under REACH or from any other source.

Article 69 (4) requires the Agency or the Member State to refer to any dossier, chemical safety report or risk assessment submitted under the REACH Regulation as well as any relevant risk assessment submitted for the purposes of other Community Regulations or

Directives. Any Member State or the Agency may request such information from any Community body holding such information.

The main source of information on substances under REACH is the registration dossier(s). A registration dossier will be produced by each manufacturer or importer registering the substance. These will be stored within IUCLID in the REACH-IT system. The registration dossier consists of a technical dossier and, in some cases a Chemical Safety Report (CSR).

A technical dossier is submitted for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer/importer. The technical dossier includes information on manufacture and identified uses and on uses the registrant advises against. The technical dossier also includes study summaries and robust study summaries. In the case of multiple registrants for one substance, most parts of the technical dossier will be submitted in a joint dossier including these summaries unless companies demonstrate that they have reasons to submit parts individually. The information required to be included in this technical dossier is all of the relevant physicochemical, toxicological and ecotoxicological information available to the registrant; the minimum required depends on the quantity manufactured or imported, with thresholds of 1, 10, 100 and 1,000 tonnes leading to increased data requirements. The time by which the registration is required to be submitted also depends, in the case of phase-in substances, on the quantity and the classification of the substance. Details of the information requirements are set out in Article 10 and Annexes VI to XI of the REACH and are included in the Guidance on registration, the Guidance on information requirements and the Guidance on the Chemical Safety Report.

For substances produced or imported in quantities of ten tonnes or more per year per manufacturer/importer, a CSA is required to accompany the technical dossier. This includes a hazard assessment (human health and environment) and a PBT/vPvB assessment for the substance. If this hazard assessment shows that the substance meets the criteria for classification according to Directive 67/548/EEC, or the substance is assessed as a PBT or vPvB, then an exposure assessment, including the relevant Exposure Scenarios (ES), and risk characterisation must also be carried out. ES include information on Operational Conditions (OCs) and Risk Management Measures (RMM) that the registrant implements and recommends for the actors down the supply chain to adequately control the risks. The results of the CSA are documented in the CSR. In addition, a Downstream User (DU) that uses a substance on its own or in preparation outside the conditions described in an ES communicated to him, needs to prepare a DU CSR, if he is not exempted in accordance with Art 37(4). DU reports to the Agency, where required, include brief descriptions of uses. More guidance can be found in the Guidance for Downstream Users

A further source of information under REACH is through dossier or substance evaluation. Under compliance check (part of the dossier evaluation) registrants may be required to submit any information needed to bring the registration(s) in compliance with the REACH requirements. Substance evaluation is the procedure by which further information (such as testing or exposure and use information) may be requested to clarify risks from substances. After the generation of any requested information, conclusions will be drawn and documented.

The amount of information available to an Authority when beginning the preparation of an Annex XV dossier will, therefore, depend on the status of the substance in REACH, and this may have an influence on the development of the dossier. Possible scenarios of data availability through REACH are:

- Substance is not registered;
- Substance has been registered but no CSR exists (i.e. the substance is produced at quantities <10 tonnes/year);
- Substance has been registered and a CSR exists;
- Substance has been registered and has undergone dossier or substance evaluation.

There could also be situations where more than one of these applies, in particular where some manufacturers or importers dealing with higher tonnages have registered the substance, but the timetable for other registrations at lower tonnages is still to be completed, or where an already registered substance is imported or manufactured by a new manufacturer/importer, resulting in a new registration.

Where a substance has not been registered, then there will be no information within the REACH-IT system at the time, apart from the possible classification and labelling inventory entries, and so other sources of information will then need to be considered. Reviews may have been produced by other fora such as the OECD, IPCS, IARC, national reviews by Member States etc., and if so it will be useful to use these to identify the information that is available. There may also be new studies published in the literature or new research reports. A more detailed search of the literature may help to identify relevant information where there are significant gaps in any available reviews, or where there are no reviews.

Given the possible importance of the outcome, it is recommended that the primary sources of data, for example the full study reports, where available to the Authority, should be reviewed for the Annex XV dossier, particularly for the key studies. Information from secondary sources should not generally be used as the basis for the proposal unless there is a high confidence in the robustness of the approach used to review the data for the secondary source (for example where it is documented that the secondary source had recently reviewed the original full study report against known and acceptable criteria).

**Confidential data**

A registrant may identify certain information in their registration as commercially sensitive. If the justification with regard to information listed in Article 119 (2) is accepted as valid by the Agency, then this information will be marked as commercially sensitive in REACH–IT. Such information can be used in the preparation of an Annex XV dossier for discussion with the Agency and Member States, as such discussions can be confidential. However, such information must not be included in any documents to be used for public consultation. The Authority therefore has to consider this when preparing an Annex XV dossier. It is recommended to include or mark confidential information in such a way (e.g. in separate annexes) that it can easily be left out when the Agency publishes an Annex XV dossier for commenting in accordance with Art 69(6).

Authorities need to pay attention also to information listed in Article 118 (2). Information to which access cannot be granted under Article 118 must not be published on the internet because the Agency would already have to deny access to such information on request in a single case on the basis of Regulation 1049/2001.

The general provisions on access to information are twofold:

- Some pieces of information will be made available over the internet in accordance with Article 119 (1).

- Access to other pieces of information will be granted by the Agency on request on a case by case basis in accordance with Regulation 1049/2001, as per Article 118 (1). Regulation 1049/2001 defines cases in which access to information has to be denied e.g. for reasons related to the protection of commercial interests which are further explained in Article 118 (2). It also requires the Agency to check with companies that have submitted information to it whether the company claims that the information asked for is confidential. The Agency then has to take a decision.

## 4.2 Obtaining further information

Any restriction of the manufacture, use or placing on the market of a substance to address unacceptable risks to human health or the environment on a Community wide basis will be adopted by the Commission if it is sufficiently justified. Logically, the Annex XV dossier for the restriction needs to contain sufficient information to support the proposal. Thus, if an Authority considers addressing an initial concern over an unacceptable risk, it will have to verify that sufficient information is available to support the restrictions proposal.

The first step should be to verify whether the **initial concern over the risk to human health or the environment can be substantiated**. Information for that purpose may be available from the Agency because it has been submitted in registration dossiers or as a result of dossier or substance evaluation or from any other source.

Generally, the restrictions procedure may be initiated with or without having completed any evaluation procedure. This depends merely on whether or not sufficient information is already available.

If more information is needed to decide whether an initial concern over the risk is justified, the evaluation mechanisms set out in REACH may be used to require registrants of the substance concerned to generate more information on its hazards and risks. Other parts of the Annex XV dossier will have to be developed by the Authority itself. The Guidance on evaluation describes the possibilities to obtain further information via these REACH procedures.

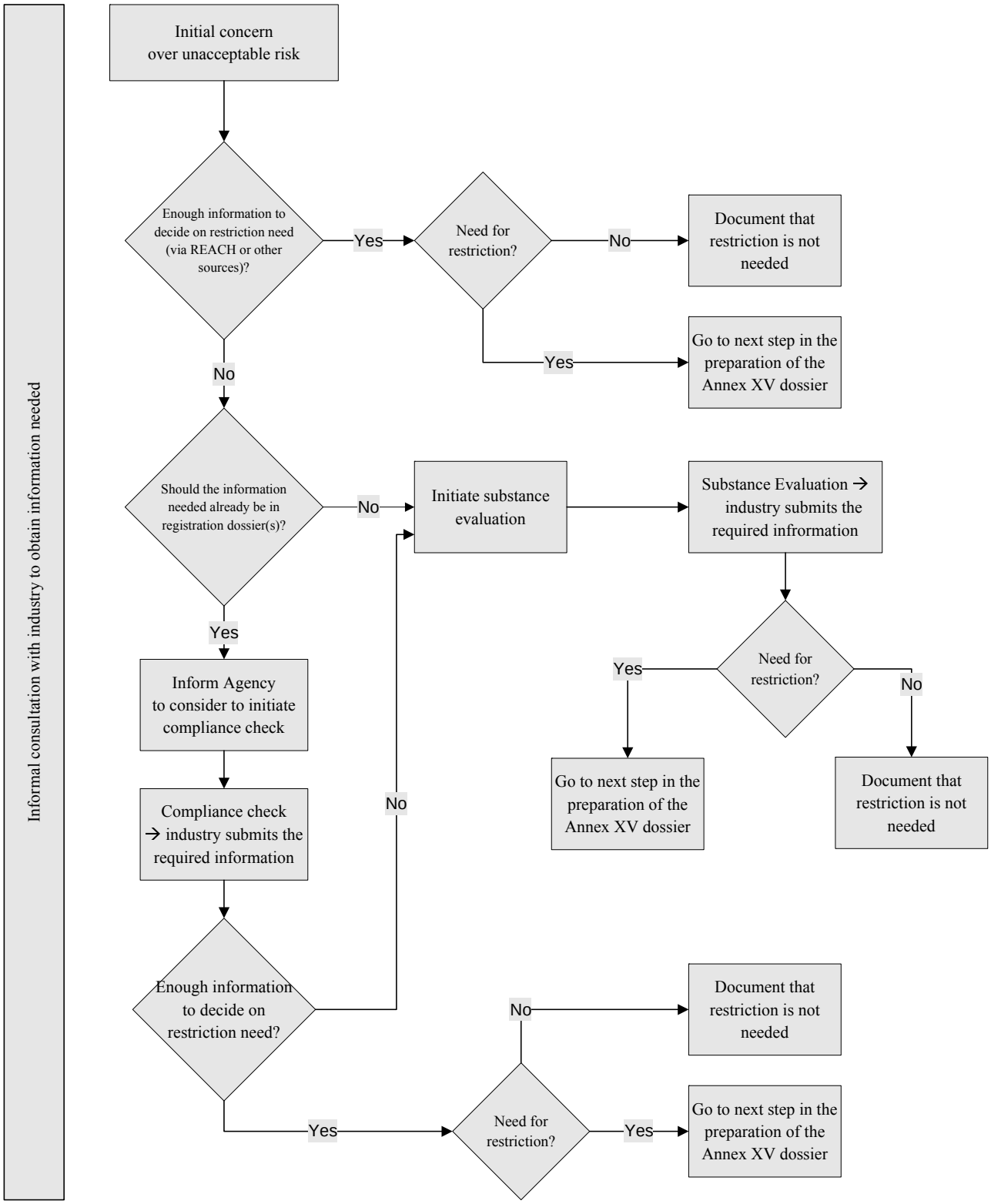
In addition to the formal way provided by the evaluation procedures to require information from registrants, the authority may decide to contact registrants or other relevant actors to request information needed. Even though it is not required, the consultation of stakeholders at this early stage is recommended. Any results from such consultation should also be included later in the Annex XV dossier.

Any examination of an initial concern over a risk – on the basis of sufficient information – will lead to one of the two conclusions:

1. The initial concern over the risk to human health or the environment is substantiated by the information. In this case the next steps for the preparation of the Annex XV dossier should be followed.
2. The initial concern over the risk cannot be substantiated. It is recommended to document the conclusion that restriction is not needed and to consider communicating it to the other Member States and to the Agency also in case this conclusion was made from the available information without an evaluation of the substance.

Figure 2 gives an overview of the possibilities to obtain the information needed for deciding which one of these two conclusions is relevant.

**Figure 2** Possibilities to obtain information from substance evaluation to decide on the need for a restriction



### 4.2.1 Dossier and substance evaluation

Evaluation may provide information that is useful for developing restrictions proposals and the outcome of evaluation should be considered. This is summarised below, the Guidance on evaluation provides further details.

**Dossier Evaluation**

A first consideration may be whether the information should already have been submitted to the Agency in a registration dossier, i.e. whether there is a registrant who is not complying with the registration requirements.

With regard to hazard information the answer to this question depends on the quantity of the substance registered as the information requirements depend on tonnage bands, and on the justification for any waiving statements. If the missing information should have been submitted in a registration dossier, the compliance check under dossier evaluation could be the right tool to generate the missing information.

If the Agency is preparing an Annex XV dossier and considers that information is missing that should have been submitted under registration, it may decide to perform a compliance check of the dossier.. If a Member State considers that information is missing that should have been submitted under registration, it should inform the Agency which may decide to perform the compliance check.. The Member State may also make use of Article 45 (5), to notify the Agency at any stage of a substance that it suggests as a priority for substance evaluation. Substances included on the Community rolling action plan for substance evaluation are a priority for dossier evaluation. The Guidance on priority setting for evaluation provides further details on how substances are prioritised for dossier and substance evaluation.

Note that the Agency also keeps a list of all dossiers being checked for compliance. This list will be made available to the Member State competent authorities.

The Agency shall use the information obtained from the dossier evaluation for the purpose of setting priorities for substance evaluation. The competent authority of the Member State shall consider how to use the information obtained *inter alia* for the purpose of preparing any restrictions or suggesting a substance to be included as a priority for substance evaluation on the Community rolling action plan.

If the information generated under dossier evaluation is sufficient to decide whether there is a risk, one of the two numbered conclusions described under point 4.2 shall be drawn and documented.

**Substance Evaluation**

If the information included in a registration dossier(s) is not sufficient to decide whether there is a risk, substance evaluation may be considered. Substance evaluation is the tool to require from registrants further information that may be used to verify whether a substance constitutes a risk to human health or the environment where there are grounds to consider that such a risk exists.

Substances to be evaluated have to be included on the Community rolling action plan. Article 45 (5) allows any Member State at any time to suggest a substance to the Agency for

inclusion in the Community rolling action plan, if the Member State possesses information suggesting that the substance is a priority for evaluation. The Agency shall then decide about the inclusion on the basis of an opinion from the Member State Committee.

The competent authority of the Member State shall examine any information submitted, and consider how to use the information obtained for the purposes of, *inter alia*, the restrictions procedure. It has to inform the Agency, the Commission, the registrants and the other Member States of its conclusions.

### 4.2.2 Informal consultation in the preparation of an Annex XV dossier

Although Annex XV includes no specific requirement for Authorities to engage in consultation, stakeholder involvement in the process is important. Consultation of industry and other stakeholders may be an important way for the Authority to obtain additional information although stakeholders have no legal obligation to provide information for the development of an Annex XV dossier. It should be noted that the term consultation is used throughout this document to refer to contacts with stakeholders aiming at voluntary submission of information and should not be confused with the formal request for commenting and providing information which will follow the submission of a finalised dossier to the Agency (such as under Article 69(6) of the REACH).

The Authority preparing the dossier should decide upon the need for consultation and the resources and time to be allocated to consultation activities. However, Authorities are encouraged to engage stakeholders and other interested parties in the development of the dossier as early in the process as possible. This will facilitate the timely collection of the necessary information and will contribute to the transparency and representativeness of the restrictions dossier. At the very least, the Authority should consider informing the identified interested parties that work related to a possible restrictions dossier has been initiated (this is not the formal notification to the Agency of the intention to produce a restrictions dossier).

Consultation for a restrictions procedure should have clearly identified objectives and be time-bound. The depth of consultation should also be proportional to the severity and complexity of the situation. The approach for and means to carry out any informal consultation depends on the case, e.g. which types and how wide groups of actors may be affected by the considered restriction. The consultation can take any form from addressing selected actors with targeted questions to an open call for contribution via internet. The documentation of stakeholder consultation is discussed in chapter 5.7.

Appendix III  ppendix III illustrates types of information that may be sought from different types of consultees for different parts of an Annex XV restrictions report. The table is not exhaustive and both the types of information and the types of consultees will vary on a case - by- case basis.

The Agency and the Commission services are not included in the table. The Agency Committees will be in charge of assessing the restrictions dossier once it has been submitted, and the Commission will be in charge of making the decision. However, the Authority may contact them with technical queries or to request advice (for example, in the interpretation of Community legislation).

Authorities should critically assess data from consultation, taking into consideration who is providing information, what vested interest each party has in the introduction (or not) of any restriction and the quality of the submitted information.

### 4.2.3 Grouping

Grouping of substances may be relevant for the restriction procedure in two different ways.

Firstly, registrants may have grouped substances for the purpose of preparing a chemical safety assessment (Annex I of the REACH Regulation, Section 0.4). This 'CSA grouping' will affect the information basis available for the restriction procedure.

It may concern grouping of substances for which the physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as described in Section 1.5 of Annex XI of the REACH Regulation. This will mean that for those properties that lack data, information can be used or interpolated from substances within the group. Another type of the 'CSA grouping' is when the registrant concludes that the CSA carried out for a substance is sufficient to assess and document that the risks of another substance are adequately controlled even if this other substance has no similar intrinsic. If a registrant uses either of these ways of grouping, he needs to provide in his CSA a justification for this. When preparing a restriction proposal the Authority needs to consider on a case-by-case basis for which substances in the group a restriction is justified.

Secondly, the Authority preparing a restriction proposal may wish to cover a number of related substances by the same Annex XV dossier. This could be the case when the key property in combination with the exposure that causes the risk leading to the proposal of a restriction is shared by several related substances. Examples of such a case from the current restrictions of marketing and use under Directive 76/769/EEC are nonylphenol and nonylphenol ethoxylates, and short-chain chlorinated paraffins. The Annex XV dossier has to provide sufficient information to support the restriction of all substances covered by the proposal.

### 4.2.4 Transparency

It is important that the process of developing a restrictions dossier is transparent. Transparency means that available information has been taken into account and is reported in an unbiased manner, and all assumptions and methodologies used are clearly explained. In this context, the analysis needs to be:

- *based on sound information*: the reliability of information sources and the subsequent assumptions need to be evaluated and documented in the report;
- *open to review*: assumptions, conclusions and decisions should be open to review so that new or improved information may be taken into account as the development of the restrictions dossier progresses; and
- *reflective of the uncertainties*: areas of uncertainty including how these have been identified, how they impede the assessment and what has been done (or would need to be done) to reduce the uncertainty, should be described in the restrictions dossier.

Uncertainties may influence the preparation of a restrictions dossier. These largely arise because of a lack of information or a lack of knowledge about the consequences of a given action, and may include:

- knowledge uncertainty (for example, uncertainty on the nature of risks from alternative substances or techniques);

- real-world uncertainty (for example, uncertainty on whether all sites involved in risk management will comply with a certain legal requirement or what the socio-economic implications of RMOs might be); and
- scientific or data uncertainty (for example, uncertainty on the quality and/or quantity of toxicity data for the substance of concern).

Uncertainties need to be addressed in the Annex XV restrictions report by:

- defining and documenting uncertainty and its boundaries (i.e. show where uncertainty exists, how it affects the analysis and justification for the proposed restriction);
- describing assumptions clearly; and
- explaining the actions taken to reduce uncertainty.

Guidance on dealing with uncertainty through a range of different analytical methods is provided in the SEA guidance (XXX). Also, the CSA guidance (XXX) provides guidance on dealing with uncertainty in the field of risk assessment.

# 5 PREPARATION OF AN ANNEX XV RESTRICTIONS DOSSIER

## 5.1 Overview

### 5.1.1 What is an Annex XV dossier?

The Annex XV dossier consists of two parts, in parallel to the registration dossiers for substances manufactured or imported in quantities of ten tonnes or more per year per manufacturer/importer which consist of a technical dossier and a Chemical Safety Report (CSR). The two parts of the Annex XV dossier are:

1 The Annex XV report. For consistency between all the documentation prepared under REACH, the format of the parts of the Annex XV report relating to the hazard and risk assessment of the substance follows closely that for (evaluation and of) the CSR. The basic format has been adapted to the specific requirements of the individual Annex XV dossiers in some cases. The formats for Annex XV report are included as Appendices to the guidance. The report will be produced and attached to the technical dossier in IUCLID.

1. A technical dossier supporting the Annex XV report and stored in IUCLID. This can include robust study summaries imported from registration dossiers available in IUCLID. These reference study records may be annotated by the Authority. Robust study summaries or study summaries can also be created by the Authority in the case of additional data being available (see appropriate guidance from the Guidance on registration).

The term Annex XV dossier is used to refer to the package of the Annex XV report and the technical dossier. The guidance on reporting given in Appendix IIrelates to the preparation of the Annex XV report.

### 5.1.2 Workflow

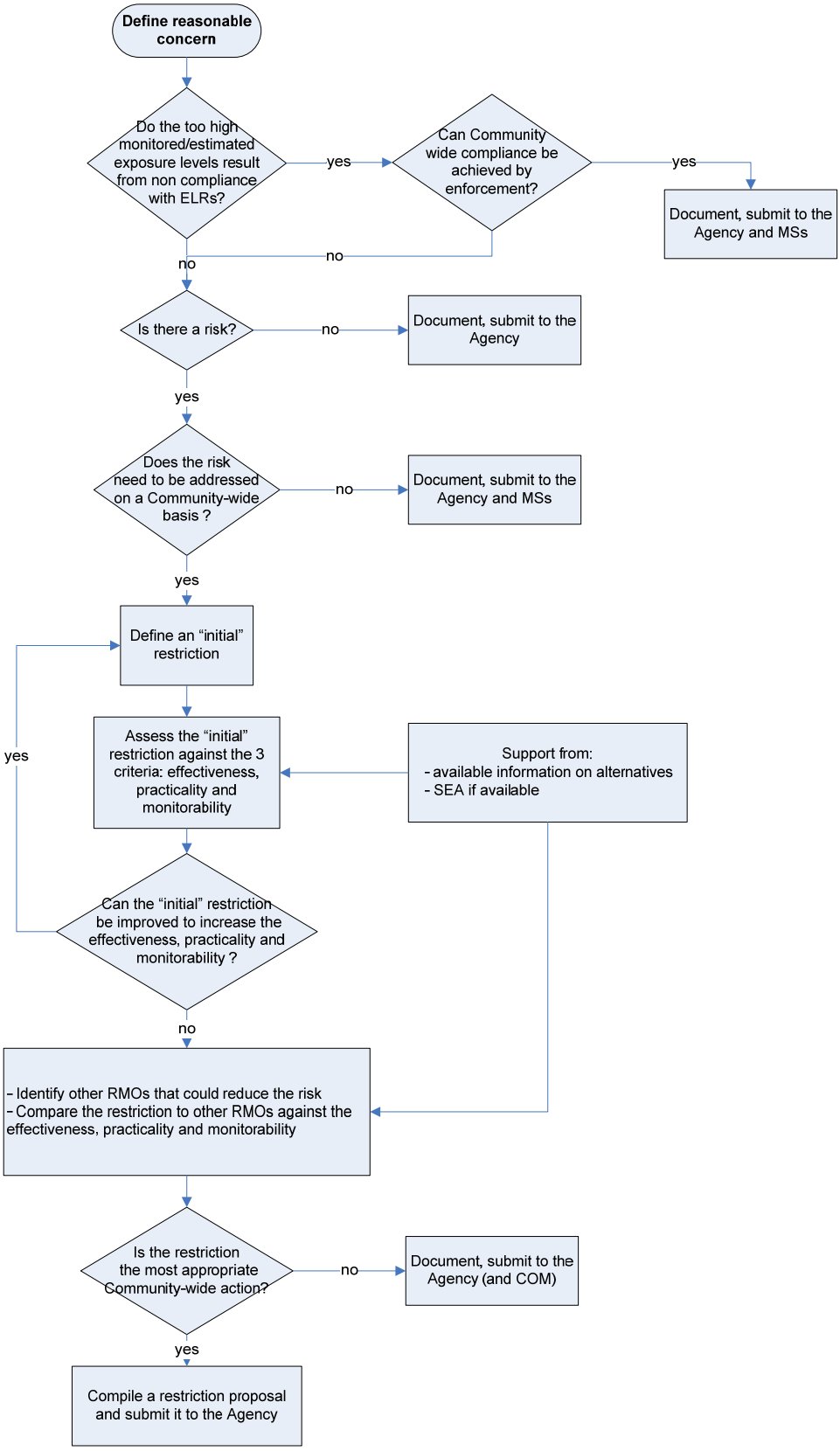
A proposal for a restriction has to:

- show that a substance on its own or in a preparation or article poses a risk that needs to be addressed (chapter 5.2)
- provide justification for restriction at Community level that
  - action is required on Community-wide basis (chapter 5.3)
  - a restriction under REACH is the most appropriate Community wide measure (chapter 5.4)
- include available information on alternative(s) (chapter 5.5)
- describe how stakeholders have been consulted during the preparation of the proposal (chapter 5.7)

In addition a restriction proposal may include a socio-economic assessment (chapter 5.6).

