ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

# Guidance for downstream users

Version 2.1
October 2014

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

**LEGAL NOTICE**

The document aims to assist users in complying with their obligations under the REACH Regulation. 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. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

**Guidance for downstream users**

**Reference:** ECHA-13-G-09.1-EN
**ISBN:** 978-92-9244-013-8
**Publ.date:** October 2014
**Language:** EN

© European Chemicals Agency, 2014

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

**European Chemicals Agency**

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

## DOCUMENT HISTORY

| Version | Changes | Date |
|---|---|---|
| Version 1.0 | First edition | January 2008 |
| Version 2.0 | Full revision of the guidance addressing structure and content. The whole guidance has been revised by correcting or deleting mistakes and inconsistencies and to reflect the best practices and experience developed so far with regard to the obligations for downstream users (DUs).<br><br>The main drivers for the update are issues related to checking compliance with exposure scenario (including scaling) and communication of information on mixtures.<br><br>The structure has been generally reviewed to render the document clearer and more readable. Information already covered by newer manuals or falling under the scope of other guidance documents has been removed. The format consisting in flowcharts with explanatory notes has been replaced by more user friendly and clear explanations of the main DU obligations.<br><br>The update includes the following:<br><br>- Revision of chapters 0 and 1 in order to eliminate outdated information and reflect the new structure of the updated guidance. The introductory chapter starts now with an overview of the REACH Regulation focusing on aspects relevant for DUs and on communication in the supply chain. The way how the reader should navigate through the guidance is explained via table and flowchart. A new sub-chapter on the explanation of the key terms has been included using part of the information originally in chapter 5.<br><br>- Revision of chapter 2 by eliminating out of date information, moving sub-chapter of REACH overview to chapter 1 and restructuring the information in order to highlight first the identification of the DU role and DU activities and then other possible roles.<br><br>- Elimination of original chapter 3; information considered still relevant was moved to chapter 1 and 2.<br><br>- Creation of a new chapter 3 where it is explained, right after the initial identification of the role, how DU should collect information on its own use(s) and its customers' use(s). Furthermore the chapter addresses communication upstream with the aim to have the use(s) identified. The approach identified as preferred is a sector description of uses as it reflects the current best practice.<br><br>- Elimination of original chapter 4. | December 2013 |

| | | |
|---|---|---|
| | - Creation of new chapter 4 to address the actions to be taken by the DU when receiving an ES. It is explained how to check compliance with the conditions of use and which are the possible outcomes of this assessment. The concept of scaling is introduced while for technical details and practical examples is provided reference to the Practical Guide. The chapter gives an overview of the possible actions to be undertaken in case the use is not covered by the ES.<br><br>- Elimination of original chapter 5. Information on key terms moved to chapter 1 and relevant information on compliance check moved to chapter 4.<br><br>- Elimination of chapter 6; relevant information moved to new chapter 4.<br><br>- Creation of a new chapter 5 where the option of preparing a downstream user chemical safety report (CSR, introduced in chapter 4) is described in details. The chapter covers legal requirements, difference with standard chemicals safety assessment (CSA), practical steps to carry out a downstream user CSA and reporting obligations.<br><br>- Creation of new chapter 6 to cover the obligation for the DU to communicate new information on hazards and risk management measures upstream and on new classification to ECHA.<br><br>- Elimination of chapter 7; relevant information on DU CSR updated and moved to new chapter 5. Technical details reduced to what is directly of interest of the DU and reference is provided to the relevant chapters of the Guidance on IR&CSA to avoid duplication.<br><br>- Elimination of chapters 8, 9, 10 and 11. Relevant information has been updated and used in the new chapters 3, 4 and 6 according to the new structure and workflow of the guidance.<br><br>- Creation of new chapter 7 covering the communication obligations in the supply chain related to mixtures. The chapter illustrates first the legal references related to mixtures. It then elaborates and provides guidance and general principles for the formulator who needs to collect and select the relevant information on substances or mixtures he receives from the suppliers and chose the most appropriate mean to communicate information on his mixture downstream which is relevant for his customers.<br><br>- Merging of chapters 12 and 13 in a new chapter 8 addressing requirements related to authorisation and restriction relevant for DUs. Existing information has been updated and reduced by providing reference to other more appropriate sources. | |

| | | |
|---|---|---|
| | - Addition of a new subchapter 8.3 to highlight the compliance with obligations related to substance in articles for DUs.<br><br>- Elimination of chapter 14. Relevant information has been moved to the new chapter 7.<br><br>- Transfer of original chapter 15 to an appendix as distributors are not DU. The content has been revised by eliminating out of date information and highlighting what is currently relevant for distributors.<br><br>- Elimination of Appendixes 1, 2, 4, 5 as the information on ES, how to develop it and examples is currently covered by other more appropriate and up to date documents.<br><br>- Elimination of Appendix 3. The formats are to be provided in electronic version and made available on the website in order to facilitate the update and the usability.<br><br>- Creation of new appendix 2 where scaling principles and methodology are described in more detail. Part of the information is taken from existing Part G of Guidance on IR&CSA.<br><br>- Creation of a new Appendix 3 where core principles for the selection of information to communicate on mixture are elaborated. The Appendix is meant to complement chapter 7.<br><br>- Update of original Appendix 6 (moved to Appendix 4) on relevant EU legislation. | |
| Version 2.1 | Corrigendum covering the following:<br><br>- Addition in chapter 7.1 of: the minimum individual concentration in mixtures of Substances of Very High Concern included in the Candidate List that triggers an obligation to provide a safety data sheet;<br><br>- Further minor editorial corrections (to the English language version only). | October 2014 |

## PREFACE

This document describes the requirements for downstream users under REACH. It is part of a series of guidance documents that aims to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation. These documents give 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 have been originally drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates these guidance documents following the Consultation procedure on guidance. These guidance documents can be obtained via the website of ECHA[1]. Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[2].

[1] echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

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

# Table of content

Table of content ..... 7
Table of tables ..... 10
Table of figures ..... 11
0 Objectives of this guidance ..... 13
1 Introduction ..... 14
1.1 Overview of the REACH processes ..... 14
1.1.1 Registration ..... 14
1.1.2 Evaluation ..... 15
1.1.3 Authorisation ..... 16
1.1.4 Restriction ..... 16
1.2 Communication in the supply chain under REACH ..... 17
1.2.1 The role of registrant in supply chain communication ..... 17
1.2.2 The role of the downstream users in supply chain communication ..... 18
1.3 Explanation of key terms ..... 21
1.3.1 Placing on the market ..... 21
1.3.2 Use, own use and identified use ..... 21
1.3.3 Exposure scenario ..... 22
1.3.4 Conditions of use ..... 22
1.4 Overview of the main downstream user obligations under REACH and how they are dealt with in the guidance ..... 23
1.4.1 Navigate through the guidance ..... 24
2 Understanding your roles under REACH ..... 27
2.1 Identification of downstream user roles ..... 27
2.1.1 Who is a downstream user under REACH? ..... 27
2.1.2 Other roles under REACH ..... 30
3 Collecting and communicating information on your uses of chemical substances ..... 33
3.1 Introduction ..... 33
3.2 Life cycle of a substance ..... 34
3.3 Communicating information on uses via sector organisations ..... 35
3.3.1 Main elements when communicating information on uses via sector organisations ..... 36
3.4 Communicating information on uses directly to the supplier ..... 37
3.4.1 Main elements when communicating information on uses directly to the supplier ..... 37
3.5 Supplier response on receiving information on customer uses ..... 39
4 Downstream users and Exposure Scenarios ..... 41

4.1 Legal requirements related to downstream users' compliance with the information received by the supplier ....41
4.2 Checking if the use and conditions of use are covered by the exposure scenario ...42
4.2.1 Checking the use ....42
4.2.2 Checking processes/activities of the exposure scenario ....43
4.2.3 Checking the conditions of use (OC and RMM) ....43
4.2.4 Scaling ....45
4.2.4.1 When scaling is applicable ....45
4.2.5 Uses advised against ....46
4.3 What to do if the use and conditions of use are covered by the exposure scenario. 46
4.4 What to do if uses and conditions of use are not covered by the exposure scenario. ....47
4.4.1 Introduction ....47
4.4.2 Do exemptions to preparing a downstream user chemical safety report apply? ....48
4.4.3 Make your use known to your supplier with the aim of having it identified..51
4.4.4 Implement the conditions of use of the exposure scenario ....51
4.4.5 Substituting the substance or substance in mixture ....52
4.4.6 Downstream user chemical safety report (DU CSR) ....52
4.5 Your use is confidential ....52
4.6 Timescales for fulfilling obligations ....52
5 Use not covered: preparing a downstream user chemical safety report (DU CSR) ....54
5.1 Legal requirements related to a downstream user chemical safety report (DU CSR) ....54
5.1.1 Obligation to report information ....55
5.2 What is a chemical safety assessment and report ....56
5.3 What is a downstream user chemical safety report (DU CSR) ....57
5.4 Key steps for the downstream user chemical safety assessment ....58
5.4.1 Review the supplier's hazard information (and adapt if necessary) ....60
5.4.2 Develop exposure scenarios (for uses not covered) ....61
5.4.3 Exposure Estimation ....61
5.4.4 Characterise the Risk ....63
5.4.5 Documenting the downstream user chemical safety assessment in the report ....63
5.5 Reporting to ECHA ....64
5.6 Annex relevant Exposure Scenario(s) to updated SDS ....64
6 Communicating new information on hazards and risk management measures upstream .66
6.1 Introduction ....66
6.2 Communicating new information on hazardous properties up in the supply chain ...66

6.3 Communicating on the appropriateness of the risk management measures upstream ....68
6.4 Reporting new classification of a substance to ECHA ....69
7 Communication in the supply chain related to mixtures ....71
7.1 Legal obligations related to mixtures under REACH ....71
7.2 Communicating information on conditions of use regarding mixtures in safety data sheets ....81
7.2.1 Collating information on substances and mixtures from suppliers ....81
7.2.2 Identifying information to communicate to downstream users ....82
7.2.3 Options for including information to communicate to downstream users ....84
7.2.4 General guidelines when communicating information downstream ....88
8 Requirements related to authorisation, restrictions and substances in articles ....90
8.1 Authorisation requirements and downstream users ....90
8.1.1 Uses exempted from authorisation ....91
8.1.2 Fulfilling authorisation requirements ....93
8.1.3 Contributing to public consultations ....96
8.2 Downstream users and restriction requirements ....99
8.2.1 Restrictions in a nutshell ....99
8.2.2 General exemption from restrictions ....100
8.2.3 Ensuring compliance with restrictions ....100
8.2.4 Contributing to public consultations ....101
8.3 Compliance with requirements related to substances in articles ....102
8.3.1 Exemptions from the requirements ....102
8.3.2 Staying prepared ....103
8.3.3 Forwarding information with articles ....103
Appendix 1 Compliance with REACH for distributors ....104
A1.1 Overview of REACH and distributors ....104
A1.2 Obligations for distributors under REACH ....104
Appendix 2 Scaling ....110
A2.1 Boundaries of scaling ....110
A2.2 Defining scaling options ....111
A2.3 Methodologies to be used for scaling ....113
Appendix 3 Core principle for selecting information to communicate with mixtures ....115
Appendix 4 EU Legislation with requirements relevant to REACH ....119
Appendix 5 Structured overview of communication needs along the supply chain ....126

# Table of tables

Table 1 Summary of the communication obligations for registered substances under REACH..17
Table 2 Examples of uses .....22
Table 3 Examples of operational conditions.....23
Table 4 Main obligations/actions of downstream users and the relevant timelines.....24
Table 5 Identification of your role – downstream user .....28
Table 6 Identification of your role – other actors treated like downstream users.....29
Table 7 Identification of your role – manufacturers/importers of substances as such, in mixtures or articles.....31
Table 8 Identification of roles – roles other than downstream user or manufacturer/importer.31
Table 9 Checking risk management measures.....44
Table 10 Options if exposure scenario does not cover the use .....47
Table 11 Checking if the exemptions from the duty of Article 37(4) to prepare a downstream user chemical safety report (DU CSR) apply.....49
Table 12 Summary of total use and “Use not covered” tonnages with associated reporting requirements .....55
Table 13 Forwarding information on classified substances and mixtures .....67
Table 14 Legal references in Title IV REACH relating to formulation of mixtures together with clarification .....74
Table 15 Generic exemptions from the authorisation requirement.....91
Table 16 Information flow in the supply chain .....107
Table 17 Core principles for selecting relevant information from exposure scenarios to communicate for mixtures .....116

# Table of figures

Figure 1 Simplified representation of communication flows under REACH (dotted-dashed lines represent industry-industry communication flow; dashed lines represent industry-authority communication) ..... 20

Figure 2 General overview of the actions triggered by information received by the downstream users under REACH ..... 26

Figure 3 Schematic presentation of potential uses of a substance at different life cycle stages. The downstream user uses are marked with "(DU)". ..... 35

Figure 4 Work process for downstream user chemical safety assessment ..... 58

Figure 5 Workflow summarising when a safety data sheet or other information on a mixture must be forwarded to downstream users and distributors. Note that a supplier is not obliged to provide a safety data sheet to consumers. ..... 73

Figure 6 Suggested simplified decision tree for formulators to identify how to communicate information on the safe use of mixtures downstream ..... 87

Figure 7 Workflow on fulfilling authorisation requirement ..... 98

Figure 8 Workflow checking compliance with restrictions ..... 101

Figure 9 The distributor and the supply chain ..... 105

# List of acronyms

| | |
|---|---|
| AC | Article category |
| BREF | Best available techniques reference documents |
| CL | Candidate List |
| CMR | Carcinogenic, mutagenic or toxic for reproduction |
| CSA | Chemical safety assessment |
| CSR | Chemical safety report |
| DMEL | Derived minimal effect level |
| DNEL | Derived No-Effect Level |
| DU | Downstream user |
| DU CSR | Downstream User Chemical Safety Report |
| ECHA | European Chemicals Agency |
| EEA | European Economic Area |
| ERC | Environment release category |
| ES | Exposure Scenario |
| (ext)SDS | Extended safety data sheet |
| GES | Generic Exposure Scenario |
| Guidance on IR&CSA | (ECHA) Guidance on Information Requirements and Chemical Safety Assessment |
| OC | Operational Condition |
| OEL | Occupational Exposure Limit |
| PC | Chemical product category |
| PNEC | Predicted No Effect Concentration |
| PPORD | Product and Processes Orientated Research and Development |
| PROC | Process category |
| RMM | Risk Management Measure |
| SCED | Specific consumer exposure determinant |
| SDS | Safety data sheet |
| SpERC | Specific environmental release category |
| SU | Sector of use category |
| SVHC | Substance of Very High Concern |

# 0 Objectives of this guidance

This guidance is intended for downstream users of chemical substances. A company can have many different roles under REACH, as a role is tied to the company's activities related to a given substance. A downstream user is a specific role under REACH. It refers to using a substance, either on its own or in a mixture, in the course of his industrial or professional activities. Manufacturer and importers are examples of other roles under REACH.

Many different types of companies can have a downstream user role, including formulators of mixtures, industrial users of chemicals and mixtures, producers of articles, craftsmen, workshops and service providers (e.g. professional cleaners) or refillers.

This guidance also provides useful information for other actors in the supply chain, who are not downstream users or manufacturers and importers, but still have obligations under REACH. This includes distributors, retailers and storage providers.

This guidance helps the reader to clarify the role(s) under REACH. It covers the obligations that a downstream user may face under REACH, as well as the different circumstances that a downstream user may encounter. Information is also provided on the downstream users web page of the ECHA website[3]. The Navigator tool[4] provides an additional form of help to identify roles and obligations under REACH with regard to the substances you are using. A range of other publications, including the Practical Guide on *"How downstream users can handle exposure scenarios"*[5], may also be of assistance.

Please note, in this guidance footnotes are in general used to provide complementary information such as references to related documents and to the legislation or explanation of additional duties.

[3] Available at echa.europa.eu/regulations/reach/downstream-users.

[4] Available at echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations.

[5] Available on the ECHA website at echa.europa.eu/practical-guides.

# 1 Introduction

## 1.1 Overview of the REACH processes

REACH[6], the European regulation on registration, evaluation, authorisation and restriction of chemicals, entered into force on 1 June 2007. The Regulation aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. It applies in all Member States of the European Union and in the EEA countries Iceland, Norway and Liechtenstein.

### 1.1.1 Registration

One of the main requirements of REACH is the **registration** of chemical substances. This means that each manufacturer or importer of a substance, if he manufactures/imports the substance at 1 tonne or more per year, must provide a defined set of information, in the form of a registration dossier, to the European Chemicals Agency (ECHA). This information includes the hazards of the substance and the expected exposure from using the substance[7].

If the substance is manufactured or imported in quantity of 10 tonne or more per year a **chemical safety assessment** (CSA) is required. Firstly, the hazards resulting from intrinsic properties of the substance are assessed (hazard assessment). If the substance fulfils certain hazard criteria[8], an assessment of the nature and extent of the exposure it is also required (exposure assessment and risk characterisation). The aim is to demonstrate that the risks stemming from exposure can be controlled with a set of operational conditions (OC) and risk management measures (RMM) designed for that use.

The CSA and its results are documented in a chemical safety report (CSR) which forms a part of the registration dossier. This should be updated whenever new relevant information is available.

***How does registration affect you as downstream user?*** The registration process yields information on the substance hazard and risk. Information on recommended risk management measures for specified uses is detailed in the chemical safety report. This is provided, where applicable, in the form of exposure scenarios that are annexed to the safety data sheet (SDS). For mixtures, the relevant information from exposure scenarios may be included in the SDS in different ways according to the case[9].

Some substances are registered as intermediates. If your use of a substance is as **intermediate**[10] **under Strictly Controlled Conditions**[11] you have to make sure that your

---

[6] 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).

[7] Some substances and uses are outside the scope of REACH. Details are provided in echa.europa.eu/guidance-documents/guidance-on-reach.

[8] Substance fulfilling the criteria for the hazard classes or categories set out in Annex I to the CLP Regulation and listed in Article 14(4) of REACH.

[9] Please see chapter 7 of this guidance for more information. Furthermore, the *Guidance for the compilation of safety data sheets* (echa.europa.eu/guidance-documents/guidance-on-reach) provides also relevant information.

[10] Intermediates are defined in REACH under Art 3(15).

use is performed in compliance to REACH requirements for intermediates. You may also be required to send a written confirmation to your supplier about your use as intermediate. Additional details on intermediates are available in the ECHA *Guidance on Intermediates*[12].

REACH applies to most of the hazardous substances in use today. Registration of substances that have been already on the market is taking place on a phased basis between 2010 and 2018 depending on the tonnage and hazardous properties of the substance[13]. New substances need to be registered before they can be placed on the market.

### 1.1.2 Evaluation

Under REACH, the compliance of individual registration dossiers of single substances may be **evaluated** by the authorities. Two types of evaluation are undertaken, dossier evaluation and substance evaluation.

ECHA is required to assess at least 5% of the registration dossiers in each tonnage band to confirm whether the information in the dossiers complies with the information requirements set in REACH. If ECHA concludes that a dossier is non compliant, it will request the registrant to update his dossier. ECHA also scrutinises the testing proposals[14] submitted as part of the registration dossiers and either grants the permission to conduct the test, refuses it, or proposes changes to the testing protocol.

Substance evaluation takes into account all registration dossiers for a given substance and is a task carried out by the Member State Competent Authorities. It is undertaken if there are reasons to consider that a substance may pose a risk to human health or the environment. During the process the Competent Authorities may approach registrants to gather more information on the substance, on its uses or on the exposure related to it.

***How does evaluation affect downstream users?*** Both dossier and substance evaluation concern the registrants, and downstream users are not directly affected by these processes.

Both processes may result in a change in the registrant's assessment and consequently uses supported and/or the conditions of use recommended. As a result, you may receive an updated safety data sheet.

Furthermore, an outcome of substance evaluation is that substances that have serious effects on human health or the environment are identified as Substances of Very High Concern (SVHCs) and placed in the Candidate List[15]. Downstream users have legal obligations if they supply substances (as such or in mixtures) that are included in the Candidate List, as described in chapter 8 of this Guidance. Also companies supplying articles containing substances in the Candidate List may have obligations to forward information on safe use and

---

[11] Strictly controlled conditions and related obligations are defined in Art. 17 and Art. 18 of REACH.

[12] Available at: echa.europa.eu/guidance-documents/guidance-on-reach .

[13] Deadline 30 November 2010: Substances manufactured/imported at 1000 tonnes/year or more, substances that are very toxic to aquatic environments and manufactured/imported at 100 tonnes/year or more and all CMR substances at 1 tonne/year or more; deadline 31 May 2013: Substances manufactured/imported at 100 tonnes/year or more; deadline 31 May 2018: all other pre-registered phase-in substances. For more information on registration, see *Guidance on Registration* at echa.europa.eu/guidance-documents/guidance-on-reach.

[14] One of the aims of the REACH Regulation is to reduce unnecessary animal testing. Therefore, companies are not allowed to undertake a test on vertebrate animals that is required under REACH Annexes IX and X without the permission of ECHA. To this end, registrants who consider that a test on vertebrate animals would be necessary to conclude on the safe use of their substance, submit a testing proposal to ECHA as part of their registration dossier.

[15] More information on SVHC and the candidate list are available at the ECHA website under echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification/candidate-list-of-substances-of-very-high-concern-for-authorisation.

to notify ECHA. Additional information on obligations resulting from inclusion of substances in the CL can be found in the dedicated ECHA web page[16].

### 1.1.3 Authorisation

SVHCs included in the Candidate List and subsequently placed in Annex XIV of REACH will require **authorisation** before they can be used. The aim of authorisation is to properly control the risks stemming from these substances and progressively replace them with suitable less hazardous alternatives or technologies where these are economically and technically viable and ensuring the efficient functioning of the single market. After a substance has been included in Annex XIV, it cannot be placed on the market or used after a given date (sunset date), unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

***How does authorisation affect downstream users?*** A downstream user may use a substance subject to authorisation provided that the use is in accordance with the conditions of an authorisation granted to an actor up in the supply chain. The downstream user can also decide to apply for an authorisation for his own use and, if relevant, for his customers' uses. This decision should be made as soon as the substance is included in Annex XIV as the processing of the authorisation application takes time.

If a substance is subject to authorisation, this information should be communicated by the supplier and the authorisation number should also be included on the label and in Section 2 of the safety data sheet[17].

Authorisation requirements relating to downstream users are detailed in chapter 8 of this guidance.

### 1.1.4 Restriction

Finally, Community-wide **restrictions** may be placed on certain substances to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance, and hence may also affect the use of a substance by a downstream user.

***How does restriction affect downstream users?*** If a restriction applies to a substance that is used by a downstream user, either on its own or in a mixture or in an article, he may only continue to use it if his use is not one of the restricted uses. The restriction process is not new under REACH, and previous restrictions under Directive 76/769/EC have been carried over into Annex XVII of REACH.

Chapter 8 of this guidance describes how restriction affects downstream users.

---

[16] echa.europa.eu/candidate-list-obligations.

[17] Please refer to the *Guidance on the compilation of the safety data sheets* available at echa.europa.eu/guidance-documents/guidance-on-reach.

## 1.2 Communication in the supply chain under REACH

REACH reversed the burden of proof concerning the safety of chemical substances: it is now up to manufacturers, importers and downstream users to ensure that they manufacture and use chemical substances in a way that does not adversely affect human health or the environment. Communication in the supply chain between registrants and downstream users is important to achieve this goal.

Downstream users can expect different communication from their suppliers depending on whether the substance or mixture is hazardous; whether the substance is registered; and on the quantity manufactured/imported by the registrant in their supply chain.

Just as before the implementation of REACH, downstream users receive information on hazardous substances and mixtures in safety data sheets. Now, with REACH, safety data sheets may have exposure scenario(s) as annexes when a hazardous substance has been registered in quantities of over 10 tonnes per year. The exposure scenario gives more specific information on how to use the substance safely, and how the workers, customers, consumers and the environment can be protected from risks.

An overview of the communication obligations for registered substances under REACH is presented in Table 1. The communication of information related to mixtures is discussed in chapter 7. The information gathered in the registration process may trigger a need to update the safety data sheets.

Suppliers may also provide a safety data sheet on a voluntary basis even for substances for which is not required.

**Table 1 Summary of the communication obligations for registered substances under REACH**

| Type of communication | Substance is not hazardous | Substance is hazardous |
|---|---|---|
| **Safety Data Sheet** | • SDS is not required.<br>• SDS may be provided voluntarily<br>• Information according to Article 32 shall be provided | • SDS is required (for substances hazardous according to Article 31(1)) |
| **Exposure scenario** | • ES is not required | • ES is required if manufacturer/importer registered above 10 tonnes/year (for substances hazardous according to Article 14(1)) |

### 1.2.1 The role of registrant in supply chain communication

The registrants compile the information on hazardous properties and uses for individual substances as part of the registration process. They have the duty to conduct a chemical safety assessment for the substances that they manufacture or import in quantities of 10 tonnes or more per year. Exposure scenarios are based on the chemical safety assessments that are conducted by the registrants for the substances. Registrants themselves may have limited knowledge on the use of the substance further down in the supply chain. Consequently, the information they receive on uses from downstream users is crucial to ensure that the information they communicate through exposure scenarios is applicable.

There are mechanisms foreseen under REACH to bring together the knowledge on the substance properties from registrants and knowledge on the substance uses from downstream users. Downstream users can even request to become a member of the Substance Exchange

Information Forum (SIEF) for a specific substance with the intention to share relevant data which they may own[18].

In order to carry out the chemical safety assessment for the substances they intend to register, the registrants first need to understand how the substance is used throughout its life cycle. This analysis is complicated by the fact that in real life most substances occur in mixtures and/or articles, while REACH requires to follow the life cycle of a substance.

The life cycle of a substance starts upon its manufacture and ends when the substance is either transformed into another substance, is released as an emission to air or waste water or becomes waste. Relatively few substances follow a simple life cycle where the substance is manufactured, used as such, and is emitted/becomes waste. More typically, a substance is manufactured and then mixed with other substances in the process of formulation. These mixtures are then used as a basis for formulating other mixtures, or used as such. There may be several further formulation steps in the substance's life cycle, and some mixtures may end up in articles. Finally, if not emitted, substances become waste that also needs to be handled safely.

REACH foresees that the registrants gather the information on how the substance is used from the downstream users. This includes listing the uses of the substance through its life cycle, uses of articles containing the substance and the waste stage as well as information on the actual conditions of use, i.e. what are the operational conditions for each use and what kind of risk management measures have been put in place for each use. The registrants use this information as a starting basis for their chemical safety assessment. In a potentially iterative process, the registrants need to come to a conclusion on operational conditions and risk management measures under which the substance can be used safely.

As there are many possibilities for a substance to be used, the compilation of information on uses needs to be done in a systematic way using harmonised approaches (see chapter 3). Sector organisations, where they exist, play a crucial role in the process, as a structured dialogue between downstream users and registrants is necessary. In short, it is advised that the sector organisations gather information from their members and convert it into generic assessment elements that cover majority of uses in their sector, and pass this information on to the registrants. Also the uses communicated directly by the downstream user to his supplier should be communicated with agreed, harmonised means. This way the information presented to the registrants contains all the necessary elements required for the chemical safety assessment, and at the same time represents reliably the existing practises in the supply chain.

After the registrants have concluded their chemical safety assessment and produced a chemical safety report, they submit it to ECHA as part of their registration dossier. The CSR may be scrutinised by ECHA, and the registrants may need to update it after a compliance check. The registrants use the CSR as a basis for generating exposure scenarios, that are annexed to the safety data sheets, for communication down the supply chain. The ECHA *Guidance on Information requirements and chemical safety assessment*, (IR&CSA) Part A[19] provides a comprehensive description of the key elements of a chemical safety assessment.

### 1.2.2 The role of the downstream users in supply chain communication

Downstream users communicate information on the substance, its uses and the conditions of safe use up and down the supply chain to ensure that every use has been assessed as safe.

---

[18] Companies that intend to register the same phase-in substance will join a Substance Information Exchange Forum (SIEF) to share data on the intrinsic properties of the substance, avoid the duplication of studies (in particular, they have the obligation to share all test data on vertebrate animals) and eventually come to the preparation of one joint submission for each substance. More information on the data sharing processes and possible involvement of downstream users, please consult the *Guidance on data sharing* available at echa.europa.eu/guidance-documents/guidance-on-reach.

[19] echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

When downstream users receive safety data sheets, they should identify, apply and recommend appropriate measures to adequately control the risk. When downstream users receive exposure scenarios, or information derived from them, they need to check if their use and foreseeable uses of their products and conditions of use are covered in it. If so, this means the uses have been included in the registrant's chemical safety assessment and assessed to be safe. If not, the downstream user has to take action. This process of checking the information in an extended safety data sheet applies both to formulators and end-users and is described in chapter 4.

When formulators receive safety data sheets and exposure scenarios, they have to pass relevant information along the supply chain to their customers. They need to decide how to best convert the information they receive on substances into information concerning safe use of mixtures. The approaches and options are described in chapter 7.

Downstream users also have a role in ensuring that the risk management measures identified in a safety data sheet are appropriate, by informing suppliers when this is not the case.

Eventually the safety information reaches the end-users of the substance, that can be either industrial or professional ones[20]. They are operators who do not have the duty to forward the exposure scenario information, but only have the duty to check that their use and conditions of use are covered by it.

A schematic representation of communication flow under REACH with one formulator level only is presented in Figure 1.

[20] The terms "industrial user" and "professional user" are explained in Table 5.