The final proposal for a restriction together with justification and supporting information will be documented in an Annex XV report.

**Figure 3** Outline of the successive components of the preparation of an Annex XV dossier proposing a restriction.



The workload for completing an Annex XV dossier will vary from case to case. Firstly, the workload will depend on the extent and nature of the case, e.g., number of uses covered and the importance and complexity of substitution. Furthermore, the workload is expected to be proportional to the availability of existing data. If for example a substance is registered and evaluated the hazard, exposure and risk related parts of the Annex XV dossier will be relatively easy to complete and the highest workload will be on preparing justifications on the need for action at Community level and that the suggested restriction is the most appropriate Community wide measure. In a case where a part or most of the information on hazards, exposures and risks required for the development of an Annex XV dossier is lacking then it is expected that this process will be more resource intensive since the relevant information needs to be gathered and the required assessments and justifications will have to be developed. In cases where further information is needed to substantiate the risk, it is recommended to first propose the substance for inclusion in the Community Rolling Action Plan for substance evaluation and then, if there is a concern, proceed with the Annex XV dossier. It is highly recommended to go through such workload considerations prior to notifying the Agency about the intention of completing an Annex XV dossier due to the restricted timeframe within which the Annex XV dossier has to be completed.

| Stage in the restrictions procedure | General types of consultees | | | | |
|---|---|---|---|---|---|
| | **Authorities in other Member States and non-EU countries** | **Trade associations and companies (manufacturers, importers and users)** | **Labour organisations** | **Consumer groups** | **Experts in academic and research community** |
| **Information on the effectiveness of implemented RMMs and compliance with ELRs** | ▪ Scope for improvement of implemented RMMs<br>▪ Information on past potential of enforcement of implemented RMMs<br>▪ Scope for introducing national measures | ▪ Scope for improvement of implemented RMMs | ▪ Scope for improvement of implemented RMMs | ▪ Scope for improvement of implemented RMMs | ▪ Scope for improvement of implemented RMMs |
| **Identification of RMOs** | ▪ Advice on past effectiveness of RMOs and implementation tools<br>▪ Information on current state and structure of the relevant markets in their territory<br>▪ Information on any previous risk management options considered and difficulties that were encountered during their implementation. | ▪ Advice on past effectiveness of RMOs and implementation tools<br>▪ Information on current state and structure of the relevant markets | ▪ Advice on past effectiveness of RMOs and implementation tools | ▪ Advice on past effectiveness of RMOs | ▪ Advice on past effectiveness of RMOs |

| **Stage in the restrictions procedure** | ▪ General types of consultees<br>▪ Authorities in other Member States and non-EU countries | ▪ Trade associations and companies (manufacturers, importers and users) | ▪ Labour organisations | ▪ Consumer groups | ▪ Experts in academic and research **community** |
|---|---|---|---|---|---|
| **Assessment of RMOs against the three key criteria of effectiveness, practicality and monitorability as well as considerations on any derogations that may be required** | ▪ Information and past experience pertaining to the assessment of RMOs<br>▪ Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives)<br>▪ Information on the availability of enforcement mechanisms and monitoring networks<br>▪ Information on criticality of uses<br>▪ Information on current R&D in the sectors of concern | ▪ Information and past experience pertaining to the assessment of RMOs<br>▪ Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives)<br>▪ Information on the availability of monitoring networks<br>▪ Information on criticality of uses<br>▪ Information on current R&D in the sectors of concern | ▪ Information and past experience pertaining to the assessment of RMOs<br>▪ Views on the practicality of RMOs (including implementation costs)<br>▪ Information on the availability of monitoring networks<br>▪ Information on criticality of uses | ▪ Views on the practicality of RMOs (including implementation costs)<br>▪ Information on the availability of monitoring networks<br>▪ Information on criticality of uses | ▪ Views practicality and monitoring issues<br>▪ Information on criticality of uses<br>▪ Cost of loss of uses of the substance/use of alternatives<br>▪ Information on current R&D in the sectors of concern |

Appendix IV Appendix IV includes examples of different types of cases where a restriction proposal is considered and the anticipated workload for the preparation of an Annex XV report.

### 5.1.3 Key terms

**RMMs and OCs:** risk management measures and operational conditions. This term is used for concrete risk management measures and operational conditions taken by Industry to control the exposure to the substance of concern. These include both emission/exposure reduction equipment and how this is operated as well as relevant process parameters that affect the emission/exposure levels. Registrants document, where required, risk management measures and operational conditions in an Exposure Scenario (ES) as a part of their Chemical Safety Report (CSR).

**ELRs:** existing legal requirements. This term is used for the existing legislative and regulatory requirements for Industry resulting from Community and national legislation other than restrictions under REACH (for example, environmental quality standards, emission limit values or occupational exposure limits). To comply with these requirements, Industry may have put in place RMMs and OCs or take other action. For the purposes of this document ELRs cover also the existing economic instruments and Industry's voluntary commitments.

**RMOs:** risk management options. This term is used for any possible changes to legislation or other requirements on Industry (e.g. in permits) to control risks accordingly. RMOs may also cover the use of economic instruments and Industry's voluntary commitments.

### 5.1.4 What to do when an Annex XV dossier is not appropriate

There may be cases where the Authority carries out work towards an Annex XV dossier but concludes at some point that in fact a dossier suggesting a restriction is not appropriate. Figure 4 shows a number of points in the development of the dossier where the Authority may conclude that a restriction under REACH is not needed or justified. In all cases, it is important that the work that has already been undertaken is not lost but is made available for possible future work. This will effectively involve documentation of the findings so far in an Annex XV dossier format even though the Authority has decided not to proceed further. It is up to the Authority to decide how much of the work they have done needs to be documented. The key outcome must be that the work undertaken by one Authority should be known and available to the Agency and other Authorities so that the process works efficiently and without undue duplication of effort.

The information documented should be submitted to the Agency so that the Agency can make the information available on the REACH-IT system where it will be accessible to other Authorities for future work. It is recommended that the Authority also submits the documented information further to the Member State authorities or to the Commission where action by Member State authorities at the national level or by the Commission under other Community legislation is anticipated. Well documented information in Annex XV dossier format will provide a good basis for taking action also under other Community legislation or at national level.

## 5.2 Information on risk

The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I of REACH Regulation. Guidance on developing Chemical Safety Report (CSR) will contain detailed guidance for the assessment of hazard and exposure and for risk characterisation. This guidance gives also advice on how to describe uses for the purpose of developing Exposure Scenarios (ES). The development of a

common system for brief descriptions of uses for the purpose of Annex VI, section 3.5 is also underway. More precise references to this guidance will be added, where relevant, when this guidance is available.

**Aim:** The aim of this task is to identify the risks that the substance on its own, in a preparation or in an article poses to human health or the environment. Furthermore, evidence needs to be provided that implemented risk management measures and operational conditions are not sufficient.

**Scope:** This stage includes hazard assessment, exposure assessment and risk characterisation. The basic approach applied in these steps is set out in the Guidance on the Chemical Safety Report. The exposure assessment needs to take into account Exposure Scenarios (ES) implemented by the industry and recommended to actors in the supply chain. It is recommended that the Authority also considers the reasons why the risk management measures and operational conditions described in the ES(s) are not sufficient and, especially, consider whether the monitored or estimated exposure levels correspond to the ESs. Furthermore, it should be considered whether the compliance with REACH or other legal requirements would sufficiently reduce exposure and whether Community wide compliance can be achieved.

The work can be targeted to focus on certain risks. This targeting may affect the hazard assessment or the exposure assessment part or both.

**Outcome:** This assessment will form a justification that the substance poses a risk to human health or the environment that is not adequately controlled. It will give a basis for the development of other parts of a restriction proposal and define the scope and focus of that work by identifying

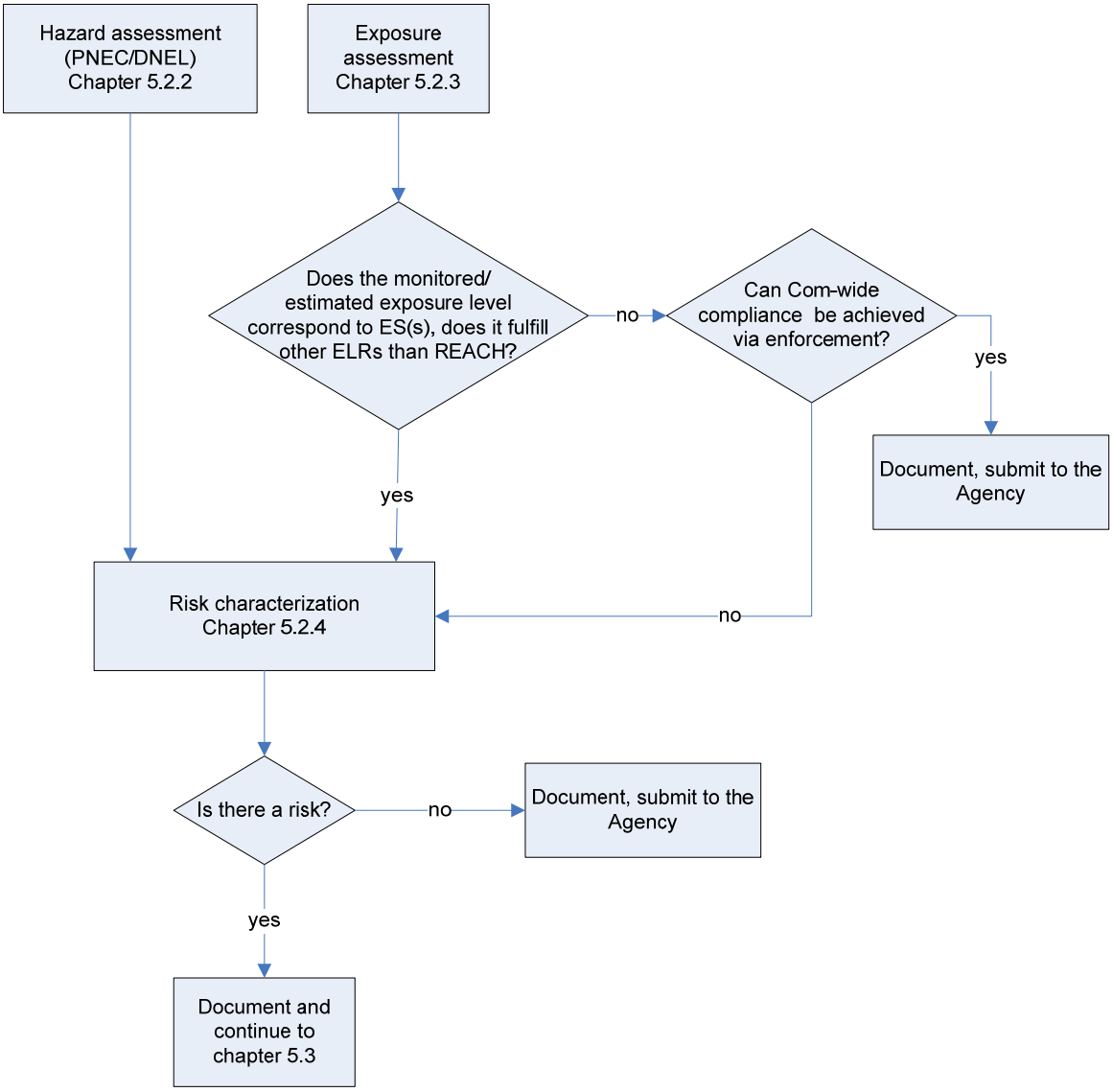
- which manufacture, placing on the market or use(s) cause the risk
- in which life-cycle stage(s) of the substance the exposure causing a risk occurs
- which human populations or environmental compartments are at risk.

The information and assessment will be documented in sections 4 to 9 of the restriction format (APPENDIX I). The results of the assessment will be summarised in the restriction proposal.

**Exits from the restriction procedure:** If the assessment shows that the substance does not pose a risk, the Authority is requested to document the assessment in the relevant parts of the restriction format and submit this documentation to the Agency with the conclusion that no further action is needed. The Agency will store the assessment in the REACH IT. The purpose of this documentation is to ensure that the work already done is not lost and can be used by other actors dealing with the substance.

If the assessment indicates that the risk would be sufficiently reduced by compliance with already existing legal requirements and that Community wide compliance could be achieved via enforcement, the Authority is requested to document this conclusion in the relevant parts of the restriction format and submit the documentation to the Agency Forum and Member State CAs.

**Figure 4** Overview of the identification of risk(s)




### 5.2.1 Targeting the assessment

The areas (e.g. manufacture/uses, sources of exposure, risks) which the Authority should address in a restriction proposal will be largely determined by the nature of the initial concern leading to the preparation of the dossier. The decision to target the dossier should be considered carefully. Any decision on when and how to target the restriction procedure needs to be taken on a case-by-case basis. It should be recognised that targeting may not be the most effective way to address the overall risks from a substance. Qualitative or quantitative sensitivity analysis may be used to support decisions on targeting. Further guidance on sensitivity analysis is provided in the Guidance on Socio Economic Analysis. The targeting decision, boundaries of the restriction proposal and underlying justification for the targeting need to be documented. Some advantages and drawbacks to targeting are summarised in the box below.

Advantages and drawbacks of targeting

Advantages may include:

- simplifies the process;
- allows resources to be used effectively; and
- the proposal for a restriction can be prepared more quickly.

Drawbacks may include:

- danger of oversimplification. Links between sources of exposure and the actual populations / environmental compartments exposed may not be obvious;
- important sources of exposure may be neglected and so not be considered;.
- the substance may have effects on endpoints other than those considered;
- the substance may have to be reassessed at a later time to address other issues;
- there may be a need to make changes to adopted restrictions later if all areas are not addressed; and
- limited coverage in the dossier may make comparison with alternatives difficult.

Two types of targeting could be considered. The first, the 'rapid restriction' targeting, is where only a limited part of the possible assessment is included. This would relate to cases where a specific concern requiring prompt action is identified, where the effects and the related exposure are clearly defined and can be addressed directly. Only those parts of the dossier relevant to the concern would be completed, taking account of relevant parts of any CSRs submitted under registration.

The second type of targeting, the 'CSR review targeting', focuses the review and assessment work on those areas considered to be of most concern, and refers to CSRs (where available). When undertaking this, the Authority may cover other areas not covered in the CSRs, where considered relevant. This may produce a more complete assessment and will be more useful in comparing the substance with possible alternatives. The assessment will be more robust if the Authority is able to review relevant information in the CSRs. The Authority should make clear in the Annex XV dossier which areas have been reviewed and agreed by the Authority, and which have been taken from the source document without further review.

The following are some examples for further targeting when reviewing information during the preparation of an Annex XV dossier :

- Human health risk versus environmental risk - it may be clear from the registration information or from substance evaluation that there is no concern about health effects, so that the dossier could address only the environmental aspects (or vice versa).
- Identifying key sources of release or exposure - not all sources may be significant:
  - The concern may be for the compartment to which the substance is released, and only certain uses (or manufacture) and related lifecycle steps may have direct releases to this compartment. Attention could be focused on these sources. There may be a need to investigate to some extent that releases from other uses do not transfer significantly to the compartment of concern after release.
  - Targeting may also take place where concerns arise from diffuse emissions and for background concentrations. In such a case, it may be possible to make order of magnitude estimates of emissions from different sources, and to identify those which are not significant contributors. These may then be omitted from further investigation.

- Human exposure is estimated as a combination of workplace, consumer and exposure through the environment. It may be possible to make a quick comparison between these possible contributions and determine that one or more do not lead to significant exposure, in which case they can be neglected. Where exposure through the environment is significant, the comments in the point above will be relevant.

- Targeted compartments - if the substance has properties which indicate that it stays in one compartment, then only the effects data for that compartment will be relevant.

Targeting may also be relevant for alternatives, but Authorities should be aware of the possible drawbacks from targeting which are relevant when considering alternatives. This issue is discussed in chapter 5.5 of this guidance and further comments on the targeting of specific aspects of the risk assessment are included in the following sections.

### 5.2.2 Hazard assessment

**Aim:** The objective of the hazard assessment in the context of restrictions proposals is to identify PNEC and DNEL values, or to determine values with other appropriate methodologies in the case of non-threshold effects, for use in the risk characterisation.

**Scope:** The Guidance on the Chemical Safety Report describes how to prepare health and environmental hazard assessment. The basic steps required for this section are:

- Information collection.
- Information review.
- Dossier sections completion

The amount of work required for these steps will depend to some extent on the degree to which the Authority is producing a targeted assessment, and also on the stage in the REACH process at which the substance is being considered, but the same general principles apply. In principle, any of the endpoints included in the Annex XV restriction report format could be relevant, and so the guidance in this section is of necessity presented in general terms. Hence for the most part no distinction is drawn between health related endpoints and environmental endpoints. There are, however, some instances where more specific comments are made or directions to more specific guidance given.

**Outcome** The information and assessment will be documented in sections 5 to 7 of the restriction format (APPENDIX I).

#### Information collection

The information needed is the PNEC and DNEL values related to the endpoints identified by the Authority as being relevant for the production of the dossier, or the study summaries from which the PNEC and DNEL values are to be derived. This may include supporting information on related endpoints or substances, and physico-chemical data needed for the interpretation of the studies.

Information sources under REACH are considered in Section 4.1 of this guidance. The main parts of the CSRs or technical dossiers of relevance are:

| Topic | Sections in technical dossiers | Sections in CSR (all in Part B) |
|---|---|---|
| Human health hazard assessment | Section 6 | Section 5 |
| Environmental Hazard Assessment | Section 5 | Section 7 |

### Information review

In most cases the starting point will be a review of the DNEL and PNEC values in the registration dossier(s). Criteria for the validity and relevance of studies are included in the CSA guidance (XXX) and this guidance should be used. In many cases there will be just one data set as submitted by the lead registrant. In cases where the registrants did not share data in compiling their registrations, the reasons provided for this should be examined. There may be a broader data base available when the different submissions are combined, and this could allow the revision of the PNECS and/or DNELs (which should be done in case this reduces or removes the concern which prompted the Authority to consider preparation of the dossier).

Bearing in mind the comments on targeting in chapter 5.2.1, the Authority is encouraged to review as many of the PNEC and DNEL values included in the registration dossiers as possible, recognising the likely limitations on available resources.

There are two possible outcomes from this review.

1. The PNECs and DNEL values are found to be suitable. In this case no further review work is required and the relevant dossier sections can be completed (see below).
2. The Authority does not agree with the derived PNEC and DNEL values. (This could be due to different interpretation of the studies on which the values are based, or to new information not included in the registration dossiers. New information may come from clarification or generation of data through substance evaluation.) In this case the Authority will need to derive new PNEC or DNEL values based on the revised interpretation of studies or on new data, using the methods in the CSA guidance.

In the situation where there are no CSRs available for the substance, the Authority will need to develop their own values from the data collected from other sources. These data should be reviewed using the CSA guidance (XXX), and the same guidance followed in deriving the PNEC and DNEL values.

The above comments are relevant to the consideration of alternative substances as part of preparing the Annex XV restriction dossier (see Section 5.5).

### Preparing the report

The relevant sections of the Annex XV restrictions report (APPENDIX I) are *Section 5* on human health hazard assessment and *Section 7* on environmental hazard assessment. The work required to complete the dossier will depend on the outcome from the review of the CSRs or of the available information.

### 5.2.3 Exposure assessment

**Overview of task**

**Aim:** The objective of the exposure assessment is to make a quantitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The exposure assessment needs to take into account the Exposure Scenarios (operational conditions and risk management measures) recommended to and implemented by actors in the supply chain.

**Scope:** The process of exposure assessment is described in the Guidance on the Chemical Safety Report, covering health and environmental exposure. The amount of work required will depend to a certain extent on the stage in the REACH process at which the substance is being considered. However, in most cases additional work on the exposure assessment is required for the Annex XV purposes. The exposure needs to be estimated for each exposure scenario, in other words in necessary detail to give clear basis to identify which manufacture or use(s), and which related life-cycle stages may cause the risk. This is necessary to enable proper identification of risks that need to be addressed.

The main parts which need to be considered in an exposure assessment in relation to an Annex XV restriction report are the same as for a CSA: emission estimation, distribution, calculation of predicted exposure concentrations, use of measured levels. However, for the purposes of a restriction proposal exposure assessment may need to take into account other sources of the exposure than those resulting from (a single) registration. The exposure assessment needs to take into account the implemented ESs (OCs and RMMs) and reflect as much as possible real world situation.

The exposure assessment section in this guidance should be considered as a tool to generate exposure levels information. The underlying methods can be used in a variety of situations of which the main ones are:

a. the assessment of exposure under the current situation and conditions in order to demonstrate a current risk;
b. the assessment of exposure remaining after the proposed restrictions are in place, to demonstrate the removal or reduction in risk; and
c. the assessment of exposure for alternative substances.

Point a includes the situation based on implemented RMMs and OCs as described in the ES, or based on a revised interpretation of these measures after review by the Authority according to chapter 5.2.3.1 of this guidance.

Points b and c are considered in the relevant sections below (chapters 5.2.3.2 and 5.5)

**General considerations**

Two examples of reasons to reassess the exposure assessments submitted by registrants and calculate revised exposure concentrations are provided here. One is that the existing registration dossiers do not address the total exposure. This is likely to arise where there are a number of separate registrations, and may relate to exposure of the environment or to human exposure. There could also be other sources of a substance, such as formation from the breakdown of another substance, or natural sources. The Authority may also wish to consider the potential contributions from manufacturers or importers who have not yet submitted registrations. Consideration of the aggregated emissions to the environment will lead to changes in the regional emissions to the environment and hence to the regional concentrations (and in the local PECs too). For human

exposure, combinations of exposures from different scenarios can be considered, together with revised indirect exposure through the environment. The exposure estimates need to take into account the ES (RMMs and OCs)in place, as reviewed by the Authority according to chapter 5.2.3.1.

A second reason is that the Authority considers that the ES used as basis for exposure estimation in the CSA will not function as described, leading to other exposures or higher levels than documented in the CSR (following review as described in chapter 5.2.3.1). This will lead to changes in emissions, with direct changes to the local concentrations and occupational, consumer or indirect human exposure concentrations as well as an effect on the overall emissions and regional concentrations. Note that the effectiveness of RMMs and OCs may also be assessed by the Agency as part of a compliance check.

Information on the physico-chemical properties of the substance and those which govern its environmental fate and distribution is needed to move from the emission estimates to exposure concentrations. These data are not considered in this guidance, the Authority should use the CSA guidance and dossier evaluation guidance in reviewing the available information and selecting the values to be used in the assessment.

The calculation of exposure concentrations requires the use of suitable models. Models for calculation of predicted concentrations are considered in the CSA guidance in terms of their suitability of the exposure assessment, and these are not discussed further here. It is assumed that in the majority of cases, the Authority will use the same model(s) as used in the CSR. If the Authority considers that a different modelling approach should be used to that used in the CSR, then this will need to be documented and justified.

Some comments on the use of measured levels are included below in this guidance, but more details can be found in the CSA guidance.

It is assumed in this guidance that at least one registration dossier containing an exposure assessment is available for the substance. If no exposure assessment is available, then the Authority would need to develop such an assessment from the beginning. The process is described in the CSA guidance and this should be followed. It is recommended that such a process be carried out in partnership with the manufacturer(s) and/or importer(s) of the substance, if at all possible. This aspect is not considered further in this guidance.

#### 5.2.3.1 Assessment of effectiveness of implemented Exposure Scenarios and checking the compliance with ELRs

**Overview of task**

**Aim:** The Authority should assess the effectiveness of the implemented Exposure Scenarios (ES) defining the operational conditions (OCs) and risk management measures (RMMs) as appropriate. The results of this assessment will be used in the development of a well-informed and realistic exposure assessment that takes into account the existing risk management practices along the supply chain.

Furthermore, the Authority should consider as appropriate and as far as reasonable whether the implemented OCs and RMMs fulfil the existing legal requirements (ELR). Furthermore, in cases where they do not seem to fulfil the ELRs, to consider whether the compliance could reasonably be achieved by enforcement. .

**Scope:** The assessment of the effectiveness of the ES (OCs and RMMs) should cover:

- ESs implemented by Manufacturers/Importers (M/I) and, where available, documented in the relevant CSRs
- ESs recommended, where required, by M/I to downstream users and documented in the relevant CSRs
- ESs implemented by Downstream users (DU) and, where available, documented in the relevant DU CSRs
- ESs implemented by DUs in addition to those recommended in the ES(s) (either due to other existing legal requirements than REACH or due to other reasons (e.g. technology used, product quality reasons etc.))

To be able to consider the compliance with ELRs the Authority needs to identify the relevant existing legal requirements that aim at reducing emissions and exposures or affect them. ELRs cover, as appropriate, both REACH and other legislation. Secondly the Authority needs to compare the ESs provided by actors in the supply chain with the identified ELRs to estimate whether the current requirements are fulfilled. The level of detail of such assessment depends on the case.

**Outcome:** The assessment of the effect of ESs on exposure is an inseparable part of any exposure assessment. For the purposes of a restriction proposal this aspect of the exposure assessment is highly relevant and needs to be documented transparently as one of the reasons for considering the need for proposing a restriction is that the ESs implemented have shown not to be in practice as effective as foreseen.

The outcome of the assessment of the effectiveness of OCs and RMMs will also be used when considering whether the estimated or modelled exposure level is a result of non-compliance with ELRs.

The overview of the ELRs already regulating the emission(s) / exposure(s) of the substance can also be used in the identification of alternative RMOs (section 5.4.4). Any observation related to the problems in enforcing ELRs should be taking into account in the assessment of enforceability of the proposed restriction

and the alternative RMOs

The information will be documented in section 9.1 of the restriction format (APPENDIX I).

**Carrying out the task**

The basic steps to carry out this task are

- Identification of the ELRs
- Identification and assessment of the effectiveness of the implemented ESs (OCs and RMMs)
- Comparison of the implemented ESs with ELRs

The information that can be used for identifying ELRs and for performing the assessment of implemented OC and RMMs and the possible information sources are outlined in **Errore. L'origine riferimento non è stata trovata.** 1.

**Table 1 Information and requirements for identification of ELRs and for assessing the effectiveness of implemented ESs**

| Types of relevant information | Possible sources of information |
|---|---|
| Identification of ELRs relevant for the emissions of / exposure to the substance<br>• Community legislation<br>• National legislation<br>• International initiatives<br>• Voluntary commitments by the industry, economic instruments | • Legislation<br>• Database of notifications under Directive 98/34/EC[2]<br>• MS competent authorities<br>International fora which the EU or individual Member States are parties to. Examples are:<br>o the United Nations Environment Programme (and the United Nations Economic Commission for Europe);<br>o and the International Labour Organisation.<br>o OECD<br>o marine protection organisations, such as OSPAR, HELCOM, BARCOM;<br>o the International Maritime Organisation;<br>• Industry associations |
| • Identification of the implemented OCs and RMMs : | • Registration dossiers,<br>• CSRs including ESs,<br>• Safety Data Sheets, including ESs<br>• Data communicated in accordance with Article 32;<br>• the relevant Community and national legislation defining (minimum) OCs and RMMs;<br>• consultation with Industry and Member State competent authorities |

[2] The 98/34/EC Directive (formerly 83/189/EEC) sets up a procedure which imposes an obligation upon the Member States to notify to the Commission and to each other all the draft technical regulations concerning products and Information Society Services before they are adopted in national law.

| | |
|---|---|
| • Assessment of the performance of implemented OCs and RMMs:<br>• emission / exposure mitigation rates<br>• monitored emission / exposure levels<br>• evidence of adverse effects on human health and the environment from the substance; and<br>• information on occurrence of RMMs (share of the actors using certain equipment etc) and when they have been / will be taken into use | • RMMs and OC library (Guidance on the Chemical Safety Report);<br>• Information on the use and effectiveness of RMMs from equipment suppliers, industry, IPPC BREF documents,<br>• Information on the use and effects of OCs from industry, IPPC BREF documents,<br>• Emission / exposure monitoring data from authorities, research institutions, industry<br>• Information from enforcement projects and joint inspections and other tasks undertaken my the Agency Forum |

**Identification of the existing legal requirements (ELRs)**

The starting point for the identification of the relevant legal obligations is the requirements under REACH. The identification of other ELRs will focus on Community-wide ELRs and their implementation in the Member States. However, depending on the case it may be useful to review also national ELRs. Differences in ELRs at national level may explain geographical variation in identified risk. The national ELRs may also be used when considering whether the identified risks should be addressed at Community-wide or national level (chapter 5.3). Observations related to non-compliance and its variation between MSs may also be relevant where available e.g. from the Forum.

International conventions, agreements and other initiatives require or encourage contracting parties (Member States, EU or both) to take action. These actions may involve new legislation or changes in existing legal requirements. These initiatives do not directly oblige industry to take action. However, a description of the international initiatives relevant for the substance under scrutiny is useful on the one hand to get a more holistic picture of the status of the substance and on the other hand the proposed restriction may contribute to fulfilling the agreed obligations under the international fora.

Questions that may be considered when identifying and describing ELRs[3] include

- Scope of the requirement: Which industry sectors or uses are covered? Which emission(s) /exposure(s) are covered? Is the substance in question directly mentioned, does the implementation require identification of the substances or is it question of a generic obligation? For national ELRs: which MSs have same or similar requirements?
- Timetable for the implementation
- What measures have been taken by the industry to fulfil the ELR?
- Information on enforcement: how is the enforcement arranged in different MSs? Are there enforcement reports available?

[3] ELRs cover also industry's voluntary commitments and any existing economic instruments

Appendix V provides a non-exhaustive list of other Community legislation under which substance-specific conditions are set.

**Identification and assessment of the effectiveness of the implemented Exposure Scenarios (ESs)**

Industry needs to comply with both REACH and other existing legal requirements (ELRs). Registrants need to document ESs (OCs and RMMs) they have implemented for the manufacture and own uses in their CSR. For downstream uses the M/I needs to recommend OCs and RMMs that adequately control the risks related to the substance in question. However, other legal obligation may require that DUs implement further measures that affect the emission(s) of / exposure(s) to the substance. These measures need be taken into account when assessing the exposure even though they are not included / required by the relevant ESs. The same basic principle applies to industry's voluntary commitments.

The assessment of the effectiveness should aim at establishing the actual reduction in emissions/exposure that results from the implementation of OCs and RMMs. Questions that may be considered include

- Are there differences in exposure scenarios (ESs) included in different CSRs?
- Effectiveness of the measure or combination of measures in reducing emission(s) / exposure(s), including variation in the effectiveness and reasons for that? Are there differences between the effectiveness of the ESs assumed in the CSA and the observed effectiveness?
- application of the different measures: What is the proportion of relevant actors that are applying each measure
- timeline of the implementation: for how long has the measure been used, are there still actors implementing the measure? What is the timetable for implementing ELRs?

**Comparison of the implemented OCs and RMMs with ELRs**

The aim is to consider whether the estimated / observed exposure levels are a result of non-compliance with REACH requirements or requirements set under other legislation. How to best carry out this comparison and the scope and level of detail of that comparison depend on, e.g., the content of the requirement and how crucial it is to the exposure levels in question. Observations related to non-compliance and its possible variation between MSs may also be of relevance for the justification of the need for action at Community level.

Furthermore, if the conclusion is that legal requirements exist but are not properly complied with, the Authority should consider whether Community wide compliance can be achieved via enforcement. Enforcement may have proven to be impossible in practice, e.g. due to increase in the number of actors or because the enforceability was not rightly assessed when designing the requirement. Such conclusions and reasons should be documented and taken into account when assessing the enforceability of the proposed restriction (see chapter 5.4.5). It is further recommended that these conclusions and underlying reasons are communicated to the Agency Forum and relevant MS enforcement authorities as well as to the authorities responsible for the legislation in question.

If the conclusion is that the risk is due to non-compliance with ELRs and there are no solid reasons why enforcement would be impossible, it is recommended that the Authority documents this conclusion and submits the documentation to the Agency Forum and MS CAs. If practicable (e.g. it

is a question of limited number of well defined actors) it is also advisable to inform the actors that are in non-compliance.

Example 2 illustrates a case where the DUs did not in practice apply RMMs and OCs defined in an ES and better enforcement was not considered to be sufficient. Furthermore, in this illustration the ESs were proven not to be as effective as assumed in the CSR and they did not always ensure adequate control even when properly applied.

#### 5.2.3.2 Environmental exposure

The CSA guidance (XXX) includes information on this aspect (Section 8). The extent to which this will be needed will depend on the number of registration dossiers available and the complexity of the use pattern of the substance. For simple use patterns it should be possible to use the information in the registration dossiers almost directly. Where there are several registrations, it may be more convenient for the Authority to combine the information under the general life cycle steps, and deal with broader areas as covered by these life cycle steps than with each ES separately. This can also help when considering options for risk management which will apply across the life cycle step. In simple cases there could be a direct correspondence between the ES and the life cycle step.

As indicated in chapter 5.2.3, the main aspects to be considered are aggregated emissions and revised RMMs as a result of the Authority review. Any revision of emission estimates as a result of revised RMMs should be carried out before calculating aggregated emissions in cases where both aspects are relevant, hence the first section here is related to RMMs.

**RMM related issues**

Section 5.2.3.1 provides guidance on assessing the effectiveness of implemented RMMs. The result of this assessment may be a change in the abatement factor(s) applied in calculating emissions (see the Guidance on the Chemical Safety Report for more on abatement factors). This section describes some possible situations and the calculations which could be performed in these cases to provide input to the demonstration of risks (and in some cases to the consideration of RMOs).

A situation may arise where there are several registration dossiers for the same substance from different manufacturers and importers, which indicate different risk management measures for the same use. In this case, the amounts to which each measure relates should be known. The regional and continental emission estimates in the registration dossiers can be added together in the same way as for the simple combined exposure case (see chapter 5.2.3). However, it may be necessary to look in more detail at the different measures identified and examine why they are different. Depending on the outcome, it may be decided to apply one of the measures to the whole tonnage used in this area. This will result in a revised emission estimate for this area, and hence a different overall exposure. This may help in identifying possible RMOs.

Similarly where different assumptions have been made in developing the exposure assessment between registration dossiers, perhaps in terms of the emission and abatement factors used or the amounts assumed to be used at a single location, then these should be reviewed together. It may be useful to examine the effect of applying the assumptions from one registration dossier to another to see whether large differences result. If so, the further investigation of the assumptions would be advisable. More data for the evaluation of exposure can be obtained through substance evaluation.

A more difficult situation may apply if more than one risk management measure is included in the same ES. This might be for example where either waste water treatment on site or collection and disposal as hazardous waste were identified as suitable risk management measures. If there is

information on the proportion of users likely to use each method then this could be taken into account. In the absence of such information, an approach would be to calculate the emissions assuming that all of the users apply one of the measures, and then re-calculate assuming that they all use the second measure. However, there may not always be an obvious realistic worst case option if the measures lead to releases to different parts of the environment, so it may be necessary to carry both options through to the overall emissions. In the example mentioned above, the option to collect wastes and spills and treat these as hazardous waste would be expected to lead to low emissions if operated correctly, and so the other option could be taken as a realistic worst case.

The Authority can consider the likely effectiveness of the proposed risk management measures in the ES. Where there are concerns about whether these measures would be implemented by all users then the emission estimates could be adapted to take into account other assumptions about their effectiveness. For example, an implementation of 50% could be assumed if this was considered more realistic; then 50% of the use could be assumed to have the indicated emission and a (presumably) higher emission rate (from a lower abatement factor) used for the other 50%. This would be used for the overall emissions; for individual sites the measure would be assumed to be present or absent. Such calculations will be useful in considering whether enforcement of measures can provide the required level of risk management.

### Aggregated or total exposures

A common reason for preparing an Annex XV restriction dossier is likely to be that there are a number of registration dossiers for a substance and the Authority has concerns that the overall exposure is not addressed in the individual registrations. In such cases an estimate of total exposure is required, using estimates of total emissions. In order to calculate overall background (regional) concentrations it is necessary to compile estimates of emissions from the whole life cycle of the substance. Estimates are needed for emissions to air, waste water, surface water, industrial soil and agricultural soil (not all of these may be relevant for all substances). The result will be revised regional concentrations for each compartment, which can be used in their own right in the risk characterisation, but will also modify the PEC or indirect human exposure values for local situations from the registration dossier ES.

The basic principles of calculating total emissions are described in the CSA guidance. The following notes relate to situations which may arise when considering restrictions (some will also be relevant to substance evaluation).

<u>Simple cases</u>

In this simple case there are a number of registration dossiers available.

- Each of the registration dossiers covers the full life cycle of the substance produced or imported by the registrant, and each has calculated the regional and continental emissions over the whole life cycle.
- The life cycles covered by the individual registration dossiers relate to different use patterns and do not overlap.
- There are no other sources of the substance.
- The Authority has reviewed the risk management measures included in the registration dossiers and concluded that they are appropriate.
- The physico-chemical properties and the environmental fate data used in the individual registration dossiers are the same.

- The exposure concentrations in the registration dossiers have been calculated using the appropriate software tool, incorporating the risk management measures in place.

In this case the regional and continental emissions from each registration dossier can be added together directly, and used to calculate the overall regional concentrations using the same model. In fact the regional PEC values from each of the registration dossiers can be added together for each compartment to give the overall regional values in this case.

In the case above the individual registration dossiers cover different use patterns and so it is realistic to assume that the region would receive the estimated regional inputs from each of these (this might not be correct for production if the production sites are widely dispersed, but for the purpose of the example this is assumed to be a minor contributor to the total emission). In other cases it is possible that the individual registration dossiers will contain emission estimates relating to the same uses (these are assumed here to be based on the same ES). Here it may not be appropriate to add these contributions directly. Instead, the total amount used for the common use across the registration dossiers should be determined, and a realistic estimate of the amount used in the region made. The emissions related to this regional amount can then be estimated as a proportion of the total emissions from this use (the sum of the emissions in the individual registration dossiers).

Other potential situations

Combining the various estimates of emissions from the individual registration dossiers will give overall emissions to the environment. Assuming these have been calculated on an EU-wide basis, an estimate of the proportion relevant for the regional emissions is needed. Information on the distribution of user industries should be considered. This may come from the registration dossier. Other sources of such information include emission scenario documents, possibly published risk assessment reports, and discussions with the submitter of the registration dossier or downstream users. In the absence of such information the assumption would be that all of the releases occurred in the region unless dealing with household use by consumers, in which case 10% use in a region would be assumed.

Some registration dossiers may address environmental emission estimation in a simplified way through the use of worst case defaults when risks to the environment are not expected, for example, where the substance is not self-classified as dangerous for the environment (but is classified for health and so a risk assessment has been conducted for the CSR). The level of detail in such a registration dossier may be relatively low in this area, as the assessment may be handled at a generic or screening level. It is perhaps unlikely that such a substance would be considered for an Annex XV restrictions dossier in relation to the environment, but there may be considerations relating to, for example, human exposure through the environment. In such cases, care will be needed in interpreting the ES and emission estimates in the registration dossier. It should be noted that even in such cases the registration dossier should demonstrate the absence of risk, so such concerns may only arise following a re-evaluation of the hazard assessment, during a substance evaluation for example. There will clearly be scope to refine the ES in such cases, and this will need to be taken into account in considering the possible measures to address the identified risk. It may be that some measures are in fact already in place but not included in the ES; discussion with the manufacturer or importer during the substance evaluation process may resolve this.

A more complex situation would be where there are several registrations which include the same use, and the ES for this use have different levels of detail. Calculations based on aggregated emissions (taking the emissions directly from the CSRs) indicate a risk. In such a case the Authority should look carefully at the contribution each of the ES makes to the total emissions. It would be expected that the more detailed scenarios would lead to lower emissions (on a kg/tonne used basis, the overall emission from the scenario also depends on the quantity of substance used). The

Authority can calculate the emissions assuming that the more detailed scenario is applied to all of this use (this situation is like that considered in chapter 5.2.3 where different measures are in place). Where this reduces or removes the risk, this indicates a possible RMO, but as discussed above there may be scope to revise the less detailed ES and provide a better description of the real situation.

**Calculated concentrations**

Once the regional emissions from all sources have been established, the regional concentrations can then be calculated using the total emissions and the appropriate models. The total emissions should include any other sources, as considered in chapter 5.2.3. The calculations methods for regional and local concentrations are described in the Guidance on the Chemical Safety Report.

As a first approximation, where the local emissions have not been changed, then local PEC values from the registration dossiers can be modified using the new regional PECs to replace the regional values in the CSR assessments. This revision of the local PECs may be needed, because the effect of considering total emissions may not be a risk at regional level but increased PEC local values which are now above the PNEC as a result of higher regional levels. This approach works best for the PEC values for surface water, soil and air. The situation for PEC values for sediments, fish and earthworms for secondary poisoning, and the food chain for human exposure is more complex and more detailed calculations (using the methods in the CSA guidance) will need to be performed to get precise values for these. However it is recommended that as a first approach, the correction outlined above is firstly applied to see if further calculation is warranted.

**Other sources**

There may be sources, relevant for estimating environmental as well as human exposure,. of release which are not considered in the registration dossiers, or that have not been fully quantified. These should be investigated by the Authority in order to determine if these are significant. This may involve identifying the quantities involved and the resulting emissions from the source. Depending on the nature of the sources, it may be necessary to estimate local emissions and hence local concentrations. However, if the sources are diffuse ones, then it is likely that only the overall emission estimates will be needed. A source of emission may be included in some registration dossiers but not in others, in which case the coverage should be extended to cover all relevant tonnages. In such cases it is suggested that initially at least the same approach is used as in the registration dossier which does include the source.

These other sources are considered in the environment section, because they are most likely to affect the environmental concentrations. They will of course have an effect on the indirect exposure of humans through the environment.

One example of a possible additional source is where the substance of interest can be formed through the breakdown of other substance(s) in the environment. This situation is perhaps most likely to come to light through studies published in the literature, or possibly through a substance evaluation process of the other substance(s). Two examples of this type of situation are included in **Example 1**. To address this type of situation, the Authority will need to estimate the potential for release from this source in relation to other sources. This involves estimating the release of the other substance(s) to the environment, the fate and degradation of the substance(s) in the environment and where possible an estimate of the amount of the substance of interest produced. These issues may be addressed in the registration dossiers for the other substance(s). It may be possible to perform rough calculations based on the amounts of the substance(s) released and a worst case estimate of the amount of the substance of interest formed. These can be compared to the releases from other sources, and if they are a minor contribution then this source can be neglected. If the source appears to be significant based on this initial approach, then more detailed estimates of the production of the

substance of interest could be made. It is likely that in most cases there will be a high degree of uncertainty in such cases. It should be noted that if such a source is found to make a significant contribution to the risks, then the risk management options may need to consider restrictions on the other substances as well as on the substance of interest.

There are other sources which can not be related to specific other substances. Combustion processes are one example where a substance can be produced as a result of the reaction taking place during the burning of materials. Emissions from such sources are generally estimated using information on the extent of the activity (for example, how much wood is burned as fuel) and emission factors for the substance from the process. Both the extent of the activity and the factors can be applicable at a generic level, so covering a range of processes. They can also be applied at a greater level of detail. The Authority should adopt a step-wise approach to such sources. A broad generic calculation of possible emissions will show if the source is significant. If so, a more detailed investigation should be carried out to refine the estimates. As this source does not relate to the use of the substance, it is unlikely that producers/importers or users will have specific information relevant to help in refining the assessment.

Some substances produced and used, and so subject to REACH, also occur naturally in the environment. This aspect may be included in the exposure assessment in the CSR, and the Guidance on the Chemical Safety Report includes a section on the assessment of metals which has relevant material in relation to background concentrations of natural substances. The natural occurrence of a substance is clearly not related to any particular producer or importer, or to the amounts produced or imported, and so any treatment of this aspect in a CSR will probably address the natural sources as a whole. Therefore there should not be any issues of aggregation of emissions from such sources across a number of CSRs. Where there are a number of CSRs for a naturally occurring substance, the Authority should check the approaches used to address this in the CSRs. The Authority can review the approaches and select the one they think is most appropriate for the substance, and then apply this in their assessment of exposure. Emissions from the usual life cycle stages can be handled in the same way as for other substances.

#### 5.2.3.3 Human exposure

The considerations for the exposure of humans are the same two basic aspects as those for the environment. One is to make sure that the combined exposure from different sources is taken into account. The second is to consider the effectiveness of the proposed RMM. As for the environmental emissions, any changes required as a result of considering the effectiveness of the RMMs should be made before estimating combined exposures.

**RMM related issues**

The examination of different registration dossiers may show different approaches to the estimation of exposures for the same (or very similar) routes. Where such differences are found, the ES in the different registration dossiers should be examined closely to identify the reasons for the differences. This may show that different RMMs are recommended, and the Authority should review these (see Section 5.2.3.1) and decide on which is the most appropriate or most likely to be used.

The Authority may also have information which shows that the proposed RMMs will not have the effect indicated, for example specific information on the efficiency of an air filter. In such cases new calculations of exposure can be made using the Authority interpretation of how the RMM will work. The same models as indicated in the exposure assessment should be used unless there are

good reasons for considering this not to be suitable for this purpose. Guidance on the use of models and calculation methods for assessing human exposure are included in the CSA guidance [XXX].

Note that exposure via the environment may be significant in some cases and so consideration of RMMs related to environmental emissions may be important.

**Combinations of exposure**

The Authority should examine the exposure assessments included in the registration dossiers and look for exposures which are considered in some and not in others. This may be because they are not relevant for the life cycle of the substance in all registration dossiers.

For example, one registration dossier addresses only worker exposure as this is the only relevant step, and a second addresses both worker and consumer exposure. The combination of the consumer exposure with the first worker exposure is not covered in either registration. Estimating the combined exposure in this case is a relatively simple matter. The CSA guidance includes sections on combined exposures of this type.