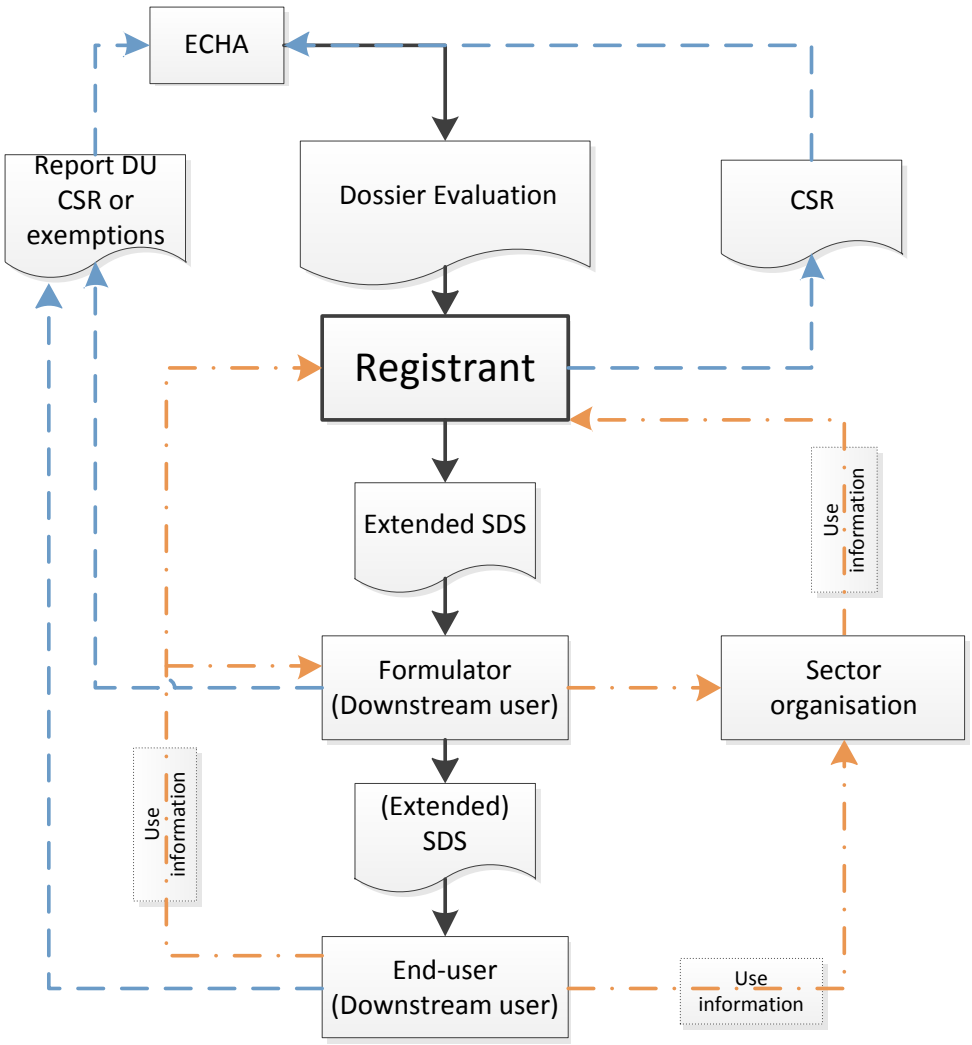


**Figure 1 Simplified representation of communication flows under REACH[21] (dotted-dashed lines represent industry-industry communication flow; dashed lines represent industry-authority communication)**

The simplified summary presented above illustrates that communication in the supply chain between the registrant and downstream user is crucial for the overall success: the better the uses and existing conditions of use are described to the registrants in the first place, the smoother the subsequent communication down in the supply chain operates.

It is important that the downstream users carefully check the information contained in the safety data sheet received before starting the communication with the supplier.

[21] Different downstream user roles are explained in Tables 5 and 6.

## 1.3 Explanation of key terms

This chapter provides a summary of key terms which are significant for downstream users.

### 1.3.1 Placing on the market

*Article 3(12)*

*Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.*

Placing a substance or mixture on the market under REACH means supplying or making it available to third parties, whether in return for payment or free of charge within the territory of the EEA (EU Member States and those EEA i.e. Iceland, Norway and Liechtenstein)[22]. In addition, import, defined as the physical introduction of a substance or mixture into the customs territory of the EU and those EEA countries, is deemed to be placing on the market[23].

### 1.3.2 Use, own use and identified use

*Article 3(24)*

*Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;*

Under REACH a "use" is almost any activity carried out with a substance as such or in a mixture. While the term use can be interpreted very broadly, there are more specific terms under REACH which are very important for downstream users as well as for registrants: the term "registrant's own use" and the term "identified use".

*Article 3(25)*

*Registrant's own use: means an industrial or professional use by the registrant;*

*Article 3(26)*

*Identified use: means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;*

A use may become an "identified use" if an actor (manufacturer/importer, distributor or downstream user) in the supply chain:

- uses (or intends to use) a substance -as such or in a mixture- or mixture himself, or
- is informed by one of his immediate downstream users in writing of an existing (or intended) use.

Some examples of use are given in the table below.

---

[22] Purchasing substances or mixture from Switzerland, which is not an EEA member, or e.g. from Japan is considered as import.

[23] The definition of "placing on the market" is provided also in CLP FAQ nr 160 while more information on the definition of "import" is provided in REACH FAQs "Import of substances into the EU". FAQs and Q&As are available at www.echa.europa.eu/support/faqs.

**Table 2 Examples of uses**

| | |
|---|---|
| Formulation of a paint | Substances and mixtures are used in a mixing process. The use consists of several activities, such as the handling of raw materials and loading of vessels, the mixing process and the filling of paint into containers. In addition, vessels may have to be cleaned. |
| Electroplating of metal | Electrolytes (substances or mixtures) are used to cover metals. The use consists of several activities, such as the preparation of the electroplating baths (filling and adjustment), the immersion of parts into the baths and the drying of parts. Cleaning and maintenance activities are also part of the use. |
| Blowing of plastic films | Raw materials of polymer compounds are mixed, filled into the extruder, heated and blown, the material is cooled and packaged. |

### 1.3.3 Exposure scenario

The exposure scenario (ES) for an identified use (or a group of uses) describes the conditions under which a substance can be used whilst controlling risks. The identified use is indicated in the title of the exposure scenario as well as under Section 1 (sub-section 1.2) of the safety data sheet.

The exposure scenario is an instrument for communicating operational conditions and risk management measures that are suitable to ensure control of risks to the users throughout the supply chain. An exposure scenario may be comprised of a number of contributing scenarios which describe various scenarios (covering the environment, workers and consumers as applicable) within a given exposure scenario.

### 1.3.4 Conditions of use

The term “conditions of use” covers the parameters which have an influence in the assessment of the exposure to a substance during the use (so-called determinants of exposure). It includes:

- the **operational conditions (OC)** of use; and
- the **risk management measures (RMM)**.

The **operational conditions** describe the conditions under which workers or consumers use a substance. This includes for example process conditions (e.g. temperature, contained or open process), frequency and duration of the use, amounts used. Operational conditions include also the physical form of the substance in the process or product (solid/liquid/gaseous, degree of dustiness of the solid state), as well as the characteristics of the surroundings within which the substance is used (e.g. size of the room and ventilation rate) and into which the substance is emitted (e.g. river flow rate and capacity of sewage system).

The term **“risk management measure”** means a measure that is introduced during manufacture or use of a substance (either as such or in a mixture) and that limits or prevents the exposure of humans or the environment. Risk management measures applied in industrial uses include, for example, containment of process, exhaust ventilation, waste gas incinerators, on-site waste (water) treatment or municipal sewage treatment. The use of personal protective equipment, such as gloves or masks, is also a risk management measure.

Table 3 below provides practical examples of operational conditions and risk management measures.

**Table 3 Examples of operational conditions**

| | Example 1 | Example 2 |
|---|---|---|
| Identified use | Industrial use of a hard surface cleaner<br>Washing and cleaning product | Industrial use of a hard surface cleaner<br>Washing and cleaning product |
| Type of activity/use | • Dilution of a concentrated solution<br>• Spray onto surfaces to be cleaned.<br>• Wiping off surface with a cloth. | • Dilution of a concentrated solution<br>• Spray onto surfaces to be cleaned.<br>• Wiping off surface with a cloth |
| **Operational condition** | | |
| Concentration | > 25% | > 25% |
| Duration | 1 hrs/day | 8 hrs/day |
| Frequency | 5 workdays/week | 5 workdays/week |
| **Risk Management Measures** | | |
| Ventilation conditions | The application takes place indoors<br>Normal air exchange of 0.5/hr | The application takes place outdoors |
| Containment | Open process | Open process |

## 1.4 Overview of the main downstream user obligations under REACH and how they are dealt with in the guidance

The main obligations and actions of downstream users are presented in Table 4. Depending on the circumstances and sometimes also on your own choices, you as a downstream user can have one or several of the following obligations:

- Identify the appropriate measures described in the safety data sheets you receive and apply them.
- If you receive an exposure scenario, or information sourced from one, check whether your current use is covered and whether you comply with the conditions described in it.
- If your use is not covered by an exposure scenario, communicate with your supplier with the aim of having your use covered by an exposure scenario, or take another action (see chapter 4.4 and chapter 5).
- Contact your suppliers if you have new information on the hazard of the substance or mixture, or if you believe that the risk management measures communicated to you are not appropriate (see chapter 6).
- If you place substances or mixtures on the market (e.g. you are a formulator), or are a producer of articles, provide appropriate information to your customers to enable safe use (see chapters 7 and 8).
- Comply with the obligations related to the authorisation or restriction of the substance that you use. Relevant information and conditions to be complied with are indicated by your supplier, usually in the safety data sheet (see chapter 8).

In addition, to facilitate communication in the supply chain you (preferably via your sector organisation), you should communicate your typical uses and conditions of use to the registrants of the substance prior to registration so that they can base their chemical safety

assessment and the resulting exposure scenarios on realistic information from downstream in the supply chain.

The obligations relating to identifying and applying risk reduction measures, to downstream user chemicals safety assessments and reporting obligations are described in Title V of REACH. The obligations under REACH related to information in the supply chain, including compilation of safety data sheets, are described in Title IV of REACH. The provisions of Title IV and V do not apply to certain substances and mixtures which pose minimum risk, for which the safe use is regulated by other pieces of legislation or that fall outside the scope of application of REACH (see Article 2).

### 1.4.1 Navigate through the guidance

The guidance is structured so that your main obligations and requirements as downstream users are dealt with in different chapters. The main obligations and actions required from you as downstream users, as well as the relevant timelines are summarised in the table 4 and the subsequent flowchart below (Figure 2). Reference to further information in this guidance is included.

The REACH regulation addresses manufacture and use of chemical **substances**, as such or incorporated in mixtures, or incorporated into articles. Throughout the present guidance the term "substances" refers to this broader understanding when applicable.

**Table 4 Main obligations/actions of downstream users and the relevant timelines**

| | Obligations/Actions | Timeline | Go to chapter(s) |
|---|---|---|---|
| **Obligations related to communication in the supply chain** | Identify roles under REACH. | 1 June 2007 onwards. | 2 |
| | Make uses known to the registrants (voluntary action). | By 31 May 2017 for the phase-in substances to be registered by 31 May 2018. | 3 |
| | Identify and apply appropriate measures to control the risks communicated in SDS or other information supplied. | Within 12 months of receiving a SDS for a registered substance. | 4 |
| | Check if own use covered in supplier's exposure scenario, and take further action in case your use is not covered. | 6 months to report unsupported use to ECHA, 12 months to implement measures after receiving SDS for a registered substance. | 4 & 5 |
| | Communicate to the supplier information that might call into question the appropriateness of the risk management measures in any exposure scenario received. | Without delay. | 6 |
| | Inform suppliers of any new information on hazards, including classification and | Without delay. | 6 |

| | | | |
|---|---|---|---|
| | labelling. | | |
| **Additional obligations for formulators and re-fillers only** | Provide information to your customers, including retailers / consumers, to enable safe use of substances or mixtures. This should be in accordance with Title IV of the Regulation. | Without delay, for information specified in Article 31(9). | 7 |
| **Obligations related to the substances subject to authorisation** | Your supplier or you need to apply for an authorisation for your use if you want to continue to use the substance listed in Annex XIV after the sunset date.<br>For substances subject to authorisation, comply with the conditions of the authorisation covering your use, and (if the supplier has applied for the authorisation) notify your use of the authorised substance to ECHA. | Notify use of authorised substance to ECHA within 3 months of the first supply of the substance. | 8 |
| **Obligations related to the substances subject to restrictions** | Check compliance with any restrictions on the substance. | As specified in Annex XVII of REACH. | 8 |
| **Additional obligations for article producers only** | Provide information to enable safe use of articles you produce or supply containing substances of very high concern in concentrations above 0.1 % w/w and, if requested, to consumers (Article 33 of REACH). | For industrial/ professional users when supplying the article; For consumers upon request and within 45 days. | 8 |
| **Additional obligations for re-importer** | Document that substance(s) are identical to those registered in the EEA by someone in your supply chain. Have documentation according to Article 31 (safety data sheet and exposure scenario where applicable) or Article 32 of REACH. | Upon re-import of the substance. | 2.1.1<br>(Table 5) |

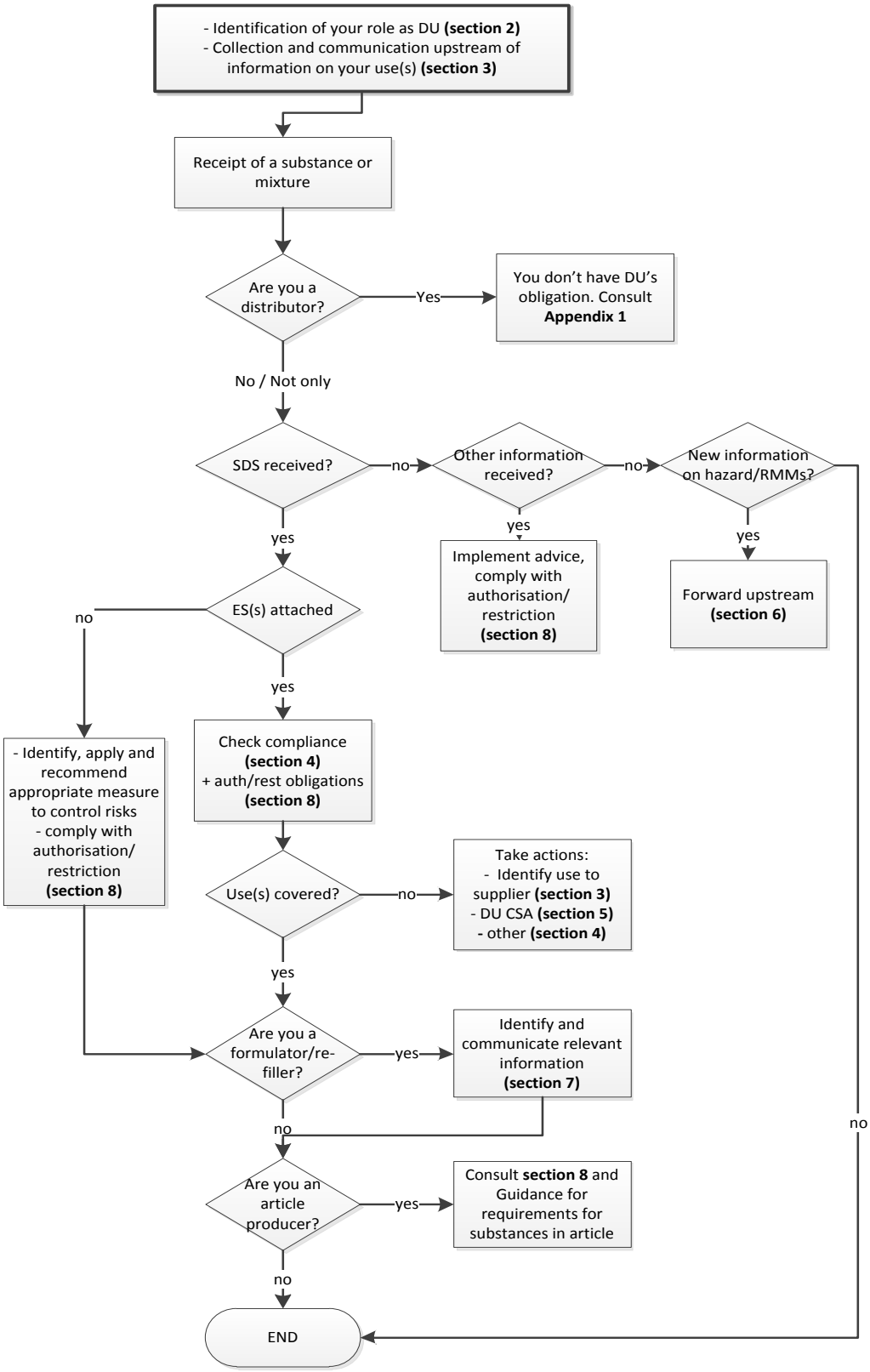


**Figure 2 General overview of the actions triggered by information received by the downstream users under REACH**

# 2 Understanding your roles under REACH

This chapter provides guidance to assist downstream users to identify their roles under REACH.

## 2.1 Identification of downstream user roles

Your obligations under REACH will depend on the exact activity you carry out in relation to each specific substance that you use, either on its own, in a mixture or in an article[24]. Firstly, it is important to check that you are not a manufacturer or an importer, as you may then have an obligation to register the substances or other obligations related to articles. Secondly, you should check if your activities correspond to the roles of a distributor or a consumer, as these roles are explicitly excluded from the definition of a downstream user. Read chapter 2.1.2 beneath to answer these questions.

If you come to the conclusion that your activity with regard to a substance is downstream use in the meaning of REACH, you need to ascertain which of the downstream user obligations apply to you.

Keep in mind that the requirements under REACH apply to you in relation to the individual substances that you use. Therefore, you may have more than one role and you should follow Tables 4, 5, 6 and 7 for each of your substances in order to identify all of your roles.

Furthermore it is to be noted that REACH applies to you also in case you carry out your activities individually, i.e. regardless the number of workers or personnel involved.

### 2.1.1 Who is a downstream user under REACH?

*Article 3(13)*

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

There are a number of downstream user roles reflecting the type of activity you carry out and your position in the supply chain. The roles of the following actors with downstream user obligations are explained in tables 5 and 6.

Table 5: Downstream user

- Formulator of mixtures
- Industrial end-user of substances as such or in mixtures
- Professional end-user of substances as such or in mixtures
- Article producer
- Re-filler.

Table 6: Other actors treated like downstream user

- Importer of substances where supplier has nominated an only representative
- Re-importer of substances.

[24] In this guidance the term substance means substance as such or in a mixture, unless otherwise indicated.

**Table 5 Identification of your role – downstream user**

| Question | Your role as a downstream user | Supporting information, examples |
|---|---|---|
| Do you mix substances purchased from EEA suppliers and mix them to make mixtures that you place on the market? | **You are a Formulator**: Actor producing mixtures.<br>Your customers/recipients may also be formulators if they use your mixtures to make other mixtures (e.g. if you supply a solution of an additive or a pigment paste).<br>Your customers/recipients may be commercial actors (and thus either formulators, industrial end-users or professional end-users under REACH) or consumers. They may use your mixtures to produce articles or apply them in other end-uses. This means that, once your customers have applied your mixture, it no longer exists in its supplied form, but is either used up in an end-use or incorporated in an article. Examples include decorative paints, cleaning products or polymer masterbatches. | If you only formulate mixtures, and no chemical reaction occurs during mixing, you do not manufacture any new substance. Dissolving a substance in water is not manufacturing a substance but a use. In contrast, an activity consisting in reacting e.g. acid with base, which results in a new substance, would be considered as manufacturing process[25] (see table 7 for further details).<br>You may be contracted to make a mixture by a third party, who owns the formulation and places it on the market. When making a mixture, you are considered a downstream user. An example is a formulator of a detergent sold under a retailer's own brand[26]. |
| Do you re-fill substances or mixtures from one container to another? | **You are a Re-filler**: Actor who transfers substances or mixtures from one container to another. | The transfer of substances or mixtures into new/different containers (re-packaging) is considered a use under REACH. Therefore, re-fillers are also downstream users, even if they do not apply the substances or mixtures in any other activity. |
| Do you operate at an industrial site and use substances which do not remain in the product? | **You are an industrial end-user**: End- user using substances which do not remain in the product (e.g. applied as processing aids) in the context of an industrial process. | If the substance(s) as such or in a mixture is not included in the product you produce, but is used to facilitate the processing or "washed off" after the production is finished, you use them solely as processing aids. |

[25] For further details on ionic mixtures, see *Guidance for Annex V* (attachment 1) at echa.europa.eu/guidance-documents/guidance-on-reach.

[26] An actor may contract a third party ("sub-contractor") to carry out a specific activity on his behalf. In cases where sub-contractors manufacture substances, they will have the obligation to register, if the substance is subject to registration (see Table 7). This is consistent with the concept of toll manufacturing under Directive 67/548/EEC (see Manual of Decisions of Directive 67/548/EEC, 7.4, p.113 available at publications.jrc.ec.europa.eu/repository/handle/111111111/5384). Sub-contractors performing the role of downstream users under REACH must comply with the downstream user obligations (see Tables 4 and 5). The principal actor might wish, for reasons of confidentiality, to undertake some of the tasks on behalf of the sub-contractor, e.g. preparing the safety data sheet/exposure scenario for the formulation. This does not change the responsibilities of the sub-contractor under REACH. The nature of the obligations is determined by the activity agreed upon by both parties in the contract. It is advisable that the allocation of the activities between the contractor and sub-contractor should be specified in the contract.

| | | |
|---|---|---|
| | You do not forward any substance or mixture to another actor. | Examples of industrial users are users of surface cleaners prior to electroplating or users of intermediates in chemical synthesis. |
| Do you operate at an industrial site and incorporate substances into articles in the context of professional activity? | **You are an article producer**: user incorporating a substance into articles.<br>**For obligations of an article producer see the *Guidance on requirements for substances in articles*[27].** | Incorporation of a substance as such or in a mixture into an article means:<br>a) inclusion into the article matrix, e.g. dying of textile fibres; or<br>b) application onto the article's surface, e.g. lacquering of steel. |
| Do you use substances and mixtures in the context of professional activities other than industrial use? | **You are a Professional end-user**: End-user using substances or mixtures in the context of professional activity, which is not considered an industrial process. | Users who apply substances in a professional capacity which is not regarded as an industrial use. This includes craftsmen, and service providers that may or may not have a fixed workplace / workshop.<br>Examples of such users are flooring contractors, mobile cleaning companies, professional painters, construction companies, farmers, and users of lubricants for equipment such as chainsaws. |

**Table 6 Identification of your role – other actors treated like downstream users**

| Question | Your role as an actor with downstream user obligations | Supporting information, examples |
|---|---|---|
| Do you import substances or mixtures from a non-EU supplier, who has nominated an only representative? | **You are an importer from a non-EU supplier which has an only representative who has registered the substance:** If your supplier has appointed an only representative, you will not be considered an importer but a downstream user. | If the non-EEA supplier has an only representative[28], this only representative takes over the responsibilities linked to the import of that substance into the EEA. Therefore you are regarded as a downstream user, even though you purchase directly from the non-EEA supplier and not from the only representative. It is recommended that you ask your non-EEA supplier whether he has such an only representative (if it's not the case, please consult table 7) and request written confirmation from the only representative that your imported substances are in compliance with REACH. |
| Do you know that a substance that you | **You are a re-importer** of substances: Actor who imports | You will need to have documentation showing that the substance is identical |

[27] Available at echa.europa.eu/guidance-documents/guidance-on-reach.

[28] An only representative is a natural or legal person who is appointed by a manufacturer of a substance outside the EU (who may manufacture substances, mixtures or articles) to fulfil the obligations as importer under REACH. Example: If you purchase from a manufacturer in Japan which has appointed an only representative then you shall be regarded as a downstream user. See *Guidance on Registration* for more information on only representatives (echa.europa.eu/guidance-documents/guidance-on-reach).

| | | |
|---|---|---|
| import from non-EU suppliers has been originally manufactured and registered in the EU up in your supply chain? | substances, as such or in mixtures, which have originally been produced in the EU.<br><br>In terms of REACH, you are considered a downstream user if you can prove that the substance was registered in the EU by someone in your supply chain. | to that registered in the EU by someone upstream in your supply chain. You can show this by tracing and documenting the supply chain and identifying the original registrant of the substance. This may apply internally, e.g. for trans-national companies which have split their production over different countries, but also for actors not belonging to the same company.<br><br>Furthermore, in order to avoid having to register the re-imported substance, you need to have available, e.g. from the registrant, a safety data sheet for hazardous substances/mixtures, or similar information.<br><br>E.g. a substance in a mixture that you bring into the EEA was first manufactured in EEA, then exported (for example to be formulated into that mixture). See *Guidance on Registration* for more information. |

### 2.1.2 Other roles under REACH

It is important to clarify – for each substance that you use in your activities – whether your role with regard to them is that of a downstream user or/and something else. In the next two tables the following roles under REACH are explained:

Table 7: Manufacturers/importers

- Manufacturer of substances
- Importer of substances as such or in mixtures
- Importer of substances in articles.

Table 8: Roles other than downstream user or manufacturer/importer

- Distributor
- Retailer
- Re-brander.

Check the tables beneath to find out if you carry out any of these roles with the substances you receive/purchase. If so, then you have additional duties under the REACH Regulation.

**Table 7 Identification of your role – manufacturers/importers of substances as such, in mixtures or articles**[29]

| Question | Your Role is... | Supporting information, examples |
|---|---|---|
| Do you produce substances or extract substances in the natural state? This includes substances created while making mixtures. | **Manufacturer** of a substance, either on its own or in one or more mixtures.<br>**See the *Guidance on registration* (in particular chapter 2.1 for the definition of manufacturer)** | The formation of "substances" during the normal use of a substance or mixture is, in principle, exempted from the registration requirement under Annex V.<br>For instance, if you use a reactive textile dye, there is a chemical reaction in your process, but this needs not to be registered, as it is a "reaction upon use", which is exempted. In contrast, if you produce calcium sulphate, as a by-product of neutralisation, and place it on the market, this is a marketed by-product and you need to register it (manufacturer/importer role). |
| Do you import substances or mixtures from outside the EEA? | **Importer** of substances as such or in mixtures<br>**See the *Guidance on registration*.** | Substances as such or substances contained in mixtures are imported if you are responsible for bringing them into the customs area of the EEA. If you import a polymer, you will need to check whether you have to register monomers and/ or other substances in the polymer. |
| Do you import articles? | **Importer of substances in articles**<br>**See the *Guidance on requirements for substances in articles*.** | REACH defines an article as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition does".<br>If the substance is present in quantities over 1 tonne per year in the articles you import and is intended to be released, you will need to register the substance.<br>If the substance is not intended to be released, but it is a substance of very high concern, you may have an obligation to notify ECHA. |

**Table 8 Identification of roles – roles other than downstream user or manufacturer/importer**

| Question | Role | Supporting information, examples |
|---|---|---|
| Are you established in the EEA and only store or place substances, on their own or in a mixture, on the market, by | **Distributor:** Actor who only stores and places on the market substances, on their own or in a mixture<br>**You are not a downstream** | To be a distributor as defined by REACH, you can only store and make substances and mixtures available to third parties (e.g. resell). |

[29] The Guidance documents mentioned in the table are available at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

| | | |
|---|---|---|
| supplying or making it available, whether in return for payment or free of charge, to a third party? | **user, but you do have obligations under REACH**<br><br>Go to Appendix 1 of this guidance. | If you undertake any activity with the substance defined as "use" under REACH, and do not merely store or place it on the market, you will be considered a downstream user and Table 4 will apply. |
| Do you affix your brand on a product that somebody else has manufactured? | **Re-brander:** Actor who affixes his own brand to a product that somebody else has manufactured.<br><br>**You are not a downstream user. You are considered a distributor and you do have obligations under REACH.**<br><br>Go to Appendix 1 of this guidance. | If, besides affixing your brand, you use the product, as understood under REACH, e.g. by transferring the substance from one container to the other, you are a downstream user and have to comply with the downstream user obligations. |
| Do you sell substances, mixtures or articles to consumers? | **Retailer:** Actor who stores and places on the market substances, mixtures or articles to final consumers and/or professional users in retail stores.<br><br>**You are not a downstream user, but you do have obligations under REACH.**<br><br>Go to Appendix 1 of this guidance. | Retailers are a sub-group of distributors.<br><br>If you undertake an activity with the substance defined as a "use" under REACH (note, for example, that refilling or mixing paints in-store is considered a use under REACH), you will be considered a downstream user and Table 4 will apply. |

# 3 Collecting and communicating information on your uses of chemical substances

Under REACH, effective communication on the safe use of a substance relies on describing the uses in an unambiguous way, in REACH terms. The registrants prepare the chemical safety assessment for the whole life cycle of that substance based on information received from downstream. When the information registrants receive initially is clear and accurate, they can then communicate clear and accurate information for the safe use of the substance downstream.

This chapter explains the life cycle approach to chemical safety assessment under REACH (chapter 3.2). It describes how downstream user's uses can be communicated to the suppliers: collective communication via sector organisation (chapter 3.3), considered most practical according to the experience gathered so far, and direct communication with the supplier (chapter 3.4). Eventually the chapter explains also what suppliers should do when they receive information about downstream user's use (chapter 3.5).

## 3.1 Introduction

Article 37(2)

*Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically), to the manufacturer, importer or downstream user who supplies him with a substance on its own or in a mixture with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.*

REACH gives downstream users the right to make a use known upstream to their supplier[30]. This may be done prior to registration, to ensure the use is covered. It may also be done after registration, because the use or conditions of use are not covered by the exposure scenario the downstream user has received.

It is not an obligation, and you do not have to communicate your use upstream. For example, you may for confidentiality reasons not want to make your use known to others. In that case, you need to carry out the chemical safety assessment yourself, if it is required for that substance (see chapter 5).

When the downstream user intends to make the use known to the supplier, he should be aware that the supplier has to comply within specified timelines, as indicated in Article 37(3). For registered substances the supplier has to comply at least 1 month before the next supply, or within 1 month of the request, whichever is later. For phase-in substance for which the last registration deadline still applies, the supplier has to comply, provided the request was made a minimum of 12 months before this deadline (i.e. before 1 June 2017). See chapter 3.5 for more details.

Identifying uses to the supplier is a crucial step for the whole process, particularly for hazardous substances where a chemical safety report is required for their registration. As a downstream user you need to comply with the conditions of safe use identified in the chemical safety report (see chapter 4). Therefore it is in your interest that i) your uses are known to the

[30] This right does not apply to recipients of articles.

registrant prior to registration and ii) the registrant's chemical safety assessment is based on the actual conditions of use down in the supply chain.

Registrants are encouraged to actively communicate, for example on their websites, which substances they intend to register and which uses they intend to cover in their registrations. Another good source for you to check whether your use will be covered is the Section 1 of the current safety data sheet – if the use is mentioned there, it will probably also be covered in the forthcoming registration and subsequent exposure scenario. Also any other technical information received from the supplier or a sector organisation website can give assurance that the use will be covered. If you still remain in doubt whether your use of the substance will be covered, you could contact your supplier directly.

## 3.2 Life cycle of a substance

Under REACH, the registrants' chemical safety assessments must cover all life cycle stages of the supported uses of the substances they intend to register. The registrants need to consider whether the six life cycle stages below are relevant for their substance and hence for their chemical safety assessment of it. For this, they need information from their downstream users[31].

1. Manufacture: A substance is manufactured from raw materials and/or intermediates. Activities with the substance during the manufacture, such as chemical processing or substance transfers are considered manufacturing. This life cycle stage has no relevance for the downstream users.

2. Formulation: A substance is transferred and mixed with other substances in order to be placed on the market in a mixture. This is the activity of formulators.

3. Use at industrial sites: This life cycle stage covers all uses of a substance carried out at industrial sites. The substance may be used in many ways including: as a raw material in a process; as a processing aid; for cleaning or sterilising; for incorporation into an article. In summary, use at industrial sites covers activities of industrial end-users, including producers of articles.

4. Uses by professional workers: As the name implies, this life-cycle stage covers all activities of a substance carried out by professional workers. These activities do not take place at industrial sites, and hence the nature of exposure stemming from them is different: they can take place anywhere, the potential group of users is large, and the amount used by a single user is typically low compared to industrial use. This life-cycle stage covers the activities of professional end-users, including craftsmen, cleaners, employees in public administration and self-employed.