Exposure of humans via the environment also needs to be taken into account. Indications that this may be significant would be where the exposure through the environment makes a significant contribution to the daily intake of humans according to the calculations in the registration dossier and the total exposure is close to the DNEL.

When combining human exposures, the Authority needs to make sure that the combinations are realistic. So the combination of two different working day exposure from two scenarios would not be appropriate. Where the same exposure route is included in several registrations, this does not necessarily lead to higher exposure of individuals.

For example, two registrations assess the exposure of consumers to a dye from cloth. Adding the exposures would not be appropriate as consumers do not wear an increased number of clothes – what this means is that more people are probably exposed to the dye.

However, the presence of the substance in a range of consumer products may well lead to a higher total exposure, and these may not all be addressed in each registration dossier. Where there are parallel assessments of exposure through the same route, then the higher (highest) value would be the most appropriate to use.

The Authority may also wish to consider whether combined exposure via the environment to a number of local sources is possible. This may occur where there are a large number of users in different use areas, and it is likely that there will be examples of each in a locality. If these are assessed in different CSRs then the possible combined exposure will not have been assessed. Direct combination or weighting in relation to numbers of sites may be possible.

#### 5.2.3.4 Measured concentrations

It is possible that regional PECs may be based on measured concentrations, which by definition would represent the overall exposures from all relevant sources. These could in principle apply to all registration dossiers, so if they are considered valid then they could be used to replace any

calculated values. The Authority may consider that information on measured levels indicates that emissions reported in the registration dossiers are being under-estimated. The Authority should review the measured data carefully. If it is possible to derive representative values for regional concentrations, then these should be used as regional PEC values in the Annex XV dossier, and used in the calculation of new local PEC values.

There may also be measured levels data relevant to local situations. The Authority will need to consider carefully the degree to which these data can be considered to be representative of a particular use across the EU. If such representativeness cannot be demonstrated clearly, then the data should be considered not suitable for a community-wide risk assessment.

Where suitable monitoring data for human exposure are available they can be used directly in place of calculated concentrations.

The Authority should consider any information on measured concentrations included in the CSRs.

Guidance on the review of monitoring data is included in the CSA guidance.

### 5.2.4 Risk characterisation

**Overview of the task**

**Aim:** The Authority needs to identify the risks which are not sufficiently managed.

**Scope:** The basic approach to risk characterisation is set out in the guidance for production of the CSA. In simple terms it involves the comparison of the estimated or measured exposure levels with the appropriate DNEL or PNEC values.

There are potentially a large number of possible risk characterization endpoints which could be included. Where the assessment has been targeted then this can be reduced to a smaller number. It is important to make clear in this section of the report exactly what parts of the possible assessment have been considered. It is useful to restate what areas have been reviewed or assessed for this dossier and what (if any) risk characterization results have been taken directly from the available registration dossiers.

When the main focus of the Annex XV restriction report is on aggregated exposures for the environment, it may be sufficient to include only the risk characterisation for this combination, where this shows a risk which is not managed. However, a more likely situation would be that the combined emissions lead to a revised regional PEC, which when combined with the local emissions leads to risks on a local scale. These would then need to be included in the risk characterisation.

Where the revision of the PECs is due to a reinterpretation of the RMMs, then only the results related to the specific Exposure Scenario may be needed. However, the Authority should make sure that all endpoints which might be affected by the change in assumptions are considered in the risk characterization. As an example, a higher exposure to workers through air may be assumed to be more realistic, but this could also lead to greater emissions to the environment via the air. This could also apply to the consideration of proposed measures to address an identified risk. In the same situation as above, extra air extraction could be used to reduce worker exposure, but could lead to an increase in air emissions.

It may help the case being made to consider the uncertainty in the risk characterisation, on both the exposure and effects side. The Guidance on the Chemical Safety Report has a section on this.

**Producing the report**

This is *Section 10* of the *Justification* part of the Annex XV restriction report (APPENDIX I). In terms of what to include in the report, the Authority will need to present the risk characterisation results which demonstrate that there is a risk. Where other parts of the risk characterisation are calculated which do not show a risk, they should be included for completeness as far as possible.

## 5.3 Justification for the need for action on a Community-wide basis

**Overview of task**

| | |
|---|---|
| **Aim:** | A restriction proposal needs to provide justification why the identified risk needs to be addressed at the Community level. |
| **Scope and Outcome** | Such justification needs to show that action on a Community-wide basis is the most appropriate option for reducing the identified risk.<br><br>This part of the justification will be documented in section 14 of the restriction format (appendix I) |
| **Exit from the restriction procedure** | If the analysis proves that action at the Community level is not needed but the identified risk should rather be addressed at national level the Authority is requested to document the identified risk and this conclusion in the relevant parts of the restriction format and submit this documentation to the Agency and Member State CAs. |

The justification for the need for the risk management action to be taken on a Community-wide basis needs to be based on risk-related considerations and needs to take into account market-related considerations. The aspects considered under these two basic elements and their relative importance will vary case by case.

<u>The risk related considerations may cover</u>

- the severity of the risk:
  - the nature and reversibility of the adverse effect
  - uncertainty in the risk assessment and the severity of consequences of wrong conclusions from the assessment
- the extent of the risk:
  - the population affected (e.g. consumers), including any vulnerable sub-groups,
  - the number of people affected
  - the area of the environment that is affected, and the geographical distribution within the EU
  - the use of substance in industry, its distribution via the supply chain including service-life of articles and waste stage

In general terms the higher the hazard and the extent of the risk the more important it is to take measures to ensure the protection of human health and the environment throughout the Community.

<u>The market related consideration</u> cover the effects of the risk management measures on the internal market

The key question that an Authority needs to answer is, *"If no Community-wide action is taken but risks are addressed at the national level, will there be a distortion of the internal market?"*. This will effectively involve the consideration of the likely effects of any possible national-level RMOs to the functioning of the internal market and evaluation of likely imbalances and inequalities that could arise. If national-level measures are taken, the burden on the enterprises subject to any new national-level regulations may result in them becoming less competitive in the internal market. This may occur if they are not allowed to manufacture a certain chemical substance or use it in specific processes, possibly resulting in an increase in their prices, a decrease in their portfolio and a loss in their share of the market. More generally, the introduction of national-level measures as opposed to a Community-wide restriction could impact upon the flexibility of those enterprises subject to the measures and their ability to respond to the changing demands of the market.

**Carrying out the task**

The development of the justification for the proposed restriction may involve the steps listed below. It should be noted that the order in which the issues are considered depend on the case.

- Based on the risk assessment conducted, identification of the key characteristics of risks which warrant action on a Community-wide basis.
- Identification of key monitoring data, estimates and projections (also presented in the *Information on risk*) that support the argument for action on a Community-wide basis. This could include, for example, monitored pollution levels being significantly elevated across the Community or statistics from authorities in several Member States showing an increased number of cases of workers/consumers suffering adverse health effects from exposure to the substance of concern.
- Identification and description of the possible national risk management options. Procedures described in section 5.4.4 of this guidance (identification of other Community-wide risk management options) can be used when developing this section.
- Identification and analysis of data on the distribution of the substance in the markets across the Community. This could include an analysis of how widespread and how controlled the manufacture, marketing and use of the substance are across different Member States.
- Assessment of any possible national-level RMOs against the key criteria of effectiveness (including proportionality), practicality and monitorability (see Section 5.4.5 of this guidance for more detail on these criteria); information on the distribution of the chemical (manufacture and use) in markets across the Community as well as the findings of an available SEA may be of significance.
- Assessment of the effects of possible national RMOs on internal market.

On the basis of the information gathered and analysed, the Authority has to draw a conclusion whether national-level RMOs could deliver the required reduction in the identified risk while not disrupting the internal market. There may be cases where a measure taken at the national level may be capable of sufficiently reducing the risk. Such examples would be when managing:

- risks that affect limited and defined geographic locations in the Community due to specific environmental conditions;
- risks associated with specific processes which take place only in specific Member States;
- risks associated with market imbalances in specific Member States; or

- risks that require urgent action in specific Member States and the action may be taken at the national level more quickly in comparison to action at the Community level.

Note that the geographical scope of the risks is not the sole defining factor: even if the identified risk is relevant to only a part of the Community, action on a Community-wide basis may be needed because the markets may develop throughout the Community in the future and the scope of the risk may cross the national boundaries. In all cases, for a national-level RMO to be suitable, it should be able to effectively reduce the risk while ensuring the balanced and fair functioning of the internal market across the Community.

### Producing the report

Refer to Appendix IIfor more information on how to fill in the relevant section of the Restriction report.

**Example 2** An example where action on a Community-wide basis is needed

Substance E is a liquid/gas which is produced in the European Union in a volume of ~100,000 tonnes. Substance E is already regulated in the working environment with occupational exposure limits already in force in x Member States. During the preparation of a restriction proposal, in the absence of more detailed information, reasonable worst-case scenarios have been used in the assessment of risk. The reasonable worst-case exposures leading to concern (i.e. the critical exposures) are 105 mg/m$^3$ and 97 mg/m$^3$ for repeated dose toxicity and acute toxicity respectively. The Time-Weighted Average (TWA) limits in Member States range from 90 to 475 mg/m$^3$ while the current Community TWA stands at 210 mg/m$^3$. Only one Member State has a TWA below the worst-case exposure of 105 mg/m$^3$ for repeated dose toxicity. On the other hand, only five Member States have an occupational exposure limit for short-term exposure; these limits range from 450 to 850 mg/m$^3$, considerably higher than the established worst-case exposure level of 97 mg/m$^3$ for acute toxicity.

With regard to the irritating properties of the substance, the CSRs show that the use of personal protective equipment eliminates the risk to occupational health. However, the Authority has reasons to question this both due to evidence that PPE is not in practise used (in other words the ES is not applied correctly by DUs) and due to lower efficiency of PPE than assumed in the CSRs.: Health risks from the use of solutions of Substance E for building surface cleaning cannot be minimised by a normal workplace protection procedures (including personal protection equipment) due to the very high irritancy of the substance, and the current practices in the Industry, especially the presence of mobile workplaces within many small-sized enterprises. Moreover, statistical data from authorities in Member States suggest that a considerable number of people employed in the cleaning industry are admitted to hospital with respiratory problems each year and these problems appear to be associated with the use of solutions of Substance E. A

survey among workers in the cleaning sector of seven large Member States suggests that only half of the workers have access to appropriate personal protection equipment on a daily basis. For around 30% of workers, the availability of such equipment will depend on the location of work and on the equipment made available from the employees. With regard to incidence of respiratory problems, those not using personal protective equipment are five times more likely to suffer acute adverse effects and three times more likely to develop a longer-term respiratory disease. The use of personal protective equipment, however, does not guarantee complete protection: almost 10% of those regularly using personal protective equipment have suffered from respiratory diseases in the last 18 months as a result of using preparations of Substance E.

Overall, the existing measures and controls on exposure to Substance E in the workplace appear to be insufficient; moreover, the risks are applicable to the whole of the Community. Even in the small number of Member States where the existing risk management measures are sufficient stringent, exposure to unacceptable levels of Substance E is not adequately prevented. This in combination with existing data from the health services of several Member States on the prevalence of respiratory problems associated with the Substance support the case for action on a Community-wide basis.

**Example 3** An example where Community-wide action is needed to prevent market distortions

Substance F is produced in the EU at a volume of around 10,000 tonnes per year and finds several uses one of which is as a dye carrier in the textiles industry. An estimated 500 textile finishing workshops in the EU use this substance. Of them, more than half are believed to be small enterprises. The use of the substance has traditionally been confined predominantly to seven neighbouring Member States (hereafter referred to as Region X).

The available CSRs and Safety Data Sheets indicate that precautions need to be taken to prevent accidental releases of the substance to the aquatic environment. However, the Agency has been notified that an undisclosed number of textile finishers use the substance outside the conditions described in the Exposure Scenarios developed by the manufacturers. This process is used for achieving specific finishing effects and downstream users have generally kept its details confidential.

A recent case of acute pollution of a lake in a Member State in Region X as a result of releases of Substance F from a textile finishing installation in 2004 highlighted the potential risk from this confidential process: the relevant competent authority investigated the incident and concluded that the confidential finishing process is based on aged technology and gives rise to significant amounts of wastewater and spent solutions that contain Substance F. Notably the relevant trade associations (both those of EU remit and national ones) have been involved in information campaigns to persuade their members across the Community to generally switch to alternative, more modern processes in the finishing of textiles. The information available to the trade associations, prior to the aforementioned accident, suggested that the confidential process had been obsolete for the last 5-10 years throughout the Community.

Following the lake pollution incident, it has been established that between 10-20% of the total of 500 textile finishing workshops may be involved in this finishing process Of them, less than 40% (i.e. 4-8% of all 500 workshops or 20-40 installations) in the Member States in Region X appear to be able to control emissions of Substance F by using modern equipment that recycles wastewater, while most of the rest dispose of their wastewater through licensed contractors. Workshops in Region X which confirmed their use of Substance F in the confidential process submitted information which suggests that the finishing process in question is still in use not

only in non-EU countries but also in EU countries outside Region X which until previously were believed by authorities to have abandoned this process altogether.

In the process of developing a restriction dossier, the Authority in charge has considered the option of introducing limits on releases of Substance F or even a restriction on its use. For the Authority, issues of concern were:

1. There have been calls for any restriction to be imposed only to enterprises and Member States that have been confirmed as being linked to the identified risk since releases result in risks at the local level rather than the regional or continental. EU textile finishers based outside Region X have also supported the introduction of a restriction (or other RMOs) at the national level only in Member States associated with the risk.

2. On the other hand, workshops in Region X which are confirmed users of the process in question have provided some confidential market research information suggesting the competitors from the other EU regions may account for at least 20% of the total EU market turnover in that particular use. They have also argued that the installation of advanced technology would result in significant downtime and expense and they expect that prices of their products would increase with consequent, loss of their market share and possible loss of employment. At the same time, enterprises outside Region X would be allowed to use this process and that would help them improve their position in the internal and global markets. Moreover, enterprises elsewhere in the EU would be allowed to use this process which would give them a competitive advantage in the internal and global markets.

3. A limit on releases of Substance F that could sufficiently reduce risks would be lower than limits currently in place in Member States outside Region X; hence there would be an unequal burden of meeting legislative obligations across the Community. Moreover, different Member States regulate these installations under different legislative frameworks.

The Authority considered the above and concluded that a Community-wide restriction (as opposed to a national measure or an emission limit) may be justified as the most appropriate RMO which will provide adequate protection of the environment and at the same time will ensure equal access and opportunity for all players in the internal market particularly given the current uncertainties on the location of users of the process of concern. The proposed restriction was that Substance F may not be used in textile finishing in the particular finishing process associated with the risks.

## 5.4 Refinement and assessment of the proposed restriction

### 5.4.1 Overview of the task

**Aim:** The aim of this task is to

- define the scope and conditions of the proposed restriction
- provide justification that the proposed restriction is the most appropriate Community wide measure assessed against the three criteria: effectiveness, practicality and monitorability

**Scope:** The task includes

- defining initially the restriction,
- assessment of initial restriction against effectiveness, practicality and monitorability and, where necessary, improvement of the initial restriction on the basis of the results of this assessment,
- identification of possible other risk management options (RMOs), and
- comparison of the restriction to the other RMOs

Defining the final proposal for a restriction can be an iterative process, where the scope of the restriction and any conditions are refined based on the findings when assessing the effectiveness, practicality and monitorability of the initial proposal. The scope of a restriction defines which uses or actions are covered by the restriction. Conditions of the restriction may include for instance timeline(s) from which the restriction applies, concentration limit(s) above which the restriction applies or conditions under which the restriction does not apply (derogation from the restriction). Information on alternatives and socio-economic analysis, where available, provide input for defining the restriction and for assessing it against the three criteria.

The possible other RMOs are identified to have a reference point against which the proposed restriction is compared to find out whether the proposed restriction is the most appropriate measure. How widely the Authority should identify other RMOs and to what level of detail it should assess them depends on the case. Information on alternatives and socio-economic analysis, where available, provide input also for this comparision.

**Outcome:**

The outcome of this task will be a proposal for a restriction. This proposal needs to define which manufacturing, placing on the market and uses are to be restricted and any conditions related to those restrictions. This part of the justification will be documented in the “Proposal for Restrictions” section of the restriction format.

This task will provide also a justification for that the proposed restriction as defined is the most appropriate Community wide measure. The justification will be documented in section 15 of the restriction format (Appendix I)

**Exit from the restriction procedure:**

If the comparison of the proposed restriction against other possible Community level RMOs shows that a measure under another legislation is more appropriate way of addressing the risk than a restriction under REACH the Authority is requested to document the assessment and this conclusion in the relevant parts of the restriction format and submit this documentation to the Agency.

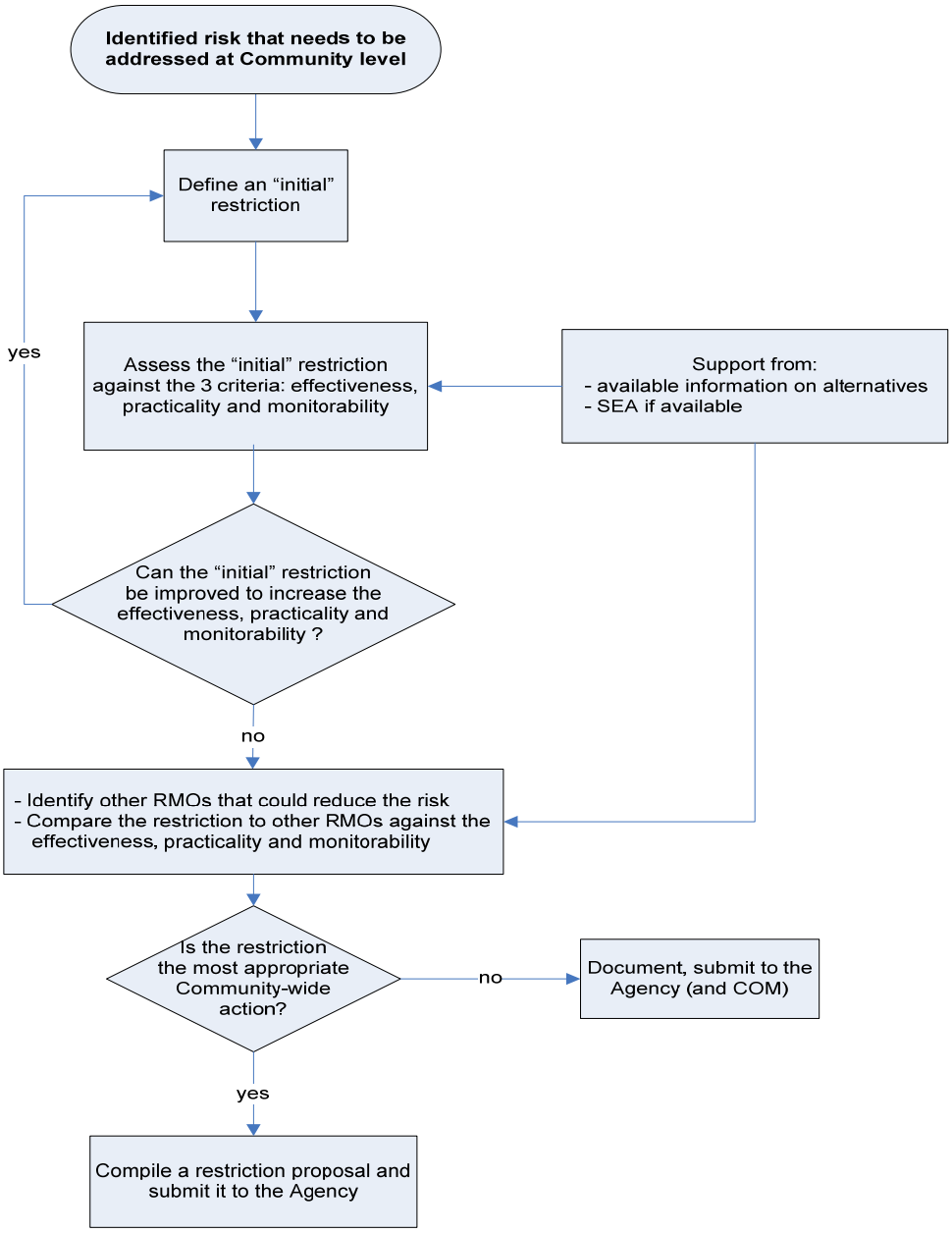
Figure 6 gives an overview of the refinement and assessment of the restriction proposal. The identified risk gives the basis for the drafting the restriction. In addition to defining which uses

cause the risk and describing the characteristics of the risk, the analysis of the effectiveness of implemented OCs and RMMs and of the compliance with ELRs provide background for developing the restriction proposal.

Availability and characteristics of alternatives (chapter 5.5) is crucial for the effectiveness and practicality of the proposed restriction and considered other RMOs. Therefore the available information on alternatives provides an important input from the drafting of the initial restriction to final justification.

Socio-economic analysis (chapter 5.6) assists in understanding the implications of the proposed restriction and other RMOs. The drafting of initial restriction and its assessment against the three criteria may give a reason for the Authority to conduct an SEA to analyse the overall impacts on the society. Information from the SEA, where conducted, will give input for the final justification that the restriction in the form defined by the proposal is the most appropriate measure.

**Figure 5** Overview of the refinement and assessment of the proposed restriction



### 5.4.2 Risk to be addressed

The information on hazard and exposure and the results of risk characterisation conducted provide a starting point for drafting an initial restriction. Information on the risk include:

- which use(s) / manufacture/other handling cause the risk
- in which life-cycle stage(s) the exposure resulting in risk occurs
- which human populations face the risk (workers, consumers or specific groups of them) and the main exposure route
- which environmental compartments are at risk

This information is used to define the scope of a restriction and to identify whether other RMOs can address the risk related to the relevant exposures.

### 5.4.3 Drafting an initial restriction

The drafting of the initial restriction should take into account the three basic criteria as defined in Annex XV:

> (i) effectiveness: the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk
>
> (ii) practicality: the restriction must be implementable, enforceable and manageable
>
> (iii) monitorability: it must be possible to monitor the implementation of the proposed restriction.

A restriction under REACH is defined as any condition for or prohibition of the manufacture, use or placing on the market. The basic structure of restrictions may vary a lot, including e.g.

- Total prohibition of manufacture, marketing and use
- Restrictions on certain uses / uses in certain processes
- Restriction on marketing a substance on its own, in preparation or in articles for consumers

A restriction will normally include conditions defining to which situation the restriction applies and how it should be implemented. Unconditional or conditional derogation for certain uses are one example of this (see below). The Authority may include conditions in the initial restriction or the assessment against the three criteria may call for adding conditions to get the restriction more effective, proportionate and practical and more monitorable. Other factors to be taken into account when drafting a restriction include equal treatment of EU manufacturers and importers and interfaces with other Community legislation. For enforcement purposes the restriction has to contain a concentration limit. The default limit is 0.1 %. However, lower values can be used, where needed, case by case if an internationally recognised test method exists.

Drafting of an initial restriction will be based on the identified risk (chapters 5.2 and 5.4.2). Information on currently existing legal requirements and compliance with them from chapter 5.2.3.1 may give background for the drafting of an initial restriction. Information from the analysis of alternatives (chapter 5.5) and socio-economic assessment (chapter 5.6) can be used to define the form of restriction and the conditions.

**Derogations**

Derogation excludes certain uses from the restriction either totally or under prescribed conditions. A well-developed derogation can increase the effectiveness and proportionality of a proposal for a restriction by:

- targeting the proposed restriction to the risks;
- accounting for the availability and suitability of alternative substances and techniques;
- defining where exactly the proposed restriction applies and how and when its implementation should take place; and
- ensuring the functioning of the internal market .

The Authority may include a derogation in the initial restriction or the assessment of the effectiveness, practicality and monitorability of the initial restriction may highlight a need for a derogation. The impact of a derogation on these three criteria need to be taken into account in the final assessment of the proposed restriction.

The Authority needs first to identify the uses, and where relevant manufacture and marketing, of the substance for which derogations may be needed based on the information on risk (chapters 5.2 and 5.4.2) and on the available information on the availability, technical suitability and risks of alternatives (chapter 5.5). Consultation with stakeholders may also provide relevant information and arguments on the need for derogations (see box below). An SEA, where available, may contribute to the identification and justification of the uses for which a derogation is needed (chapter 5.6). Generally, the main reasons for including derogations into a restriction proposal are related to:

- technical considerations (when it is not possible to produce the end-product or achieve the same functionality by using an alternative);
- human health and/or environmental considerations (when the alternatives pose a greater risk(s) than the substance of concern);
- economic considerations (the use of an alternative would result in significant economic impacts or distortion to the internal market); or
- regulatory and contractual considerations (for example, the use of products that contain the substance requires prior approval and without a derogation there would be insufficient time available to gain approval for alternative products).

Possible role of a voluntary stakeholder consultation in identifying the need for derogations

Depending on the case, the need for derogation may arise from:

- an Industry argumentation (for example, where Industry wants to protect a particular critical application of the substance of concern);
- an argumentation by another Member State (when, for example, a derogation would be needed in the context of some of the policies of that Member State);
- the analysis of collected information and from general consultation with interested parties, other Member States and the Agency (for example, the analysis of information on the availability, technical suitability and risks of alternatives); and
- the information and analysis presented in any SEA developed by the Authority.

A derogation included in a restriction for a certain use of substance can be with or without conditions. Under an **unconditional derogation** the use of the substance is allowed to continue in the future without any conditions attached to that use. This type of derogation may result from a combination of high criticality and importance of the application of concern, a recognised lack of suitable and safer alternatives and high associated costs of the proposed restriction.

Alternatively derogation may include conditions, for instance

- **process-limited derogations**, use is allowed within a certain process, or by utilising a specific technique, when there is evidence that a process which utilises/involves the substance is not associated with unacceptable risk (as opposed to other processes)
- in **time-limited derogations**, use is allowed only for a certain period of time, within which Industry will have to introduce changes or develop alternatives. Consultation of stakeholders, literature and the information on alternatives may provide evidence that a period of time is required before changes in processes or alternatives are introduced.
- A time-limited derogation may be **progress-limited** when use of the substance is allowed with Industry's commitment to work towards the development of alternatives. The derogation is contingent upon Industry showing that progress in the research on and development of alternatives is actually being made. Such a derogation could require Industry to set up monitoring schemes, establish reporting requirements and schedules.

Derogation is justified if the benefits outweigh the drawbacks. The box below gives examples of issues to be considered when assessing the potential advantages and drawbacks of including a derogation in a restriction.

Examples of potential advantages and drawbacks of including a derogation in a restriction

The potential advantages of a derogation may include:

- the protection of uses of the substance which are critical to society as a whole;
- benefits to human health and the environment from avoiding the use of less safe alternatives. Quantification of benefits can be useful (the SEA guidance (XXX) can be consulted);
- the limitation of potentially disproportionate costs to certain Industry sectors;
- the protection of the functioning of the internal market and of the competitiveness in the global market of EU enterprises which might otherwise be impacted upon by the proposed restriction

Possible drawbacks of a derogation may include:

- any residual risk to human health and the environment from the derogated uses;
- the potential for those granted a derogation to obtain a competitive advantage over EU competitors not covered by the derogation.

**Example 4** Examples of derogations protecting the functioning of the internal market

Well-developed and targeted derogations could make a restriction more balanced and support its justification. This could be the case in the following examples:

- a number of SMEs is involved in the activity targeted by the proposed restriction. The proposed restriction is expected to result in enterprises investing in new technology; however, many SMEs are unable to make such an investment in the short term due to its disproportionate cost. Hence, a time-related derogation would protect the role of these SMEs in the internal market; and
- a number of enterprises are using very different technologies which are highly integrated within the supply chain, and the end-users vitally rely on the performance of the end-product (for instance, users of silicon wafer chips). The substance of concern may be one of the few qualified chemical substances that can ensure that the end-product meets the requirements of specified performance tests. If the chemical is banned or its use is seriously restricted, the quality and performance of the end-product will change and may not meet the requirements of the end-users. Therefore, a restriction on the use of the substance of concern could distort the market by making the enterprises using the substance uncompetitive, as they would not be able to meet the requirements of the end-users of their products. Hence, a derogation could be considered as a step towards the protection of a potentially very critical application.

**Example 5** Examples of conditional derogations

**Application for which a process and progress-limited derogation is proposed**

Unacceptable risks to the environment from the use of hydraulic fluids based on Substance N have been identified. The Authority considers that a restriction is the most appropriate option for Community-wide action, especially given the international nature of the aviation industry.

The information collected during the preparation of the restriction dossier suggests that there are no current alternatives for hydraulic fluids for aircraft systems and there is no known alternative chemistry which will provide adequate protection to the relevant aircraft systems.

Changing formulations in aviation hydraulic fluids requires extensive review, testing, and approval by all airframe manufacturers prior to use of the new formulation in commercial aircraft. Historically, this process has taken at least 10 years from identification of the need for changes to actual commercial manufacture.

In recognition of the long timeframes involved in cdeveloping a replacement and getting this approved, this application could be derogated. The Authority might consider the inclusion of a derogation in the restriction proposal according to which Substance N may be used in aviation fluids. Conditions for the derogation might include:

- the derogation would be subject to on-going review to evaluate progress in developing alternative hydraulic fluids, albeit with no set deadlines for phase-out, as there are no candidate replacements at this time;
- the aviation industry would need to report to the Commission on a 2-year basis on progress made in the development of substitute chemicals and/or hydraulic fluids.

  The aviation industry would be expected to present evidence of research progress on substitutes (chemicals and technologies); and
- the derogation would be re-assessed (and extended, withdrawn or modified) after 10 years from entering into force.

**Application for which a time-limited derogation is proposed**

Substance N is no longer used in the manufacture of fire fighting foams, there being suitable alternatives. Current (and future) risks are associated with the use of remaining Substance N-based fire fighting foam stocks (which may have up to 12 years' shelf life remaining).

Analysis during the restriction procedure suggests that a restriction should be introduced on the marketing and use of the substance for its use in fire fighting foams. However, the use of the available alternatives is accompanied by uncertainties as regards the possible overall reduction in environmental risk; as a result, measures requiring the immediate destruction and replacement of Substance N-based foams could result in unknown risks to environment.

A derogation might be considered to be appropriate; this could be a conditional five-year delay in destruction of the remaining foams. The five-year delay in destruction of these foams would allow to reduce the environmetal impact from the destruction, provide for the users for a smoother transition to alternative formulations and would reduce the costs associated with an immediate replacement of Substance N foams. This five-year delay, however, could be conditional on a number of actions by the holders of foams:

- the removal of stocks from active service;
- at the end of the five years period all remaining foams containing Substance N would be destroyed in accordance with waste legislation;
- in the event that Substance N-based foams are required within the five year period, contained fire waters would not be permitted to be released to wastewater without the notification and agreement of the relevant national authorities and the application of emissions controls based on existing legislative requirements and guidance

### 5.4.4 Identification of possible other RMOs

The identification of possible RMOs will concentrate on the identification of appropriate Community legislation other than REACH that could be used to address the identified risk(s).

Appendix Vpresents a non-exhaustive list of EU legislation that the Authority may consider. In addition there may be sector or use specific legislation that can be used (e.g. directive on fuel quality where the risk arises from the use of a substance as additive in petrol). The aim of the identification of other RMOs is to find those that have potential to reduce the identified risk, i.e. their scope cover the use(s) in question and requirements under them can address the relevant exposure. Issues to be considered when identifying the potential RMOs include in addition to information on risk as described above

- Information on currently existing legal requirements and compliance with them from chapter 5.2.3.1. The past performance of RMOs when applied for other substances / uses / manufacturing (so that those RMOs that have proved insufficient in the past in cases of similar risks or for similar substances may not be considered further).
- Current (and foreseeable) practices and capabilities of the Industry sectors of concern that may render an RMO feasible or unfeasible (for instance, if a limit value on emissions would need to be set so low that the available technology does not allow for such a limit to be met under normal operational conditions, such measure cannot be implementable)
- Available information on alternatives (from chapter 5.5). Other RMOs than a restriction may be more suitable for controlling the identified risk from uses for which no alternatives exist and efforts of finding other RMOs can be focused to those uses.

**Examples of identification of possible RMOs**

- if an unacceptable risk to the aquatic environment has been identified, the Water Framework Directive could be a possible legislative framework for addressing the risk;
- if the risks are associated with the emissions of the substance from Industry sectors within Annex I of the Integrated Pollution Prevention and Control Directive, this could provide a possible legislative framework; and
- if the substance is a volatile organic compound, then the Volatile Organic Compounds Directive could be considered.

It should be noted that the identified risks may be best addressed by a combination of RMOs. Such a combination may also include a restriction under REACH for certain uses. In that case, the Authority should submit to the Agency an Annex XV dossier proposing a restriction for these uses and document the need for other Community wide measures for the rest of the uses.

Voluntary actions by industry may also be considered as an alternative for a restriction under REACH, however, voluntary actions have a relatively limited scope in this process. The ES(s) should include OCs and RMMs implemented or recommended by industry, including those based on existing voluntary commitments (if any). The effect of such voluntary actions is, therefore, already taken into account in assessment of 'remaining' risks.

Emissions due to aggregated tonnages may cause risks even if each M/I has implemented or recommended OCs and RMMs that adequately control the risks caused by his volume. This is an example of a case where a voluntary action by industry could still provide an option to reduce the risks sufficiently. Industry would in this case include the necessary RMMs and OCs in revised ES(s), document them in CSR(s) and communicate them to downstream users via SDS(s). However, this procedure would be a result of communication with relevant industry during the preparation of an Annex XV dossier and, in case the voluntary action by industry reduces the risks to an acceptable level, the MS would not anymore need to submit an Annex XV dossier to the Agency. If the consultation with industry or other information would show that a voluntary action is not feasible, effective, practical or monitorable, the MS can document these considerations in the Annex XV dossier justifying why a restriction under REACH is the most appropriate measure.

### Documentation

The identified RMOs need to be shortly described for further comparison with the proposed restriction. It is also useful to give an overview on how the possible RMOs would address the identified risks. Table 3 gives an example of possible way to present the RMOs.

**Table 2 Generic example of presentation of the applicability of the initial restriction and other considered RMOs to the identified risks**

| Use of the substance | Compartment/population at risk | Applicability of identified RMOs | | | | |
|---|---|---|---|---|---|---|
| | | Initial restriction | RMO 1 | RMO 2 | RMO 3 | RMO4 |
| **Use 1** | Endpoint 1 (e.g. aquatic environment) | ✓ | ✓ | ✓ | | |
| | Endpoint 2 (e.g. occupational exposure) | ✓ | | ✓ | ✓ | |
| **Use 2** | Endpoint 1 (e.g. aquatic environment) | ✓ | ✓ | ✓ | | |
| | Endpoint 2 (e.g. terrestrial environment) | ✓ | | ✓ | | ✓ |
| | Endpoint 3 (e.g. STP micro-organisms) | ✓ | | ✓ | | ✓ |
| **Use 3** | Endpoint 1 (e.g. aquatic environment) | ✓ | ✓ | ✓ | | |

### 5.4.5 Assessment of the proposed restriction

Annex XV gives three main criteria that are relevant for a restriction: effectiveness, practicality and monitorability. These three criteria are used for

- developing the restriction proposal: The three criteria guide how to define the scope and conditions of the initial restriction. Assessment of the initial restriction against the three criteria is used to reveal needs to and ways how to improve the initial restriction.
- the criteria guide the identification of possible other RMOs
- the final justification need to show that the proposed restriction is the most appropriate Community wide measure assessed against these criteria.

The other RMOs considered are used as a reference point for assessing whether the proposed restriction is the most appropriate Community-wide measure. In cases where the development of the restriction proposal and identification of other RMOs show that one or a combination of these other RMOs would be more appropriate than restriction under REACH, the Authority may wish to assess this/these other RMOs more closely to provide the relevant Commission service better basis for taking appropriate action.

The following chapters list factors that can be taken into account in the assessment. The level of detail and depth of the assessment as well as the weight the different factors deserve depend on the case. The Authority should include in the assessment a description and analysis of uncertainties related to the assessment.

The following chapters refer to the assessment of the initial restriction but the same considerations will also be relevant for the assessment of the proposed restriction and the considered other RMOs.

#### 5.4.5.1 Assessment of the effectiveness

Effectiveness criteria are further described in Annex XV: ‘the restriction must be targeted at the effects or exposures that cause the identified risks, capable of reducing these risks to an acceptable level within a reasonable period of time, and proportional to the risk’;

The assessment of the effectiveness needs to combine the two different aspects of the effectiveness: risk reduction capacity and proportionality of the initial restriction.

*Risk reduction capacity:*

- Does the initial restriction reduce the exposure to a level allowing adequate control of the identified risk?
- The assessment of the effect of the initial restriction on the exposure level related to the identified risk may vary from a statement based on a rough estimation to a calculation of the 'new' exposure situation according to guidance in chapter 5.2. For example, if the initial restriction prohibits a certain use but not all uses there may be a need to check that the regional concentration is reduced low enough.
- Do the alternatives required due to the initial restriction cause other risks to the human health or the environment?
- Based on the available information on alternatives (chapter 5.5) estimation of foreseeable risks to the human health and the environment.
- How long will it take before the initial restriction has reduced the exposure level to an acceptable level?
- What can be regarded as a reasonable period of time for reducing the exposure depends on the scale and severity of the risk.

*Proportionality:*

- Is the initial restriction targeted to the identified risk and does it not inadvertently affect uses or actors in the supply chain which are not associated with the identified risk?
- Do the efforts needed from the actors to implement and from the authorities to enforce the initial restriction correspond in amount or degree to the adverse effects that are being avoided;
- Does the initial restriction ensure a good balance between costs and benefits and is it cost-effective
- What is the length of time allowed for the actors to comply with the restriction?
- Depending on the availability of alternatives and actions needed to change to using them the time allowed for the actors to comply with the restriction may have a major effect on the costs of the restriction.
- Is the initial restriction consistent with legal requirements already in place;

In cases where the assessment of the risk reduction capacity concludes that the initial restriction does not ensure reduction of the exposure to a level that allows adequate control of identified risk in reasonable timeframe or that the initial restriction is not targeted to the identified risk, the Authority need to either change the scope or conditions of the restriction or check if other possible RMOs can address the risk. Also a combination of a restriction on certain uses and other RMOs addressing the remaining application may be a possibility. The Authority needs also to check that the measures taken by the industry to comply with the restriction will not cause equivalent or higher level of other risks.

In the same way, the assessment of proportionality may require refining the initial restriction or closer consideration of other RMOs.

Bringing these two aspects of the effectiveness of the initial restriction together may show that refining of and decision making on the restriction proposal would benefit from the SEA. Where the Authority finds that the uncertainties related to the assessment may have a major effect on the conclusions, the Authority may decide to generate more information or conduct an SEA to reduce uncertainties.

#### 5.4.5.2 Practicality

Annex XV defines that the practicality of the proposed restriction and of the other RMOs involves three aspects: implementability, enforceability and manageability

*Implementability*: the actors involved have to be capable in practise to comply with the initial restriction. To achieve this, the necessary technology, techniques and alternatives should be available and economically feasible within the timeframe set in the restriction

*Enforceability*: The authorities responsible for enforcement need to be able to check the compliance of relevant actors with the proposed restriction or other considered RMOs. The restriction should be drafted in a way that allows the enforcement authorities to set up an efficient supervision mechanism(s). The resources needed for enforcement have to be proportional to the avoided risk.

*Manageability*: the proposed restriction or other considered RMOs should be manageable (taking into account the characteristics of the sectors concerned, for instance, the number of SMEs) and understandable to affected parties; the means of its implementation should be clear to the actors involved and the enforcement authorities and access to the relevant information should be easy. Furthermore, the level of administrative burden for the actors concerned and for the authorities should be proportional to the risk avoided.

#### 5.4.5.3 Monitorability

According to Annex XV it must be possible to monitor the results of the implementation of the proposed restriction. Monitoring is here understood widely and may cover any means to follow up the effect of the proposed restriction in reducing the exposure. The most appropriate means of monitoring depend on the type of restriction and the related conditions. Such monitoring may include for example

- follow up of the amounts of substance manufactured and imported
- follow up of the amounts of substance used for different uses
- measuring of the concentration of the substance in preparations or articles
- measuring of the relevant emission and/or exposure levels
- follow up of the measures taken to reduce the exposure levels in accordance with conditions set in the restriction

To assess the monitorability of the initial and final proposed restriction and of the other RMOs considered the Authority should outline a monitoring proposal. Such a proposal should include the indicators that need to be monitored, the stakeholders to be involved in the monitoring activities, the scope and location of monitoring and the frequency of monitoring.

Factors to be considered when assessing the monitorability of the initial restriction include:

- Availability of indicators: are there indicators to monitor the results of the restriction that are feasible and allow sufficiently accurate monitoring of the results (for instance, is it possible to practically monitor the concentration of the substance in articles imported into the Community or the implementation of a restriction in an Industry sector with a large number of SMEs? Or, are the available (preferably standardised) scientific methods suitable for reliably measuring the concentration and fate of the substance in the environment?);
- Ease of monitoring: the cost and the proportionality of the distribution of the administrative burden for those responsible for the monitoring activities; the monitoring of the proposed

restriction or other considered RMOs should be easy to set up and administer and its cost and administrative burden should be proportional to the risk avoided

- Availability of monitoring mechanisms: consistency with the existing monitoring responsibilities of the authorities and actors involved; are the current monitoring mechanisms suitable for the monitoring or can they easily be adapted to cover the proposed restriction or other considered RMOs?

The overall assessment of the monitorability should answer the question of whether the outlined monitoring system allows to observe if the risk reduction targets have been achieved with proportionate resources?

#### 5.4.5.4 Overall assessment of the proposed restriction and comparison to other RMOs

The Assessment of the initial restriction against the three criteria is used to refine the restriction and find out if there is a need to consider other RMOs more closely. When the assessment concludes that the initial restriction can not anymore be refined the Authority needs to combine the separate assessments against the three criteria to an overall assessment of the proposed restriction.

This overall assessment need to take into account the uncertainties related to the assessment against the individual criteria and related to combining them. This overall assessment and the related uncertainties may reveal that conducting an SEA would be useful for further refinement of the restriction proposal or for the decision making purposes.

The overall assessment of the proposed restriction needs to be compared to the considered other RMOs. This comparison will provide a justification that the proposed restriction is the most appropriate Community wide measure. The presentation of the results of the overall assessments and the comparison is important especially when several options have been identified as potentially suitable for the management of the identified risk. The presentation should aim to provide a clear illustration of the strong and weak points of each option and to rank the options against the key criteria. Such a table may be included in *Section 15* of the *Justification for proposed restrictions*.

Table 4 presents an example of how the comparison of the proposed restriction and considered other RMOs can be summarised. The Authority may choose how to score the identified options against the criteria; this could be by using ‘pluses’ and ‘minuses’ or terms such as ‘low-medium-high’ or any other qualitative or semi-quantitative indicators.

**Table 3 E**xample o**f an assessment matrix of the proposed restriction and considered other RMOs against the three key criteria**

| Criterion | Parameter | Proposed restriction | RMO 1 | RMO 2 | RMO 3 |
|---|---|---|---|---|---|
| **Effectiveness** | Risk reduction capacity | | | | |
| | Proportionality | | | | |
| | **Overall** | | | | |
| **Practicality** | Implementability | | | | |
| | Enforceability | | | | |
| | Manageability | | | | |
| | **Overall** | | | | |
| **Monitorability** | Availability of indicators | | | | |
| | Ease of monitoring | | | | |
| | Availability of monitoring mechanisms | | | | |
| | **Overall** | | | | |

If the comparison of the proposed restriction against other possible Community level RMOs shows that a measure under another legislation is more appropriate way of addressing the risk than a restriction under REACH the Authority is requested to document the assessment and this conclusion in the relevant parts of the restriction format and submit this documentation to the Agency. It should be noted that this conclusion can be achieved already earlier in the process, for instance, when assessing the sources of emissions and exposure as in example 6

**Example 6** Example of the referral of a substance to another legislative framework

Due to the high volume of Substance I used in the EU and monitoring data indicating a risk, the Agency on request by the Commission started developing an Annex XV dossier. During the development of a restriction dossier, it was concluded that the only significant release of Substance I is due to the breakdown of one of its precursors, Substance J. In fact, an environmental risk arises from several precursors to Substance I but the production of these precursors has decreased significantly and the main risk remaining is caused by the use of Substance J as a herbicide.

Substance J is being dealt through other legislative measures i.e. the Biocidal Products Directive and the Plant Protection Products directive. As a result, no restriction dossier is to be developed for this particular risk from Substance I and the documentation of risk should be referred to the Commission services responsible for the implementation of the two aforementioned Directives.

### 5.4.6 Documenting the proposed restriction and the justification

The proposed restriction is documented in the *Proposal* part of the Annex XV restriction report. The proposal for a restriction needs to specify the scope of the restriction: what are the uses covered by the proposed restriction and any general or use specific conditions. Conditions may include for instance concentration limits, conditional or unconditional derogations, timeframes for the implementation or other aspects defining the exact boundaries and ways of implementing the restriction.

The justification that the proposed restriction is the most appropriate Community wide measure will be included in *section 15 of the justification* part of the restriction report (APPENDIX I).

## 5.5 Information on alternatives

### 5.5.1 Overview of the task

**Aim:** Annex XV requires the Authority to document the available information on alternative substances and techniques in the restriction proposal.

The aim is to provide information for the analysis of whether the equivalent function provided by the substance can be obtained by other substances or techniques and for assessing the net impact of the proposed restriction to the human health and the environment. This will facilitate in defining a proportionate restriction that is targeted to the identified risk.

**Scope:** The term 'alternative' is used in this guidance to mean alternative chemical substances or alternative techniques (processes and technologies) or combinations thereof that can be used to replace (partially or totally) the substance of concern in a given use or a number of uses by providing the equivalent function that the substance delivers in those uses or by making the function redundant.

Available information on alternatives may cover any information relevant for developing the restriction proposal, for its later assessment by the Agency and for the decision making by the Commission, including

- information on the risks to human health and the environment related to the manufacture or use of the alternatives; and
- technical and economical feasibility, availability, including the time scale.

The depth of the analysis of alternatives beyond documenting what is readily available will rely on the decision of the Authority. The Authority should take a flexible approach so that the time and effort allocated to the assessment of alternatives is proportional to the needs of each case.

**Outcome:** Information on alternatives is used when refining the restriction proposal. It is used in developing the justification that the proposed restriction is the most appropriate Community wide measure especially when assessing the effectiveness and practicality of the proposed restriction (ref Chapter 5.4.5). Furthermore, the information can be used if the Authority decides to develop a socio-economic analysis or interested parties submit input to one.

In addition, the available information on alternatives needs to be documented in the restriction report sections 11 to 13.