5. Consumer uses: This life cycle stage covers all uses of the substance carried out by consumers. Consumers are not considered downstream users under REACH.

6. Article service life: If a substance ends up in an article, the so called service life of that article is to be considered under this life cycle stage. In layman terminology this means using the article (either by industrial users, professional users or consumers), but it must be noted that using an article does not mean "use" as defined under 3(24) of REACH.

[31] For the roles referred to in the steps below, refer to chapter 2.1.

It is important to note that information on the waste generated at each stage and possible emissions from waste treatments may be relevant and hence to be forwarded, if available, to the supplier to support the registration process.

Figure 3 below depicts in a simplified way potential uses at each stage of the life cycle of the substance.

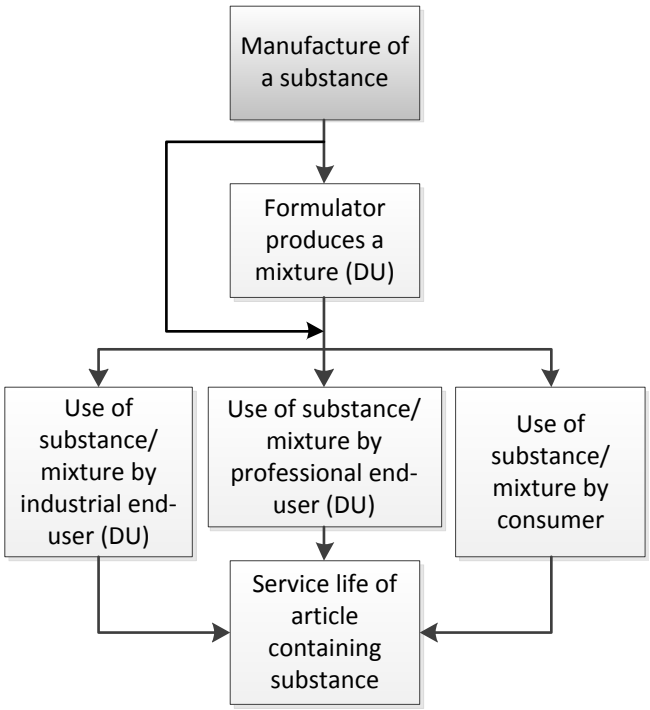


**Figure 3 Schematic presentation of potential uses of a substance at different life cycle stages. The downstream user uses are marked with "(DU)".**

## 3.3 Communicating information on uses via sector organisations

Collective communication via sector organisations has been found to be an efficient way of handling the flow of communication on uses, where such sectors exist.

The typical approach is for sector organisations to collect information from their members on the tasks and activities and to generate "use mappings". Use mappings collate the uses and conditions of use of substances within their sector. They should, to the extent possible, cover the whole life cycle of the substances, on their own, in mixtures or in articles.

The uses are documented in one or more standard description(s) of use for the sector. These descriptions are published on the sector organisation websites, and they typically consist of:

- A brief general description of the use, composed of:
    - a short verbal/technical description of the use; and
    - an agreed set of use descriptors for that use; and
- A typical set of operational conditions and risk management measures for that use, preferably expressed in the format of harmonised exposure assessment elements for worker (industrial or professional), environmental and consumer exposure. These include, for example:
    - a generic exposure scenario for worker exposure;
    - a specific environmental release category for that use; and

- a specific consumer exposure determinant for that use (if relevant).

Such sector-specific descriptions represent the common understanding within the supply chain on the typical uses and conditions of use for a substance. They also help to communicate information to suppliers without having to disclose confidential business information or to document detailed information on your use.

You should contact your organisation to know whether such standardised descriptions of use exist for your sector. If they do, you should confirm that these standard descriptions cover your use and conditions of use. For the typical uses within a given sector this is expected to be the case. You should also check whether you understand the safety advice documented in these harmonised elements, as you need to comply with the extended safety data sheets that result from the sector level use mappings. If you remain in doubt, you should contact your sector organisation.

It may also be that such standardised descriptions of use do not yet exist in your sector, and you may be contacted by the sector organisation. If so, you should be able to reply to your organisation's enquiries by describing your use in the harmonised terminology. Templates have been developed for gathering use information. You should understand what standardised elements have been built, and what information you should provide to your sector organisation in order to compile the information at sector level.

For substances that are yet to be registered, the collection and compilation on information on the uses should preferably take place via sector organisations whenever possible. It is desirable for you to provide information requested by your sector organisation to develop standardised descriptions of use, although it is not an obligation.

### 3.3.1 Main elements when communicating information on uses via sector organisations

The main elements you should be familiar with in order to obtain a clear and standardised definition of your use(s) are the following.

*A short verbal/technical description of the use*
It is desirable that the verbal description of typical uses within a sector are harmonised at the sector level. For your uses, explain the processes and activities that you carry out with the substance (formulators) or mixtures (formulators and end-users), so that harmonisation over the whole membership can be done at the sector level.

*Use descriptors*
The verbal description of use is supported by a system of standard use descriptors that characterise the different aspects of a given use. These include the main user sector (industrial users, professional users or consumers), sectors where end use of substance may happen (SUs), application techniques or process types defined from the occupational perspective (PROCs), broad conditions of use defined from the environmental perspective (ERCs), chemical product type in which the substance is supplied to end use (PCs) and article types where substance ends up (ACs). For further information on the use descriptor system, please see ECHA *Guidance on IR&CSA*, Chapter R.12[32].

Many use descriptors have been incorporated as input elements into the commonly used exposure assessment tools, and a link between the use descriptor and the assumptions on the related exposure has been built in the tools. Be aware that the choice of the use descriptor may heavily impact the outcome of the exposure assessment.

*Generic exposure scenarios (GES)*
Generic exposure scenarios document the typical conditions of use for a typical product or

[32] For use descriptor system, please see ECHA *Guidance on IR&CSA chapter R.12* available at echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

process within a sector. The conditions of use are expressed in a form that can be fed into the commonly applied exposure assessment tools. The applicability of a GES may refer to ranges of substance properties (e.g. vapor-pressure-bands or DNEL-bands). GESs have been mainly developed to cover conditions of use that are relevant for worker exposure[33]. Some sectors have also included environmental exposure in the GESs.

*Specific environmental release categories (SpERCs)*
Specific environmental release categories document the typical use conditions for products and processes in a sector from the environmental perspective. This includes the emission factors resulting from the use conditions. The conditions of use are expressed in a form that can be fed into the commonly applied exposure assessment tools. SpERCs are published on the respective web pages of the sector associations.

*Specific consumer exposure determinants (SCEDs)*
Specific consumer exposure determinants document the typical conditions of use related to substances in consumer products. The conditions of use are expressed in a form that can be fed into the commonly applied exposure assessment tools. This includes information on concentration, application form of product and sets of information related to consumer habits and practises (e.g. frequency of use, room sizes).

GES, SpERCs and SCEDs are being developed by many sector organisations.

## 3.4 Communicating information on uses directly to the supplier

Communication via sector organisations may not be feasible, for example where the uses are infrequent or exceptional, or where there is not a suitable sector organisation. In such cases, you need to describe your use and conditions of use directly to your supplier to have them included in the chemical safety assessment.

If you are a formulator or article producer, you can also collect information on the foreseeable uses of your products further down in the supply chain from your customers, with a view to provide information on the whole life cycle of the substance to your supplier. In this case, you should involve your key customers in the collection of information on the uses further downstream.

When communicating with your supplier on uses, and when collecting information from your customers and even further downstream, you are advised to use the publicly available templates[34] or supplier questionnaires developed for the purpose of collecting information on uses. They give orientation on which information is needed on the use and conditions of use for preparing a chemical safety assessment.

### 3.4.1 Main elements when communicating information on uses directly to the supplier

In requesting that your use becomes an identified use, you must provide sufficient information on your own operational conditions and risk management measures to enable the supplier to start developing an exposure scenario covering your use. This should include, for example, the following:

- short description of process/activity
- short description of article type in which you incorporate the substance

[33] Please note that the term “generic exposure scenario” can be also used to refer to a documentation of a set of conditions of *safe* use. In this case the conditions of use compiled into the generic exposure scenario have been assessed safe.

[34] See the downstream user section of the ECHA website (echa.europa.eu/regulations/reach/downstream-users).

- applicable use descriptors[35]
- applicable SpERC
- physical state of substance (solid or not)
- duration and frequency of exposure
- process temperature if elevated
- outdoor or indoor activity
- for indoor activity, if local exhaust ventilation is available
- respiratory protection and type in place
- eye protection and type (goggles) in place
- hand protection and type (gloves) in place
- concentration of the substance in a mixture
- release rate from your processes to water, air and soil (if it takes place)
- environmental risk management measures in place and their efficiency
- information on measured exposure data available.

For more hazardous substances and for uses where high exposure is expected, the standard set of information may not be adequate for the registrant to finalise the chemical safety assessment. You should make him aware, for example, if your uses create aerosol or dust, potentially result in direct skin or mouth contact or include application to a large surface indoors. Also events in the article service life that may lead to exposure from articles are relevant to inform the registrant about.

The type of information that is needed to enable your supplier to develop an exposure scenario is similar to what is collected by sector organisations when they prepare sector-specific description of uses. Please refer to chapter 3.3.1 for explanations of these elements. When collecting information on your own use, you should structure your information collection, depending on which level of detail is needed.

You are advised to collect information that is readily available within your organisation, for example, process descriptions, risk assessments at workplaces, environmental permits or measurements of emissions, or exposures related to your products. Appendix 4 to this guidance lists EU legislation from which information relevant to REACH may be available.

If this information is not sufficient for carrying out a CSA (either by you or your supplier), you may be able to fill the gaps by talking to technical experts, sales people and others within your organisation.

If gaps remain, you may need to consult external sources. Standard process descriptions may be available from industry associations or from regulators. BREF notes[36] describing specific

[35] See *Guidance on IR&CSA, chapter R.12* at echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

processes or emission scenario documents may be available[37]. The Technical Notes for Guidance prepared under the Biocidal Products Directive[38] may be helpful for substances used in biocides and in similar application types or processes.

## 3.5 Supplier response on receiving information on customer uses

As described in previous chapters, a downstream user may contact his supplier to make a downstream use known.

The supplier who deals with the query may be a distributor, a downstream user or a manufacturer/importer who has registered the substance. If the supplier is a distributor, he should forward the information to his own supplier without delay. If you, as a downstream user, are the supplier (such as a formulator who supplies substances as such or in mixtures further downstream), you can choose whether to forward the information to your own supplier or deal with it directly yourself.

The supplier dealing with the query can respond in a number of ways, including:

- The supplier can assess the use and update or prepare a chemical safety assessment as applicable. If appropriate, the supplier then provides the resulting exposure scenario to the customer.

- The supplier can conclude that he is unable to include the use as an identified use because it is not safe for human health or the environment. In this case, this becomes a use he advises against. The supplier must provide the user and ECHA with the reason(s) for that decision in writing without delay.

If the supplier concludes that the use is unsafe, and the downstream user disagrees, they should discuss this further. It is possible that the supplier's assessment is based on incomplete or incorrect information, for example not taking into account the specific operational conditions or risk management measures that are in place at the site. If this is the case, the downstream user should provide additional information on the conditions of use that will enable the supplier to revise his assessment.

If the supplier still concludes that the use is unsafe and he communicates the reasons, the supply of the substance can continue if the downstream user carries out a downstream user chemical safety assessment and demonstrates that the use is safe (see chapter 5).

The supplier may need to update the information provided to customers, such as the safety data sheet or Article 32 information.

The supplier has to respect the following timeframes for preparing or updating the chemical safety report:

- For substances which have not yet been registered: the use must be included in the chemical safety report and the resulting extended safety data sheet before the deadline

---

[36] Best Available Techniques (BAT) reference documents are designed to demonstrate best available techniques for each sector covered by the International Plant Protection Convention (IPPC) (available at: eippcb.jrc.ec.europa.eu/reference/) . Please note that BREF notes do not necessarily contain treatment efficiencies for specific substances.

[37] Emission scenario documents are available for various sectors at EU level (Technical Guidance document for the assessment of risks according to the new substances directive and the Biocidal Products Directive), and through the OECD. They describe specific processes and provide default emission factors for the environment.

[38] ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents. Please note that on 1 September 2013 the Biocides Products Regulation entered into operation and ECHA took over the regulatory management of biocides. ECHA makes related Guidance documents available on its website.

for registration, provided that the downstream user has made his request at least 12 months before that deadline.

- For registered substances: the use must be included in the chemical safety report and the resulting extended safety data sheet before he next supplies the substance or mixture to the downstream user, provided that the request was made at least one month before the supply (or within one month after the request, whichever is the later).

It may arise that, for valid reasons, no actor in the supply chain assesses the use. If so, the user further downstream should be informed without delay and he needs to take alternative action to fulfil his obligations.

One possible action is to source another supplier who supports his use/conditions of use. If no other supplier supports his conditions of use, the downstream user should consider implementing the measures in the exposure scenario he receives. Alternatively, if the downstream user considers the use is safe under his conditions, he can demonstrate this by preparing a downstream user chemical safety report (see chapter 4.4). Another option to fulfil his obligations is to substitute the substance or process with a safer alternative.

# 4 Downstream users and Exposure Scenarios

This chapter describes the obligations for a downstream user upon receipt of information from the supplier. In particular it provides guidance on how a downstream user can determine whether his use and/or conditions of use are supported by this information. It also describes what to do based on the outcome of that evaluation.

## 4.1 Legal requirements related to downstream users' compliance with the information received by the supplier

Article 37(5)

*5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:*

*(a) the safety data sheet(s) supplied to him;*

*(b) his own chemical safety assessment;*

*(c) any information on risk management measures supplied to him in accordance with Article 32.*

As a downstream user, you are required to identify and apply the appropriate measures that allow you to control risks. These measures are normally communicated to you by the supplier via the safety data sheet.

If you are supplying to customers, you may have to communicate appropriate measures to them. Chapter 7 provides detailed guidance for formulators supplying mixtures.

The downstream user should receive a safety data sheet for hazardous substances and mixtures. The safety data sheet may include one or more exposure scenarios attached to it. Exposure scenarios describe the conditions under which a substance as such or in mixtures can be used safely. They are explained in chapter 1 of this guidance and detailed information about exposure scenarios is provided in Part D of the *Guidance on IR&CSA*[39].

Article 37(4) relates to the obligation to prepare a chemical safety report for any use outside the conditions described in an exposure scenario, unless specified situations apply. These cases are described in chapter 4.4.2.

Article 37(4)

*A downstream user of a substance on its own or in a mixture shall prepare a chemical safety chemical report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.*

*...*

Consequently, the first step when you receive a safety data sheet and attached exposure scenario(s), is to check whether your use and/or your conditions of use are covered by that scenario. If you supply the substance further downstream (e.g. you are a formulator of mixtures), you should also assess if the foreseeable uses of your products containing the substance are covered by the exposure scenarios that you have received from your suppliers.

[39] echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

When you check if your use and conditions of use are covered, the outcome of such a check may result in the following situations.

1. Use, operational conditions and risk management measures correspond to those specified in the exposure scenario (see chapter 4.3 of this guidance for more detail).
2. Use, operational conditions and risk management measures do not exactly correspond to the exposure scenario, but adjustments may be applied to balance the differences and maintain as a minimum an equivalent level of exposure (see chapter 4.2.4 of this guidance).
3. Use and/or conditions of use are not covered by the exposure scenario. In this case you have multiple options and you will need to decide what action to take. Chapter 4.4 of this guidance provides more information. You do not need to take further actions[40] if you are exempted from preparing your own CSR under any of the other letters contained in Article 37(4) of REACH.

An explanation on how to check use and use conditions is provided in the following chapter 4.2 and in the *Practical Guidance 13 "How Downstream users can handle exposure scenarios"*[41].

The obligations of Article 37 are triggered by receiving a safety data sheet with a registration number (Art 39.1 of REACH).

## 4.2 Checking if the use and conditions of use are covered by the exposure scenario

In order to compare your use(s) and your conditions of use with the information in the exposure scenario, you may need to collect information on your own use(s), and the foreseeable uses of your products by your customers. Information may be gathered from various sources, including documentation prepared for other legislation (e.g. the Chemical Agents Directive[42], compliance with environmental permits under the Industrial Emission Directive[43]), workplace measurements and/or emission monitoring data as well as the experience of your site personnel, such as technical experts and sales persons. The level of detail of the information required will depend on the level of detail of the information in the exposure scenario. The meaning of key terms used in this chapter is explained in chapter 1.3 of this guidance.

### 4.2.1 Checking the use

As first step, you have to check if your use and foreseeable uses of your products are included within the "identified uses" covered by the exposure scenarios attached to the safety data sheet. Identified uses are named in the safety data sheet, normally under section 1.2 and in

---

[40] In this sentence is intended that no further actions are needed under REACH, but there may be actions required under other applicable EU legislation on protection of human health and the environment (see appendix 4 for details).

[41] echa.europa.eu/practical-guides.

[42] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive), CAD directive. The directive is available at eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01998L0024-20070628:EN:NOT.

[43] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).

the title section of the attached exposure scenarios. The naming should be consistent with the title of the exposure scenario even though the title section of the exposure scenario may contain additional information (e.g. list of use descriptors) which is not necessarily included in section 1.2 of the safety data sheet [44]. There may be different exposure scenarios with different conditions of use that relate to the same identified use. Also, one exposure scenario can be used for various identified uses with similar conditions of use. A standard system for describing uses is provided in Chapter R.12 of the *Guidance on IR&CSA* and in Chesar Manual 2[45].

### 4.2.2 Checking processes/activities of the exposure scenario

The second step is to check if your processes/activities are covered. The activities/processes are described in section 1 of the exposure scenario in a short text and/or list of use descriptors (i.e. PROCs and ERCs[46]). The activities relating to the identified use will only include those where exposure to the relevant substance or substances in mixture is expected. Assess whether you carry out activities with the substance or substances in mixture that are not listed and may cause higher or different exposures than those listed.

### 4.2.3 Checking the conditions of use (OC and RMM)

#### 4.2.3.1 Comparison of operational conditions (OCs)

Compare the information given in the exposure scenario with your own operational conditions. If you have carried out a risk assessment under the Chemical Agents Directive, you may use that information for compliance checking. Information from applications for environmental permits may also be a valuable information source. In case of differences between the description of conditions of use in the exposure scenario and your own practice it does not always mean that the use is not covered. In chapter 4.2.4 of this guidance you may find information on how to check if your conditions of use are covered by the exposure scenario.

The exposure scenario may also specify factors describing basic parameters about the surrounding environment or the workplace (for example air volume available) to which substances are emitted. This information is important in estimating exposures as it specifies, for example, the dilution of a substance in the natural, workplace or consumer environment.

#### 4.2.3.2 Comparison of risk management measures (RMMs)

Compare the information given on risk management measures, including their effectiveness, with those you apply.

Effectiveness is the key information related to risk management measures. It is the degree of exposure or emission reduction achieved by application of the risk management measure (for example local exhaust ventilation reduces the substance concentration in workplace air by 50%, gloves reduce dermal exposure by 80%). In some cases you may need to make qualitative assumptions when the numeric values are not comparable, for example when the exposure scenario specifies that a waste gas incinerator should destroy 95 % of the organic

---

[44] It is recommended to avoid including potentially long list of use descriptors in section 1.2 of the safety data sheet. Alternative and more viable ways are mentioned in the *Guidance on the compilation of safety data sheet* (chapter 4.1) available at echa.europa.eu/guidance-documents/guidance-on-reach.

[45] ECHA *Guidance on IR&CSA* is available at echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment; Chesar manuals are available at chesar.echa.europa.eu/web/chesar/support/manuals-tutorials.

[46] Use descriptors such as PROCs and ERCs are defined in the ECHA *Guidance on IR&CSA, chapter R12 – Use descriptor systems* available at echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

compounds in the waste gas and you only have information on the concentration of organic carbon in the emitted waste gas. To find out how effective your risk management measures are, you should discuss with technical staff, and/or consult maintenance instructions or measurement protocols of technical devices. Furthermore, producers of these devices could provide information on functioning and effectiveness.

**Table 9 Checking risk management measures**

| Information in exposure scenario | Outcome of your check |
|---|---|
| • Half mask (protection factor 10 assumed)<br>• Gloves (nitrile) should be worn<br>• No environment related measures needed under given operational conditions of use | • Appropriate half masks are worn<br>• Appropriate gloves are used<br>• No environmental measures are implemented |
| Residual paints and empty cans must be disposed of as hazardous waste | Wastes are disposed of as hazardous waste |

You can be sure that your risk management measures are covered if their effectiveness is equal to, or higher than, what is specified in the exposure scenario. This would be the case if, for example, you use half masks with a protection factor of 25 and the exposure scenario requires, as a minimum, a protection factor of 10.

Note that a given risk management measure may have a different effectiveness for different (groups of) substances. Gloves may, for example, be more or less suitable for the conditions of use or waste gas incinerators may fully destroy organic compounds but have no effect on metals. If you are unsure, contact the supplier of the relevant risk management equipment. It is also important to mention that the hierarchy of risk management measure defined in worker legislation[47] or best available technologies defined in the environmental legislation (Best Available Techniques reference documents (BREFs) adopted under both the IPPC Directive and the Industrial Emission Directive[48]), must be taken into account when assessing the effectiveness of a risk management measure.

If you adopt a risk management measure that is considered higher in hierarchy by other applicable legislations and more effective compared to the risk management measure in the ES you may conclude that your conditions of use are covered. For example the exposure scenario indicates use of PPE with 90% effectiveness and you have an enclosed system where residual releases are <3% (equal 97% effectiveness). In this case, your risk management measure can be considered higher in hierarchy and also more effective and therefore your conditions of use are covered.

#### 4.2.3.3 Discrepancy between OC and RMM's from different suppliers

If you purchase a substance from more than one supplier, you may receive exposure scenarios and contributing scenarios which are not comparable. They could differ in scope (number and types of uses covered), in conditions of use or there may be differences in the substance properties.

You should check if your conditions of use are covered by the most stringent of the exposure scenarios received. If so, your use is also covered by the other exposure scenarios.

[47] Council directive 98/24/EC. Note that Appendix 4 provides an (not exhaustive) overview of relevant EU legislation.

[48] BREF documents can be downloaded at eippcb.jrc.ec.europa.eu/reference.

If your conditions of use are covered by another exposure scenario received, but do not lead to the lowest exposure communicated to you in all exposure scenarios, a competent person should undertake the following:

a. verify that the substance, its properties and the use are actually the same;
b. confirm that the selected measures ensure safe use, even though they are less stringent than measures recommended by other suppliers;
c. document the justification for your decision.

When exposure scenarios from different suppliers diverge, you should contact your suppliers and inform them of the differences with a view to aligning their exposure scenarios. Alternatively one of the actions described in chapter 4.4 could be undertaken.

### 4.2.4 Scaling

If your conditions of use differ slightly from the exposure scenario of your supplier, you may be able to demonstrate that, under your conditions of use, the exposure levels (for humans and the environment) are equivalent or lower than under the conditions described by the supplier. If so, you can conclude that you implement, as a minimum, the conditions described in the exposure scenario communicated to you in the safety data sheet.

The way in which you determine if your conditions are equivalent or lower is termed “scaling”. When scaling is applied, modification of one factor can be compensated by modification of another factor. Scaling is intended to provide you with a simple way of checking if your conditions are “equivalent” to the conditions defined in the exposure scenario.

If applicable, your supplier should provide information in the exposure scenario to help you to determine if your use is covered by scaling the determinants of exposure.

#### 4.2.4.1 When scaling is applicable

Scaling is a mathematical approach whereby the conditions of use described in an exposure scenario may be modified in order to determine if the actual conditions of use on a downstream user site are still covered by the exposure scenario. Safe use of the substance must still be assured. The application of scaling may allow you to implement conditions of use that differ from those described in the supplier’s exposure scenario without the need for further action described in chapter 4.4.

Scaling can only be applied if the registrant has used an exposure estimation tool in his CSR in order to calculate the exposure to humans and to the environment for specific uses of the substance. Scaling cannot be applied if the registrant has based his assessment on measured exposure data. This is because an assessment based on measured exposure data relates to the actual conditions of use during measurement.

Scaling options applicable to the exposure scenario covering one (or more) uses of a substance have to be communicated by your supplier in the extended safety data sheet for the substance which is supplied to you. If no scaling rules are provided, then scaling is not applicable to the use of the substance.

Scaling options should be provided in the Section 4 of the exposure scenario “Guidance for downstream user” if your supplier has prepared an exposure scenario which is in line with ECHA *Guidance on IR&CSA Part D* and Chesar[49].

[49] The updated Part G of the *Guidance on IR&CSA* is available at echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment; Chesar Manual 6, Annex 1 provide instruction as well as instructions for using the revised ES format developed in the context of Chesar development and can be found at chesar.echa.europa.eu/support/manuals-tutorials.

If scaling is appropriate, then the information provided by the supplier must include:

- the mathematical method which has to be applied (this could be a formula, or a web interface to a scaling tool or to the same exposure estimation tool used by the supplier for his assessment);
- the (determinants of exposure) parameters which can be scaled;
- the boundaries of scaling (to what extent changes in some parameters can be compensated by variation in other parameters).

Additional information on methodology of scaling is available in Appendix 2 of this guidance. Examples on scaling will be developed and included in the Practical Guide *"How downstream users can handle exposure scenarios"* available on the ECHA website[50].

### 4.2.5 Uses advised against

If Section 1.2 of the safety data sheet specifies that your use is advised against, communicate with your supplier, as described in chapter 3.5.

After having confirmed the use is advised against, consider the following options:

- stop this use of the substance as such or in a mixture;
- switch to a supplier who has covered your use with the necessary risk management measures;
- undertake a downstream user chemical safety report to verify that the use is safe.

## 4.3 What to do if the use and conditions of use are covered by the exposure scenario.

If the conclusion of your check is that your use is covered by the exposure scenario received, no further action under REACH is needed.

You should nevertheless document your check and any action you may have taken to guarantee the compliance with the conditions of use in the exposure scenario including the outcome from scaling calculations (if applicable). This can be relevant for example to facilitate checking the use of other mixtures that you use in the same application. You may also consider integrating compliance checking in your health, safety and environmental management system. You should also include all the necessary safety information in any safety data sheet prepared by you and supplied to your customers.

If you are applying the ES you have received from your supplier (i.e. you implement the conditions of use from the ES you have received from your supplier), you can also use measured exposure data to demonstrate that you are working within the boundaries of the ES. The results from worker and environmental monitoring can help to verify that exposure levels at your site are within the range of the safe use. This information can also be used as supporting evidence for inspectors. If your measured data indicates that application of the exposure scenario may lead to unsafe conditions of use (e.g. RCR> 1 for humans and/or for the environment), you should immediately inform your supplier and take actions to control the risks.

[50] echa.europa.eu/practical-guides.

## 4.4 What to do if uses and conditions of use are not covered by the exposure scenario.

This subchapter aims to assist downstream user in deciding what to do if his use is not covered by the conditions of use set out in the exposure scenario.

### 4.4.1 Introduction

You may have established that the use and/or conditions of use of your substance, as such or in a mixture, are not covered by the exposure scenario received from your supplier. If so, a number of options are available under REACH, as described in Article 37(4). The following list summarizes the key options that are available to you:

1. make your use known to your supplier with the aim of making it an "identified use" and included in the supplier's chemical safety assessment: in this case, you need to contact your supplier and provide information on your use/conditions of use (not covered by the ES) to allow the supplier to refine his assessment and send you an updated ES covering your use/use conditions (see chapter 3.3 and 3.4 of this guidance). The supplier has to assess the use within one month or before the next supply, whichever is later.); or

2. implement the conditions of use described in the exposure scenario you have received; or

3. substitute the substance with a different substance for which an exposure scenario is not required or where an exposure scenario(s) is available which covers your conditions of use. Alternatively, substitute the process with a process not requiring the substance; or

4. find another supplier who provides the substance with safety data sheet and exposure scenario that covers your use; or

5. prepare a downstream user chemical safety report (DU CSR) (check first if any exemptions apply, see chapter 4.4.2).

The advantages and disadvantages associated with these options are outlined in Table 10.

**Table 10 Options if exposure scenario does not cover the use**

| Option | This option could be best if | Advantages | Disadvantages |
|---|---|---|---|
| Exemptions apply (see chapter 4.4.2) | Case-by-case | No changes in process or substances / mixtures needed. | |
| Make your use known to your supplier (see 4.4.3) | - this does not raise confidentiality concerns for you;<br>- you don't understand whether your use is covered because the exposure scenario you received is too general or broad. | - A more specific assessment by your supplier based on your conditions of use may show that there is no risk.<br>- Allow the supplier to better understand how a customer's use is to be covered | Your supplier may not be able to respond favourably. |
| Implement conditions of use (see | - your use is not covered by the (similar) conditions of use in several exposure scenarios; | - Certainty that the use is assessed and does not pose any | - Upgrading existing or introducing new |

| | | | |
|---|---|---|---|
| 4.4.4) | - you have problems in complying with other legislation and consider modifying your risk management in these areas too. | risks.<br>- Synergies for compliance with other legal obligations.<br>- Potential benefit in the long run. | risk management measures can be costly.<br>- New/different OC/RMM can conflict with other relevant legislation with defined use conditions.<br>- Changes in the process may be needed.<br>- Unnecessary additional costs due to RMMs which may be too conservative. |
| Substitute your substance or mixture (see 4.4.5) | - you have very few substances or mixtures which are not covered by the exposure scenario;<br>- you want to substitute the substances / mixtures also for other reasons. | - Several risks can be eliminated or reduced.<br>- Product quality may improve. | - Substitution may require time and resources.<br>-Changes in the process may be needed.<br>- Substitution may be not possible.<br>- Suitable substitute may not be registered or fully assessed yet. |
| Find supplier with exposure scenario covering your use | | No changes to current practice, except sourcing of raw materials. | Change of source |
| Downstream user chemical safety report (4.4.6) | - you do not want to disclose information on your use- you have enough information and expertise to do the assessment;<br>-OCs and RMMs are relatively unique and not representative of the sector in general. | - Safe use is demonstrated and documented.<br>- You can continue using the substance. | - Resource and some expertise are required.<br>- Changes in the process may be needed if adequate control of risks cannot be demonstrated with existing conditions of use. |

### 4.4.2 Do exemptions to preparing a downstream user chemical safety report apply?

If your use is not covered by the exposure scenario, article 37(4) states that you have to prepare a chemical safety report, unless one of the six exemptions mentioned in the same

provision apply. Therefore, you should first check if any of the exemptions of Article 37(4)(a) to 37(4)(f) of REACH apply to you[51] before commencing a chemical safety report.

Table 11 lists the exemptions of Article 37(4) of REACH.