### 5.5.2 Information sources

The information sources on the risks for human health and the environment related to alternative substances are the same as described in chapter 4. Consultation with stakeholders (see Chapter 4.2.2), literature, statistics and experience from the implementation of other legislation are the main information sources for other aspects on alternatives: availability, technical and economical feasibility of alternatives and risks to human health and environment related to alternative techniques.

Consultation with Industry stakeholders and other experts could be particularly relevant in the assessment of the availability and technical and economical feasibility of alternative substances and techniques. Downstream users (associations or individual companies), in particular, who know the technical requirements of their process and products and have a vested interest in using the best raw materials and techniques, may provide useful information. Other possible consultees include manufacturers and importers (associations or individual companies) of alternative substances and techniques, MS authorities having experience on using alternatives e.g., from the implementation of other legislation and research organisations.

The Authority should scrutinise any information made available from consultees taking into consideration the consultees' vested interests, the business relationships between organisations holding similar or opposite views on restrictions and alternatives, and the scientific robustness of the submitted information. The Authority should present in the *Information on stakeholder consultation* part of the restriction report what information was supplied by whom and how this has been used to ensure the transparency of the analysis. Any uncertainties on or assessment of the quality or completeness of the information submitted by stakeholder may also be discussed therein.

### 5.5.3 Issues to be considered

The guidance on developing an socio-economic analysis (SEA) and the guidance on preparing an authorisation application will also contain guidance relevant for identification and analysis of alternatives. The references will be added, where necessary, when these other parts of the guidance package are available.

**Description of the use and function of the substance**

Information on and assessment of risk(s) (chapter 5.2) provides a list of uses that cause a risk to human health or the environment. For the purpose of collecting available information on alternatives a description of uses should be completed by a description of the technical or other functions provided by the substance in these uses. Furthermore, an explanation why these functions are needed may be useful. This is essential to ensure that the identification of alternatives is based on a sound understanding of the role played by the substance in the production process and final products. The function that a substance serves may be due to its mechanical, physical or chemical properties, and the substance may act as an input to production, i.e. a raw material, or as a processing aid. In some cases, a substance may be used for environmental or health and safety reasons. The different functions provided by a substance should be described in terms of their:

- technical and processing related role – what are the specific technical performance requirements for the function;
- quality, durability or end product performance related role; and
- economic importance in terms of reduced costs.

For different functions, data on the associated quantity of the substance used and on trends in use would be useful for assessment of future availability of alternatives. If possible to obtain information on the number of companies using the substance, on their size (turnover and number of employees) and on their locations would further complete the picture.

#### 5.5.3.1 Identification of alternatives fulfilling the function(s)

Once the functions provided by a substance have been described, alternative substances and techniques that meet the equivalent function or make the original function redundant, i.e. **alternatives that are technically feasible**, can be more easily identified.

Substitute substances or processes that are already being used by some companies are usually selected for further assessment because they provide an obvious starting point against which the risk, performance and cost of other alternatives can be compared. However, more innovative alternatives can also be considered. For example, one may wish to consider other alternatives such as new technologies involving product re-design (e.g. provision of a powder in a solid or liquid form) and/or changes in processes (e.g. adoption of metal working techniques that require no lubricants).

Questions to be considered when collecting information include

- For which of the uses of concern the alternative is technically feasible? What are the uncertainties related to the technical feasibility (e.g., only laboratory / pilot plant scale evidence of the functioning, used in other process but under different conditions (pH, temperature…) etc)
- Whether or not adoption of the alternative substance would require changes in any of the processing systems associated with the chemical of concern? Is research and development necessary in order to move to the alternative? Would training of users be required?
- Would the use of alternative technique result in complete or partial replacement of the substance in the uses of concern? What research and development is necessary in order to apply the alternative technique? Would training of users be required?

#### 5.5.3.2 Assessment of availability of alternatives

An important issue in identifying the availability of alternatives is timing: alternative substances may not be available immediately or they may not be available in the required tonnages but could become available at some point in the future. To assess this, knowledge of the relevant markets and the current trends and research within them would be useful. It would also be useful to consider any experience with the use of alternatives within or outside the Community. On alternative techniques the same basic consideration applies: is the necessary equipment already available in market in sufficient quantities.

The time needed to invest, install and take into operation alternative techniques should be considered. This applies also to alternative substances that need changes in processes or equipment.

There is a reciprocal relationship between a proposed restriction and the availability of alternative substances and processes: limited availability of alternatives may limit the choices for restrictions but, at the same time, a restriction may affect the (future) availability of alternatives. The Authority may use the available information to make assumptions on the time that may be required for the alternatives to become available and, based on these assumptions, to consider the need and conditions of a time-limited derogation for one or more uses

Questions to be considered when collecting information include

- What tonnages of alternative substance would be required?
- At what tonnage are they currently used in the EU / worldwide, what are the trends in manufacture and uses?
- What is needed to change to the alternative techniques? Is there knowledge on the suitability and availability of e.g. equipment or raw materials required to transfer to the alternatives?
- Is there need for further research and development?
- What is the timeframe for investing to, installing and taking to operation the necessary equipment?

Experience suggests that even with the alternative substances and/or technologies already known, it may take up considerable time to carry out the quality and performance tests. Examples in the box below illustrate this:

- Sometimes years of continuous development are needed to bring alternatives with an equal and comparable performance to existing formulations on the market (e.g. surfactant formulations).
- for certain uses some alternatives exist but that a significant period of time for research would be needed for alternatives to be made available at the industrial scale (e.g. additives in the rubber industry).
- Similarly, no alternatives for certain substances in aviation hydraulic fluids are available at present. According to industry sources, there have been many attempts to find alternatives for certain substances.
- Even with the alternative substances and/or technologies already known, it may easily take up more than 3 years for users to carry out the quality and performance tests. In other cases the alternatives might be already available but the approval procedure required by other specific pieces of legislation for the alternative, introduces a further delay into the process.

**Example 7** Variable availability of alternatives when more than one uses require risk management action

Substance K is used in a variety of uses. Those of interest include: (a) mist suppressant in the metal finishing sector; (b) component in surfactant formulations; (c) chemical agent in several uses in the rubber industry; (d) chemical agent in the semiconductors industry; and (e) chemical component of aviation hydraulic fluids.

Information received through consultation suggests that there are currently no known alternative chemical mist suppressants to Substance K for the metal finishing sector; previous generations of chemical mist suppressants having failed due to excessive pitting of coatings and rapid breakdown during electrolysis. However, this does not necessarily mean that Substance K cannot be replaced. Consultation and literature review has suggested that its use may not be necessary if the chemical that produces the mist which poses occupational health risks is replaced. Substitution of the mist-prone chemicals would result not only in the reduction of the likely health risks but may result also in significant cost savings. However, it appears that suitable alternatives for the chemical that tends to create hazardous mists may not be available for all metal finishing processes.

With regard to surfactant formulations, as a result of many years of continuous development, alternatives to Substance K have been indicated as providing an equal and comparable performance to formulations based on Substance K.

For the rubber industry, alternatives to Substance K on an Industry-wide basis (or even an enterprise-wide basis at the research scale) are not currently available, although efforts are reportedly being made. Consultation has suggested that replacement efforts have resulted in an 83% decrease in the total amount of Substance K used in synthetic rubber products since 2000.

For the semiconductors industry, suitable alternatives are not currently available; for certain uses, some alternatives do exist but work on these is still ongoing. Industry sources have suggested that at least five years of research would be necessary for alternatives to be made available at the industrial scale.

Similarly, no alternatives for aviation hydraulic fluids are available at present. According to industry sources, there have been attempts over the last 30 years to find acceptable alternatives to Substance K. There are currently no promising leads for a substitute for Substance K now in use, and there are no assurances that an acceptable alternative will be identified in the short or longer term.

From the above, it can be concluded that the approach to different uses of the substance cannot be uniform. The Authority should consider whether derogations should be introduced for certain metal finishing applications and for the use of Substance K in the rubber, semiconductor and aviation industries. Time-limited derogations could be a suitable option, especially in the rubber and semiconductor industries where the availability of alternatives may change in the bear future.

**Assessment of human health and environmental risks related to the alternatives**

This assessment of risks related to the alternatives has a comparative nature. It should document whether the transfer to alternative substance or technique would result in reduced overall risks to human health and the environment. It is therefore important not only to consider the risks that are considered unacceptable and resulted in developing the restriction proposal, but alsopossible other risks resulting from the alternative. The aim is to assess the effects of the adoption of alternatives in

- reducing the identified risk (it does not contribute to the identified risk at the same or higher level)
- causing other risks that can not be adequately 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 alternatives to determine whether they would result in a lower level of risk;
- examining information on environmental concentrations of the substitutes and data on current levels of exposure from publicly available sources or impacts associated with alternative options; and
- if appropriate, quantifying and valuing the change in risk following the approach set out above for the substance of concern.

It would obviously not be appropriate to require that the risks associated with alternative substances or techniques are assessed in the same detail as the risks associated with the substance of concern. The level of effort that is to be put into this aspect above the documentation of available information will be a matter of judgment and up to the Authority. For example, the simple comparison of hazard profiles may indicate that alternative chemicals 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 the appropriate parts of chapter 5.2 of this guidance and the guidance on preparing chemical safety assessment. Appendix VIincludes considerations on the assessment of alternative substance and illustrates a tiered approach for an assessment.

**Assessment of economical feasibility of alternatives**

The authority is requested to document the available information on the economical feasibility of the alternatives. That could include for the main alternatives, if data are available:

1. Describe the net compliance and other costs (taking into account both increases and decreases in costs) faced by actors in each link of the supply chain;
2. Assess financial viability and the ability of the different actors to pass costs down the supply chain; and
3. Where impacts on competitiveness are likely to be significant at the sectoral level, consider trade and wider economic and employment effects.

### 5.5.4 Reporting the information on alternatives

The available information on alternatives needs to be documented in the sections 11 to 13 of the restriction report. It would be useful to summarise the available information on alternatives as an overall assessment. This should give for alternatives that are technically feasible and which deliver the same functionality as the substance of concern an overview of the knowledge on the risks to human health and the environment and on the economic feasibility.

The Authority may consider summarising the available information in tables such as Table 5.

**Table 4 Example of a table for the evaluation of potential alternative substances [*substance name*] in [*use*]**

| Parameter | | Questions to be answered | Alt 1 | Alt 2 | Alt 3 |
|---|---|---|---|---|---|
| **Technical feasibility** | | Can it perform the same functions as the substance in question? | | | |
| | | Will it require changes (in processes, equipment, storage facilities, training, etc.)? | | | |
| **Availability** | Current and future availability | Is it available in the required tonnage / amount in the EU / worldwide? | | | |
| | Timeframe | How fast could enterprises make the switch? What would be the downtime, if any? | | | |
| **Risk assessment** | Human health | Information on the hazards: properties causing the concern for the substance to be restricted / other properties | | | |
| | | Information on risks related to properties causing the concern for the substance to be restricted / other properties. Information on other risks related to the alternatives. | | | |
| | Risk to the environment | Information on the hazards: properties causing the concern for the substance to be restricted / other properties | | | |
| | | Information on risks related to properties causing the concern for the substance to be restricted / other properties. Information on other risks related to the alternatives. | | | |
| | Assessment of net risk | Would the alternative result in a sufficient reduction in the net risk? Are there new risks associated with the alternative? | | | |
| **Economic feasibility** | Net costs | Net compliance and other costs (taking into account both increases and decreases in costs) faced by actors in each link of the supply chain | | | |
| | | Financial viability of the alternatives | | | |
| | | Ability of the different actors to pass costs down the supply chain | | | |
| | | Trade and wider economic and employment effects | | | |
| Uncertainties. What is the level of uncertainty in the assessment of the feasibility, risks and economic viability of alternatives? | | | | | |

Note: The analysis presented in the *Information on alternatives* could be summarised in this table with the use of crosses and minuses or 'low-medium-high' or, in the case of costs and benefits, by providing the estimated monetary costs and benefits for each alternative, if this information is available. For the assessment of the overall uncertainty, 'low-medium-high' indications may be provided for each alternative; a detailed discussion on uncertainty in the main text should also be provided.

## 5.6 Socio-economic assessment

**Aim:**

Annex XV invites the Authority preparing a restriction proposal to analyse the socio-economic impacts of the proposed restriction.

The aim of an SEA is to facilitate the Authority in preparing a proportional and well informed restriction proposal. Furthermore, an SEA included in Annex XV dossier is valuable for the SEA Committee when it gives its opinion on the proposal and for the Commission taking the decision.

**Scope:**

An SEA aims at assessing the proposed restriction in terms of

- the net benefits to human health and the environment and
- the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

'Net benefits' above should take into account reduced risk due to restriction and possible risks caused by the transfer to alternatives. Similarly, 'net costs' should take into account both costs to actors due to restriction and possible cost savings caused by the transfer to alternatives.

It would be useful if an SEA prepared covered all relevant aspects effecting the benefits gained by introducing the proposed restriction and costs caused by it. However, as there is no legal requirement to produce an SEA the Authorities are encouraged to include in the restriction proposal any relevant parts of SEA or inputs to one in absence of full SEA. In any case it is crucial to document clearly which aspects have been covered.

The methods to be used when developing SEAs for restriction proposals are described in the Guidance on Socio Economic Analysis.

**Outcome:**

SEA is used when refining the restriction proposal. It is used in developing the justification that the proposed restriction is the most appropriate Community wide measure especially when assessing the effectiveness and practicality of the proposed restriction (ref chapter 5.4).

Furthermore, an SEA or inputs to one will be documented in 'socio-economic analysis' section of the restriction report.

### 5.6.1 The importance of socio-economic analyses in the preparation of restriction dossiers

Although an SEA is not a mandatory part of a restriction proposal, Authorities may wish to prepare one as an SEA:

- helps in ensuring that the restriction proposal is proportional and well-informed
- facilitates the assessment of the effectiveness and practicality of the proposed restriction

- provides a good basis for the SEA Committee to prepare its opinion on the proposal and for the Commission to take the decision; and
- provides a valuable mechanism for involving stakeholders in the decision-making process and developing a shared understanding of the implications of imposing a restriction (or other legal requirements or of taking no action).

Interested parties are able to comment the Annex XV dossier and the proposed restriction, as well as submit full SEAs, or inputs to one, to the SEA Committee. It will be up to the SEA Committee to balance in its opinion the inputs received from such parties with the information provided by the Authority. Thus, preparation of an SEA by the Authority during the restriction procedure can help ensure that the Authority's arguments on the justification for the proposed restriction are given due weight in the overall decision-making process.

### 5.6.2 Incorporation of the findings of an SEA into the Annex XV restriction report

The process of preparing an SEA will bring together information from several of the other components of the restriction procedure and, in turn, will provide inputs to an Annex XV restriction report. This is illustrated in Figure 6.

Information that may feed from the development of other parts of the Annex XV restriction report into the SEA process includes:

- description of the type and magnitude of risk
- information on the Industry sectors and uses associated with unacceptable risks (from the risk assessment and risk characterisation);
- information on existing legal requirements (ELRs) and on the effectiveness of implemented exposure scenarios (OCs and RMMs);
- description of the proposed restriction and information on possible other risk management options (RMOs) and appropriate legislative frameworks for their implementation;
- description of the remaining (and possible new) risks when the proposed restriction or the possible other RMOs are in place
- information on the availability, risks and feasibility of alternative substances and techniques.

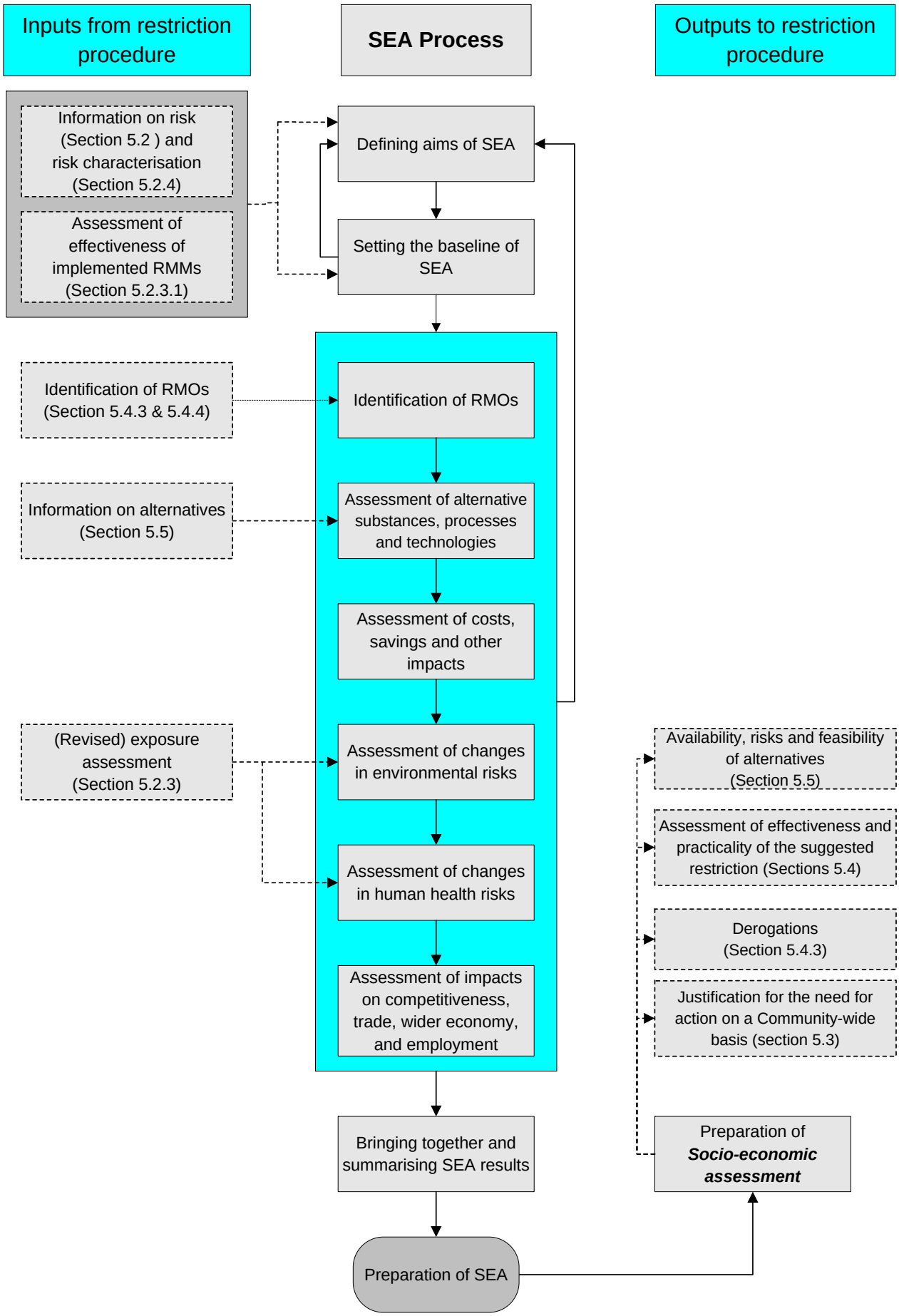
The SEA process should build on such data but may also involve the collection of additional data from manufacturers, importers and downstream users submitting information through consultation (for instance, information on current markets for the substance and its products, expected trends in usage, innovations or technical developments within the sectors of concern, etc.). The analysis of this information will result in the development of the SEA document the results of which will be summarised in the *Socio-economic assessment* part of the Annex XV report. However, the SEA findings should not be used in isolation to the remainder of the restrictions report but rather feed into several other parts of the report under preparation, such as:

- the identification of RMOs, which may benefit from any additional information to be made available to the Authority through consultation for the SEA;
- the assessment of alternatives, which may benefit from any additional information on the availability of alternatives as well as the assessment of their economic feasibility;
- the assessment of the effectiveness and practicality of the proposed restriction and their comparison to other RMOs, which may benefit from any additional information alternatives and from the assessment of costs, savings and other impacts under different RMOs;

- the refinement of an initial restriction proposal by identification which uses / manufacturing / marketing should be restricted and under which conditions to ensure a proportional restriction that is targeted to the identified risks, which may benefit from the analysis of alternatives and the assessment of costs, savings and other impacts for different RMO within the SEA; and
- the overall assessment of advantages and drawbacks and the market-related considerations for the proposed restriction, which may benefit from the general analysis and conclusions of the SEA and, particularly, the analysis of potential market harmonisation issues.

The Guidance on Socio Economic Analysis provides more detail on the incorporation of the findings of an SEA into an Annex XV restriction report.

**Figure 6** Links between SEA and the preparation of an Annex XV restriction report



### 5.6.3 Socio-economic considerations in the absence of an SEA

Since an SEA is not a compulsory component of the restriction procedure, it is possible that it may not be undertaken during the preparation of an Annex XV restriction report. In the absence of a full SEA, the Authority may wish to consider some of the key elements of an SEA to support its arguments in the Annex XV restriction report. Such elements could be:

- the prevailing trends in the manufacture, marketing and use of the substance in the EU;
- the costs of alternatives, the benefits and risks arising from their use and any impacts from their use on product quality or availability; and
- a discussion on the importance of the substance to enterprises and Industry sectors of concern

These key elements may be further supported by additional analysis on more complex issues such as:

- a discussion on how innovation and technological development may affect future use of the substance;
- a discussion of the comparison of the costs of the restriction to the benefits; and
- a discussion on uncertainty in cost estimates.

The need for and the level of detail of the discussion on the above issues will be influenced by the characteristics of risk, the range of available RMOs and any constraints on time and resources.

## 5.7 Information on stakeholder consultation

Annex XV requires the Authority to document any consultation of stakeholders and how their views have been taken into account. The Annex XV report should describe:

- who has been consulted
- what information has been asked for, how the consultation was carried out and when in the process of preparing an Annex XV report
- how the information has been taken into account in preparing the Annex XV dossier
- if the information was not taken into account, the main reasons for that

The information obtained from the stakeholder consultation should be reported in a transparent way. The report should include an overview of the evaluation of the uncertainties related to the information and the subsequent assumptions made. These assumptions, conclusions and all decisions should be open to review.

# 6 REFERENCES

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, P196, 16.8.1967, p 0001-0098.

Council of the European Union (2006). Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regualtion (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 2001/21/EC. Council of the European Union, 12 June 2006, Brussels.

OECD (2005). Manual for Investigation of HPV Chemicals. Chapter 3.2. Guidance on the Development and Use of Chemical Categories in the HPV Chemicals Programme. Organisation for Economic Co-Operation and Development (available from: http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html).

UNECE (2005). Globally Harmonized System of Classification and Labelling of Chemicals (GHS). First Revised Edition. United Nations Economic Commission for Europe (available from http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html).

# 7 GLOSSARY AND ABBREVIATIONS

| | |
|---|---|
| Annex XV dossier | A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report. |
| Annex XV report | A report produced as part of the Annex XV dossier according to the guidance and format outlined in this document. |
| BCF | Bioconcentration factor. |
| CAS number | Chemical Abstracts Service registry number |
| CMR | Carcinogenic, mutagenic and toxic to reproduction. |
| CSA | Chemical safety assessment. |
| CSR | Chemical safety report. |
| DMEL | Derived minimum effect level |
| DNEL | Derived no effect level |
| Downstream user | Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. Art 3(13) of REACH Regulaion |
| ELR | Existing Legal Requirement (see Section 5.1.3) |
| Exposure scenario | The set of conditions, including opearional 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. Art 3(37) of the REACH Regulation |
| Full study report | A complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed. Art 3(27) of REACH Regulation |
| IARC | International Agency for Research on Cancer |
| Intermediate | A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. *(continues)* Art 3(15) of REACH Regulation |
| IPCS | International Programme on Chemical Safety |
| IUCLID | The database underlying the REACH-IT system. |

| | |
|---|---|
| Log Kow | The $\log_{10}$ value of the octanol-water partition coefficient. Also often referred to as log P. |
| Manufacturer | Any natural or legal person established within the Community who manufactures a substance within the Community. Art 3(9) of REACH Regulation |
| NOEC | No observed effect concentration. |
| OECD | Organisation for Economic Co-operation and Development |
| PBT | A persistent, bioaccumulative and toxic as defined in Annex XIII. |
| PNEC | Predicted no effect concentration. |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| POP | Persistent organic pollutant. |
| REACH-IT | The information technology (IT) system for creating and administering documentation under REACH. |
| Restriction | Any condition for or prohibition of the manufacture, use or placing on the market. Art 3(31) of REACH Regulation |
| RMM(s) | Risk management measure(s) (see Chapter 5.1.3). |
| RMO(s) | Risk management option(s) (see Chapter 5.1.3). |
| Robust study summary | A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Art 3(28) of REACH Regulation |
| Study summary | A summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study. Art 3(29) of REACH Regulation |
| Substance | A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. Art 3(1) of REACH Regulation |
| vPvB | Very persistent and very bioaccumulative as defined in Annex XIII. |

## APPENDIX I FORMAT FOR RESTRICTION REPORT

# Annex XV dossier

# RESTRICTION PROPOSAL

**Substance Name:**

**EC Number:**

**CAS Number:**

**Submitted by:**

**Version**

# RESTRICTION PROPOSAL

**Substance Name:**

**EC Number:**

**CAS number:**

**Restriction proposal:**

# INFORMATION ON HAZARD AND RISKS

## 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

### 1.1 Name and other identifier of the substance

Chemical Name:
EC Number:
CAS Number:
IUPAC Name:

### 1.2 Composition of the substance

*For each constituent/ impurity/ additive, fill in the following table (which should be repeated in case of more than one constituent). The information is particularly important for the main constituent(s) and for the constituents (or impurity) which influence the outcome of the dossier.*

Chemical Name:
EC Number:
CAS Number:
IUPAC Name:
Molecular Formula:
Structural Formula:
Molecular Weight:
Typical proportion %

Real proportion (range) in %

## 1.3 Physico-Chemical properties

**Table 1** Summary of physico-chemical properties

| REACH ref Annex, § | Property | IUCLID section | Value | [enter comment/reference or delete column] |
|---|---|---|---|---|
| VII, 7.1 | Physical state at 20°C and 101.3 KPa | 3.1 | | |
| VII, 7.2 | Melting/freezing point | 3.2 | | |
| VII, 7.3 | Boiling point | 3.3 | | |
| VII, 7.4 | Relative density | 3.4 density | | |
| VII, 7.5 | Vapour pressure | 3.6 | | |
| VII, 7.6 | Surface tension | 3.10 | | |
| VII, 7.7 | Water solubility | 3.8 | | |
| VII, 7.8 | Partition coefficient n-octanol/water (log value) | 3.7 partition coefficient | | |
| VII, 7.9 | Flash point | 3.11 | | |
| VII, 7.10 | Flammability | 3.13 | | |
| VII, 7.11 | Explosive properties | 3.14 | | |
| VII, 7.12 | Self-ignition temperature | | | |
| VII, 7.13 | Oxidising properties | 3.15 | | |
| VII, 7.14 | Granulometry | 3.5 | | |
| XI, 7.15 | Stability in organic solvents and identity of relevant degradation products | 3.17 | | |
| XI, 7.16 | Dissociation constant | 3.21 | | |
| XI, 7.17, | Viscosity | 3.22 | | |
| | Auto flammability | 3.12 | | |
| | Reactivity towards container material | 3.18 | | |
| | Thermal stability | 3.19 | | |
| | [enter other property or delete row] | | | |

# 2 MANUFACTURE AND USES

## 2.1 Manufacture

## 2.2 Identified uses

## 3.3 Uses advised against

# 3 CLASSIFICATION AND LABELLING

## 3.1 Classification in Annex I of Directive 67/548/EEC

## 3.2 Classification according to GHS

## 3.3 Self classification(s)

*This should include the classification, the labelling and the specific concentrations limits. The reason and justification for no classification should be reported here.*

*It should be stated whether the classification is made according to Directive 67/548/EEC criteria or according to GHS criteria*

# 4 ENVIRONMENTAL FATE PROPERTIES

## 4.1 Degradation

### 4.1.1 Stability

*Corresponds to IUCLID 4.1*

### 4.1.2 Biodegradation

#### 4.1.2.1 Biodegradation estimation

#### 4.1.2.2 Screening tests

#### 4.1.2.3 Simulation tests

### 4.1.3 Summary and discussion of persistence

## 4.2 Environmental distribution

### 4.2.1 Adsorption/desorption

*Corresponds to IUCLID 4.4.1*

### 4.2.2 Volatilisation

*Corresponds to IUCLID 4.4.2*

### 4.2.3 Distribution modelling

## 4.3 Bioaccumulation

### 4.3.1 Aquatic bioaccumulation

#### 4.3.1.1 Bioaccumulation estimation

*e.g. use of Kow, predicted BCF*

#### 4.3.1.2 Measured bioaccumulation data

### 4.3.2 Terrestrial bioaccumulation

### 4.3.3 Summary and discussion of bioaccumulation

## 4.4 Secondary poisoning

*Assessment of the potential for secondary poisoning*

# 5 HUMAN HEALTH HAZARD ASSESSMENT

## 5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

## 5.2 Acute toxicity

### 5.2.1 Acute toxicity: oral

### 5.2.2 Acute toxicity: inhalation

### 5.2.3 Acute toxicity: dermal

### 5.2.4 Acute toxicity: other routes

### 5.2.5 Summary and discussion of acute toxicity

*C&L including weight-of-evidence considerations.*

## 5.3 Irritation

### 5.3.1 Skin

### 5.3.2 Eye

### 5.3.3 Respiratory tract

### 5.3.4 Summary and discussion of irritation

*C&L including weight-of-evidence considerations.*

## 5.4 Corrosivity

## 5.5 Sensitisation

### 5.5.1 Skin

### 5.5.2 Respiratory system

### 5.5.3 Summary and discussion of sensitisation

*C&L including weight-of-evidence considerations.*

## 5.6 Repeated dose toxicity

### 5.6.1 Repeated dose toxicity: oral

### 5.6.2 Repeated dose toxicity: inhalation

### 5.6.3 Repeated dose toxicity: dermal

### 5.6.4 Other relevant information

### 5.6.5 Summary and discussion of repeated dose toxicity

*Classification &Labelling, dose-response estimation including weight-of-evidence considerations.*

## 5.7 Mutagenicity

### 5.7.1 *In vitro* data

### 5.7.2 *In vivo* data

### 5.7.3 Human data

### 5.7.4 Other relevant information

### 5.7.5 Summary and discussion of mutagenicity

*Classification &Labelling, dose-response estimation including weight-of-evidence considerations.*

## 5.8 Carcinogenicity

### 5.8.1 Carcinogenicity: oral

### 5.8.2 Carcinogenicity: inhalation

### 5.8.3 Carcinogenicity: dermal

### 5.8.4 Carcinogenicity: human data

### 5.8.5 Other relevant information

### 5.8.6 Summary and discussion of carcinogenicity

*Classification & Labelling, dose-response estimation including weight-of-evidence considerations.*

## 5.9 Toxicity for reproduction

### 5.9.1 Effects on fertility

### 5.9.2 Developmental toxicity

### 5.9.3 Human data

### 5.9.4 Other relevant information

### 5.9.5 Summary and discussion of reproductive toxicity

*Classification & Labelling, dose-response estimation including weight-of-evidence considerations.*

## 5.10 Other effects

## 5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

### 5.11.1 Overview of typical dose descriptors for all endpoints

### 5.11.2 Correction of dose descriptors if needed (for example route-to-route extrapolation)

### 5.11.3 Application of assessment factors

### 5.11.4 Selection / identification of the critical DNEL(s) / the leading health effect

# 6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

## 6.1 Explosivity

*Including C&L*

## 6.2 Flammability

*Including C&L*

## 6.3 Oxidising potential

*Including C&L*

# 7 ENVIRONMENTAL HAZARD ASSESSMENT

## 7.1 Aquatic compartment (including sediment)

### 7.1.1 Toxicity test results

#### 7.1.1.1 Fish

Short-term toxicity to fish

Long-term toxicity to fish

#### 7.1.1.2 Aquatic invertebrates

Short-term toxicity to aquatic invertebrates

Long-term toxicity to aquatic invertebrates

#### 7.1.1.3 Algae and aquatic plants

#### 7.1.1.4 Sediment organisms

#### 7.1.1.5 Other aquatic organisms

### 7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

#### 7.1.2.1 PNEC water

#### 7.1.2.2 PNEC sediment

## 7.2 Terrestrial compartment

### 7.2.1 Toxicity test results

#### 7.2.1.1 Toxicity to soil macroorganisms

#### 7.2.1.2 Toxicity to terrestrial plants

#### 7.2.1.3 Toxicity to soil microorganisms

#### 7.2.1.4 Toxicity to other terrestrial organisms

Toxicity to birds

Toxicity to other above ground organisms

### 7.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

## 7.3 Atmospheric compartment

## 7.4 Microbiological activity in sewage treatment systems

### 7.4.1 Toxicity to aquatic microorganisms

### 7.4.2 PNEC for sewage treatment plant

## 7.5 Calculation of Predicted No Effect Concentration for secondary poisoning (PNEC oral)

## 7.6 Conclusion on the environmental classification and labelling

# 8 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

## 8.1 Comparison with criteria from Annex XIII

## 8.2 Assessment of substances of an equivalent level of concern

## 8.3 Emission characterisation

## 8.4 Conclusion of PBT and vPvB or equivalent level of concern assessment

# 9 EXPOSURE ASSESSMENT

## 9.1 General discussion on releases and exposure

### 9.1.1 Summary of the existing legal requirements

### 9.1.2 Summary of the effectiveness of the implemented risk management measures

## 9.2 Manufacturing

### 9.2.1 Occupational exposure

### 9.2.2 Environmental release

## 9.3 "Use 1"

*For each use include such a sub-chapter. Subsequently, if there is another "Use 2" this will lead to sub-chapter 9.4 "Use 1" including 9.4.1 Human exposure, 9.4.1.1 Occupational exposure, 7.4.1.2 Consumer exposure and 9.4.2 Environmental release. The other sub-chapters will then be renumbered.*

### 9.3.1 Human exposure

#### 9.3.1.1 Occupational exposure

#### 9.3.1.2 Consumer exposure

### 9.3.2 Environmental release

## 9.4 Other sources (for example natural sources)

### 9.4.1 Human exposure

#### 9.4.1.1 Occupational exposure

#### 9.4.1.2 Consumer exposure

### 9.4.2 Environmental release

## 9.5 Environmental exposure assessment

### 9.5.1 Summary of emissions

### 9.5.2 Predicted environmental concentrations

#### 9.5.2.1 Regional concentrationsAtmosphere

Aquatic compartment

Sediment

Soil compartment

#### 9.5.2.1 Local concentrations

Atmosphere

Aquatic compartment

Sediment

Soil compartment

#### 9.5.2.3 Exposure concentrations of man via the environment

### 9.5.3 Measured levels

Atmosphere

Aquatic compartment

Sediment

Soil compartment

Secondary poisoning

### 9.5.4 Selected environmental concentrations of risk characterisation

Atmosphere

Aquatic compartment

Sediment

Soil compartment

Secondary poisoning

## 9.6 Combined human exposure assessment

# 10 RISK CHARACTERISATION

## 10.1 Human health

### 10.1.1 Workers

### 10.1.2 Consumers

### 10.1.3 Indirect exposure of humans via the environment

### 10.1.4 Combined exposures

## 10.2 Environment

### 10.2.1 Aquatic compartment (including sediment and sewage treatment plant and secondary poisoning)

### 10.2.2 Terrestrial compartment (including secondary poisoning)

### 10.2.3 Atmospheric compartment

### 10.2.4 Microbiological activity in sewage treatment systems

# INFORMATION ON ALTERNATIVES

## 11 INFORMATION ON THE RISKS TO HUMAN HEALTH AND THE ENVIRONMENT RELATED TO THE MANUFACTURE OF USE OF THE ALTERNATIVES

## 12 AVAILABILITY OF ALTERNATIVE, INCLUDING THE TIME SCALE

## 13 TECHNICAL AND ECONOMICAL FEASIBILITY

# JUSTIFICATION FOR RESTRICTION AT COMMUNITY LEVEL

## 14 JUSTIFICATION THAT ACTION IS REQUIRED ON THE COMMUNITY-WIDE BASIS

## 15 JUSTIFICATION FOR THE PROPOSES RESTRICTION

### 15.1 Effectiveness

### 15.2 Practicality

### 15.3 Monitorability

# SOCIO ECONOMIC ASSESSMENT

# OTHER INFORMATION

*(It is suggested to include here information on any consultation which took place during the development of the dossier. This could indicate who was consulted and by what means, what comments (if any) were received and how these were dealt with. The data sources (e.g. Technical Dossiers, CSRs, other published sources) used for the dossier could also be indicated here.)*

# APPENDIX II INFORMATION ON HOW TO FILL-IN THE ANNEX XV RESTRICTION REPORT

## Overview

The Annex XV dossier consists of two parts. This guidance considers the production of the Annex XV report. Production of the technical dossier is not addressed here; the appropriate guidance from RIP 3.2/3.3 [XXX] should be followed along with guidance on IUCLID5. Authorities are encouraged to create a technical dossier for the substance as part of producing the restrictions dossier.

The Annex XV restrictions report consists of six parts; these are:

- *Proposal;*
- *Information on hazard and risk;*
- *Information on alternatives;*
- *Justification for restriction at Community level;*
- *Socio-economic assessment; and*
- *Information on stakeholder consultation.*

## Proposal

The first part of the Annex XV restrictions report outlines the proposed Community-wide restriction. This contains details on the identity of the substance (substance name, CAS/EC number(s)), registration number(s) (if available), molecular formula, structural formula, purity and impurities). The summary also states the restriction proposed, the uses it applies to, any proposed conditions, specific concentration limits, and any derogation including their conditions and timeframe for their implementation.

The *Proposal* should be a self-sufficient presentation of the conclusions of the restrictions procedure and should be precise and not open to interpretation.

## Information on hazard and risk

The second part of the Annex XV report presents the technical and scientific information which demonstrates the risk(s) which are not adequately managed by the registration procedure. It takes the form of a hazard and risk assessment and uses the same basic format as the chemical safety report. The format has ten sections as described below. Specific comments on the content for some of the sections are included in this guidance. For other sections, reference is made to other guidance for their completion.

*Section 1*: Identity of the substance and physical and chemical properties. The CSA guidance (XXX) should be used to complete this section. It is expected that most (if not all) of the required information will be taken from the registration dossiers.

*Section 2*: Manufacture and uses. This section should include the results of the analysis of the production and use information in the various CSRs.

*Section 3*: Classification and labelling. Inclusion of the classification information may be useful in presenting a complete picture of the substance. Chapter 4.1 of this guidance may be useful, as will the CSA guidance (XXX).

*Section 4*: Environmental fate properties. For the evaluation of these properties, the CSA guidance (XXX) should be used. This section should be used to present the property values which are used in the calculation of the PEC values. It is expected that these will come mostly from the registration dossiers.

*Section 5*: Human health hazard assessment. This section presents the DNEL values for the substance, with supporting information as required. Some brief notes on this section are included in Chapter 5.2.2, but for the most part the CSA guidance (XXX) should be used.

*Section 6*: Human health hazard assessment of physicochemical properties. This is unlikely to be relevant for a restrictions dossier. If needed, the CSA guidance should be used.

*Section 7*: Environmental hazard assessment. This section presents the PNEC values to be used in the environmental risk assessment, with supporting information as required. Some brief notes on this section are included in Section 5.2.2, the CSA guidance (XXX) should be used for the most part.

*Section 8*: PBT and vPvB assessment. Inclusion of the conclusions of a PBT assessment may be useful in presenting a complete picture of the substance. It may be useful to read the guidance on preparing an Annex XV dossier for a Substance of Very High Concern, as well as the CSA guidance (XXX).

*Section 9*: Exposure assessment. This section presents the estimates of emissions to the environment, and the subsequent environmental exposures, and the estimate of exposure to workers, consumers and man via the environment. Guidance on this section is included in Chapter 5.2.3.

*Section 10*: Risk characterization. This section presents the results of the risk characterization. Guidance on this is included in Chapter 5.2.4.

**Information on alternatives**

The third part of the Annex XV report will provide an overview of the available information on alternative substances and techniques (as discussed in Chapter 5.5 of this guidance). This section will discuss:

*Section 11:* the information on the risks to human health and the environment related to the manufacture or use of alternatives;

*Section 12:* the availability of alternatives, including the time scale;

*Section 13:* their technical and economical feasibility of the alternatives.

### Justification for restrictions at Community level

The fourth part of the Annex XV report contains a justification for community-wide action (which is discussed in Chapters 5.3 to 5.4.6 of this guidance). The format for this part of the report has two sections:

*Section 14*: Justification that action is required on a community wide basis i.e. the outcome of the analysis of the need for action on a Community-wide basis.

*Section 15*: Assessment of the proposed restriction against the three key criteria. This section of the report presents the assessment of the proposed restriction against the three key criteria of effectiveness, practicality and monitorability in comparison with the other RMOs that have been given consideration.

### Socio-economic analysis

This part may be included in the report if an SEA has been undertaken by the Authority. The content and layout is discussed in more detail in the relevant SEA guidance (XXX).

### Information on stakeholder consultation

The final part of the Annex XV report concerns any other information that is considered to be relevant to the dossier. These will include:

- List of stakeholders consulted;
- Overview of consultation (for example, details of any consultation which took place during the development of the dossier, including what methods for consultation were used, what comments (if any) where received and how these were dealt with); and
- Other information.

This section should not contain any new technical information. All technical information should be reported in the *Information on hazard and risk* in the Annex XV restrictions report.

## APPENDIX III NON-EXHAUSTIVE LIST OF THE TYPES OF INFORMATION THAT MAY BE INFORMALLY REQUESTED AND COLLECTED FROM DIFFERENT TYPES OF STAKEHOLDERS

| **Stage in the restrictions procedure** | **General types of consultees** | | | | |
|---|---|---|---|---|---|
| | **Authorities in other Member States and non-EU countries** | **Trade associations and companies (manufacturers, importers and users)** | **Labour organisations** | **Consumer groups** | **Experts in academic and research community** |
| **Information on the effectiveness of implemented RMMs and compliance with ELRs** | • Scope for improvement of implemented RMMs<br>• Information on past potential of enforcement of implemented RMMs<br>• Scope for introducing national measures | • Scope for improvement of implemented RMMs | • Scope for improvement of implemented RMMs | • Scope for improvement of implemented RMMs | • Scope for improvement of implemented RMMs |
| **Identification of RMOs** | • Advice on past effectiveness of RMOs and implementation tools<br>• Information on current state and structure of the relevant markets in their territory<br>• Information on any previous risk management options considered and difficulties that were encountered during their implementation. | • Advice on past effectiveness of RMOs and implementation tools<br>• Information on current state and structure of the relevant markets | • Advice on past effectiveness of RMOs and implementatio n tools | • Advice on past effectiveness of RMOs | • Advice on past effectiveness of RMOs |

| Stage in the restrictions procedure | General types of consultees | | | | |
|---|---|---|---|---|---|
| | **Authorities in other Member States and non-EU countries** | **Trade associations and companies (manufacturers, importers and users)** | **Labour organisations** | **Consumer groups** | **Experts in academic and research community** |
| **Assessment of RMOs against the three key criteria of effectiveness, practicality and monitorability as well as considerations on any derogations that may be required** | • Information and past experience pertaining to the assessment of RMOs<br>• Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives)<br>• Information on the availability of enforcement mechanisms and monitoring networks<br>• Information on criticality of uses<br>• Information on current R&D in the sectors of concern | • Information and past experience pertaining to the assessment of RMOs<br>• Views on the practicality of RMOs (including implementation costs such as the costs of loss of uses of the substance/use of alternatives)<br>• Information on the availability of monitoring networks<br>• Information on criticality of uses<br>• Information on current R&D in the sectors of concern | • Information and past experience pertaining to the assessment of RMOs<br>• Views on the practicality of RMOs (including implementation costs)<br>• Information on the availability of monitoring networks<br>• Information on criticality of uses | • Views on the practicality of RMOs (including implementation costs)<br>• Information on the availability of monitoring networks<br>• Information on criticality of uses | • Views practicality and monitoring issues<br>• Information on criticality of uses<br>• Cost of loss of uses of the substance/use of alternatives<br>• Information on current R&D in the sectors of concern |

## APPENDIX IV EXAMPLES OF WORKFLOW AND ANTICIPATED WORKLOAD IN DIFFERENT CASES

The following paragraphs present examples of different substances and the anticipated workload for the preparation of an Annex XIV restrictions report.

**Substance A: CSRs and information from substance evaluation give rise to concern**

| | |
|---|---|
| **Substance identification:** | Substance A; manufactured by three EU companies and imported by five others; each company manufactures/imports it in volumes over 1,000 t/y. Finds several uses. |
| **REACH status:** | Substance has been registered by all eight companies, all registration dossiers include a CSR. |
| **Substance evaluation status:** | On the basis of dossier evaluation and on grounds of the aggregated tonnage from the submitted registrations, the Agency placed Substance A on the Community rolling action plan for evaluation. The substance evaluation was subsequently completed by a Member State and the further information received clarified and confirmed concerns with regard to exposure from its use in two specific uses. |
| **Trigger for the restrictions procedure:** | The available information, including those resulting from substance evaluation, have highlighted the need for a Community-wide restriction. The identified risks are clearly defined and the assessment of the effectiveness of implemented RMMs show that the risk is currently not adequately managed. |
| **Information on alternatives:** | Five alternatives are known and already in use in the two uses of concern, although all five are not available in the required tonnages at present. For three, registration dossiers and CSRs are available and implemented RMMs in the uses of concern are documented. |
| **SEA information:** | No information on possible socio-economic implications from a possible restriction is available, however, the Authority considering a restriction believes that an SEA is not necessary. |
| **Work completed before the start of the restrictions procedure** | The following elements are thus available to the Authority: (a) trigger for considering a restrictions proposal; (b) definition of concern; (c) risk assessment; (d) assessment of effectiveness of implemented measures; (e) assessment of alternatives; and (f) establishing the need for a further risk management action on a Community-wide basis. The Authority has actually already established that a restriction is needed; SEA is not required. |
| **Remaining work under the restrictions procedure and the envisaged workload** | The following elements need to be completed by the Authority: (a) derogation issues; (b) preparation and documentation of the justification for the proposed restriction; and (c) compilation and submission of Annex XV dossier to the Agency. Part of the justification for a proposed restriction (the risk-related justification) is available. In this scenario it is expected that the identification of derogations required and the formulation of the justification for the |

proposed restriction will be the most resource intensive processes. The workload will very much depend on the amount of consultation that is needed in order to formulate and justify the derogation/s required and the justification of the restriction.

**Suggested timing of notification of restrictions procedure**

At the discretion of the Authority. Most of the work for the restrictions proposal has already been undertaken.