**Table 11 Checking if the exemptions from the duty of Article 37(4) to prepare a downstream user chemical safety report (DU CSR) apply**

| Exemption from Article 37(4) of REACH | Explanation - your own use | Explanation - customer's use[52] |
|---|---|---|
| 37(4)(a) No safety data sheet required for substance or mixture | If your supplier is not obliged to provide you with a safety data sheet for a substance, you do not have the obligation to prepare a DU CSR for your use of that substance.<br><br>It is possible that you may receive a safety data sheet and exposure scenarios on a voluntary basis. This may be, for example, the case when a substance is not classified. If the SDS is voluntary, the requirement to make a downstream user chemical safety assessment does not apply. | If you supply your customers with a mixture, but your mixtures do not require a SDS (e.g. substances are used in concentration below threshold limits), information according to Article 32 of REACH needs to be forwarded (see also chapter 7). |
| 37(4)(b) No chemical safety report is required to be completed by the supplier | A downstream user chemical safety assessment (and consequent DU CSR) is only required for those substances in a mixture for which the manufacturer or importer (registrant) had to complete one, or which have not been diluted in the mixture you use to below the concentration thresholds in Article 14 (2) of REACH. You should find relevant information in Section 15 (sub-section 15.2) of the safety data sheet on whether a CSA has been carried out by the registrant. Further detail is given in chapter 7 of this guidance. | If you make a chemical safety assessment for the use of a substance in your mixture, you only have to consider doing it if your suppliers had to make a chemicals safety report. |
| 37(4)(c) Use is less than 1 tonne per year | See discussion below this table. Note that if you claim this exemption, you need to report to ECHA, see chapter 5.5. | |
| 37(4)(d) As a minimum the conditions of | See chapter 4.2 of this guidance for details on coverage of as a minimum the conditions of use. | |

[51] Even if you are exempted from performing a DU CSR, you still have to perform risk assessment and apply measures to guarantee safe use of the substance /mixture in accordance to applicable EU EHS legislations (e.g. Chemical Agents Directive).

[52] If you supply substances and/or mixtures down to the supply chain (e.g. you are a formulator), you have to provide information about your products to your customers (e.g. via the safety data sheet). In order to prepare such information, you have to assess if the ESs of the substances (as such or in mixtures) that you have received from your suppliers, cover also the foreseeable uses of your products by your customers. If one or more uses by your customers are not covered, you have the option to prepare a DU CSR to cover these uses or you may consider other options (see chapter 4.4.1 of this guidance). Please check chapter 5 of this guidance for more information on DU CSR and chapter 7 of this guidance for information to be communicated on mixtures. For additional information on communication in the supply chain, please consult the Practical Guide "*How downstream users can handle exposure scenarios*".

| | |
|---|---|
| use are covered | |
| 37(4)(e) Substance is diluted below concentrations of Article 14(2) | If you use a mixture containing a substance below the lowest of the concentration thresholds in Article 14(2) of REACH, you do not have to prepare a DU CSR for that substance. Also, if you dilute a substance in your own product below the lowest of the concentration thresholds in Article 14(2) of REACH, a DU CSR to cover the use of that substance in your product is not required. Nevertheless, you do have to consider all information in compiling your safety data sheet if one is required. |
| 37(4)(f) Substance is used for PPORD | See discussion below this table. Note that if you claim this exemption, you need to report to ECHA, see chapter 5.5. |

**Re: Article 37(4)(c) (table 11) – total use of the substance or mixture is less than 1 tonne per year[53]?**

The amount considered as "used" includes the amount stored as well (even if storage is already covered by the ES of your supplier). Furthermore, the tonnage limit applies to the total amount used, regardless of the number of different uses, the supplier and whether or not an exposure scenario was received.

If this exemption applies, you are still required (according to Article 37(6) of REACH) to consider the use of the substance and identify and implement measures to ensure control of risk to humans and the environment based on information received from your supplier. If you supply the substance to others, you must identify and communicate appropriate measures to your customers in the safety data sheet, if one is required. You also have to report to ECHA (see chapter 5.5).

**Re: Article 37(4)(f) (table 11) - Use in product and process orientated research and development**

If you are using the substance, as such or in a mixture, in process and product oriented research and development (PPORD[54]), you are not required to make a DU CSR, provided that *"[…] the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment".* In this case you have to report the information specified in Article 38(2) of REACH to ECHA. This also applies to research and development activities which you have notified under Directive 67/548/EEC, as these notifications are no longer valid after June 1st 2008. Note that reporting to ECHA is not required for the use in PPORD if this use is less than 1 tonne per year (Article 38(5) of REACH).

Note that substances with which you carry out process and product oriented research and development could be subject to authorisation requirements or restrictions.

If you are included in your supplier's notification for process and product oriented research and development, as a listed customer, you will need to implement the conditions communicated

[53] It should be noted that in the context of Article 37 of REACH the tonnage should be based on the calendar year and not on the 3-year average which was designed for registration purposes.

[54] REACH defines: "*Product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;*". Please note that scientific research and development can cover analytical activities. Please refer to Q&A on Application for authorisation nr 585 at echa.europa.eu/support/qas-support/qas. More guidance on which activities are regarded as PPORD is given in the ECHA *Guidance on Scientific Research and Development (SR&D)* and Product and Process Oriented Research and Development (PPORD)), available at echa.europa.eu/guidance-documents/guidance-on-reach.

by your supplier (including any conditions imposed by ECHA). It is your obligation to implement these conditions[55]. If you want to use the substance for other purposes than process and product oriented research and development, the substance has to be registered for that use (unless exempted). In this case you need to inform your supplier of this to ensure that your use of the substance has been registered (in such case you have to receive a safety data sheet with a registration number and attached exposure scenario covering your use (if applicable) or you need to register the substance for your use).

If you are using a substance with which you receive an exposure scenario for process and product oriented research and development, without being a customer included in the notification of your supplier, all the obligations of a downstream user apply.

### 4.4.3 Make your use known to your supplier with the aim of having it identified

It is possible that your use is completely “missing” from the supplier’s exposure scenario (chapter 4.2.1). If this is the case, you have the option to make your use known in writing to your supplier, with the aim of making it an identified use. See chapters 3.3 and 3.4 of this guidance for more detail.

It is possible that one of the processes/activities for your identified use is completely "missing" from the supplier's exposure scenario (chapter 4.2.2). If this is the case, you have the option to make your processes/activities known in writing to your supplier, with the aim of including them in the exposure scenario.

### 4.4.4 Implement the conditions of use of the exposure scenario

If your conditions of use are not covered by the exposure scenario, you could also change the way your substance or mixture is used and implement the conditions indicated in the exposure scenario. You should ensure that you consider all exposure scenarios that do not cover your use conditions, in order to bring yourself into compliance with all of them in one action. This option is particularly worth considering when:

- exposure scenarios of several substances do not cover your conditions of use and similar risk management measures are recommended in them;
- you have encountered difficulties in complying with existing environmental or workers legislation in the past.

Implementing the exposure scenario could entail:

- adding new risk management measures; and/or
- upgrading existing risk management measures; and/or
- changing the operational conditions according to the information in the exposure scenario;
- changing the process (for example, enclosure of machinery) or product design (for example, reducing the concentration of the substance or substance in a mixture in your product) according to the information in the exposure scenario.

[55] A safety data sheet must be supplied if the substance or mixture is classified as hazardous according to CLP (or a mixture as dangerous according to the DPD until 1 June 2015) or may need to be supplied on request if the mixture in not classified as hazardous/dangerous but contains hazardous substances. If a safety data sheet is not required, information on the conditions to be implemented according to the PPORD notification should be communicated, based on Article 32 of REACH.

If you decide to change your process, or to install additional risk management measures, you must implement these within one year after receipt of a safety data sheet with registration number and the exposure scenario (Article 39(1) of REACH).

### 4.4.5 Substituting the substance or substance in mixture

Substitution of the substance may be achieved by exchange of raw materials and/or by optimising process design in such a way that the substances under question become superfluous. If you, as downstream user are planning to substitute a substance with another substance you have to be sure that the exposure scenario of the substitute, if required, will cover your use and conditions of use. You should also look at the physicochemical properties and hazard profile of the substitute in order to assure that the new substance will pose lower risks than the original one. Other factors to consider when you plan to substitute a substance may be:

- changes would have to be discussed with customers and potentially tried out with the downstream users;
- changes would have to be clearly communicated in advance to customers who may have long requalification times;
- costs for substitution (e.g. tests, qualification/certification, change of processes/equipment etc.);
- ease and practicability of change;
- if a substance (as such or in the mixture) is listed on the candidate list (see REACH Article 59), it may have to be authorised in future;
- availability of alternatives;
- outcomes of a socio-economic analysis.

The *Guidance on the preparation for an application for authorisation*[56] contains advice on how to assess the availability and feasibility of substitution and could help you in organising substitution.

### 4.4.6 Downstream user chemical safety report (DU CSR)

Preparing a DU CSR means that you yourself assess whether the risks from your use of the substance as such or in a mixture are adequately controlled. Further information is given in chapter 5 of this guidance.

## 4.5 Your use is confidential

You may want to consider that your use of the substance as such or in a mixture is confidential. In this case you have the same three options described above to achieve compliance with REACH: you can substitute the substance with one that does not require an exposure scenario or one that covers your use, you can adapt your use to the exposure scenario provided by your supplier or you can prepare a DU CSR that shows adequate control.

## 4.6 Timescales for fulfilling obligations

Article 39 (1) states:

*Downstream users shall be required to comply with the requirements of Article 37 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.*

[56] echa.europa.eu/guidance-documents/guidance-on-reach.

If your use is advised against (as described in the safety data sheet Section 1.2) then within 12 months you have to:

- cease that use, or
- prepare a DU CSR that includes that use.

If you conclude that your use is outside the conditions described in the received exposure scenarios (after checking as outlined in chapter 4), then within 12 months you have to:

- implement the conditions described in your supplier's exposure scenario and recommend the conditions to your customers; or
- request your supplier to clarify if your use is already covered and if not, ask him to include your use in his assessment; or
- find another supplier that supports your use; or
- prepare a DU CSR (unless you qualify for an exemption from undertaking a DU CSR).

The time period starts on receipt of the safety data sheet with the registration number, however it is not possible to check if your use is not covered without the receipt of exposure scenarios. It is recommended that if you receive a safety data sheet without any exposure scenarios attached that you formally communicate with your supplier to check the reason why. Document this action, and if and when you receive the exposure scenario(s).

Article 39(2)

*Downstream users shall be required to comply with the requirements of Article 38 at the latest six months after receiving a registration number communicated to them by their suppliers in a safety data sheet.*

Downstream users must report to ECHA in accordance with the requirements of Article 38 of REACH (see chapter 5.1.1) within 6 months after having received a safety data sheet containing a registration number.

# 5 Use not covered: preparing a downstream user chemical safety report (DU CSR)

When a downstream user checks whether his use is covered in the exposure scenario received from the supplier, as described in chapter 4, he may establish that his use (including the use(s) further downstream) is not covered.

One of the options presented in chapter 4.4 is to undertake a downstream user chemical safety assessment (DU CSR). This chapter provides guidance on carrying out this assessment and on documenting it in the DU CSR. The issues discussed in this chapter include:

- what are the requirements related to the DU CSR;
- what is scope of the DU CSR;
- how to carry out the assessment and prepare the DU CSR;
- how to communicate with ECHA and the customers.

## 5.1 Legal requirements related to a downstream user chemical safety report (DU CSR)

Article 37(4) of REACH states that:

Article 37(4)

*A downstream user of a substance on its own or in a mixture shall prepare a chemical safety report in accordance with Annex XII for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.*

You are required to prepare a DU CSR for:

- any use not covered or outside the conditions communicated via an exposure scenario;
- any use advised against by your supplier (if you choose to continue to use the substance, so that you can document that the use is safe).

Annex XII of REACH sets out the general provisions for downstream users to assess substances and prepare chemical safety reports.

Before commencing a DU CSR, it is advisable to check all your options, and if any of the exemptions in Article 37(4) of REACH apply, as described in chapter 4.4. One of these exemptions, Article 37(4)(c) is if “the downstream user uses the substance or mixture in a total quantity of less than one tonne per year;”. If this applies, the downstream user must still ensure that the risks are adequately controlled, as specified in Article 37(6) of REACH:

Article 37(6)

*Where a downstream user does not prepare a chemical safety report in accordance with paragraph 4(c), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.*

### 5.1.1 Obligation to report information

Article 38(1) states:

*Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 6 or 18, the downstream user shall report to the Agency the information specified in paragraph 2 of this Article, in the following cases*

*a) the downstream user has to prepare a chemical safety report in accordance with Article 37(4); or*

*b) the downstream user is relying on the exemptions in Article 37(4)(c) or (f)*

You have to report to ECHA if you have to prepare a DU CSR.

You also have to report to ECHA if you do not need to prepare a chemical safety report because you are relying on exemptions from undertaking a DU CSR due to:

- the use of a substance or mixture in a total quantity of less than one tonne per year (Article 37(4)(c));
- the use of the substance for product and process oriented research and development (PPORD), provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment. Note that reporting to ECHA is not required if the use for PPORD is less than one tonne per year. (Article 37(4)(f)).

If your total use remains less than one tonne per year across all uses, then all uses not covered by the received exposure scenarios have to be reported to ECHA.

*Article 38(5)*

*Except where a downstream user is relying on the exemption in Article 37(4)(c), reporting [...] shall not be required in respect of a substance, on its own or in a mixture, used by the downstream user in quantities of less than one tonne per year for that particular use*

If you have to prepare a downstream user CSR, you do not have to report a particular use (that is, a use not covered) to ECHA that is less than one tonne per year. This exemption applies only if your total use of the substance (including uses which are covered by a CSA) is one tonne or more per year. The table below summarises the links between the tonnages and the requirements.

**Table 12 Summary of total use and "Use not covered" tonnages with associated reporting requirements**

| Total Use (tonnes per year) | Particular Use not covered (tonnes per year) | DU CSR required? | Need to report to ECHA? |
|---|---|---|---|
| <1 | - | Exempt | Yes |
| >1 | >1 | Yes | Yes |
| >1 | <1 | Yes | No |

This is further illustrated with the examples below:

**Example 1**: You use a registered substance of total 5 tonnes per year (total use >1 tonne per year). You use 0.8 tonnes of it in a spray application process, and the remaining 4.2 tonnes in a dipping process. Your spray application use is not covered in the exposure scenarios you receive, but your dipping use is covered.

- You have to prepare a DU CSR as per Article 37(4), because your supplier and the other actors up the supply chain do not attach an ES to the safety data sheet to cover your spray application process and your total use of the substance is more than one tonne per year.
- You do not have to report to ECHA, because the particular use not covered (spraying) is less than one tonne per year while your total use is more than one tonne per year. This corresponds to the last row in Table 12.

**Example 2**: You use a registered substance of total 0.8 tonnes per year and use all of it in a spray application process. Your use is not covered in the exposure scenarios you receive.

- You do not have to prepare a DU CSR because your total use of the substance is < 1 tonne per year.
- You do have to report to ECHA that your use is not covered. This corresponds to the first row in Table 12.

Details on how to report to ECHA are provided in chapter 5.5 and on the Downstream User pages of the ECHA website[57].

## 5.2 What is a chemical safety assessment and report

A **chemical safety assessment** aims to identify the conditions of use under which a substance can be used safely throughout its entire life-cycle. It includes hazard and exposure assessments, as well as a risk characterisation. The registrant of a substance carries out an assessment and documents it in the **chemical safety report** as part of the registration process. The registrant's chemical safety report is submitted to ECHA. The complete report is not made publicly available.

Exposure scenarios are a core element of the chemical safety assessment of certain hazardous substances[58], and describe operational conditions and risk management measures that provide adequate control of the risks. Relevant information from exposure scenarios in the registrant's chemical safety assessment are communicated to downstream users. The exposure scenario for communication is annexed to the safety data sheet. They should include practical and proportionate information against which a downstream user can check his use(s) without need for further assessment.

[57] echa.europa.eu/regulations/reach/downstream-users.

[58] Substance meeting criteria specified in Article 14(4) of REACH.

## 5.3 What is a downstream user chemical safety report (DU CSR)

When a downstream user has decided to perform a chemical safety assessment, a DU CSR documents the results of that assessment. The assessment establishes conditions of use to ensure that the risk (to human health and environment) for the use(s) not covered in the received exposure scenarios is adequately controlled.

A DU CSR is a different and generally smaller undertaking than the CSR required for registration. The differences include the following:

- You do not have to make a hazard assessment. This is the detailed information reported in sections 1 to 8 of a registrant's chemical safety report. A DU CSR is usually based on the hazard information provided in the safety data sheet, unless a downstream user chooses to carry out his own hazard assessment.
- You only assess the uses not covered by your supplier. This is much less than the registrant's chemical safety report which assesses all identified uses of the substance (this is the information reported in sections 9 and 10 of a registrant's chemical safety report).
- You do not need to use IUCLID, the software used by registrants to submit dossiers to ECHA.
- The DU CSR is not submitted to ECHA. It may be checked by the national enforcement authority and needs to be kept available by the downstream user.

If the assessment establishes that the risk is not adequately controlled, then changes to your conditions of use must be implemented and the assessment must be repeated. If you are a supplier, you may need to communicate information from the assessment you carried out in the safety data sheets that you provide to your customers.

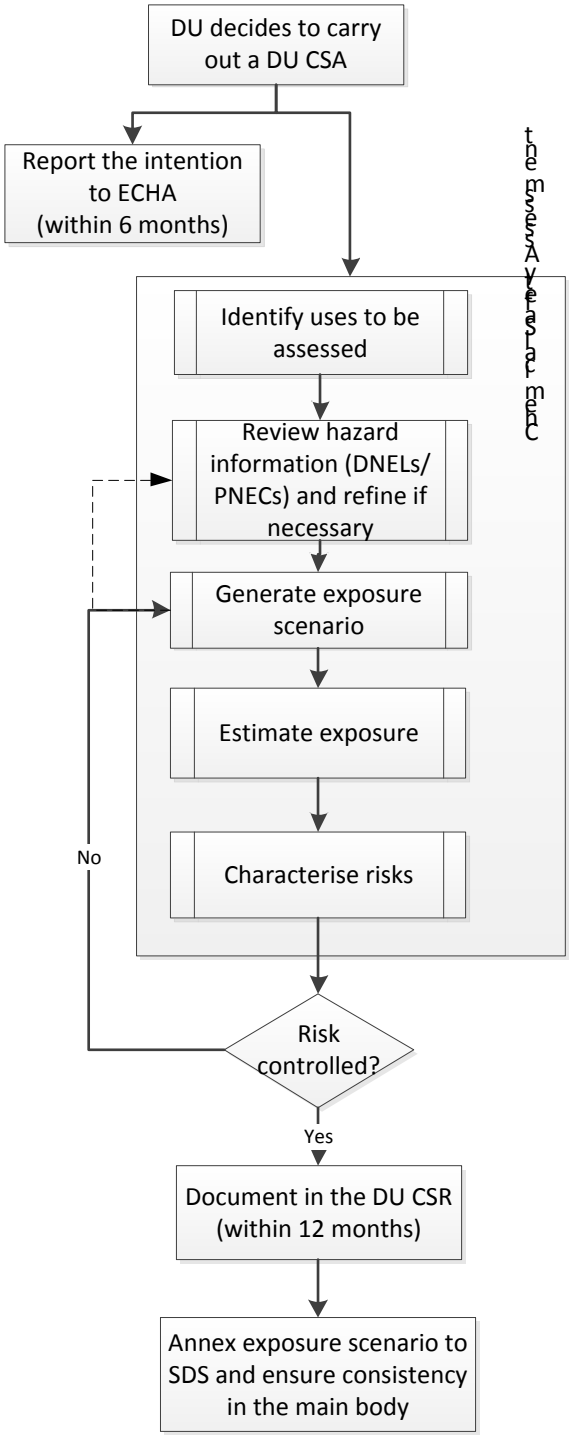


**Figure 4 Work process for downstream user chemical safety assessment**

## 5.4 Key steps for the downstream user chemical safety assessment

The approach taken for a downstream user chemical safety assessment under REACH is similar to that for risk assessments at workplaces and for the environment, with the differences stemming from the specific legislative requirements. The work process is illustrated in Figure 4 and the main steps are outlined below. It is expected that the person undertaking a DU CSR

has some expertise and competence in undertaking risk assessment. Parts D and E of the *Guidance on IR&CSA*[59] provide additional and detailed guidance.

i. Identify the uses to be assessed

Start the process with the identification of the uses to be assessed. Begin with your use of the substance, and cover any identified uses further down the supply chain, if you have decided to cover your customers' uses.

ii. Review the hazard information provided by your supplier

Determine if the exposure related hazard information provided in Section 8 of the safety data sheet received from your supplier is adequate for the identified use(s). Normally all relevant exposure routes should have been considered and data provided where attainable. In case of difficulties, such as how to deal with missing information, consult chapter 5.4.1 for how to proceed.

iii. Generate exposure scenarios for the uses you want to assess

Develop initial exposure scenarios, containing a technical description of processes and/or activities carried out with the substance, and the operational conditions and risk management measures for the uses to be assessed. See chapter 5.4.2.

iv. Estimate the exposure

The exposure estimation provides a firm basis on which to demonstrate that exposure is adequately controlled. The potential for exposure can be estimated using measured exposure data, exposure estimation tools or control banding. Section 9 of the safety data sheet provides physical and chemical properties of the substance which a DU might find useful for carrying out the exposure estimation. Part D and Chapters R14 to R18 of the *Guidance on IR&CSA* provide advice on exposure estimation.

v. Characterise the risk

Compare estimated exposure levels with quantitative or qualitative hazard information, to show that the risks are adequately controlled. For quantitative assessment this is referred to as the risk characterisation ratio (RCR). If, based on the initial ES, the risks are not adequately controlled, further iterations are needed, to refine the conditions of use until the risk is shown to be adequately controlled. More information on risk characterisation can be found in the Part E of the *Guidance on IR&CSA*.

vi. Document in the DU CSR

[59] echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

The assessment, including the final exposure scenarios indicating that the risk is adequately controlled must be documented in the DU CSR. Information on safe use relevant for the next level of DU (and further) in the supply chain must be integrated into the extended safety data sheet, if applicable.

### 5.4.1 Review the supplier's hazard information (and adapt if necessary)

Safe threshold values must be provided by your supplier (Section 8.1 of the safety data sheet (REACH Annex II)) where a CSR is required, and they have been derived. These values will also be reported on the ECHA web pages "information on chemicals"[60]. Normally, a downstream user will use the DNEL/PNEC values provided.

Note that a REACH chemical safety assessment is based on DNEL/PNECs rather than occupational exposure limit (OEL) values or emission limit values.

In exceptional cases you may find that:

(i) DNELS/PNECs have not been provided

(ii) you decide that the supplier's hazard assessment is not appropriate

#### *(i) DNELs/PNECs not provided*

This may simply be an oversight on the part of your supplier, so you should formally communicate with the supplier to check why the relevant DNEL or PNEC is not available.

It may be the case that the DNELs/PNECs have not been derived. If you have sufficient REACH experience and technical competence (for example, if you have done your own registrations), you may decide to:

- ask your supplier (or his supplier) to forward an inquiry to the SIEF, to ask if there are other members in the SIEF interested in, or currently deriving, that value;

- derive the value yourself using Chapters R8 and R10 of the *Guidance on IR&CSA*[61] and the Practical Guide "How to prepare toxicological summaries in IUCLID and how to derive DNELs" [62] (note that this requires a high level of toxicological and ecotoxicological expertise).

If, after having reviewed the evidence/relevant data, you determine that a DNEL/PNEC cannot be derived, you may decide to undertake a qualitative risk assessment. In this case you may refer to Part E of the *Guidance on IR&CSA* and to *Practical Guide "How to undertake a qualitative human health assessment and document it in a chemical safety report"*[63]. This practical guide assumes some knowledge of the intrinsic properties of the used substances characterised through CLP and the resulting risk assessments of chemicals.

---

[60] echa.europa.eu/information-on-chemicals.

[61] echa.europa.eu /guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

[62] echa.europa.eu/ practical-guides.

[63] echa.europa.eu/ practical-guides.

***(ii) Supplier's hazard assessment is not appropriate***

If, based on your knowledge of the substance, you decide that the hazard information received is not appropriate, you may formally communicate with your supplier. You should provide your reasoning, and ask him to review the hazard information.

If you have sufficient REACH experience and technical competence (for example, if you have done your own registrations), you may decide to update the hazard assessment yourself, using the relevant sections (e.g. Part B, Chapters R.2-R.10 etc.) of the *Guidance on IR&CSA*.

### 5.4.2 Develop exposure scenarios (for uses not covered)

Downstream users are normally familiar with the conditions of use for the use(s) not supported. The substances are generally used onsite, or for a use that a customer has informed you about. Consequently there is a good basis for developing exposure scenarios.

Generic exposure scenarios have been developed by some industry sectors and some companies. These apply to various substances / mixtures and cover a broader range of conditions of use. If your sector has developed such generic exposure scenarios that are applicable for your use, you can utilise these as a starting point, and adapt them if necessary.

The risks for workers, the environment and consumers should be considered. When the substance is part of an article, the life-cycle of the article should also be taken into consideration. Waste stages, if relevant, should also be included.

If you are a supplier and will be communicating the exposure scenarios to your customers, it is advisable that you work with the standardised use descriptor system (see the *Guidance on IR&CSA*, Chapter R.12: Use descriptor system[64]).

You may also be notified of a use by your customers; in this case you may decide if you want to cover it in your chemical safety report or to notify it up the supply chain (to your supplier(s)).

You may be able to demonstrate, based on qualitative considerations, that certain exposure routes are negligible and do not have to be quantified to be confident that risk is controlled. Some arguments and examples are provided in Chapter R.5 of the *Guidance on IR&CSA*.

### 5.4.3 Exposure Estimation

Exposure estimation is important both for quantitative and qualitative risk assessments. There are a number of ways in which the exposure can be estimated and the risk characterised, including:

A. Measured exposure data

B. Exposure estimation tools

C. Control banding

**A. Measured exposure data**

Measured exposure data refers to personal exposure or environmental emission measurements undertaken for the activity / process category of interest or similar tasks. Many downstream users are likely to have measured exposure data available, which were undertaken in accordance with their environmental health and safety monitoring program.

The reliability and representativeness of any data used needs to be assessed as the purpose for which it was collected may affect how it can be used in a REACH exposure assessment. Due

[64] echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

consideration should be given to the basis and conditions under which the data was collected and the standards and protocols implemented for data collection (e.g. EN 689 for assessing workplace atmospheres, or "Testing Compliance with OELs for Airborne Substances" (BOHS, 2011) etc.). This should be documented in the DU CSR. Further information is provided in the *Guidance on IR&CSA*, Chapter R.14: Occupational exposure estimation[65].

If measured exposure data is not available, suitable analogous data may be appropriate. This is typically data based on similar operations, using the same substance or data based on the same operation, but for similar substance properties. When using analogous data, the assessor must ascertain that his estimation gives a result on the safe side, to avoid an underestimation of the risk.

### B. Exposure estimation tools

A number of exposure estimation tools are widely available, such as:

a. DU CSR / Scaling tools (typically based on Ecetoc TRA)
b. Ecetoc TRA (worker, consumer, environment)
c. Stoffenmanager (worker)
d. Advanced Reach Tool (ART) (worker)
e. EUSES (environment)
f. ConsExpo (consumer)

These tools are publicly available, and are free of charge. Links and summary descriptions of the tools, including applicability and limitations, are provided in Chapters R.14, R1.5 and R.16 of the *Guidance on IR& CSA*, where additional approaches and tools are also described. The tools vary in their level of sophistication and applicability. Some are conservative screening models, others incorporate greater specification of parameters, giving a more robust estimation for certain scenarios.

The correct use of these tools and interpretation of the results requires expertise.

### C. Control banding

A control banding tool, such as the EMKG-Expo-Tool, can be used for inhalation exposure calculations in the working environment. This is an exposure predictive tool which is based on the assumption that the workplace exposure is determined by the exposure potential of the handled substance and the applied control strategy. Based on information on the substance and conditions of use, the tool predicts a lower and an upper value for the exposure range. The upper value of the exposure range should normally be used for the risk characterisation, i.e. the comparison with the DNEL-value.

The EMKG-Expo-Tooltool can be downloaded from the Internet[66]. Its application in chemical safety assessment is described further in Part D and in Chapter R.14 of *Guidance on IR&CSA* Stoffenmanager can also be used as a control banding tool and it's available on the internet.

Chapter R.14 explains that several control strategies (with different RMMs) can be selected and the effect of these strategies on the exposure estimate can be calculated.

---

[65] echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

[66] reach-helpdesk.de/en/Exposure/Exposure.html.

### 5.4.4 Characterise the Risk

To characterise the risk, compare exposure levels to quantitative or qualitative hazard information (REACH Annex I, 6). When suitable predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs) are available, derive risk characterisation ratios (RCRs) in order to decide if risks are adequately controlled for each environmental compartment and for each human population known to be or likely to be exposed (REACH Annex I, 6.4). If all risk characterisation ratios are below 1, the risk is considered as adequately controlled and the conditions of use can be documented as the "final exposure scenario". This is termed a quantitative risk characterisation.

$$\text{Risk Characterisation Ratio RCR} = \frac{\text{Exposure}}{\text{DNEL or PNEC}}$$

DNEL: Derived No Effect Level

PNEC: predicted no-effect concentrations

If there are no DNELs/PNECs to compare with because of non-threshold effects, carry out a semi-quantitative (in case a DMEL[67] is available) or qualitative assessment of the likelihood that these effects are avoided when exposure scenarios are implemented (REACH Annex I, 6.5). The methodologies used are often based on hazard and control banding, and may be applied as long as there is sufficient justification that under the conditions of use the risk is controlled. Further information can be found in the Practical Guide "How to undertake a qualitative human health assessment and document it in a chemical safety report"[68].

Site-based risk assessments carried out due to the requirements of other legislation may also provide useful information.

### 5.4.5 Documenting the downstream user chemical safety assessment in the report

When documenting the downstream user chemical safety assessment, include all relevant headings of the chemical safety report format given in Annex I of REACH.

The DU CSR includes:

Part A. A declaration that the risk management measures outlined in the relevant exposure scenarios are implemented by the downstream user for his own uses and that the risk management measures outlined in the exposure scenarios for the identified uses are communicated down the supply chain (as applicable).

Part B. Information on the DNELs/DMELs/PNECs used and additional information on your own hazard assessment, if performed, the exposure assessment (with any necessary argumentation and supporting documents) and risk characterisation for all assessed uses. This corresponds to sections 9 and 10 of the format in section 7 of Annex I.

You are not required to submit the DU CSR to ECHA. You are, however, required to keep the chemical safety report up to date and available. It is advisable to check any new safety data

[67] Derived minimum effect level.

[68] More information can be found by reading the Practical Guide "How to undertake a qualitative human health assessment and document it in a chemical safety report" available at echa.europa.eu/practical-guides.

sheet you receive for the substance to establish whether relevant data which may affect your assessment has changed.

## 5.5 Reporting to ECHA

If you are required to report to ECHA (termed a Downstream User Report), two options are available:

(i) a Webform via the downstream user pages of the ECHA website[69]: this is recommended for most downstream users, in particular those who are not familiar with IUCLID

(ii) via REACH-IT/IUCLID: this is recommended for downstream users who are already users of IUCLID and who want to maintain their report records in the REACH-IT system. Support is provided by the Data Submission Manual "How to prepare and Submit a Downstream user report using IUCLID 5"[70].

If you need to report that classification[71] is different to that of your supplier you can only do that using option (ii), via REACH-IT.

You should go to the web page on downstream user reports[72], to select which reporting option you want to use.

The information to be provided for unsupported uses includes:

- the identity and contact details of the downstream user;
- the registration number of the substance;
- the identity of the substance;
- the identity of the supplier;
- a brief general description of the use(s) and conditions of use; and
- a proposal for additional testing on vertebrate animals if this is foreseen.

The brief general description of use should identify the use(s) not covered, describe the factors which influence the exposure levels and outline the main risk management measures. It is not a chemical safety report. The downstream user report should be available onsite for inspection by national authorities.

## 5.6 Annex relevant Exposure Scenario(s) to updated SDS

If you have prepared a DU CSR for your customers' uses you are required to place the relevant exposure scenarios (for communication) in an annex to the safety data sheet you supply to them (Article 31(7) of REACH).

---

[69] echa.europa.eu/regulations/reach/downstream-users.

[70] echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

[71] According to Regulation (EC) No 1272/2008 (CLP Regulation).

[72] echa.europa.eu/regulations/reach/downstream-users/downstream-user-reports.

As part of the communication, information on scaling should also be provided, where scaling is applicable. For more details on scaling, including the principles, the communication of scaling options, and the boundaries of scaling see Appendix 2.

More information is provided in the *Guidance on the compilation of safety data sheets*[73]. Chapter 7 of this guidance provides more detailed guidance for communicating information on mixtures.

[73] echa.europa.eu/guidance-documents/guidance-on-reach.

# 6 Communicating new information on hazards and risk management measures upstream

This chapter provides guidance on how to comply with the obligations placed on downstream users by REACH to:

- communicate new information on the hazardous properties of substances and mixtures up the supply chain to suppliers;
- communicate up the supply chain any information that might call into question the appropriateness of risk management measures identified in a safety data sheet; and
- report to ECHA if his classification of a substance is different from that of his suppliers.

## 6.1 Introduction

Sometimes you may not agree with the information provided to you by your supplier via an extended safety data sheet. If you consider that the proposed risk management measures are not appropriate, or if you, for a justified reason, classify your substance differently to your suppliers, you need to take action to inform your supplier or report to ECHA, respectively. Moreover, you may have additional information concerning the substance. In this case you need to actively communicate this to your supplier(s).

## 6.2 Communicating new information on hazardous properties up in the supply chain

Article 34

(a)*: Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:*

*(a) new information on hazardous properties, regardless of the uses concerned;*

With any substance or mixture you receive, you may receive information from your supplier, either in the form of a safety data sheet or information according to Article 32 of REACH. If you receive no specific information, it should mean that the suppliers have concluded that the substance or mixture is not hazardous and can be handled without any specific risk management measures.

There is no definition in REACH of what constitutes “new” information, or what source and quality of data is acceptable. New information may relate either to substances or to mixtures. The main criteria for deciding whether you hold new information are that:

- the information is not communicated to you by your supplier;
- the information is not available in public data bases or literature;
- the information is relevant for the substance or mixture you receive from the supplier;
- you have good evidence to support the information;
- the information could have consequences for the management of the risks of the substance.

New information could be observations on any adverse effects on human health or the environment (e.g. observations on acute human health effects at workplace) or, if you have carried out testing of substances and mixtures, results of those tests.

For non-classified substances and mixtures, you may not receive any information from your supplier at all. In this case, the obligation to inform suppliers about "new information" also applies. Therefore if you have an indication that a substance or mixture for which you have received no information (neither according to Article 32 nor a safety data sheet) is hazardous, you should inform your supplier of this.

Table 13 below lists the Sections of the safety data sheet which you should check against your own information on the substance. If your information is different from that in your supplier's safety data sheet, you must communicate this up in the supply chain to him.

**Table 13 Forwarding information on classified substances and mixtures**

| Information received under a given Section of the safety data sheet | Substance / Mixture | "New information" and requirements / conditions to forward it up the supply chain |
|---|---|---|
| 2: Hazards identification | | Substances: it is obligatory to forward new information on hazards, including new information from testing and other sources that change the classification of the substance.<br>Mixtures: if you test the mixture you purchase and this information differs from that in the safety data sheet of the supplier, it is obligatory to forward this information, or if you recognize that the classification of the mixture is obviously incorrect or incomplete |
| 8: Exposure limit or biological values | | In national or other Community legislation and/or workplace risk assessments different limit values are imposed on you. You should inform your supplier if specific limits applicable in your case change. |
| 8: Derived no effect levels (DNELs) and predicted no effect concentrations (PNECs) | DNELs & PNECs in mixture SDS may refer to different substances. | If you carry out tests, e.g. in the scope of a DU CSR to refine a PNEC/DNEL value, it is obligatory to forward the information upstream.<br>If you do not test, but reach different conclusions on these values, e.g. because you use different data or interpret it differently, you may communicate this information upstream. |
| 9: Physicochemical properties<br>10: Stability & reactivity<br>11: Toxicology<br>12: Ecotoxicology | | New information from testing, practical experience, or other sources, should be forwarded to your supplier, if relevant to the substance or mixture you obtained from him. |
| (2), (3), 15, (16): R-phrases or hazard statements | | Contact your supplier to clarify whether your supplier has classified differently than yourself or has made a mistake in the safety data sheet. |

Any actor holding new information on hazards should report to his immediate supplier, regardless of whether or not his supplier is the registrant of the substance. You may first want to communicate only the fact that you have new information on a substance or mixture, and the result. You do not have to forward the test report. If your supplier is interested in

obtaining the full study report, you may wish to negotiate the conditions for providing such information. Please note that if you yourself receive new hazard information from your own customers, you are required to pass the information to the next actor up the supply chain.

Note that the downstream user has also the option to request to become a member of a SIEF as "data holder" with the intention to share relevant information. For more information please consult the *Guidance on data sharing*[74].

There are no specific deadlines for communicating information on hazards upstream. You should always do so as soon as you become aware that, compared to the information received from your supplier, you have "new information". The requirements relate to the main body of the safety data sheet, as well as the exposure scenario. Note also that this type of supply chain communication does not involve any reporting to ECHA.

New information on hazards may influence your supplier's recommendations on risk management measures. If you are a formulator, you should assess whether the new information warrants that new safety information is communicated with your mixture to your customers (see also chapter 7 of this guidance).

## 6.3 Communicating on the appropriateness of the risk management measures upstream

REACH Article 34*: Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:*

*(a)[…]*

*(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.*

This provision of REACH aims at ensuring that the risk management measures communicated to you in a safety data sheet and/or exposure scenario, and which you are required to implement, are adequate to control the risks. It is also your means to react to the supplier's recommendation of measures which are not technically feasible. In short, communicating any information calling into question the appropriateness of risk management measures to your supplier will contribute to a better quality of safety data sheets. The communication requirements relate to the main body of the safety data sheet, as well as the exposure scenario.

Information on risk management measures under Section 8 of the safety data sheet addresses measures for all identified uses. They are described in a general manner or just refer to the use-specific risk management measures in the attached exposure scenarios. This subchapter gives some examples of when you may consider the risk management measures recommended under Section 8 of the safety data sheet to be inappropriate. This applies to both quantitative and qualitative measures.

- The recommended measures are not effective for the type of substances: for example, your supplier recommends waste gas incineration during the processing of a mixture containing metals. The incineration will remove organic compounds but not metals (which will be released as themselves or as various compounds of the metals).
- The recommended measures are overprotective: for example, full arm gauntlets for a substance which is not classified for acute effects. The recommended measures

[74] echa.europa.eu/guidance-documents/guidance-on-reach.

relate to exposure routes that do not occur: an example would be that a gas scrubber is recommended for a non-volatile substance.

If your current practice differs from the recommendations, it may mean not only that the recommended measures are inappropriate, but also that the measures are applicable for other identified uses but not for yours, or that your current use of the substance or mixture is not safe. Another reason may be that your installations are adapted to other and more hazardous substances and therefore you have more strict conditions of use than proposed by your supplier. This does not necessarily mean that the recommended risk management measures are inappropriate. Check why you use the substance as such or in a mixture differently and document the findings. Information from technical staff (measures are not feasible) or health, safety and environmental management (risk assessments / measurements / new information on hazards) may be helpful.

When communicating on inappropriate risk management measures, REACH does not specify what information exactly you should forward, or in what format. You need to provide sufficient information to justify why you consider that the recommendations are not appropriate. The type of information depends on the reason why you call into question the recommendations. If you regard the measures as ineffective or overprotective, you need to indicate why this is the case, perhaps with reference to your own operational conditions and the findings of your risk assessments. If the recommendations contradict classification and labelling or existing legislation (e.g. hierarchy of RMM established by the Chemical Agents Directive), reference to this is sufficient. When you are forwarding information concerning risk management measures in the exposure scenario, it can include, for example, the documentation of your exposure scenario check, measurement results or any other type of information supporting the conclusion that the measures are inappropriate.

Apart from reacting to communicated risk management measures, you may also provide information pro-actively to your supplier, in order to make sure that his exposure scenario will cover your conditions of use (see chapter 3 of this guidance).

When your supplier receives information from you, he should review his chemical safety assessment and determine whether changes are needed to risk management measures, either in the main body of the safety data sheet, in the relevant exposure scenario(s) or both. He may then respond either by changing his recommendations according to your information or by arguing that your information does not call into question his recommendations. In this case, your supplier may not change his recommendations and you may not receive an updated safety data sheet. He may also decide not to redo his assessment because he considers it too burdensome, or conclude that based on the new information your use is a use advised against. For your options in this situation, please see chapter 4 of this guidance.

## 6.4 Reporting new classification of a substance to ECHA

Article 38(4): *A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.*

If you classify a substance, and your classification is different from that of all of your suppliers (as communicated in the safety data sheet under Section 2 for a substance as such, or Section 3 for the substance as a component of a mixture), you must report your classification to ECHA. This information is added to the C&L information for that substance in ECHA's database.

Before you report your classification to ECHA, it is recommended that you contact your supplier(s) to discuss whether an agreed classification could be found between you. This is mandatory if you use new data for classification that was not considered by your supplier (see chapter 6.2). If you agree on a classification and this is reflected in the supplier's updated safety data sheet, reporting obligation to ECHA lapses.

The requirement to report your own classification only applies to substances that you use, as such or in mixtures, in quantities of 1 tonne per year or more (Article 38(5) of REACH). Practical instructions on how to report downstream user classification to ECHA can be found in the "Q&A on Downstream users reports"[75].

[75] echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/downstreamusersreports.

# 7 Communication in the supply chain related to mixtures

This chapter provides guidance to downstream users who formulate mixtures. It presents the main obligations under REACH relating to mixtures and describes how information relating to the safe use of mixtures can be communicated in the supply chain.

Additional guidance relevant for formulators is provided in the "Guidance on the application of CLP criteria", which covers the classification of mixtures, in the ECHA web page dedicated to CLP[76] and in the *Guidance on the compilation of safety data sheets*[77].

A mixture is defined in Article 3(2) of REACH and Article 2(8) of the CLP Regulation as *"a mixture or solution composed of two or more substances"*. A mixture may be in a liquid, a gas or a solid phase (such as alloys and plastic pellets). A substance diluted with a solvent (such as water) is a mixture.

The physical state of the mixture may affect the level of exposure to a substance in the mixture for an identified use. This should be considered when establishing the conditions of use, such that the risk is adequately controlled.

This chapter is addressed primarily to formulators. It is also relevant to re-fillers and any manufacturer, importer or distributor placing a mixture on the market. These roles are described in chapter 2.

## 7.1 Legal obligations related to mixtures under REACH

The legal obligations under REACH that are of most relevance to formulators when they are communicating information on mixtures are outlined below. For completeness, some reference to relevant requirements under CLP Regulation is included. A decision chart for the main obligations is provided in Figure 5.

The articles in REACH that apply in particular to formulators of mixtures, together with comments on the interpretation of these articles, are presented in Table 14. The table covers the obligations relating to mixtures contained in Title IV of the Regulation.

As a supplier of mixtures you may have the following obligations:

1. **Classify, label and package mixtures.**

   i. Until 1 June 2015 – classification should be in accordance with the Dangerous Preparations Directive (DPD 1999/45/EC) and in addition, by choice, in accordance with the CLP Regulation before that date. Labelling should be in accordance with either DPD or CLP Regulation. If labelled in accordance with CLP, the classification according to CLP has to be included;

   ii. After 1 June 2015 – classification, labelling and packaging must be in accordance with the CLP Regulation. However, any mixtures which are placed on the market in accordance with DPD before 1 June 2015 are not required to be relabelled and repackaged in accordance with CLP until 1 June 2017 (Article 61 of the CLP Regulation).

[76] echa.europa.eu/regulations/clp.

[77] Available at echa.europa.eu/guidance-documents/guidance-on-reach.

A supplier should notify ECHA regarding the classification of substances (as such or in a mixture) if he is the manufacturer or importer and the classification and labelling has not been notified as part of registration (Article 40 of CLP).

2. **Provide safety data sheets** for mixtures compiled in accordance with Annex II of REACH, as amended by Regulation 453/2010:

   i. for all mixtures classified as hazardous that are supplied to downstream users and distributors;

   ii. on request for non-classified mixtures which contain (Article 31(3) of REACH):

      - at least one substance posing human health or environmental hazards in an individual concentration ≥1% by weight for non-gaseous mixtures and 0.2% by volume for gaseous mixtures; or
      - substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in an individual concentration ≥0.1% by weight (non-gaseous mixtures only); or
      - substances of very high concern that are included in the Candidate List of substances for authorisation for other reasons in an individual concentration ≥ 0.1% by weight (non-gaseous mixtures only); or
      - substances for which there are Community workplace exposure levels;

   An exemption applies to obligation (i) above. If the mixture is offered or sold to the general public and sufficient information for safe use is provided, a safety data sheet need not be supplied unless requested by a downstream user or distributor. These obligations are detailed in Article 31 of REACH.

3. **Communicate relevant information down the supply chain when no safety data sheet is required:**

   i. provide any information related to authorisation or restriction, as well as information needed to ensure safe use;

   ii. provide the registration number(s) for substances subject to authorisation, restriction, or for which it is necessary to provide information enabling implementation of safe use conditions.

   The means of communication will depend on the amount of information required, but could include measures such as product inserts, product information sheets and labelling. These obligations are detailed in Article 32 of REACH.

4. **Comply with general obligations relating to downstream users**. These are contained in Title V of the Regulation and are detailed elsewhere in this guidance. In particular, you should:

   i. communicate information about the uses of substance(s) in the mixtures to your supplier with the aim to make these identified uses. This is optional. Refer to chapter 3 for more details.

   ii. check whether your uses (and the foreseeable uses of your customers) are covered in the information you receive from your suppliers. Implement or recommend the conditions described in the exposure scenario communicated in the safety data sheet (whether in annex or integrated in the main body) or take alternative action. Refer to chapter 4 for more details on the available options and consequent obligations;

iii. communicate up the supply chain, if there is a doubt about the appropriateness of the risk management measures identified in the safety data sheet received or if any new information on hazards becomes available. Refer to chapter 6 for more details;

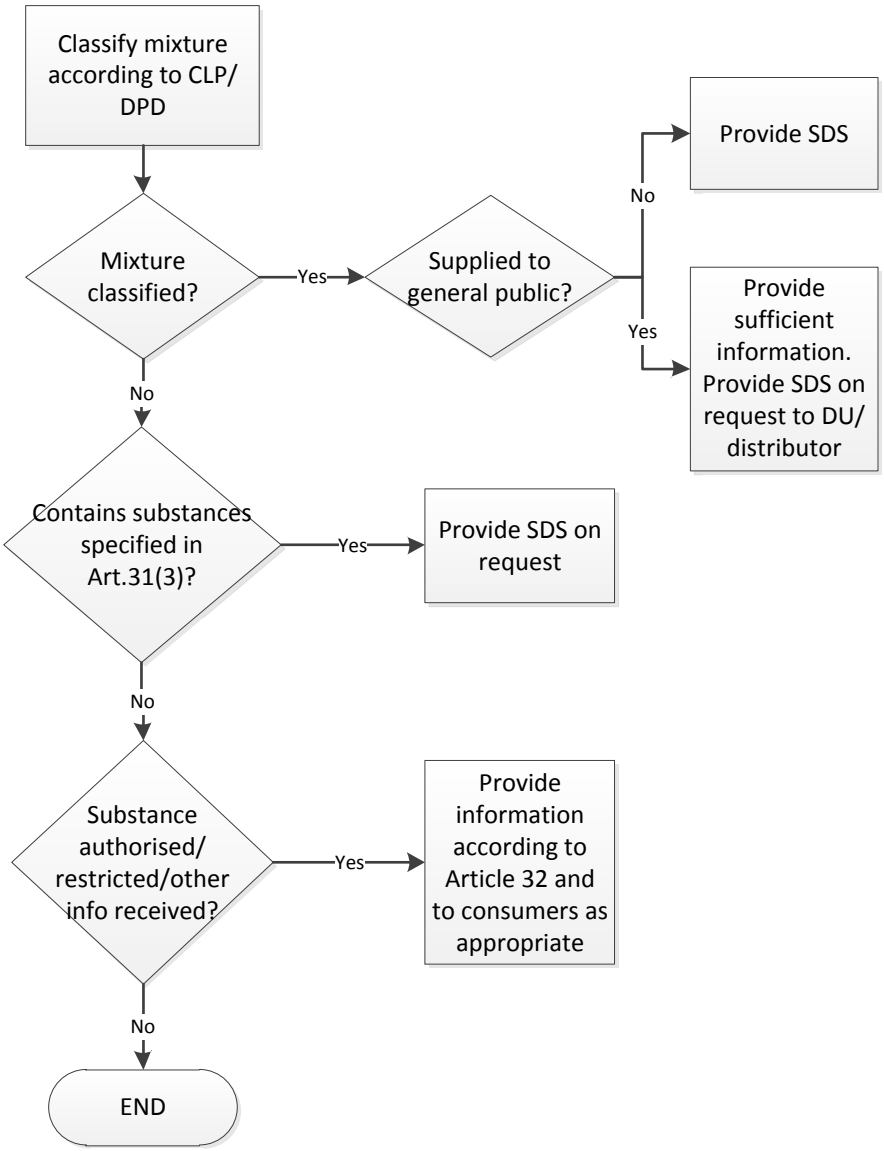


**Figure 5 Workflow summarising when a safety data sheet or other information on a mixture must be forwarded to downstream users and distributors. Note that a supplier is not obliged to provide a safety data sheet to consumers.**

**Table 14 Legal references in Title IV REACH relating to formulation of mixtures together with clarification**

| REACH Article | Regulation | Clarification |
|---|---|---|
| 31(1) | *The supplier of a (...) mixture shall provide the recipient of the (... ) mixture with a safety data sheet compiled in accordance with Annex II:*<br><br>*(a) where a (...) mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC; (...)* | An SDS is required if the mixture is classified as dangerous according to DPD. The requirements for the SDS are presented in Annex II of REACH. A detailed guidance is provided in the *Guidance on the compilation of SDSs*.<br><br>Some of the requirements of Annex II change on 1 June 2015, to implement the transition to the CLP Regulation. The SDS for any mixtures which are on the market before 1 June 2015 (in accordance with DPD) does not have to be updated until 1 June 2017. However, if a supplied product is labelled according to CLP, the SDS must be in compliance with the later version of Annex II (June 2015).<br><br>Note that the requirements relating to providing an SDS apply to all hazardous substances and mixtures, and not only those that are registered under REACH. Also, sub paragraphs (b) and (c) of Article 31(1) refer only to substances.<br><br>Recipients are downstream users and distributors (incuding retailers). Aconsumer is not a recipient, and there is no obligation to providea consumerwith a SDS. |
| 31(2) | *Any actor in the supply chain who is required, under Articles 14 or 37, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment.* | The information in the SDS must be consistent with the CSA for the substance. If a CSA is prepared for a mixture as a whole, the SDS can be based on this CSA.<br><br>A CSA for a mixture is not defined in REACH. Annex I and Annex XII of REACH refer to |

| | | |
|---|---|---|
| | *If the safety data sheet is developed for a mixture and the actor in the supply chain has prepared a chemical safety assessment for that mixture, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the mixture instead of with the chemical safety assessment for each substance in the mixture* | CSA/CSR for single substances for registrants and downstream users respectively. |
| 31(3)[78] | *The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:*<br><br>*(a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or*<br><br>*(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or*<br><br>*(c) a substance for which there are Community workplace exposure limits.* | An SDS must be provided on request even if the mixture is not classified as dangerous but meets subparagraphs a, b or c.:<br><br>Re(a) These concentration limits apply whether the substance is classified or not.<br><br>Re (b) Regarding PBT/vPvB substances, this applies both for substances known to be PBT/vPvB and for substances that are treated as if they are PBT/vPvB. The list established in accordance with Article 59(1) is the Candidate List for eventual inclusion in the Authorisation List.<br><br>Re(c) This applies regardless of concentration in the mixture.<br><br>From CLP regulation, an SDS must be provided on request if certain substances are present at a concentration ≥0.1% (including a Category 2 caricinogen or Cat1 or Cat 2 reproductive toxin. See Tables 3.6.2 and 3.7.2. in CLP) |
| 31(4) | *The safety data sheet need not be supplied where (…) mixtures that are dangerous in accordance with Directive 1999/45/EC, offered or sold to the general public, are provided with sufficient information to enable* | For mixtures that are classified, Article 31(1) requires the supplier to provide an SDS to downstream users or distributors (also termed |

[78] Note that this article will be amended from 1 June 2015 with regard to the classification of mixture as hazardous and to the classification of substances in the mixture triggering the obligation (Article 59 of the CLP Regulation).

| | | |
|---|---|---|
| | *users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.* | "recipients").<br><br>However, if these mixtures are also available to the general public, the requirement to provide an SDS to recipients is waived if the supplier provides sufficient information to ensure that the mixture can be used without adverse effect to human health or the environment, for example by labelling or with product inserts.<br><br>The supplier must ensure (i) that the information provided to the recipient is sufficient, and (ii) that the mixture is offered or sold to the general public.<br><br>A recipient is entitled to receive an SDS on request. A supplier is not obliged to provide an SDS to a consumer. |
| 31(5) | *The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise.* | Exposure scenarios are part of the SDS and the requirement to supply it in an official language of the Member State also applies to them, unless the relevant Member State provides otherwise.<br><br>Formulators may choose to request exposure scenarios in other languages, such as English, to facilitate collation of information from a number of countries. There is no legal obligation on the supplier to provide them, although he may choose to for business reasons. |
| 31(6) | *The safety data sheet shall be dated and shall contain the following headings: (...)* | The SDS headings are listed in Article 31(6). |
| 31(7) | *Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet (...)* | A formulator may be required to prepare a CSR if his use or customer use of a registered substance is outside conditions of exposure scenario (Article 37). If the formulator is also a manufacturer or importer, he may be required to prepare a CSR, if the |

| | | |
|---|---|---|
| | | requirements of Article 14 apply.<br><br>If a formulator prepares a CSR, he has to include the relevant exposure scenarios in an annex to the SDS. |
| 31(7) ctd. | *Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.* | A formulator must convey relevant information through the supply chain. Information can be obtained from exposure scenarios and the SDS provided. The formulator can:<br><br>(i) incorporate the relevant information in the main body of the SDS.<br><br>(ii) append safe use information for the mixture to the SDS<br><br>(iii) attach the relevant exposure scenarios to the SDS<br><br>Specific legal obligations apply if the conditions described in exposure scenarios are not implemented or recommended (Article 37(4)). Consequently, it is recommended that conditions of use incorporated in an SDS that were sourced from an exposure scenario for a substance in the mixture are clearly identified as such. See chapter 7.2.3 for more details. |
| 31(7) ctd. | *Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 37(2).* | This provision ensures that downstream users, who have made a use known, receive the information on safe use in an ES, and not incorporated into the body of the SDS. |
| 31(8) | *A safety data sheet shall be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied.* | Where a SDS need not be supplied (Article 31(4)), a reasonable time-limit for provision of the SDS following a request is normally acceptable. |

| | | |
|---|---|---|
| 31(9) | *Suppliers shall update the safety data sheet without delay on the following occasions:*<br>*(a) As soon as new information which may affect the risk management measures, or new information on hazards becomes available*<br>*(b) once an authorisation has been granted or refused;*<br>*(c) once a restriction has been imposed;*<br><br>*The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.* | A formulator has to update the safety data sheet without delay if the safety advice or hazard information needs to be changed, or if there is new information on authorisation or restriction.<br><br>When formulators receive an extended SDS for a registered substance, it is likely to include new information such as additional risk management measures, DNELs/ PNECs or new classification. Formulators should review if they need to update their safety data sheet due to the information received. |
| 31(10) | *(...)*<br>*Where mixtures are classified in accordance with Regulation (EC) No 1272/2008 during the period from its entry into force until 1 June 2015, that classification may be added in the safety data sheet, together with the classification in accordance with Directive 1999/45/EC. However, until 1 June 2015, where substances or mixtures are both classified and labelled in accordance with Regulation (EC) No 1272/2008 that classification shall be provided in the safety data sheet, together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively, for the substance, the mixture and its constituents.* | Until 1 June 2015, transitional provisions apply regarding the classification of mixtures. Until this date, the SDS for a mixture should include classification information according to the DPD requirements. It may also include classification according to CLP if it is already available.<br><br>However, if the substances or mixtures are both classified *and* labelled according to CLP Regulation prior to 1 June 2015, classification in the SDS must be provided in accordance with both CLP and DSD/DPD. |
| 32(1) | *Any supplier of (...) a mixture who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the following information:*<br>*(a) the registration number(s) (...), for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;*<br>*(b) (...) details of any authorisation granted or denied (...);*<br>*(c) details of any restriction imposed (...);* | Whenever no SDS needs to be supplied in accordance with Article 31 REACH, the supplier of the mixture has to provide the recipient with the information listed in Article 32(1) REACH. Thereby it is ensured that the recipient always receives the necessary information to take appropriate risk management measures. |

| | | |
|---|---|---|
| | *(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied (...)* | |
| 32(2) | *The information referred to in paragraph 1 shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a mixture after 1 June 2007.* | Similarly to a SDS, this information must be actively provided by the supplier to the recipient. |
| 32(3) | *Suppliers shall update this information without delay on the following occasions:*<br>*(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;*<br>*(b) once an authorisation has been granted or refused;*<br>*(c) once a restriction has been imposed.*<br>*In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months. Any updates following registration shall include the registration number.* | The information referred to in paragraph 1 must be updated without delay under the stated circumstances. These are the same as Article 31(9) above.<br>Note that Article 32 refers to recipients, namely downstream users and distributors. The requirements do not apply with respect to supply to consumers. |
| 33 | *Duty to communicate information on substances in articles* | See chapter 8 of this Guidance and, for complete details *Guidance on requirements for substances in articles* |

| | | |
|---|---|---|
| 34 | *Any actor in the supply chain of a substance or a mixture shall communicate the following information to the next actor or distributor up the supply chain:*<br><br>*(a) new information on hazardous properties, regardless of the uses concerned;*<br><br>*(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses. (…).* | If the formulator or downstream user becomes aware of any new information about the hazards related to a substance or a mixture, they have to notify their supplier.<br><br>For example, it may come to his attention that the risk management measures recommended in the ES or SDS are not sufficient (for example, due to occurrence of illness linked to the exposure to the substance or substance in the mixture, even though the recommendations presented in the ES were followed).<br><br>Similarly, the risk management measures recommended in the ES or SDS may be overly precautionary (based for example on workplace monitoring data, extensive health surveillance records).<br><br>Chapter 6 provides more information on upstream communication. |
| 35 | *Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or mixtures that they use or may be exposed to in the course of their work.* | The "information provided" includes any information provided as "sufficient information" if the mixture is also sold to the general public, and the exemption in Article 31(4) applies.<br><br>However, if additional information, as contained in the SDS, is necessary for safe use, then the SDS should be made available to workers and their representatives |
| 36 | *Obligation to keep information* | This article provides details obligations relating to recording and storing information. |

**Please consult the Guidance on the compilation of safety data sheets for additional details.**

## 7.2 Communicating information on conditions of use regarding mixtures in safety data sheets

A formulator is obliged to "include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses" (Article 31(7) of REACH). The objective is to convey information that helps to protect human health and the environment in a way the recipient can easily understand.

This subchapter of the guidance addresses how a formulator can fulfil this obligation. It describes how a formulator can:

- **collate the information** he receives from his suppliers such that it is readily accessible for further processing (Chapter 7.2.1);
- **identify the information** that is relevant to communicate downstream (Chapter 7.2.2);
- **communicate the information** effectively (Chapter 7.2.3).

### 7.2.1 Collating information on substances and mixtures from suppliers

As a formulator, you typically purchase substances and mixtures from a number of suppliers. The information you receive from different suppliers may differ in format and in how the use and the conditions of use are described.

You need to collate and align the information received from the different suppliers before you can identify and select the information to communicate downstream. You can then directly compare the information with respect to the substances, the uses and the conditions of use.

When collating and aligning extended safety data sheets, difficulties may arise in practice, particularly in the early stages of communication of REACH related information in the supply chain. These difficulties typically relate to gaps or conflicts in information contained in exposure scenarios, and the point in time when information is received and issued.

Guidelines for how you can deal with these issues are presented below. Some of these points are discussed in further detail in chapter 4.

#### 7.2.1.1 Guidelines relating to collating information

The following guidelines are intended to assist the process of collating information you receive from your suppliers. All guidelines are not relevant to every situation, as it depends on the methods you use to identify and communicate the information.

***Receiving information from your suppliers***

i. Establish whether the substances in your mixtures have been registered in REACH, and if you expect to receive exposure scenarios for these substances.

ii. If you should receive exposure scenarios for some of the substances (as such or in mixtures) in your mixtures, but have not received them, contact your supplier.

iii. If, for any reason, you do not receive exposure scenarios for substances and/or mixtures you use in your formulations, review the information provided by your suppliers in the safety data sheet when identifying the information to communicate for your mixture.

iv. If you receive exposure scenarios for a relevant use from one supplier but not from another supplier for the same substance, you can use the information received. However, you should first verify that the properties and hazards of the substances received from the different suppliers are the same. Check also that the suppliers who have not included that use did not deliberately omit that use for valid reasons.

In the unlikely event that a use is advised against by one supplier but not by another, you are obliged to communicate with your suppliers under Article 34(b) of REACH.