**Substance B: Further information from substance evaluation confirms concern**

| | |
|---|---|
| **Substance identification:** | Substance B; manufactured by several EU companies. |
| **REACH status:** | Substance has been registered by all manufacturers. All the dossiers include a CSR. Dossier evaluation has been completed, testing proposals have been approved and tests conducted and on the basis of test results CSRs have been updated with new ES and RMMs which allow for adequate control of the risks from the substance. |
| **Trigger for the restrictions procedure:** | Scientific research supported by monitoring data suggests that releases of Substance B may have been underestimated and the actual regional levels of the substance in the environment may pose unacceptable risks to the aquatic environment and to human health. The implemented RMMs and ELRs may not be sufficient to manage the risks. |
| **Substance evaluation status:** | In the light of the new information, a Member State notified the Agency and the Agency included Substance B on the Community rolling action plan and subsequently the Member State undertook its evaluation. The substance evaluation was completed and the further information received confirmed the concerns with regard to the regional concentrations of the substance. |
| **Information on alternatives:** | Information from registration dossiers and CSRs is available for a number of other substances of similar chemical structure. None of them are used in the applications of Substance B, although conditions of safe use and RMMs are observed in their individual uses. Current research suggests that Substance B could possibly be replaced in some of its uses with new technology, although this has not been tested on a large scale. |
| **SEA information:** | The relevant trade associations representing the manufacturers and users of Substance B have commissioned a study on the socio-economic impacts of different RMOs. The Authority has not decided on whether an SEA should be undertaken. |
| **Work completed before the start of the restrictions procedure** | The following elements are thus available to the Authority: (a) trigger for considering a restrictions proposal; (b) definition of concern; and (c) risk assessment. |
| **Remaining work under the restrictions procedure** | The following elements need to be completed by the Authority: (a) information on alternatives; (b) establishing the need for further risk management action on a Community-wide basis; (c) derogation issues; (d) preparation and documentation of justification for a proposed restriction; and (e) compilation and submission of Annex XV dossier to the Agency. Part of the justification for a restriction is available. Possibly an SEA (some material is available to the Authority). |
| **Envisaged workload for each Stage** | In this case the hazard assessment will be available before the Authority starts work on the restrictions proposal, and the substance evaluation will have provided sufficient evidence that the implemented |

RMMs and ELRs are inadequate; therefore, the exposure assessment will practically be available and only the risk characterisation will need to be finalised in detail. The risk-related justification for risk management action and the justification for it to be addressed on a Community-wide basis will generally have been established in advance, however, for most other elements of the restrictions report, additional work will be required (especially on alternatives, derogations and SEA, if the Authority decides to undertake one).

**Suggested timing of notification of restrictions procedure**

The timing of notification is unclear and will depend on the progress of preparatory work on revising the exposure assessment and, possibly, assessing the availability and suitability of alternatives. If an SEA is to be undertaken, more time will be required for the preparation of the Annex XV restrictions dossier. It is suggested that the Authority at least establishes the need for a Community-wide restriction before formal notification of the restrictions procedure.

**Substance C: Substance not subject to registration and evaluation**

| | |
|---|---|
| **Substance identification:** | Substance C; not manufactured or imported in the EU. Substances X, Y and Z are precursors to Substance C which forms a building block for their molecules. |
| **REACH status:** | Substance C is not subject to registration; Substances X and Y have been registered by all their manufacturers/importers and all registration dossiers include a CSR. Substance Z is subject to registration but not yet registered due to low volume. |
| **Trigger for the restrictions procedure:** | Substances X, Y and Z have been identified as being degraded following release to the environment to give rise to Substance C as a breakdown product. Information generated by reference to structurally related substances suggests that Substance C may be very toxic to the environment and to human health; monitoring results suggest that levels of the substance in the environment may be increasing. |
| **Substance evaluation status:** | In the light of the recent research and monitoring data, the two registered precursors were added to the Community rolling action plan and subsequently evaluated; a single Member State undertook both substance evaluations and requested from registrants information on the degradation of the substances under environmental conditions and the nature of the degradation products. The further information resulting from the substance evaluations confirmed the risks from Substance C and concluded that implemented RMMs and ELRs targeting the precursors cannot adequately manage the risks from the substance (although the existing measures can adequately control the risks from the precursors themselves). |
| **Information on alternatives:** | No information on alternatives to the precursors is available. |
| **SEA information:** | No detailed information is available; however, the uses of the precursors that give rise to Substance C appear to be of critical importance as they relate to the manufacture of special type fire fighting foams used in large-scale industrial fires. |
| **Work completed before the start of the restrictions procedure** | The following elements are thus available to the Authority: (a) trigger for considering a restrictions proposal; (b) definition of concern; and (c) an assessment of effectiveness of implemented measures. |
| **Remaining work under the restrictions procedure** | The majority of the elements of the restrictions procedure will need to be completed by the Authority, although part of the justification for a proposed restriction (the risk-based justification) is available. |

| | |
|---|---|
| **Envisaged workload for each Stage** | Substance C is a breakdown product of other substances and therefore no registration dossier for it exists. The preparation of an Annex XV restriction dossier will involve extensive work throughout the restrictions procedure. Information from the registration dossiers of the precursors and their evaluation and (Q)SARs could be used, however, a risk assessment of the substance will be necessary to assess the need for and the details of a restriction. |
| **Suggested timing of notification of restrictions procedure** | The timing of notification will depend on the progress of preparatory work. An SEA would appear to be an important tool in developing a justified and proportional restriction and if it is to be undertaken, more time will be required for the preparation of the Annex XV restrictions dossier. It is suggested that the Authority first establishes the need for a Community-wide restriction and then considers starting the assessment of alternatives as well as an SEA of possible RMOs before formal notification of the restrictions procedure. |

**Substance D: Amendment to an existing Annex XVII restriction**

| | |
|---|---|
| **Substance identification:** | Substance D; manufactured and imported by several EU companies, and has a range of uses. |
| **REACH status:** | Substance D has been registered by all manufacturers. All the dossiers include a CSR Three specific uses are already restricted under REACH; a further use has been granted an unconditional derogation. |
| **Trigger for the restrictions procedure:** | Enforcement and monitoring of other legislation has provided evidence that existing controls set at the Community level (emission limit values) cannot adequately manage the risk to the environment. The Authority has contacted Industry to request that exposure scenarios are reviewed and RMMs are updated to ensure adequate protection of the environment. The revised CSRs have been evaluated by the Agency and have been found to be inadequate. |
| **Substance evaluation status:** | Substance evaluation was completed before the original restrictions were introduced. |
| **Information on alternatives:** | The availability and suitability as well as the risks from alternatives are well known and were documented at the time of the original restrictions. Since then new techniques have been developed both for the restricted uses and those not subject to restrictions. |
| **SEA information:** | SEAs had been prepared by both the Authority and interested parties at the time of the original restrictions. |
| **Work completed before the start of the restrictions procedure** | The elements of the restrictions procedure were developed when the original restrictions were developed and proposed. Below, it is shown which elements would have to be reviewed in the 'new' restrictions procedure. |
| **Remaining work under the restrictions procedure** | Since the issues surrounding the use of Substance D are well known, the 'new' restrictions procedure will focus on specific elements such as: (a) preparation and documentation of justification for the proposed restriction; and (b) compilation and submission of Annex XV dossier to the Agency. |
| **Envisaged workload for each Stage** | The previous work on developing the original restrictions will provide a solid basis for the 'new' restrictions proposal. The exposure assessment and risk characterisation as amended by the registrants and evaluated in the compliance check by the Agency are likely to lend themselves to quick revision as will probably be the case with the assessment of the RMOs. SEA, if undertaken, could be the element that would require most work. The hazard assessment, risk-based justification for action on a Community-wide basis and the assessment of alternatives will largely be already available. |
| **Suggested timing of notification of restrictions procedure** | The timing of notification is unclear and will depend on the progress of preparatory work on revising the exposure assessment and, possibly, assessing the availability and suitability of alternatives. If an SEA is to be undertaken, more time will be required for the preparation of the Annex XV restrictions dossier. It is suggested that the Authority at |

least establishes the need for a Community-wide restriction before formal notification of the restrictions procedure.

## APPENDIX V EXAMPLES OF EXISTING COMMUNITY LEGISLATION UNDER WHICH SUBSTANCE-SPECIFIC CONDITIONS ARE SET

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| **Environment-Water** | | | |
| Directive 96/61/EC Integrated Pollution Prevention and Control (IPPC) Directive | Industry branches listed in Annex 1, mainly large industry installations, for some branches production threshold | • Community emission limit values (not used so far); and<br>• in plant by plant permits emission limit values or other conditions to control the risk for the environment. | • BREFs can be used to support the work of Member State competent authorities. |
| Directive 2000/60/EC Water Framework Directive (WFD) | Inland surface water, transitional waters, coastal waters and groundwaters | • Community EQS for substances listed in Annex X;<br>• Community wide emission controls for point and diffuse sources of substances listed in Annex X; and<br>• river basin measures to control point and diffuse source discharges liable to cause pollution.<br>• Note however Article 61 (5) (c) (ii) | • Daughter directives for hazardous substances listed in Annex X and for groundwaters under development; and<br>• Annex X will be reviewed regularly. |
| Directive 76/464/EEC Dangerous Substances Directive<br><br>Note that this is repealed and replaced by Directive 2006/11/EC | Lists I & II of substances dangerous to the aquatic environment | • List I discharges must be authorised, such authorisation laying down emission standards for discharges to waters and, where necessary, to sewers. Competent authorities were required to draw up an inventory of the discharges; and<br>• for List II, Member States must establish pollution reduction programmes including water quality objectives. | • To be integrated into WFD by 2013 |

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| **Environment-Air** | | | |
| Directive 96/61/EC IPPC Directive | Industry branches listed in Annex 1, mainly large industry installations, for some branches production threshold | • Community emission limit values (not used so far); and<br>• In plant by plant permits emission limit values or other conditions to control the risk for the environment.<br>• Note however Article 61 (5) (c) (i) | • BREFs can be used to support the work of Member State competent authorities<br>• Emission control principle |
| Directive 1999/13/EC Volatile Organic Compounds (VOC) Directive | Activities listed in Annex I; and<br>solvent consumption thresholds in Annex IIA. | • Emission limit values (Annex IIA); and<br>• fugitive emission values (% of solvent input) (Annex IIA). | • Emission limit values are for the sum of all VOCs used in the activity not for individual substances |
| **Environment-Other** | | | |
| Directive 2002/95/EC Restriction of Hazardous Substances (RoHS) Directive | Electrical and electronic equipment falling under categories set in Annex IA to Directive 2002/96/EC (Waste Electrical and Electronic Equipment) | • New equipment may not contain Pb, Hg, Cd, Cr(VI), PBB, PBDE; and<br>• exempted applications listed in an Annex. | • Stakeholder consultation on proposals for additional exemptions ongoing |
| Directive 91/157/EEC, Directive 98/101/EC<br><br>Note that with effect of 26/9/2008, this will be repealed and replaced by Directive 2006/66/EC | Batteries and accumulators | • Marketing of batteries and accumulators containing more than 0,00005 % of Hg prohibited (exemption: more than 2 % of Hg in button cells) | • The revision of the directives is under preparation |

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| **Environment-Other** | | | |
| Directive 86/278/EEC Sewage Sludge Directive | Protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture | • Limit values for concentrations of heavy metals in the soil (Annex IA), in sludge (Annex IB) and for the maximum annual quantities of heavy metals which may be introduced into the soil (Annex IC) | • At present, it applies to metals only. |
| Regulation 850/2004 Persistent Organic Pollutants | It implements the provisions of the Stockholm Convention. | • Dioxins, furans and PCBs are listed as unintentionally released POPs for which the releases should be continuously and cost-effectively reduced as soon as possible. | |
| **Occupational health** | | | |
| Dir 98/24/EC Chemical Agents at Work Directive | Hazardous chemical agents present at the workplace | • Community binding OELs (annex I);<br>• binding biological limit values (annex II); and<br>• prohibitions of the production, manufacture or use at work of (currently 4) substances listed in Annex III. | • Some indicative OEL values have been established for 63 substances by Directive 2000/39/EC |
| Directive 90/394/EEC, Directive 99/38/EC Carcinogens and Mutagens Directive | Exposure of workers to carcinogens and mutagens; and<br>covers also substances unintentionally released by processes listed in Annex I. | • OELs in annex IIIA; and<br>• possibility to set other related provisions in Annex IIIB (not used so far). | • Reduction and replacement of carcinogens and mutagens in so far as technically possible<br>• Prevention and reduction of exposure to carcinogens and mutagens via use in closed systems in so far as technically possible |

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| **Occupational health** | | | |
| Directive 92/85/EEC Pregnant Workers Directive | Exposure of pregnant workers and workers who have recently given birth or are breastfeeding; and covers carcinogenic substances and mutagenic substances. | • Employer to assess the nature, degree and duration of exposure for Annex I substances; and<br>• exposure to agents listed in Annex II to be prohibited. | |
| Directive 94/33/EC Protection of Young Workers at the Workplace Directive | Harmful exposure to the physical, biological and chemical agents referred to in point I of the Annex | • Article 7 (2) prohibits the employment of young people for work involving harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affect human health | |
| **Consumers** | | | |
| Directive 98/83/EC Drinking Water Directive | Water intended for human consumption | • Minimum limit values for substances listed in Annex 1 part B | |
| Directive 88/378/EEC Toys Directive | Toys as defined in Article 1 | • Limit values for bioavailability of metals resulting from the use of toys | • Use of certain substances in toys restricted by Directive 76/769/EEC |

| Instrument | Coverage | Conditions | Notes |
|---|---|---|---|
| **Consumers** | | | |
| Directive 89/197/EEC Food Additives Directive | Additives to be used in foodstuffs | • Positive list of substances (only these to be used in foodstuffs and only certain conditions specified therein) | |
| Regulation 726/2004/EC Medicinal Products | Safety, quality and efficacy of medicinal products for humans and domestic animals; and medicinal products listed in Annex and medicinal products fulfilling requirements set in article 3.2 and 3.3 and the applicant requests a marketing authorisation at Community level. | • Marketing authorisation of medicinal products for human and veterinary use in the centralised procedure at Community level;<br>• only authorised medicinal products may be placed on the market (authorisation at Community or national level);<br>• the authorisation may include conditions or restrictions; and<br>• an application has to include evaluation of the potential environmental risk and specific arrangements to limit the risk need to be envisaged. | • Directive 2001/83/EC (as last amended by Directive 2004/27EC) and Directive 2001/82/EC (as last amended by 2004/28/EC) cover marketing authorisations for medicinal products for human and veterinary use outside the Centrally authorisation procedure (Community authorisations) |
| Regulation 648/2004/EC Regulation on Detergents | Detergents and surfactants to be used in detergents | • Lays down requirements on degradability of surfactants to be used in detergents | |
| Framework Regulation 1935/2004 and all the legal instruments deriving from this, such as Council Directive 78/142/EC on Vinyl chloride Food contact materials | Sets up general requirements for all food contact materials. | • The different legal instruments that have been produced under this Framework Regulation regulate migration levels and contents of different substances in food contact materials | • Follow this link for further details:<br>• http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm |
| Directive 2004/42/EC VOC Paints Directive | The use of organic solvents in certain paints and varnishes and vehicle refinishing products | • For the paints, the Directive sets up two sets of limit values for the maximum contents of VOCs in g/litre of the product ready for use.<br>• For vehicle refinishing products there is only one set of limit values for the VOC contents.<br>• It also lays down special labelling provisions. | |

# APPENDIX VI CONSIDERATIONS ON THE ASSESSMENT OF RISKS FROM ALTERNATIVE SUBSTANCES

## Aspects Related to Risk Assessment

In order to be able to compare the risks arising from the alternatives available one needs to take a flexible approach towards the assessment of such alternatives. Ideally the assessment should address all possible risks throughout the entire lifecycle of the alternatives, 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, 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.

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. The tiered approach explained below, starts from a comparison of the hazardous properties, and ultimately ends into a full assessment of the risk arising from the alternatives, each tier increasing the level of complexity and data required. The complexity of the assessment required is highly dependent on the properties of the alternative substances or techniques, in the sense that if for example a clearly less hazardous substance is available then a comparison of the hazardous properties would 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 emission characterisation would be suitable, nevertheless care should be taken to assess other possible secondary effects of the alternative, such as a possible increases in the production of hazardous waste or increased energy consumption. It may be the case that the substance of concern 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 alternative processes. In such cases, the combined effects of such changes may be difficult to predict and assess; therefore, the analysis may at least 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.

The comparison of different hazards and their magnitudes, sometimes will also require value judgments about the acceptability of different risks to different endpoints. Simultaneously ranking health, safety and environmental risk may require the Authority to be involved in trade-offs which are not always straightforward. New risks may be difficult to compare to the original risks because they may be of a radically different nature. For example, a chemical 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 this case, the Authority 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 time and resources available to the Authority to prepare and submit the restriction dossier is limited and this will have an influence in setting the boundaries of the risk assessment of the alternatives.

***The assessment of the hazards and risks of alternatives***

The depth of the risk assessment of alternatives should be decided on a case-by-case basis. The process of assessing the hazards and risks will be different when considering alternative processes and alternative techniques.

For alternative substances, a tiered approach 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 hazard information for the alternatives. Where registration dossiers and other REACH-related information (Articles 31 and 32) are available, these should be reviewed by the Authority. If such sources are not available, other sources should be consulted. 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 restriction proposal;

  *Part B*: Comparison of the hazard information of alternatives to that of the substance of concern. 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 suitable. This comparison should first look at those hazard properties of highest concern such as PBT/vPvB, and CMR characteristics. If both the substance and the alternative substances have similar properties of concern or when all potential alternatives have PBT/vPvB/CMR properties, the Authority should take into consideration information on the potential exposure and any evidence of possibilities to better control the exposure. 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 will be available and these may be compared to those for the substance of concern. 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 or when there is an obvious concern about the alternatives.

- *Tier 2*: Revision of risk assessment for the substance of concern when partly replaced by an alternative substance. The Authority will need to establish how the use and releases of the substance of concern may be affected by the use of an alternative substance before the revision can be undertaken.

- *Tier 3*: This would involve the use of information on the alternative substance (properties and hazards) within the Chemical Safety Assesssment for the substance of concern to perform a quick revised exposure assessment and risk characterisation for the alternative for the applications associated with the identified risk; There may be three possible situations of increasing complexity:
  - If the exposure assessment for the substance of concern shows that the release estimates do not depend on the substance properties, then the existing emission estimates for the original substance may be used.
    - When the alternative has similar physico-chemical and environmental fate properties to the original, 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

        - when the alternative does not have similar physico-chemical and environmental fate properties to the original, 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.
    - 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 original 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.

- *Tier 4*: As in Tier 3, plus assessment of risks from manufacture of the alternative substance. If the alternative substance has been registered and the registration dossiers already include an exposure assessment for its manufacture, this can be used in the preparation of the restriction proposal. If such exposure assessment is not available, then the Authority may consider developing a quick targeted exposure assessment for the manufacture of the alternative.

- *Tier 5*: use of exposure scenarios specific to the alternative substance (rather than those for the substance of concern) to perform an assessment of risks for the alternative for the applications of concern across all compartments/populations at risk. This will effectively be similar to Tier 3 only that the Exposure Scenarios will be specific to the alternative substance for the applications associated with the identified risk. If the alternative substance has been registered and the registration dossiers already include an exposure assessment for the applications of concern, this can be used for the purposes of the restriction proposal. If a new exposure assessment is required, the guidance for the CSA should be followed, with any relevant parts from this guidance document.

- *Tier 6*: as for Tier 5, plus assessment of secondary effects from manufacture and use (for instance, waste generation, energy consumption, etc.). This may be undertaken only when the relevant information is readily available.

Performing tiers 1 to 6 would in most cases entail a significant volume of work and may only be pursued if the necessary information is already available i.e. a full safety assessment of the alternative substance has already been undertaken separately. The Authority should start from Tier 1 and work to a more detailed assessment taking into account any information, time and resource limitations and keeping the level of detail proportional to the characteristics and magnitude of risk.

The ultimate aim of the assessment of alternatives is to indicate that alternative substances or techniques that lead to lower exposures or risks are available for given uses and therefore the information needed to arrive to such a conclusion should be reported in the dossier. This should be carried out by completing *Section 2* of the *Information on alternatives*. As the

amount of information to be included will vary on a case-by-case basis, a detailed format has not been developed for this section. Where the information to be presented is extensive, the Authority may find it useful to present it using the relevant parts of the format for the *Information on hazard and risk* part. This may be particularly useful where exposure and risk calculations have been performed. Depending on the extent of the information, a separate annex may be useful.

Example

Four enterprises within the EU manufacture Substance L with a total of six production installations. Substance L is used in a variety of uses including polycarbonate production, epoxy resin production, phenoplast resins, unsaturated polyester resin production, can coating manufacture, PVC production and processing, thermal paper manufacture and others. The risk assessment has suggested that there is a need for limiting the risk in relation to the aquatic and sediment compartments for phenoplast resin production.

The Authority has consulted widely with the EU paper industry and has undertaken literature searches to identify possible alternative substances and techniques. While no suitable alternative techniques for paper recycling have been identified, a total of five have been suggested as replacements for Substance L. The available information for all five of them, however, was very limited compared to that for Substance L. This was due to the fact that these five substances were not registered yet as they were not manufacture/imported in the same tonnages as Substance L. As a result, a number of working assumptions had to be made for the assessment of risk to the environment. The following approach was adopted:

- A review of the properties of each substitute in order to provide an initial PBT/vPvB assessment and comparison with Substance L was carried out;
- The EUSES model was then used to replicate the revised results of the analysis of Substance L undertaken in the risk assessment;
- This enabled the emissions to the environment at continental, regional and local levels to be ‘back-calculated’;
- The EUSES model was then re-run with the same emission quantities (i.e. kg/year) but replacing the key properties for Substance L with values relevant to each substitute in turn; and
- PNEC values for the alternatives have been derived from effects data collected through consultation and literature review.

The findings of this analysis suggest that not all potential alternatives were suitable for replacing Substance L. Alternative substances 1, 4 and 5 generally appear not to pose unacceptable risk to the environment; however, alternative substances 1 and 4 are possible PBT or vPvB substances. Overall, it can be concluded that suitable alternatives for Substance L exist and this should be reflected in the Annex XV restriction report.

Overview of alternatives for Substance L

| Parameter | Sub L | Alt 1 | Alt 2 | Alt 3 | Alt 4 | Alt 5 |
|---|---|---|---|---|---|---|
| **vPvB?** | No | Possibly | Unlikely | Possibly | Unlikely | Unlikely |
| **PBT?** | No | Possibly | Unlikely | Possibly | Possibly | Unlikely |
| **PNEC (aquatic)** | 1.6 µg/l | 16 µg/l | 0.42 µg/l | 30 µg/l | 30 µg/l | 100 µg/l |
| **Assessment factor** | 1,000 | 10 | 1,000 | 1,000 | 1,000 | 1,000 |
| ***Phenoplast resin production*** | | | | | | |
| **RCR - aquatic** | >1 | 0.05 | **67** | **1.7** | <0.01 | <0.01 |
| **RCR - sediment** | >1 | 0.56 | **760** | **19** | 0.06 | 0.02 |
| **RCR - STP** | <1 | No data | 0.06 | 0.57 | 0.35 | 0.35 |

Note: RCR stands for Risk Characterisation Ratio (= PEC/PNEC)