***Collating information you receive***

v. Align the received exposure scenarios into consolidated versions, if this is necessary both to facilitate information handling and /or to generate standardised exposure scenarios. You may need to harmonise the terminology, and match the substances, uses and the conditions of use. Scaling may be useful when aligning exposure scenarios. See chapter 4 and appendix 2 for further information on scaling.

vi. If you receive exposure scenarios for the same substance from different suppliers, you need to match the contents. Check the classification to make sure that the hazard description of the substances and/or mixtures is the same. If this is not the case, clarify why the differences in classification arise and whether this has an influence on the content of the exposure scenarios attached.

vii. If you establish that the substance and its properties are the same, but the risk management measures differ significantly from different suppliers, take the steps described in chapter 4.2.3.3.

***Updating information you receive***

When you receive updated extended safety data sheets from your suppliers, ensure that you review the information that you communicate downstream. Your safety data sheet needs to be updated without delay when new information becomes available and is relevant for your customers (namely, information which affects risk management, and new information on hazard, on authorisation or on restriction).

### 7.2.2 Identifying information to communicate to downstream users

When the exposure scenario information on the substances is received and collated, the formulator then identifies the information to communicate downstream for mixtures.

The main objective is to communicate the appropriate conditions of use. These are the operational conditions (OC's) and risk management measures (RMMs) that are necessary to protect human health and the environment when using the mixture. This should be undertaken in a systematic way that is proportionate to the risk. Factors such as the composition of the mixture, the hazardous properties of the mixture and of each substance in the mixture, as well as the uses should be taken into account.

Industrial and regulatory bodies are currently developing and/or testing methodologies to support formulators undertaking this process. These methodologies are not described here but further information on these activities and relevant links will be provided as soon as they are established. This is an evolving area, and the appropriate methodology will depend on the

situation. At the time of publication of this guidance, many of the methodologies being developed fall within one of following general approaches:

A. *Exposure Scenario approach:* **Build** information on conditions of use for the mixture from the exposure scenario information received.

B. *Existing Controls approach*: **Check** existing information on conditions of use for the mixture against the exposure scenario information received from suppliers.

#### 7.2.2.1 Exposure Scenario approach

The starting point for the ***exposure scenario approach*** is the relevant exposure scenarios for the individual substances. From these, the appropriate information on conditions of use for the mixture is identified. This is also referred to as the "top down" approach.

Depending on the number of hazardous substances and the routes of exposure, the safe use information may be consolidated in a number of ways. These ways often start by taking the most stringent risk management measures or by identifying the lead-components that determine the appropriate conditions for each exposure route.

The current methods for identifying the lead components are generally based on the classification and/or on the DNELs/PNECs of the single substances. Substance properties that determine the exposure potential, such as vapour pressure, may also be taken into account.

When identifying conditions of use for the mixture in this way, the risk associated with a hazardous raw material for which an exposure scenario has not been received (for any reason), should also be taken into account. The safe use information should also be consistent with the measures required according to the classification of the mixture.

#### 7.2.2.2 Mixture Use approach

The starting point for the ***mixture use approach*** is the information on operational conditions and risk management measures which is currently provided for safe use of the mixture as a whole. The conditions are usually based on the classification and labelling of the mixture, the related precautionary statements, and additional good practice advice based on experience or generic assessment[79]. This is also referred to as the "bottom up" approach.

The existing controls may be found in locations that include: Section 8 of the safety data sheet; control sheets from control banding tools such as COSHH[80]; BREF documents (Best Available Techniques Reference Documents); sector specific publications; or generic exposure scenarios developed by sector organisations. (Generic exposure scenarios document the typical conditions of use for a typical product or process within a sector. See chapter 3.3 for more information.)

The existing controls are checked against those contained in the exposure scenarios received from the supplier for the component substances. This is to confirm, and document, that the conditions of safe use that are communicated by the formulator are supported by exposure scenarios the formulator has received from his suppliers. Alternatively, the formulator could provide his suppliers with all the uses and conditions of use he recommends, to request that they are supported.

If the existing controls are not supported by the exposure scenarios, the formulator must take appropriate action in accordance with the downstream user obligations of Article 37 of REACH as described in chapter 4.

---

[79] Guidance on classification of mixtures is provided in chapter 1.6 of the *Guidance on the Application of the CLP criteria* available at echa.europa.eu/guidance-documents/guidance-on-clp.

[80] hse.gov.uk/coshh/.

#### 7.2.2.3 Factors which indicate a more detailed evaluation may be needed

A simple evaluation of the information that is available on the hazard and conditions of use is sufficient in the majority of situations. Often the well-established rules for classification and labelling of mixtures can help to reduce the complexity of judgement for the formulator.

However, more complex cases arise when a more detailed evaluation is required. Indicators of when this is likely to occur are presented below. A more detailed consideration of the possible complexities, and the core principles to apply, are presented in Appendix 3. The methodology implemented should include a step to check whether a more detailed evaluation is required.

Some situations when more detailed evaluation should be considered include:

a. There could be an **interaction between the substances** in the mixture, either to enhance or diminish the hazardous property.

   This may be due to physical interaction between the component substances (for example, the mixture may be formulated to have particular technical properties that inadvertently affect the availability of the component substances from release from the mixture). Alternatively there may be synergistic effects on combined exposure from two or more substances (for example, human exposure to solvents).

b. Mixtures contain substances with **significant long-term hazards** in concentrations that are **below the general cut-off point for the classification** of the mixture.

   Although the mixture as a whole is not considered hazardous, there may be the need to consider risk management measures to minimise exposure. This refers to substances that are carcinogens, mutagens, toxic to reproduction (CMRs) or sensitisers (dermal or respiratory).

c. Mixtures contain substances that are **PBT or vPvB** in concentrations below 0.1 %.

   Although the concentration is low there may be the need to consider risk management measures to minimise the amounts of substance released into the environment.

d. **Hazards are identified for a component substance**, which however do not lead to a classification as hazardous, and hence the **mixture is not classified**.

   This may, for example, be the case for a substance with adverse effects on sediment and soil organisms. It is likely to have PNECs assigned for soil and sediments and potentially corresponding risk management measures in the exposure scenarios for the substances.

e. Both classification and PNECs/DNELs are available for the component substances but lead to **conflicting conclusions** regarding the lead substances for determining risk management measures.

f. When the substances in the mixture are likely to influence the **performance of the environmental risk management measures** for the single components

### 7.2.3 Options for including information to communicate to downstream users

Once the information has been received and collated from suppliers and the relevant information has been identified, you are now ready to consider how best to communicate

information on the appropriate operational conditions and risk management measures for the mixtures to users further downstream.

The way in which you include this information depends on aspects such as the uses, the level of detail, the recipient and business considerations. The information requirements differ for different customer groups. For example, customers who are formulators are likely to require a lot of detail. Other customers may be end users and use the mixtures directly, such as lubricants, adhesives, cleaning agents and coatings. End users may have limited familiarity with chemicals and need information that is clear and concise. In practice, the customers for a given mixture often fall within a spectrum of needs and abilities.

If you prepare a chemical safety report for the mixture or its component substances, the relevant exposure scenarios shall be annexed to the safety data sheet. Otherwise, the formulator can choose the most appropriate means to include the information such as:

(i) integrate the information into the main body of the SDS; or
(ii) append safe use information for the mixture; or
(iii) attach relevant exposure scenarios for the substances in the mixture in an annex.

The formulator can select the most effective method or provide information in different ways to different customer groups as appropriate. The process should be as efficient as possible, proportionate to the risk, and relevant and understandable to the recipients.

A simplified decision tree of how to communicate the information is illustrated in Figure 6. Aspects to consider are discussed further here.

#### 7.2.3.1 Integrate information into the main body of the safety data sheet

One option is to integrate the relevant information from the exposure scenarios received from your suppliers into the main body of the safety data sheet. This is the recommended approach when communicating to end users, if it is applicable. This is the case when, for example, there are a relatively small number of identified uses and/or conditions of use.

Integrating information has the advantage that it is clear and concise. However, it is usually not suitable if diverse advice on the operational conditions and risk management measures for various uses is necessary. One of the options described in the following subchapters may be more appropriate.

Integrating information in the main body of the safety data sheet is not an option if you were required to prepare a CSR, either in the role of registrant or as a downstream user. In this case, the relevant exposure scenarios must be placed in annex to the safety data sheet.

When you integrate information sourced from an exposure scenario of your supplier into the main body of the safety data sheet, the legal obligations associated with Article 37(4) of REACH still apply to the recipients of your mixture. These are detailed in chapter 4, and relate to implementing the exposure scenario or taking alternative action. Consequently, it is recommended that operational conditions and risk management measures sourced from an exposure scenario are clearly identified as such. The way in which this is done will need to consider technical and business considerations.

The location of information in the safety date sheet is specified in Annex II of the Regulation. Information on exposure controls and personal protection is provided in Section 8. Regulatory information, including whether a chemical safety assessment has been carried out for the substance (or a substance in the mixture) is provided in Section 15. Other information, which could include sources of data in compiling the safety data sheet, information on scaling etc. can be provided in Section 16.

#### 7.2.3.2 Append safe use information for the mixture

Safe use information for the mixture can be derived from the exposure scenarios of the use of the component substances in a mixture received from your suppliers and consolidated into a single description of the safe use of the mixture. The information to include is identified using an approach described in chapter 7.2.2.

The safe use information is appended to the safety data sheet, and is identified as being sourced from exposure scenarios. It consists of the relevant information from the exposure scenarios you received from your suppliers and the risk management measures to ensure safe use. Check with your sector organisation if a standardised format for safe use information has been proposed.

Appending safe use information for the mixture can be a suitable approach when useful information cannot be readily integrated into the main body of the safety data sheet. This is often the case when there are a wide range of uses, with different conditions of use, and when the scenarios are more complex.

Appending safe use information for the mixture is not an option if you were required to prepare a CSR, either in the role of registrant or as a downstream user. In this case, the relevant exposure scenarios must be placed in annex to the safety data sheet.

#### 7.2.3.3 Attach relevant exposure scenarios for the substance(s) in an annex

The relevant exposure scenarios for the substance(s) in the mixture can be placed in an annex to the safety data sheet. This is likely to be the most suitable approach when communicating to customers who are also formulators, and who are generating safety data sheets for their own mixtures. It may also be suitable for end users when the appropriate risk management measures for an identified use are clearly specified in one exposure scenario for each identified use.

The attached exposure scenario may be the same as received from your supplier or, where you have a number of suppliers for the same substance, may be collated and consolidated from the exposure scenarios you receive.

If you were required to prepare a CSR, either in the role of registrant or as a downstream user, the relevant exposure scenarios must be attached (Article 31(7) of REACH). This is the only situation where there is no alternative option available to the formulator.

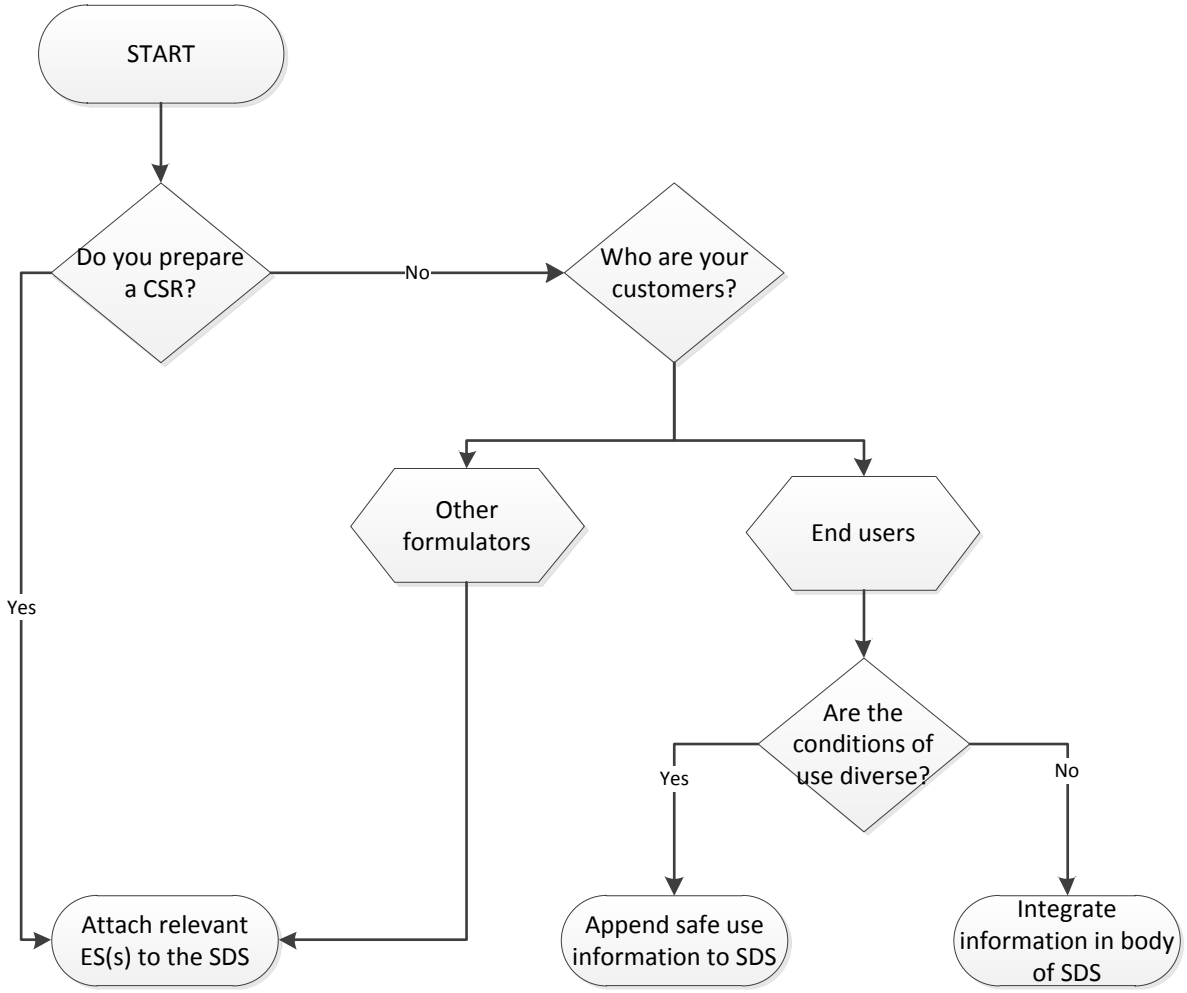


**Figure 6 Suggested simplified decision tree for formulators to identify how to communicate information on the safe use of mixtures downstream**

### 7.2.4 General guidelines when communicating information downstream

The previous subchapters have outlined the main considerations relating to communicating information on mixtures as a formulator. General guidelines to consider when communicating information are summarised here:

**a) Only relevant identified uses are included**. For example, uses such as formulation at own site and consumer use are not relevant if you are supplying to industrial/professional end users only.

**b) Only the exposure scenarios that are relevant for the mixture are included.** If you are forwarding exposure scenarios received from your supplier, it may not be necessary to annex exposure scenarios for every registered substance in the mixture, but only for those substances which are necessary to indicate the conditions of safe use. However recipients who are also formulators may prefer to receive all exposure scenarios.

**c) The operational conditions and risk management measures are appropriate and proportionate**. The conditions of use should be suited to the mixture, the uses and the sector/user group. They should provide adequate protection, without being overly precautionary.

**d) Important information is easy to retrieve and to understand**. Include structural elements such as a table of contents to aid retrieval of information. Avoid an overload of information as the essential information can then be difficult to find. Include information on exposure estimation and scaling only if is of relevance to recipients (typically also formulators).

**e) Standardised methods and descriptors are used as far as possible.** Clear descriptions and terms that are readily understandable by the reader should be used. The standard use descriptor system, standard phrases (EuPhraC phrases[81]) and harmonised exposure scenario formats support the smooth processing of exposure scenario information, automation and translation. However, the familiarity of the recipient with this terminology should be considered, and sector specific terminology used as appropriate.

**f) The supplier's exposure scenarios for substances are grouped into relevant identified uses or use and exposure categories, as far as feasible.** Grouping can be implemented using generic exposure scenarios or a "use and exposure category". A use and exposure category is an exposure scenario covering a wide range of processes or uses. When such groupings are applied as appropriate, it can promote clarity and convenience, without losing information necessary to adequately control the risks.

**g) The information in the exposure scenario is consistent with the information in the main body of the safety data sheet.** A summary of the relevant key information from the annexed exposure scenario should be included into the core Sections of the safety data sheet, with a cross-reference to the details in the exposure scenario. Appendix 2 of the ECHA *Guidance on the compilation of safety data sheets* provides more guidance to the actor who needs to include exposure scenario information in the safety data sheet.

**h) Information on operational conditions and risk management measures sourced from an exposure scenario of your supplier should be clearly identified as such.** This applies if it is integrated into the main body of the safety data sheet or appended to it in some form. The legal obligations associated with Article 37(4) of REACH apply to the recipients of your mixture if the conditions described in exposure scenarios are not implemented.

---

[81] esdscom.eu/euphrac.html.

**i) All relevant information received is included.** You will receive information on substances and/or mixtures in your mixture in a variety of forms, either integrated in the safety data sheet, appended as safe use information for a mixture, or annexed in an exposure scenario. Ensure that information received other than in an exposure scenario is not overlooked when identifying information to communicate to your customers.

**j) Safety data sheets and exposure scenarios are provided in the national language of the Member State where the substance is placed on the market**. This applies unless provided otherwise by the member state concerned (Article 31(5) of REACH). Use of EuPhraC[82] phrases help to promote harmonisation and good translations. ECHA-term[83], a multilingual database for chemical terminology developed by ECHA, also helps to improve the quality of translations and enhance clear communication.

**k) The safety data sheet is reviewed as soon as new information becomes available.** A challenge for formulators is that new information arrives at different times. Contact your supplier to ensure all exposure scenario are received, as far as possible. When relevant information is received, you must update your own safety data sheet. For substances for which ESs are not yet available, use existing information from the safety data sheet to identify appropriate risk management measures. If an exposure scenario becomes available after publication of your safety data sheet, an update is required if the hazard information or safety advice needs to be changed (in general when relevant new information becomes available, as given in Article 31(9) of REACH). Review all incoming information from suppliers to ensure that the necessary information is communicated downstream.

**l) The process is documented.** Activities such as communication with suppliers, identification of information to be communicated and communication downstream should be recorded and maintained in accordance with Article 36 of REACH.

---

[82] esdscom.eu/euphrac.html.

[83] echa.cdt.europa.eu/SearchByQueryEdit.do.

# 8 Requirements related to authorisation, restrictions and substances in articles

## 8.1 Authorisation requirements and downstream users

This chapter describes the actions that downstream users are required to take in relation to substances subject to authorisation. The authorisation system (REACH Title VII) provides for Substances of Very High Concern to be first identified and put on the Candidate List, then gradually included in Annex XIV of the REACH Regulation (the "authorisation list"). Once included in Annex XIV, they cannot be placed on the market or used after the so-called "sunset date". An actor may continue his use of a substance in Annex XIV after the sunset date only if an application for authorisation has been made before the latest application date, but a decision on the application has not yet been taken, or his use is in accordance with the conditions of an authorisation granted to him or to an actor up his supply chain for that use. Moreover, a manufacturer, importer or downstream user can continue placing on the market an Annex XIV substance for a use which his immediate downstream user has been granted an authorisation. There is no tonnage trigger for this requirement.

An application for authorisation can be submitted by a manufacturer, importer or downstream user on their own or together. A duly mandated Only Representative (OR) of a non-EEA manufacturer can also submit an application for authorisation.

It is very important to realise that an authorisation is specific to actors within a given supply chain, for given uses of a given substance.

Authorisations will be granted for (specific) uses[84] for which the applicant shows that the risks posed by the substance are adequately controlled. Authorisations may also be granted where the applicant can show that the socio-economic benefits of a use outweigh the risks and that there are no suitable alternative substances or technologies available. Authorisations will be granted by the Commission and are subject to reviews, the time-interval being decided on a case-by-case basis. ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) provide the Commission with opinions on the application for authorisation. Your use can be included in the authorisation granted to an actor up your supply chain. Alternatively you can make an application for authorisation for your use or for uses by your downstream users, either on your own or together with the manufacturer/importer, ORs or other downstream users. How to apply for an authorisation is explained in detail in the *Guidance on the preparation of an application for authorisation*[85]. More details on the authorisation procedure are provided on the dedicated section of the ECHA website[86].

If a substance is subject to authorisation there is a need for proactive communication between the applicant (e.g. the supplier of the substance) and the downstream users before the application is submitted to ensure that all concerned uses are covered. Once authorisation is granted the downstream user of the authorisation holder should receive information about that by his supplier, either in sub-sections 15.2 of the safety data sheet or in accordance with Article 32 of REACH, and is required to notify ECHA. The authorisation number has also to be

---

[84] Please note, although identified uses described in the registration context are a good basis for the description of uses applied for, they may need to be further refined under the authorisation context. Use descriptors are recommended to be used in an application of an authorisation.

[85] Available on the ECHA website at echa.europa.eu/guidance-documents/guidance-on-reach.

[86] echa.europa.eu/addressing-chemicals-of-concern/authorisation.

mentioned in the label of substances and mixtures placed on the market in accordance with Article 65 of REACH, and the recipient must be informed pursuant to Article 32 of REACH.

### 8.1.1 Uses exempted from authorisation

The REACH Regulation foresees exemptions from the authorisation requirements for uses of substances placed on Annex XIV under certain conditions. You should check if your substance can benefit from such an exemption before considering any other action.

A) **Generic exemptions from the authorisation requirements**: substances on Annex XIV may be used for uses which are exempted from authorisation. Thus, if your use is exempted from authorisation, you can continue your use without an authorisation after the sunset date. Nevertheless, you have to implement the conditions of use and risk management measures communicated to you, for example, in an exposure scenario annexed to a safety data sheet.

Exemptions from authorisation do not have to be communicated by your suppliers. Therefore, you should check whether your particular use is exempted. Table 15 lists the exemptions from the authorisation requirements according to REACH. Further information on exemptions can be found in the section on Q&A on application for authorisation[87].

**Table 15 Generic exemptions from the authorisation requirement**

| Exemption (short) | Description of the exemption: | REACH Article |
|---|---|---|
| **Out of scope** | Substances not within the scope of REACH<br>See also scope of REACH in the navigator and the *Guidance on registration*[88] | 2 |
| **Intermediates** | On-site isolated intermediates and transported isolated intermediates. | 2 (8) (b) |
| **Medicinal products for human and veterinary use** | Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. | 2 (5) (a) |
| **Food or feedingstuffs** | Use in food or feedingstuffs according to Regulation (EC) No 178/2002 including use:<br>- as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption;<br>- as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to | 2 (5) (b) |

[87] Available on the ECHA website at echa.europa.eu/support/qas-support.

[88] You can start a Navigator session at echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations. Guidance documents are available in the "Support" section of the ECHA website at echa.europa.eu/guidance-documents/guidance-on-reach.

| | | |
|---|---|---|
| | flavourings for use in foodstuffs and to source materials for their production and Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council;<br>- as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition;<br>- in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition. | |
| **Scientific research and development**[89] | Use in scientific research and development as defined in Article 3(23) of REACH[90]. | 56(3) |
| **Plant protection products**<br>**Biocidal products**<br>**Motor fuel**<br>**Fuel in combustion plants** | Use in plant protection products within the scope of the Council Regulation (EC) No 1107/2009<br>Use in biocidal products within the scope of the Biocidal Products Regulation (BPR 528/2011)<br>Use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (Art. 56(4)(c) REACH)<br>Use as fuel in mobile or fixed combustion plants of mineral oil products and use of fuels in closed systems (Art. 56(4)(d) REACH) | 56(4) |
| **Cosmetic products** | Use in cosmetic products within the scope of Council Directive 76/768/EEC in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health | 56(5)(a) |
| **Food contact materials** | Use in food contact materials within the scope of Regulation (EC) No 1935/2004 in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a),(b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health | 56(5)(b) |
| **Concentration-based exemptions: PBTs, vPvBs or substances of similar concern** | Use of substances when present in mixtures below a concentration limit of 0.1% weight by weight (w/w) for substances referred to in Article 57(d), (e) and (f) of REACH | 56(6)(a) |
| **Concentration-based exemptions: CMRs category 1A and 1B** | Use of substances when present in mixtures below the lowest concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which results in the classification of the mixture as dangerous) | 56(6)(b) |

[89] Please note that scientific research and development can cover analytical activities. Please refer to Q&A on Application for authorisation nr 585 at echa.europa.eu/support/qas-support.

[90] Article 3(23) of REACH defines scientific research and development as "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year*".

B) **Exemptions included in Annex XIV**: in addition to the generic exemptions listed in the previous paragraph, entries in Annex XIV to REACH may include the following exemptions:

- product and process orientated research and development below the specified maximum quantity (Article 56(3) of REACH);

- uses or categories of uses under the specified conditions (Article 58(1) and (2) of REACH).

In Annex XIV you will find information on which uses are exempted and whether the exemption is subject to further conditions. Any information or conditions in Annex XIV has to be implemented, or you cannot regard the use as exempted.

It is recommended to document the basis on which your use is exempt from authorisation requirements in order to have it ready for inspectors.

C) For **uses of mixtures** there is no authorisation requirement below certain concentration limits[91].

D) Although incorporation of a substance into an **article** in the EU requires authorisation, use of (imported) articles is not subject to authorisation[92].

### 8.1.2 Fulfilling authorisation requirements

If you use a substance on Annex XIV you should:

- check the latest application date of the substance[93];
- ensure that your supplier is including your use (and/or uses by your DUs) in the authorisation application or consider to apply for authorisation.

In addition you are obliged to:

- ensure an authorisation was granted to you or an actor up your supply chain, for your use (if you want to continue to use the substance after the sunset date);
- comply with the conditions of the authorisation decision, and
- report to ECHA if you use a substance under the authorisation granted to an actor up your supply chain[94].

It is important to check the Authorisation List as it develops to see whether any of the substances that you use are on it. This list is typically updated once a year, after a final decision by the European Commission. The concerned substances are indicated in ECHA's draft

[91] These are laid down in Article 56(6) of the REACH Regulation.

[92] However, note that for substances in Annex XIV, after their sunset date ECHA has to consider whether the use of substance in articles poses a risk that is not controlled and if that is the case, ECHA has to prepare a restriction proposal to address this concern.

[93] Latest application date is indicated in Annex XIV. This is the latest date by which an application for authorization has to be submitted to insure that the use can be continued after the sunset date even if the decision has not be made by that time.

[94] If you have applied for the authorisation yourself, no notification of ECHA is required.

and final Annex XIV recommendations to the Commission, which are published about 1 and 1.5 years before the update, accordingly.

If you incorporate such substances into mixtures, it may be beneficial for business purposes to ensure that your customers' uses are included in the application for authorisation. If your customers' uses do not comply with the conditions of authorisation, they will need to cease the use of your mixture or to ask for an authorisation that covers their use.

The applications for authorisation are made to ECHA and can be submitted by the manufacturer(s), importer(s), downstream user(s) of the substances and/or duly mandated ORs. The uses applied for can be the applicant's own use(s) and/or uses for which the applicant intends to place the substance on the market.

An application for authorisation needs to specify the use for which an authorisation is requested, and to document in a chemical safety report how the risks are adequately controlled and/or minimised. It also needs to include an analysis of alternatives and, where suitable alternatives are available, a substitution plan. Applications for substances for which no DNELs/PNECs exist or where exposure exceeds the DNEL shall include a socio-economic analysis (SEA).

Contact your supplier well in advance of the latest application date to find out whether an application will be made by him or another actor up your supply chain.

In case your supplier intends to apply for authorisation, you should verify with him which conditions of use he will specify in the application.

If your use is not to be covered by an authorisation submitted by a supplier in your supply chain and you decide to apply for an authorisation, you could ask your supplier access to his chemical safety report to prepare your application dossier. If your supplier makes an application covering your use(s), he may ask you for support in describing appropriate operational conditions of use and risk management measures. Further information and cooperation requests may relate to the assessment of alternatives, development of substitution plans or carrying out a socio-economic analysis. Further help is given in the *Guidance on the preparation of an application for authorisation* and in the *Guidance on the preparation of socio-economic analysis as part of an application for authorisation*[95].

#### 8.1.2.1 Assess the need for actions concerning your use and applying for authorisation

You can anticipate the need to take actions concerning authorisation requirements for the use of a substance by monitoring the ECHA website at different steps of the process leading to the inclusion in the Annex XIV. Once the substance is in Annex XIV, and if no suppliers intend to apply for an authorisation for your use, consider in advance whether substituting the substance may be a better option than continuing the use. Guidance on assessing alternatives and making substitution plans is provided in the *Guidance on the preparation of an application for authorisation*.

If any actor up the supply chain has not applied for an authorisation covering your use, this may be for a number of reasons; for example because your use is not known to your suppliers, the application was not profitable for other actors or the risk associated with the use proved not to be adequately controlled. If you believe that the risks associated with the substance can be adequately controlled in your use, or that the socio-economic benefits of your use outweigh the risks, you may decide to apply for an authorisation for your use.

It is possible to prepare and apply for an authorisation with a group of actors for same use or different uses of the substance. For example, you could consider:

[95] Both available in the "Support" section of the ECHA website at echa.europa.eu/guidance-documents/guidance-on-reach.

- informing your supplier and asking him to apply for the authorisation, or
- submitting the application with your supplier, and/or
- submitting the application with other downstream users who need authorisation for the same use, and/or
- submitting the application with your customers (if they are also downstream users) who depend on the substance or mixture you sell them.

It is important to remember that if no application for authorisation covering your use is made (either by you or an actor up the supply chain), you must stop using the substance by the sunset date and the substance as such, or in a mixture, may not be supplied to your customers for further uses after that date.

#### 8.1.2.2 Sunset date

In case the substance you use is subject to authorisation and none of the exemptions applies to your use, you can continue using a substance as such, or in a mixture or article, until its so-called "sunset date" is reached. The sunset date is specified in Annex XIV for each substance. After the sunset date, you may only use the substance as such or in a mixture or incorporate it into an article if an authorisation has been granted to you or to an actor up your supply chain and you comply with the conditions of the authorisation, or if you or your supplier has applied for an authorisation before the latest application date but the decision is pending.

#### 8.1.2.3 Comparing authorised uses and conditions with your own use

If an authorisation has been granted to an actor up your supply chain your supplier should provide enough information to enable you to use the substance according to the conditions of this authorisation. He may provide additional information related to the authorisation, e.g. when the granted authorisation will be reviewed. This information can in any case be found on the ECHA website[96].

Where Article 31 of REACH applies the supplier must communicate the conditions under which the substance can be used according to the authorisation in an exposure scenario annexed to or in the main body of the safety data sheet.

Checking if a use is covered by an authorisation is similar to the "normal" checking of coverage of an exposure scenario (chapter 4 of this guidance).

The conditions communicated (e.g. in the exposure scenario) are to be applied strictly. You may apply stricter conditions leading to lower exposure (shorter durations, less frequent use, more tightly encapsulated processes etc.).

To comply with the conditions of the authorisation, you may have to upgrade or modify your process to implement the conditions described in the exposure scenario.

#### 8.1.2.4 – Notifying ECHA

If you are relying on an authorisation granted to your supplier or another actor up the supply chain, you must notify ECHA at the latest 3 months after first receiving an authorised substance as such or in a mixture (Article 66 of REACH). A notification format will be provided via web form and will require as a minimum the following information:

- your identification and contact details;

[96] At echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list.

- the authorisation number, which you will find on the label and/or in the safety data sheet of the substance or mixture or in the information provided according to Article 32 of REACH;
- brief general description of use.

Furthermore, if you are in compliance with the conditions of the authorisation, it is advisable that you document this for internal follow-up and future use (for example, if you make any changes to your process, then you will need to re-check your compliance).

#### 8.1.2.5 – Communicating relevant information downstream

If you are a formulator and supply mixtures to your customers, you have to forward the authorisation number and any information on the conditions of the authorisation that is relevant for your customer. The authorisation number must also be provided on the label (Article 65 of REACH) and in Section 2 of the safety data sheet when one is required.

Since the authorised substance is a SVHC, if you produce articles, you have to supply your customers with information on the authorised substance, if it is contained in the article in concentrations above 0.1 % (w/w). Further guidance on this is provided in chapter 8.3 and, in more detail in the *Guidance on requirements for substances in articles*[97].

#### 8.1.2.6 – Time-limited review period

Authorisations are subject to a time-limited review in which context the Commission may decide to withdraw or amend the authorisation. To be noted that an authorisation may be reviewed at any time by the Commission if the circumstances of the authorised use change so as to affect the risks or the socio-economic impact, or if new information on alternatives becomes available.

This will normally be reported in the safety data sheet or in the information communicated to the downstream user according to Article 32 of REACH. Otherwise, this information can be found in the Commission decision published in the Official Journal[98] and on ECHA website[99]. Holders of authorisations must submit a review report at least 18 months before the expiry of the time-limited review period[100].

### 8.1.3 Contributing to public consultations

During the authorisation process you can provide comments on the substance concerned at different steps of the process:

- When a proposal for identification of a substance as SVHC has been submitted: ECHA particularly welcomes comments related to the substance identity and/or intrinsic properties used to justify the identification as SVHC. Comments questioning CLH are not to be considered in this context. Other types of comments, particularly those on uses, can be made and will be taken into account at the next stage in the process.

- When the SVHC is recommended by ECHA for inclusion in Annex XIV: information on the complexity of the supply chain is particularly welcome. ECHA also welcomes

---

[97] All the guidance documents are available in the "Support" section of the ECHA website at echa.europa.eu/guidance-documents/guidance-on-reach.

[98] eur-lex.europa.eu/JOIndex.do.

[99] echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list.

[100] More details on the process and the timeline are provided on the dedicated section of the ECHA website at echa.europa.eu/en/regulations/reach/authorisation/applications-for-authorisation/authorisation-process/steps.

comments on the review periods, the transitional arrangements and on those uses which could possibly be exempted from the authorisation requirement. ECHA takes the comments received into account when updating the draft recommendation.

- When the application for authorisation is under evaluation by the Committees during the opinion making phase: ECHA welcomes comments related to the existence and suitability of alternative substances or technologies to the uses applied for authorisation. RAC and SEAC then evaluate the relevance of this new information for the application and balance it against the Applicant's assessment and response to these comments.

- After the decision has been made (e.g. new information on alternatives becomes available) on the specific application for authorisation.

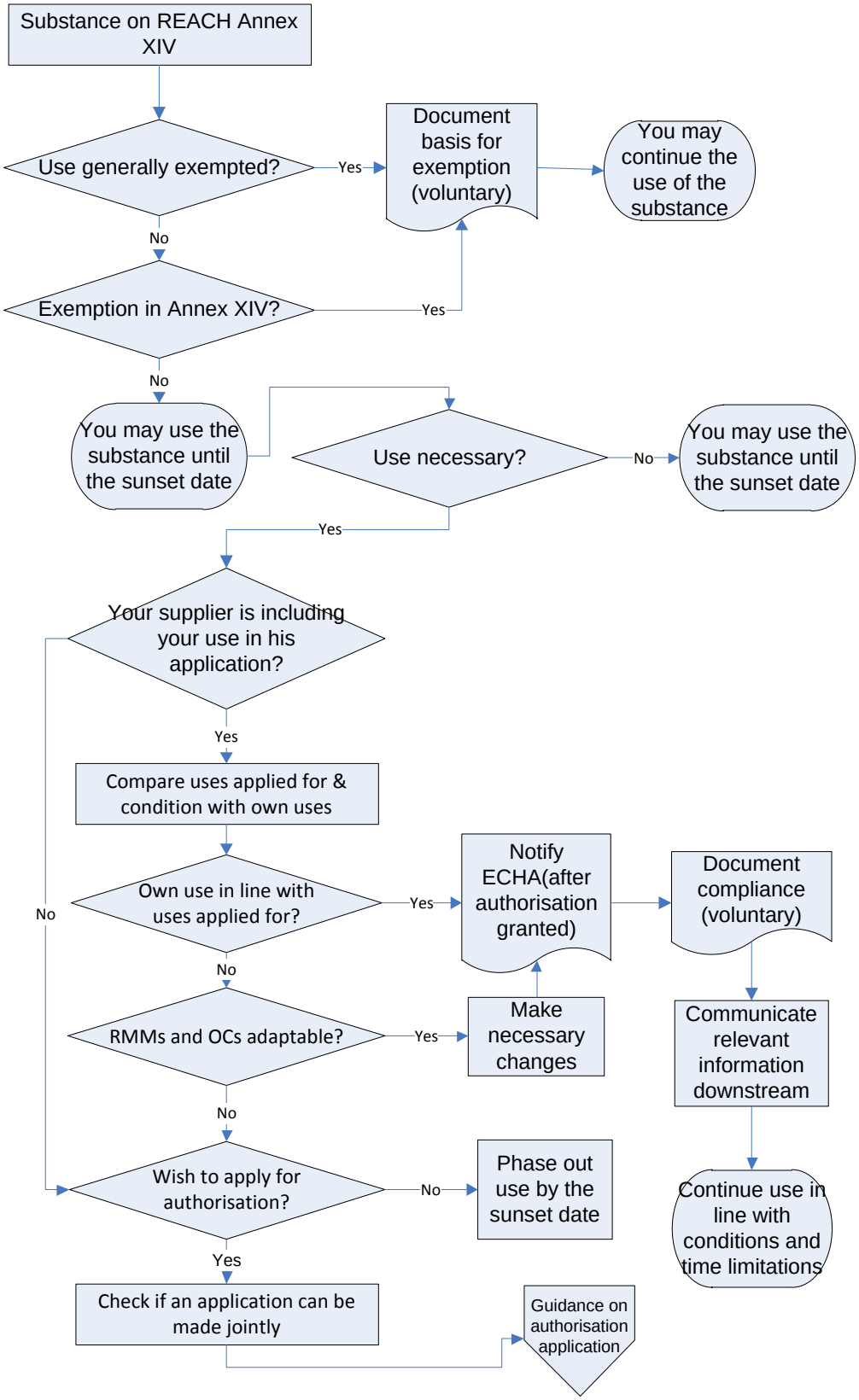


**Figure 7 Workflow on fulfilling authorisation requirement**

Further information related to applications for authorisation in general, and more specifically related to supply chain and downstream users' considerations, can be consulted at the ECHA website in the Q&A section[101].

## 8.2 Downstream users and restriction requirements

This chapter covers the requirements of REACH concerning restrictions and what a downstream user should do to ensure compliance with restrictions. It provides guidance on how a downstream user can provide information during the preparation of the restriction proposals and how they can get information on existing restrictions.

### 8.2.1 Restrictions in a nutshell

Article 67

*General provisions*

*1. A substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. …*

Article 68

*Introducing new and amending current restrictions*

*1. When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended…by adopting new restrictions, or amending current restrictions…for the manufactures, use or placing on the market of substances on their own, in mixtures or articles…Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.*

Under REACH, restrictions may limit your use of a substance. If restrictions apply to a substance that you use, on its own, in a mixture or an article or when incorporating the substance into an article during the production of the article, you may only continue to use it if you comply with the restrictions. Restrictions under REACH are very similar to the marketing and use restrictions under Directive 76/769/EC, made before the entry into force of REACH. Therefore, only brief guidance is provided here. Restrictions introduced under Directive 76/769/EC were carried over into Annex XVII of REACH.

Your EEA supplier must include information on whether a substance he supplies is subject to restriction in Section 15 of the safety data sheet or in other information supplied to you according to Article 32 of REACH. If a restriction is imposed, your supplier must provide you with an updated safety data sheet or other information without delay. You can consult the list of restrictions in Annex XVII on the ECHA website[102].

More information on the restriction procedure is available on the ECHA website[103]. There you can find out also which substances are considered for restriction, and the type of restriction proposed.

---

[101] echa.europa.eu/support/qas-support.

[102] Available at echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions.

[103] At echa.europa.eu/regulations/reach/restriction.

In some cases, the restriction may take the form of an outright ban on the use of the substance, in which case you will no longer be able to use it. In other cases, specific uses may be prohibited or other conditions applied, to control the risks of the substance.

It should be noted that even though a substance is on the authorisation list (Annex XIV) due to specific intrinsic property, there can be a restriction for this substance due to its other intrinsic properties. In addition, there can be a restriction of a substance listed in Annex XIV when the substance is present in article(s). If all uses are prohibited by a restriction in Annex XVII, this substance need not be included in the authorisation list or will be removed from it.

### 8.2.2 General exemption from restrictions

Restrictions do not apply to the manufacturing, placing on the market or uses of a substance in scientific research and development in a volume less than one tonne per year when carried out in controlled conditions.

This general exemption from restrictions may not be communicated to you by your suppliers. Therefore, you should check whether your particular use is exempted.

### 8.2.3 Ensuring compliance with restrictions

#### 8.2.3.1 Information on restrictions

Your supplier must specify, under Section 15 of the safety data sheet, whether the substance that you use is subject to restriction. If you do not receive a safety data sheet, your supplier is obliged to communicate this separately, according to Article 32 of REACH. You find the restrictions also on the ECHA website[104]. Further information on interpretation on restrictions can be found on the support page of the ECHA website[105], where the FAQs and “Questions and Answers on restrictions” are available.

#### 8.2.3.2 Comparison with conditions of restriction

If the restriction takes the form of a prohibition on use, you have to phase out the use of the substance by the date specified in Annex XVII of REACH. If the restriction takes another form, compare the conditions of the restrictions, as set out in the safety data sheet or other information you receive from your supplier, with your conditions of use, your risk management measures and the mixtures or articles you produce.

#### 8.2.3.3 Communication downstream

If you are a formulator, and you include a substance subject to restrictions in a mixture that you place on the market, you must communicate information on the restrictions applying to that substance to your customers in the safety data sheet or other information that you provide to them. Further information on how a formulator of a mixture can comply with his communication requirements is given in chapter 7 of this guidance.

---

[104] At echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions.

[105] Available at echa.europa.eu/support/qas-support.

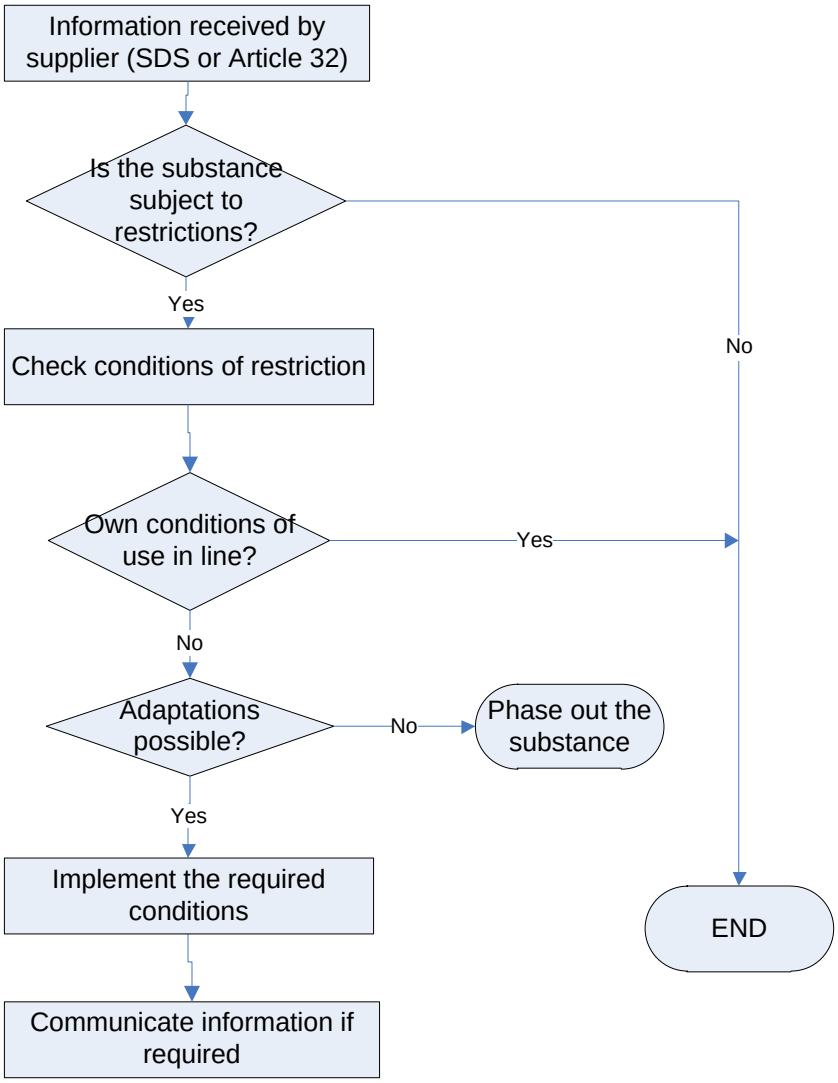


**Figure 8 Workflow checking compliance with restrictions**

### 8.2.4 Contributing to public consultations

It is important to underline that downstream users, as well as any other interested party, will have the possibility to provide information and comments on the substance concerned at different steps of the restriction process:

- when a proposal to restrict a substance has been submitted and the restriction report is published by ECHA;

- after ECHA publishes the draft opinion of SEAC (all interested parties may comment only on the SEAC draft opinion at this stage);

During the public consultation phases interested parties can submit comments on the proposed restrictions and the dossiers underlying them. You may also prepare a socio-economic analysis, or information which can contribute to one, examining the advantages and drawbacks

of the proposed restrictions. More information is given in the *Guidance on socio-economic analysis - Restrictions*[106].

In general, please refer to the dedicated page on the ECHA website[107].

## 8.3 Compliance with requirements related to substances in articles

Companies producing articles[108] should be aware that they may also have roles other than downstream user only and hence particular obligations.

As a producer of articles, who incorporates substances into articles, you have to register substances which are intended to be released from the articles under normal or reasonably foreseeable conditions of use if the quantity of the substance in the articles is over 1 tonne per year (Article 7(1) of REACH), if the substance has not already been registered for that use[109]. In case the used quantity is equal to or above 10 tonnes per year a CSR also needs to be prepared. If the incorporation into and use of the article has not been covered in the registration, you can also inform the manufacturer or importer of the substance (you can refer to chapter 3 of this guidance). If the registration is then updated to include the incorporation into the article and the use of the article, you don't need to register the substance in the article.

If the article contains above 0.1% w/w of a Substance of Very High Concern (SVHC) on the Candidate List and the quantity of the substance is over 1 tonne per year in the article, you have to notify ECHA (Article 7(2) of REACH) within 6 months after the SVHC is included in the Candidate List.

If the article contains above 0.1% w/w of a SVHC on the Candidate List you have to inform your customers on safe use of the article, including as a minimum the name of the SVHC in the article (Article 33(1) of REACH). Consumers can also request information about Candidate List substances in articles (Article 33(2) of REACH).

Furthermore, the content of substances in articles can be restricted under the restrictions procedure. Therefore, article producers have to follow the restrictions outlined in Annex XVII of the REACH Regulation.

Detailed guidance on the obligations related to substances in articles is provided in the *Guidance on requirements for substances in articles* available on the ECHA website[110]. In this chapter a summary of the information which is most relevant for downstream users is provided.

### 8.3.1 Exemptions from the requirements

Substances that have been registered for that use, i.e. where the registration dossier covers the incorporation into the article and the service-life of the article is adequately considered and assessed, do not need to be registered again or notified pursuant to Article 7(6) of REACH.

---

[106] Available at echa.europa.eu/guidance-documents/guidance-on-reach.

[107] echa.europa.eu/addressing-chemicals-of-concern/restriction.

[108] Please note that importers of articles are not considered downstream users under REACH. See table 6 and the *Guidance on requirements for substances in articles*.

[109] The same obligation applies to importers of articles.

[110] Available at echa.europa.eu/guidance-documents/guidance-on-reach.

For the substances that are already registered, producers of articles should already have communicated their use to the registrant for the purpose of registrations or checked whether their use is covered, based on information provided by the registrant before and after registration. Producers of articles will therefore, in most cases, not have to submit a notification for a Candidate List substance in articles or register a substance intended to be released from an article. Hence, you will normally be covered by the exemption if the communication through the supply chain and the assessment of all identified uses have been properly carried out.

Furthermore, if the importer or producer of an article can exclude exposure during normal or reasonably foreseeable conditions of use, including disposal, the notification requirement does not apply. In these cases, the producers and importers have to provide appropriate instructions to the recipient of the article. In addition producers and importers need to keep this documentation available in case of enforcement actions to come.

### 8.3.2 Staying prepared

Regardless of your role in the supply chain, it is recommended to make an inventory of your use(s) of substances which are on the Candidate List since there may be other obligations following from their use in articles (see following chapter 8.3.3). The Candidate List is updated regularly and the updates can be followed on the ECHA website[111]. The website also contains the Registry of Intentions, where member states and ECHA/the Commission can make public their intention to identify a substance as a SVHC for inclusion on the Candidate List.

### 8.3.3 Forwarding information with articles

If you supply an article containing a substance on the candidate list in concentrations of 0.1 % w/w or more in the article, you are obliged to forward information on safe use to the recipients of the article you produce (Article 33 of REACH). The information includes as a minimum the name of the SVHC in the article. The recipients may be other enterprises that use the article but also retailers, which provide articles to consumers. Similarly, your supplier of an article shall provide you with information if the article contains substances on the Candidate List in concentrations above 0.1 % w/w. This requirement still applies after the substance is included in Annex XIV.

All actors, article producers, importers or distributors/retailers must provide this information to consumers on request, within 45 days and free of charge.

REACH does not specify a format for providing information with articles. You should choose a format that will ensure that the recipient can readily understand the information.

[111] At echa.europa.eu/regulations/reach/authorisation/the-candidate-list.

# Appendix 1 Compliance with REACH for distributors

This appendix sets out the main aspects of the REACH Regulation which are relevant to distributors including retailers. They are not downstream users under the REACH Regulation. Before reading this appendix, chapter 2 of this guidance should be consulted in order to identify whether the role of a **distributor** or a **retailer** under REACH applies to you.

## A1.1 Overview of REACH and distributors

A **distributor** under REACH is any natural or legal person established within the EEA, including retailer, who only stores and places on the market a substance, on its own or in a mixtures, for third parties[112] (see Article 3(14) of REACH). A **retailer** under REACH is an actor who sells substances and mixtures to private consumers and/or professional users in retail stores. Retailers are a sub-group of distributors. **Storage providers,** who only store substances or mixtures for third parties, are also a sub-group of distributors. As long as these actors do not perform any operations or activities with them which would be defined as "use" under REACH (as specified in table 8), their obligations are limited to forwarding information in the supply chain as described in this chapter.

It is important to note that you should check carefully your own role. In fact you may also have roles besides distributor/retailer under REACH. The most common additional roles of a distributor are:

- **Importer** of substances, mixtures or articles. In this case you may have obligations to register and other obligations related to the import of substances/mixtures or of articles. Consult the *Guidance on registration* and the *Guidance on requirements for substances in articles* for further details[113].
- **Re-filler,** who transfers substances or mixtures from one container to another, is a downstream user, and as such has to comply with the obligations of a downstream user under REACH.
- Other **downstream users** roles, if, for example, you blend the substances with other chemicals to produce a mixture.

This chapter aims to help you to identify the obligations related to your specific role as a distributor. For identification of obligations in relation to other possible roles you might have under REACH you should consult the relevant guidance as indicated above and in chapter 2 of this guidance. To obtain general information on the aims and functioning of REACH, you could also use the REACH Navigator[114] or the introductory information on REACH on the ECHA website[115].

## A1.2 Obligations for distributors under REACH

As a distributor, your main obligation under REACH is to pass on information on the goods you distribute from one actor in the supply chain to another. This includes safety data sheet for

---

[112] A person who solely stores and places articles on the market (i.e. neither substances on their own nor in a mixture), for third parties is not a distributor according to the definition in the REACH Regulation.

[113] All the guidance documents and other supporting material are available in the "Support" section of the ECHA website at echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations.

[114] Available at echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations.

[115] echa.europa.eu.

substances and mixtures. Furthermore, there is a requirement for certain information to be provided for substances, mixtures or articles when a safety data sheet is not required.

You are not a downstream user of substances/mixtures according to REACH, but have a key position regarding information flow within the supply chain. You may have direct contact with the manufacturer/importer and the end-user of a substance/mixture, but the supply chain may also consist of several actors, where you as a distributor are placed between two downstream users in the chain. Figure 9 illustrates in a simplified way the possible role of distributors in the supply chain. In principle, your role is similar to that before REACH. Therefore, your previous experiences and methods for delivering information in the supply chain could also be used under REACH.

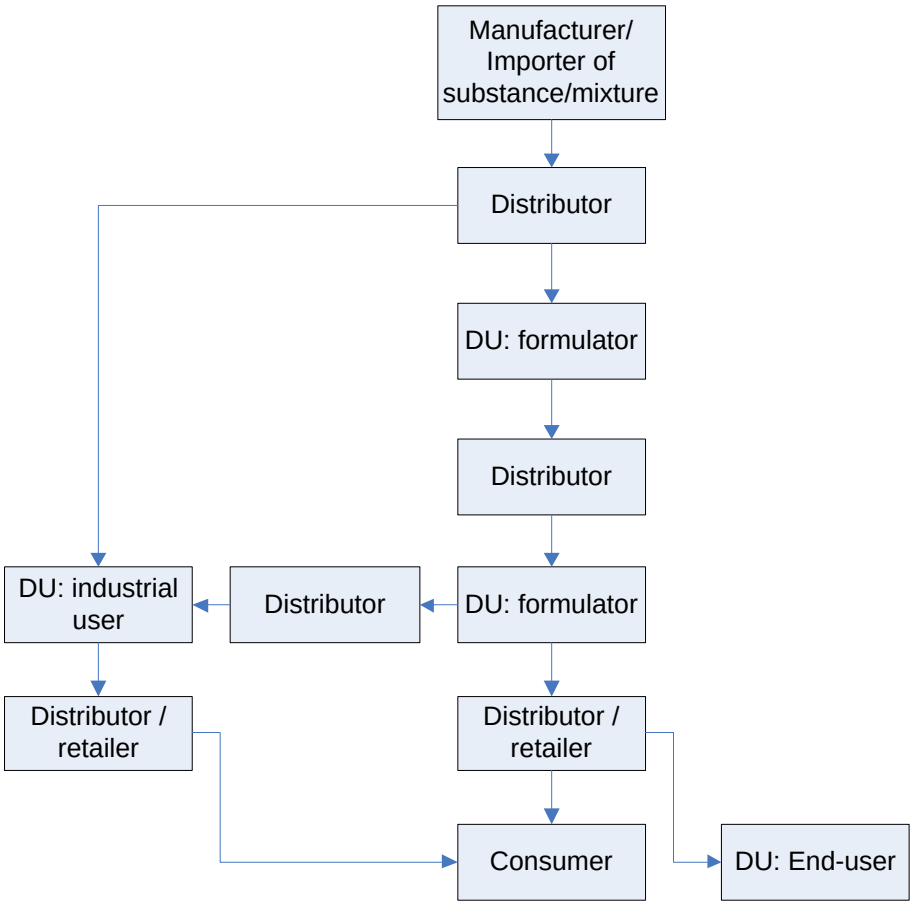


**Figure 9 The distributor and the supply chain**

Communication up and down the supply chain is a critical point for the success of REACH and the distributor represents a fundamental link between suppliers and downstream users in many supply chains. You may decide if necessary to proactively initiate communication between a manufacture or an importer of substances and your customers, who will often be downstream users. The downstream user could be a formulator of mixtures, as well as an end user of substances and mixtures, and he may need to communicate with the supplier for different reasons. If this is the case, it is your role as a distributor to pass the request for further information from your customer to your supplier and to deliver the response of the supplier to the same customer (i.e. the downstream user). This can happen, for example, in the following situations:

- a formulator or end-user of substances or mixtures, i.e. the downstream user, wants, as is his right, to make a use known in writing to his supplier with the aim of making this an identified use;

- the downstream user provides a description of his use(s) in writing to the supplier in order to support the supplier in the preparation of the registration dossier;

- the downstream user may also decide to make his own chemical safety assessment, for his use (s) and/or his customers' use(s) of a substance or a mixture (as described in chapter 5). In this case the downstream user may not be able to make his own chemical safety assessment on the basis of the information in a safety data sheet or exposure scenario delivered to him; he may need additional information from the supplier on, for example, the hazardous properties of a substance or the exposure assessment.

According to the situation, the type of information that you as a distributor may have to pass on could include the following.

- Information related to the identification of uses, either from manufacturers / importers to downstream users via questionnaires or from downstream users to suppliers, for example via standard brief general descriptions of use.

- Health and safety information on possible hazards and risks of your product up and down the supply chain. You have the duty to pass on information about hazards and safe handling received from the supplier to your customers. This may include the safety data sheet[116] (with or without the exposure scenario) if appropriate. Furthermore you may have to pass on information on authorisation or restrictions applying to a substance.

- Information to allow safe use of an article to your customer when it contains more than 0,1% w/w of a SVHC included in the Candidate List.

- Specific requests for information from a downstream user to the supplier, if the downstream user wants to make a DU CSR.

- New information on hazardous properties or on the appropriateness of the risk management measures from the downstream users to the suppliers.

You may need to document that you have asked for information from your supplier and communicated information delivered to you further down the supply chain and vice versa. You are therefore recommended to send requests to suppliers and information to customers in writing, either on paper or electronically. Procedures for communication and handling of documents in relation to the obligations under REACH could be described and included as a part of your quality assurance system.

Furthermore you should note that a distributor has to keep information on a substance on its own or in a mixture for at least 10 years after the last supply of the substance or the mixture (Article 36 of REACH).

Examples of information you are obliged to pass up and down the supply chain is given in Table 16.

116 The distributor may provide the safety data sheet and exposure scenario in the national language and adjusted to specific national rules. He may also add his own information in Section 1 of the safety data sheet e.g. an emergency number. See also Table 16 Information flow in the supply chain.

**Table 16 Information flow in the supply chain**[117]

| Subject | Type of information received | Type of information to be forwarded | Remarks |
|---|---|---|---|
| **Preparatory activities** | | | |
| Manufacturer/importer before registration of a substance | Questionnaires from suppliers of substances/mixtures concerning the identification of use(s) including the operational conditions of use(s). | Responses to questionnaires from suppliers. | Preparatory activities before registration of a substance could include identifying uses and conditions of use. Preparatory activities are expected to take place in the 11 year period during which all existing substances in amounts of 1 tonne/year or more, per manufacturer/importer, have to be registered. |
| Downstream user preparatory activities and requesting that a use becomes an identified use[118] | Responses to questions from suppliers and additional questions for clarification of use conditions. | Information on the uses of a substance as such, in mixtures and in articles, possibly accompanied by a request to make a use identified for inclusion in the registration of the manufacturer/importer. | |
| **Safety data sheet and other information on a substances and mixture** | | | |
| Safety data sheet and related information | Safety data sheet with or without exposure scenario(s). | New information on hazard properties, information calling into question the appropriateness of risk management measures and requests for a REACH-compliant safety data sheet if not received by due date[119]. | Safety data sheets have to be passed to the downstream user. They have to be in the national language and include specific national provisions, e.g. on workers' health.<br>New information on hazards and information questioning recommended risk management measures have to be forwarded. |
| Safety data sheet for a mixtures and DU CSR for a substance[120] | Delivery of information for making a safety data sheet for a mixture, on request from downstream user. | Requests for additional substance information needed for making a DU CSR.<br>Requests for a safety data sheet when concentration of | If a customer makes a DU CSR for a substance as such or in a mixture, he may request information on substance hazards.<br>You may receive requests from |

[117] The table illustrates general examples of the types of information which could be exchanged in the supply chain.

[118] See chapter 3 this guidance.

[119] See chapter 6 of this guidance.

[120] See chapter 5 and chapter 7 of this guidance.

| | | | |
|---|---|---|---|
| | | hazardous substances in a mixture is above a threshold value for providing of safety data sheet[121]. | customers for safety data sheets for non-classified mixtures. If hazardous substances are contained above the threshold values of article 31 (3) of REACH you shall provide it. |
| Information in the supply chain when no safety data sheet is required | Information:<br>- On a substance subject to authorisation or restriction.<br>- Needed for identifying appropriate risk management measures. | Information:<br>- On a substance subject to authorisation or restriction.<br>- Needed for identifying appropriate risk management measures. | Even if no safety data sheet is required, you may receive and forward information from the supplier according to Article 32 of REACH.<br>A non-classified mixture may contain, e.g. a substance subject to authorization below the concentration limits specified in Article 31(3) of REACH. Then the supplier must send this information, together with the registration number (and the authorisation number) and any other information necessary to use the mixture safely. |
| Information to consumers | Information on:<br>- the classification, as a minimum.<br>- Recommendation on safe conditions of use has also to be included. | Information on:<br>- the classification, as a minimum.<br>- Recommendation on safe conditions of use has also to be included. | Classified substances or mixtures for the general public do not require a safety data sheet if sufficient documentation to enable safe use is provided. |
| **Authorisation / restriction[122]** | | | |
| Information in the supply chain for an SVHC | Questions from suppliers on the use(s) of a "substance of very high concern", on its own or in mixtures. | Answers to questions from suppliers on the use(s) but also questions from the downstream user on the substance concentration in mixtures (and articles). | For substances (expected to be) under authorisation/restriction, communication in both directions can be expected. This could be when substances are included in the Candidate List |
| **Information on substances in articles[123] (Article 33 of REACH)** | | | |

[121] Article 31(3) in: REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 13. December 2006.

[122] See chapter 8 of this guidance for more information on compliance for downstream users with the authorisation and restrictions.

[123] See chapter 8 of this guidance and the *Guidance on requirements for substances in articles* for more detailed information.

| | | | |
|---|---|---|---|
| Information in the supply chain for articles | For articles with a substance on the Candidate List present in a concentration > 0.1 % (weight/weight):<br>- Available information on safe use of the articles. Name of the substance as a minimum | Downstream user may request information on the content of “substances of very high concern” in articles. | You have to pass the information from your supplier of an article to your customers (downstream users and distributors/retailers). Furthermore, you should pass any requests upstream. |
| Information to consumers for articles | For articles with a substance on the Candidate List present in a concentration of 0.1 % or more (weight/weight):<br>- Available information on safe use of the articles. Name of the substance as a minimum. | Requests from a consumer about an article containing a “substance of very high concern". | If you receive a request from a consumer, you have to provide him with the information, free of charge, within 45 days after you have received the request. |

# Appendix 2 Scaling

***Note*: This appendix is mainly addressed to registrants and to downstream users who have prepared DU CSR but are not registrants of the substance.**

The exposure scenario can be described flexibly with a variety of combinations of operational conditions (OC) and risk management measures (RMM). If the calculated exposure levels are based on the recommended operational conditions and risk management measures or even stricter, the downstream user does not have to do any additional verification. However, due to the fact that the parameters do not all work in the same direction, there can be situations where additional checking may be needed based on the change of OCs/RMMs. If the supplier has provided scaling options in the safety data sheets, the downstream user can use scaling to check if his combination of operational conditions and risk management measures (different from the combination proposed in the exposure scenario as received from the supplier) may still lead to, at least, the same level of control of risks. Thus, by applying scaling, downstream users do not develop new exposure scenarios with the same equations, but they calculate whether their situation is within the boundaries of the exposure scenario described by the supplier. It is important to mention that scaling options can only be provided by registrants or suppliers of chemicals who have prepared a CSR and if the registrant (or supplier preparing a CSR) has used an exposure estimation tool in their assessment. Scaling is not possible if the supplier has based his exposure assessment on measured exposure data. In this case the assessment is not based on a model and no scaling formula can be derived. Only those who have undertaken a chemical safety assessment and prepared a CSR may know to what extent the conditions of use of downstream users may be covered by the exposure scenario they have developed as part of their assessment. In assessing the exposure to a substance for a specific use, registrants (or other suppliers preparing a CSR) take into account multiple factors beyond the specific conditions of such use (e.g. impact to the environment at a regional scale, exposure to consumers from multiple sources, workers exposed to the same substance in different activities, workers exposed to multiple substances during their working shift etc.). For this reason registrants (or other suppliers preparing a CSR) may sometimes identify and recommend operational conditions and risk management measures leading to exposure levels which may be seen to be “very conservative” for a specific use, but which may be justified by broader considerations that are reported in the CSR but are not known to downstream users.

Scaling options defined by registrants (or other suppliers preparing a CSR) should be easy to implement by downstream users. Scaling is limited to simple calculations with the scope to demonstrate that variation in some parameters is compensated by variation in other parameters in order to guarantee that the resulting level of exposure (from application of downstream users conditions) is the same or lower than the level of exposure resulting from strict application of the exposure scenario as received from the suppliers. Downstream users should be able to apply scaling and to rely on the simple outcome from the scaling method in order to understand if their conditions are covered by the exposure scenario. If a downstream user concludes that application of scaling options is not sufficient to demonstrate that his use conditions are covered by the exposure scenario and that further assessment is needed, he can provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance to prepare an exposure scenario for his use (Art 37(2)). If the DU does not want to make his use known, he must prepare a DU CSR or check for other options (see chapter 4.4 of this guidance).

## A2.1 Boundaries of scaling

The exposure scenario represents a set of conditions of use that should be implemented by downstream users in order to guarantee that a substance is used safely. This means that if such conditions are implemented by a downstream user, the levels of exposure to the substance during its use will not generate adverse effects for humans (i.e. workers and consumers) and the environment. In this case the exposure scenario “covers” the use and no

additional action is needed by the downstream user (see *Guidance on IR&CSA Part D* for further information on exposure scenario building and definition of safe use).

If, instead, one or more conditions of use at downstream user site exceed the limits set in the exposure scenario, levels of exposure to the substance may be higher than levels obtained by applying the conditions defined in the exposure scenario.

If this is the case, the conditions of use from downstream users have to be considered outside of the exposure scenario boundaries.

If scaling options are provided in the safety data sheet, downstream users may use the scaling method to check levels of exposure resulting from the application of their conditions of use.

The following principles have to be taken into account when scaling is applied:

- scaling cannot be used by downstream users to justify conditions of use leading to levels of exposure exceeding the levels of exposure resulting from application of the conditions in the exposure scenario;
- by applying environmental scaling downstream users have to assure that the quantity of the substance released to the environment/ time (release rate) do not exceed the release rate obtained by applying the ES as received by the supplier.

It has to be noted that in general scaling has a limited range of applicability. Besides what already explained, the following additional considerations should also be taken into account to understand why it is so.

1. **Interpretation of the legal requirements**. Article 37(4)(d) of REACH requires that downstream users may not need to prepare a CSR if they implement and recommend ***as a minimum*** the conditions communicated to them in the exposure scenario as received by their suppliers.
2. **Reliability of CSR information**. The information in the ESs annexed to safety data sheets is consistent with the information in the Chemical Safety Report which is a key element of the registration dossier. ECHA consider the information contained in CSRs as the primary source of information which is needed for other REACH processes (e.g. authorisation, substance evaluation, restrictions etc...).

## A2.2 Defining scaling options

In order to define specific scaling options to be communicated to downstream users, registrants (or other suppliers preparing a CSR) have to establish if scaling may be applied to the conditions described in the exposure scenario and, if so, define the boundaries which cannot be exceeded via scaling in order to guarantee that resulting levels of exposure (after scaling is applied) do not increase.

For each relevant exposure route, the registrant (or other suppliers preparing a CSR) needs to:

**Step 1**

Determine a set of operational conditions and risk management measures (key determinants of exposure) or integrative parameters (e.g. Environmental release factor) for which control of risk for the exposure route can be demonstrated. This is the set of operational conditions and risk management measures to be communicated in the exposure scenario.

**Step 2**

Assure that Risk Characterisation Ratio ($RCR_{ES}$) and/or exposure/release levels are communicated in the section 3 of the exposure scenario (see *Guidance on IR&CSA Part D " exposure scenario building"*[124]) or made available via other appropriate means. The derivation of the RCRs is described in Part E of the *Guidance on IR&CSA*.

**Step 3**

For each of the relevant key determinants, which are likely to vary in the actual use situations consider if the use of scaling is relevant or if broader range of conditions can be considered. If, for example, the derived levels of exposure are well below threshold limits (if available) and they are expected to be below the limits for any reasonable values of OC/RMM, there is no reason for scaling (e.g. a substance is normally used in concentration <25% for <4hrs/shift in industrial settings. No specific risk management measure is required to control exposure to workers. If expected levels of exposure for use of the same substance at pure state for > 4 hrs / shift are still below threshold limits, you might consider issuing an exposure scenario with this set of conditions instead of proposing scaling as an option). In this case, the exposure scenario could be described with a broader set of operational conditions and risk management measures that ensure control of risks and allows, in the meantime, for more flexibility at the downstream user level.

- List all determinants specified in the exposure scenario for the considered exposure route and target group. On a Tier 1 level, the following determinants would typically be used for scaling:
  - workers: exposure duration, concentration per activity, RMM effectiveness, amount used;
  - consumer: concentration/amount;
  - environment: amount per year/per emission day, number of emission days, release fractions/RMM effectiveness[125].
- List the operational conditions and risk management measures which are likely to be different in the actual use situations.
- Identify the scalable parameters. These parameters have to be selected among the determinants working as input parameters of the tool used for the exposure assessment. Define the method to be used for scaling for the target group and exposure route. The method has to be based on the method used by the supplier: it can be an available Tier 1 tool, an algorithm, or a higher Tier tool. An exposure estimation tool (Tier 1 or higher Tier tool) can be used by downstream users for scaling assuming it is publicly available and is reliable also for non-expert users. The registrant should also use the exposure scenario to communicate the input parameters that are needed for the calculations.
- Find the range in which the OC/RMM can vary. These ranges are determined by the possibility to demonstrate that:

---

[124] echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

[125] What is important in the environmental exposure assessment are the overall release fractions. These may be composed of two factors: one factor accounting for the release fraction if no abatement is introduced ($f_1$) and one factor accounting for the effectiveness of abatement ($f_2$). The overall release factor would then read $f_1*(1-f_2)$ or if $f_2$ is expressed as a percentage: $f_1*(100-f_2)$.

- o resulting levels of exposure do not exceed the levels of the exposure scenario;
- o regional environmental concentration will not be affected;
- o the OCs/RMMs used for scaling are independent of each other; and
- o the basic assumptions for the derivation of exposure level still hold.

- In the process of finding and selecting the range include uncertainty analysis of the conclusions (see Chapter R.19 of the *Guidance on IR&CSA*[126] for details on how to make uncertainty analysis).
- If the same determinant is relevant for other exposure routes, ensure that you are specifying an applicable range, which holds for all exposure routes.
- Validate and document in the CSR that the proposed scaling mechanism is valid, i.e. control of risks is demonstrated and exposure levels of the exposure scenario are not exceeded.

**Step 4**

Communicate the method and the determinants in the exposure scenario.

The exposure scenario should contain scaling method (e.g. an algorithm, link or reference to web based tool or reference to the same tool used for exposure estimation), parameters which can be scaled and the ranges for which the scaling can be used. Scaling option should be communicated in the section 4 of the exposure scenario.

Downstream users may use different RMM than those indicated in the section 2 of the exposure scenario if alternative measures are explicitly mentioned in the ES as part of the scaling options (e.g. in the section 4).

Furthermore, instructions on how to use the scaling tools and the ranges for the determinants should be clearly communicated.

## A2.3 Methodologies to be used for scaling

A simple method to calculate whether one condition, i.e. a key determinant of exposure, compensates another can be performed in cases where the relationship between the respective determinants of exposure and the resulting levels of exposure (and thus the RCR) is linear. Then, the factor describing the difference between actual conditions and those specified in the exposure scenario can be derived and compared with the compensating factors for other determinants. When the linear scaling applies, the downstream user can check compliance by multiplying or dividing with the ratios between the actual value of an OC and the prescribed value of the OC in the exposure scenario.

The basic assumption of linear relations between an exposure determinant and the exposure level cannot be used for qualitative OC, e.g. the physical state of a mixture (liquid, solid or gas). Also, if the relevant parameters are interrelated, e.g. area covered and amount used (relevant for example in surface coating), linear calculation cannot be used.

Linear relations between the determinants and the exposure level are often valid only for small changes of the variable. Applying the rule over a larger range of the variables requires that the assumption of linearity is indeed valid. So, when using the linear scaling for the exposure scenario, the ranges for the determinants, in which the assumption of linearity between the

[126] echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

determinant and the exposure level still holds, have to be specified in the exposure scenario, by the supplier.

In conclusion, it may be considered to apply the linear scaling to increase flexibility, but it should be clear when doing so, that linear or other relationships between variables must be justified and that a sufficient margin of variability in resulting exposure is considered in practice. When applying the rule over a larger change in values for the variables, it is essential to know that the linearity is indeed applicable. This requires that the particular use of linear scaling is well documented in the Chemical Safety Report and is based on accepted algorithms for exposure assessment (e.g., coming from the same equations that constitute the Tier 1 tools). Furthermore, it requires that the linear scaling is well-described in the exposure scenario, as well as the relevant boundaries that apply.

In addition to simple linear algorithm the registrant (or other supplier preparing a DU CSR) may prepare a tool enabling the downstream user to check his own use. Such a tool can have the form of an algorithm, simple look-up tables, an excel sheet, a database, or a web-based tool (e.g. provided by industry associations). It can also be the exposure tool, which the registrant used for exposure calculations, e.g. ECETOC TRA and EUSES (In addition to the specific tool to be used for scaling, the registrant, or other supplier preparing a DU CSR, needs also to communicate via the exposure scenario, the input parameters that can be used for the calculations and the ranges for which scaling can be used (see chapter A.2.2 of this guidance).

Industry associations have provided some web-based scaling tools for downstream users (e.g. formulators). These tools enable downstream users to check whether - based on their knowledge about the processes in which his products are used - the exposure scenario indicated by the substance manufacturers are appropriate to ensure control of risk or modifications are needed. Downstream users may use these tools to check whether they work within the conditions of use for control of risk as prescribed by their suppliers, or whether they have to modify certain parameters in the exposure estimate to demonstrate control of risks (more realistic exposure estimates).

Information about these tools is available on websites of major downstream user sector organisations.

# Appendix 3 Core principle for selecting information to communicate with mixtures

Chapter 7.2.2 outlines possible approaches when identifying the information to communicate downstream. The objective is to select the operational conditions and risk management measures that should be applied to protect humans and the environment when the mixture is used.

The methodologies to support formulators undertaking this process are not described in this guidance document. However, the concepts that underpin the methodologies are presented in Table 17. These principles can help to identity the factors to consider when selecting the relevant information from exposure scenarios to communicate downstream with the mixture. The approach used can be tailored to suit the needs of different users.

The principles are presented in three sections: general, human health (toxicological) and eco-toxicological. They are listed in approximate order of increasing “sophistication”. Simpler situations are near the beginning of the relevant section in the table. Rare and complex cases, requiring a more detailed evaluation, are at the end of the sections. The examples presented are often a simplification of the actual situations encountered, but are intended to illustrate the principle. The proposed solution may only be applicable to some scenarios, such as worker or industrial.

The principles are not prescriptive. Each principle does not all apply to every mixture, and every situation. Case-specific expert judgement is required for complex cases. A general guideline is that in cases where there is no interaction between substances, the effects on human health and on the environment from exposure to a mixture can depend on the hazardous properties of either the whole mixture (e.g. for skin and eye irritation) or the individual component substances (e.g. for CMR substances).

For environmental effects, it should be kept in mind that the separate substances may have different environmental fates and manifest their effects in different environmental compartments. The impacts on the environment of aggregated and synergistic effects are not normally taken into account by formulators.

When a substance is classified as hazardous with respect to physicochemical properties, the relevant information to enable proper control measures to be taken is provided in Section 9 of the safety data sheet.

**Table 17 Core principles for selecting relevant information from exposure scenarios to communicate for mixtures**

| Ref no. | Principle | Example (two substances A and B) / Comment |
|---|---|---|
| | **General considerations** | |
| 1 | A simple approach may be adequate. If the RMMs for the individual substances are the same or similar, these can be assigned to the mixtures for the same OCs, taking into account any effect due to additivity and/or concentration. | Substance A requires local exhaust ventilation (LEV) (90% effectiveness) for given operational condition (OC) (conc. 15%, duration >4 hours). Substance B requires enhanced general ventilation (70% effectiveness) for the same OCs. LEV with 90% effectiveness is identified for Mixture AB, corresponding to the lower exposure level. |
| 2 | If the RMMs for the individual component substances differ, the RMMs for the mixture can be derived using the most stringent RMMs recommended for each route of exposure for the individual substances of the mixture, for the same OC's. This is a "worst case" approach. It is a simple yet conservative method that may be suitable in some situations. However, the RMMs recommended should not be over-precautionary or impractical. | Substance A requires LEV (90% effectiveness). Substance B requires gloves (80% effectiveness). Assuming the OCs for both substances are aligned to be the same, the RMMs for the mixture AB will be a combination of the RMMs for the substance driving the inhalation risk (LEV) and the RMMs for the substance driving the dermal risk (gloves), namely LEV with 90% effectiveness and gloves with 80% effectiveness. |
| 3 | The selection of RMMs based on information in the ES of the substances should be consistent with the classification of the mixture and the precautionary statements derived from that classification. The final RMMs selected for the mixture should therefore always be compared with information on classification and labelling. | For mixture AB, the RMMs selected from the ESs depend on the type of activity. For long term exposure, either use in closed systems or use of LEV is specified. For short term exposures, use of RPE is specified.<br>Mixture AB is classified as a respiratory sensitizer with precautionary statement P261: (Avoid breathing dust/fume/gas/mist/vapours/spray). The selected RMMs are compared with the classification and labelling information. It is concluded that there is no conflict between recommended measures from ES and classification. |
| | **Human health (toxicological) hazards** | |
| 4 | When the mixture is classified as hazardous with respect to toxicological properties, the classification of the mixture should align with the selection of the OCs and RMMs to adequately control the risk from using the mixture in most instances. Normally, new animal studies should not be conducted. | Mixture AB is classified as a skin irritant (based on concentration of irritant component). For uses with long term exposure, a closed system is proposed, while for short term exposure such as transfer, or consumer use protective gloves or avoiding skin contact are specified. This is consistent with the classification |

| | | |
|---|---|---|
| **5** | Known interactions and combined effects between substances should be taken into consideration.<br>If the classification of the mixture for a given endpoint differs to that of the classification of the substances, this indicates that the toxicity of (one of) the substances may be accentuated or diminished by other substances in the mixture. This is an alert to deal with this in assessing the risk and deciding on RMMs. | Examples of interactions and combined effects are:<br>(i) Where the chemical properties are affected (e.g. pH of the mixture).<br>(ii) Where the biological properties are affected (e.g. one component may enhance the dermal absorption of a second component).<br>(iii) where more than one substance acting on the same target organ (e.g. organic solvents on the central nervous system). |
| **6** | For mixtures which contain substances that are carcinogens, mutagens, toxic to reproduction (CMRs) or sensitisers (dermal or respiratory) even in concentrations below the cut-off point for classification, the conditions of use for the mixture should take into account the risk to human health from CMR or sensitising substances: risks are to be minimised. Hence, the risk assessment and recommendations related to safe use of the mixture should be based on the component substances themselves, present below cut-off point for classification. | Substance A is category 1B carcinogen. Substance B is not classified. Mixture AB contains < 0.1% of Substance A, and hence is not classified as a carcinogen. Nevertheless, the need to include the RMMs recommended for substance A as part of the RMMs for the mixture should be reviewed. |
| **Ecotoxicological hazards** | | |
| **7** | The environmental risk results from the release of the mixture to one or more of the environmental compartments – air, water, soil. Classification with respect to ecotoxicological properties refers only to effects on the aquatic (pelagic) compartment. RMMs should cover all emission and environmental risks. | Even though a mixture is not classified with respect to hazards in the aquatic (pelagic) environment, there may still be a risk to other compartments such as sediment and soil. |
| **8** | The effects on the environment from exposure to a mixture can depend on the hazardous properties of either the whole mixture or the individual component substances. For emissions to water and soil, the first step is to identify the environmental release patterns relevant for the mixture uses, in particular whether the environmental compartments are exposed to the undiluted mixture as such or just to some component. | For example, for the outdoor use of a biocide with substance A and B, the soil and/or water is directly exposed to the undiluted mixture. Any interaction between A and B is highly relevant. Conversely, for a mixture AB that is emitted through a WWTP, the mixture is diluted, substance A may, for example, remain in water and substance B go to sediment (or soil via sewage sludge application. Consequently the environmental compartments are exposed to the single components as emitted after waste water treatment. The original mixture no longer exists in the environment. |

| | | |
|---|---|---|
| **9** | Substances in a mixture may have different environmental fates and manifest their effects in different environmental compartments. | For a mixture A+B emitted through a WWTP, Substance A may remain in the aqueous compartment and Substance B may be trapped in the sediment. |
| **10** | Known interactions and combined effects between substances should be taken into consideration as this may alter the efficiency and feasibility of the RMM compared with the substance on its own. These interactions must be carefully considered when RMM proposed for different components are suggested for the whole mixture. | For example, if the solubility of Substance A is increased by Substance B, a solvent, sedimentation during water treatment may be prevented. |
| **11** | When the physico-chemical and/or environmental fate properties of the components in the mixture are very different, the effectiveness of the RMM may also differ for each component. This may result in different release patterns for each component, so that the composition of the mixture emitted differs from that of the marketed mixture. | For example, substance A and B have differing physico-chemical properties, and the effectiveness of the RMM is 90% and 10% for substance A and B respectively. If the formulated mixture contains A+B at 50% each, the mixture released to the environment is 5% of Substance A and 95% of Substance B |
| **12** | Mixtures with substances with PBT or vPvB properties are treated on a substance basis. The OCs and RMMs for the mixture should ensure minimisation of releases to the environment (and consequently human health) from PBT/vPvB substances. The RMMs suggested for other components (including also human health RRM) may affect the releases of the PBT/vPvB components. | For example, Substance A is highly acutely toxic by inhalation and the RMM recommends a high level of extract ventilation but Substance B is a volatile PBT substance and ventilation will increase its emission to air. |

# Appendix 4 EU Legislation with requirements relevant to REACH

| EU Directive[A] | Main Elements with respect to chemicals | How does it affect DUs | How does it link with REACH[B] |
|---|---|---|---|
| ***Workers Health*** | | | |
| Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive) | Requires employers to identify risks arising from chemical agents through risk assessment. Risks should be reduced by substitution, prevention, protection and control.<br><br>Where a national occupational exposure limit value (OEL) is exceeded, the employer must remedy the situation through preventative and protective measures.<br>The production, manufacture or use at work of certain chemical agents and activities set out in Annex III is prohibited. | The provisions for risk assessment may be challenging to implement, especially if you use many different chemical agents.<br><br>OELs are important risk reduction tools in specific work scenarios. However agreed values for OELS and not available for all substances, although indicative values for certain substances are listed in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC and 2009/161/EU<br><br>Prohibitions specified in Annex III may be difficult to implement and control, especially if you are a small company. | Greater availability of information on substance properties and potential hazards, through the Registration process.<br><br>The SDS communicates the conditions of use under which risks are controlled, including necessary risk management measures. |
| Council Directive 2004/37/EC on 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work | Requires employers to assess risks, replace carcinogens and mutagens with less hazardous products (where possible) and use closed systems for manufacture and use. Where a closed system is not technically possible, the level of exposure is to be reduced to as low a level as possible. In addition, employers are to design processes and engineering control measures so as to avoid or minimise releases the workplace. | The provisions are important risk reduction tools in specific work scenarios but may be challenging to implement at small and medium-sized enterprises. Resources for control are required. | (Ext)SDS can assist you by giving clear recommendations on the most appropriate risk management measures necessary to control exposure to carcinogenic or mutagenic substances. |

| | | | |
|---|---|---|---|
| Council Directive 92/85/EEC of 19 October 1992 (including COM(2000) 466 final/2) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding | The employer is required to assess the nature, degree and duration of exposure, in the undertaking and/or establishment concerned, in order to assess any risks to the safety or health and any possible effect on the pregnancy or breastfeeding and decide what measures should be taken. | The provisions are important risk reduction tools in specific work scenarios but may be challenging to implement at small and medium-sized enterprises. Resources for control are required. | Information in (ext)SDS may assist SMEs to identify the risks associated with substances and give clear guidance on the RMM required to address them |
| Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace | Employers must provide PPE free of charge and give information to workers on the risks which the wearing of the PPE protects them against. Employers must ensure that the PPE is appropriate for the risks involved, by undertaking a risk assessment, without itself leading to any increased risk. | The directive does not give detailed information to the employer how to select the proper PPE.<br>The provisions for risk assessment may require some effort to implement, especially if you are a small company. | Information in (ext)SDS may assist you to identify the risks associated with substances and give clear guidance on the risk management measures required to address them. |
| Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) | Employers shall carry out a risk assessment, which should include, as far as technically achievable, any effects on workers' health and safety resulting from interactions between noise and work-related toxic substances | You need to identify whether any ototoxic substances are present in the workplace. Even if these can be identified, calculating the impacts of interactions with noise levels may be difficult. | Information in (ext)SDS may assist you to identify the presence of any ototoxic substances and give clear guidance on the risk management measures required to address them |
| ATEX 137 (Directive 99/92/EC) on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres and ATEX 95 (Directive 94/9/EC) concerning equipment and protective systems intended for use in potentially explosive atmospheres. | ATEX 95 is for the manufacture of equipment, and ATEX 137 is for the use of equipment in potentially explosive atmosphere. Employers must classify areas where explosive atmospheres may occur into zones. The classification given to a particular zone, and its size and location, depends on the likelihood of an explosive atmosphere occurring and its persistence if it does. Equipment and protective systems intended to be used in zoned areas must meet the requirements of the directive. | DUs may need to carry out the risk assessment and area classification (zoning). | Under REACH greater information is available on substance properties such as flammability and explosivity, and those "uses" where there may be a potential for an explosive atmosphere to arise.<br>Where you have already taken action in response to this Directive, this may provide good information and material for risk management measures for REACH |

| | | | |
|---|---|---|---|
| The Seveso III Directive 2012/18/EU adopted on 4th July 2012, and entered into force on 13th August 2012. Member States have to transpose and implement the Directive by 1st June 2015. | This Directive lays down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment. Using a two-tier approach based on substance threshold quantities, site owners must comply with requirements on risk assessment, emergency planning, land-use planning etc. | If DUs satisfy the criteria for their sites to fall under Seveso, then they have certain obligations related to e.g. risk assessment. | The improved quality of substance information made available under REACH would benefit the DUs in terms of knowing the nature of the hazard, in particular with regard to the risk assessment component of Seveso.<br><br>Where you have already taken action in response to this Directive, this may provide good information and material for risk management measures for REACH. |
| ***Product Safety examples***[127] | | | |
| 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety | The directive places an obligation on importers and manufacturers of products intended for consumer use to ensure that their products do not present unacceptable risks to human health or property under normal and reasonably foreseeable conditions of use. Manufacturers must provide consumers with relevant information to enable them to assess the risk inherent in a product and to take precautions against those risks. If the manufacturers or the distributors discover that a product is dangerous, they must notify the competent authorities and, if necessary, cooperate with them. For such products the Commission manages the Rapid Information System RAPEX and can adopt “emergency measures” in cooperation with Member States. | Satisfactory assessment of the risks posed by chemicals within products is required, in the absence of reliable information from suppliers. | Information in (ext)SDS may assist manufacturers to identify the risks associated with substances and mixtures that they use and to determine whether they are appropriate for consumer products.<br><br>REACH will introduce requirements concerning substances within articles for the first time. This will enable you to identify whether imported articles meet the requirements of the GPSD. |

[127] There is a number of sector specific legislation so only a few examples are provided in the table. Other legislation that may be relevant includes: Fertilisers (2003/2003/EC), Cosmetic Products (1223/2009/EC), Detergents (648/2004/EC), Aerosol Dispenser Directive (75/34/EEC).

| | | | |
|---|---|---|---|
| Council Directive2009/48/EC on 30 June 2009on the approximation of the laws of the Member States concerning the safety of toys | Toys placed on the market should not jeopardise the safety and/or health of users or of third parties. They must not contain hazardous substances or mixtures in amounts which may harm the health of children using them (except where essential to the functioning of the toy, when they are subject to a maximum concentration).<br><br>The amount of certain chemicals that may be contained in materials used for toys is specified. | Certain substances (Carcinogenic, Mutagenic or toxic for Reproduction), are no longer allowed in accessible parts of toys. For certain other substances tolerable limit values have been introduced and certain heavy metals which are particularly toxic, may no longer be intentionally used in those parts of toys that are accessible to children.<br><br>Satisfactory assessment of the risks posed by chemicals within products is required and reliable information from suppliers may be missing.<br><br>Lack of data from suppliers may make it more difficult to assess the concentration of substances within inputs. | Information in (ext)SDS may help manufacturers to identify the presence of hazardous substances in mixtures (and articles) that they use. The risk management measures specified may assist you to identify whether the substances can be safely used in the manufacture of toys. |
| The Construction Products Regulation (305/2011/EU - CPR) which repeals the Construction Products Directive (89/106/EEC – CPD) was adopted on 9 March 2011 | Buildings must be designed and built in such a way that it will not be a threat to the hygiene or health of residents or neighbours. The CPR's objective is to ensure reliable information on construction products in relation to their performances. This is achieved by providing a "common technical language", offering uniform assessment methods of the performance of construction products. | Standards may be developed where demands on technical performance are in conflict with the need to reduce risks relating to harmful substances. | (Ext)SDS may help construction companies to identify safe uses of mixtures and necessary risk management measures |

| | | | |
|---|---|---|---|
| Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) | This regulation concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product. | A chemical safety report is not required for active substances manufactured or imported for use in biocidal products only and covered by Article 15(2) of REACH and co-formulants in quantity below 1 tonne per year. However, exposure scenarios are required to be attached to SDS in accordance with Art 31(7) for active substances when they do not meet the requirements of Art 15(2) e.g. non-biocidal uses, biocidal uses taking place outside the EEA. | Components that may be included in a biocidal formulation, other than the active ingredient, may be registered in REACH, and information available from that process for communicating in the supply chain. |
| ***Environmental Protection*** | | | |
| Directive 2008/1/EC Integrated Pollution Prevention and Control codified as of 15 January 2008, (replaced on 7 January 2013 by IED Directive 2010/75/EU, however its provisions remain applicable until 6 January 2014). | The aim is to prevent or reduce pollution to ensure a high level of environmental protection, based on an application for a permit which can only be issued if certain environmental conditions are met. The application for a permit must include descriptions of raw and auxiliary materials, nature and quantities of foreseeable emissions, proposed technology or other techniques for preventing or reducing emissions, and measures planned to monitor emissions. | If no need to reduce emissions of the chemical is mentioned in the relevant BREFs, expert knowledge is needed on where the chemical is likely to be emitted in significant quantities. In addition, applicants have to identify and assess emission reduction possibilities. | (Ext)SDS may provide useful information on the nature and concentration of substances contained within raw and auxiliary materials, which will help in determining foreseeable emissions.<br>They may also provide useful information on emission control measures. |
| Directive 20011/65/EU of 08 June 2011 on the restriction of use of certain hazardous substances in electrical and electronic equipment (recast), including updates 2008/385/EC, 2009/428/EC and 2009/443/EC. | The Directive restricts the use of specified hazardous substances in electrical and electronic equipment | If you manufacture electrical and electronic equipment, you may not be aware of the composition of components that they use. You need to be able to document compliance with the Directive, which requires knowledge of the composition of components. | REACH introduces requirements concerning substances within articles for the first time. This enables you to identify whether imported articles meet the requirements of the Directive.<br><br>Any new restriction under this Directive shall be coherent with authorization and restriction provisions under REACH. |

| | | | |
|---|---|---|---|
| Waste Framework Directive 2008/98/EC of 19 November 2008. | This Directive sets the basic concepts and definitions related to waste management, such as definitions of waste, recycling, recovery. It introduces the "polluter pays principle" and the "extended producer responsibility".<br>The list of "hazardous waste" developed under Directive 91/689/EC remains applicable. Member States must record and identify sites where disposal of hazardous waste takes place, prohibit mixing of different categories of hazardous waste and to ensure that waste is properly packaged and labelled in the course of collection, transport and temporary storage. | Any wastes included on the list are considered hazardous and face particular requirements relating to their disposal. You may, however, not be aware that your wastes contain materials placed on the list. | (Ext)SDS may provide useful information on the nature and concentration of substances contained within raw and auxiliary materials, which will help in identifying hazardous wastes.<br>They may also provide useful information on safe waste disposal. |
| Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations (replaced on 7 January 2013 by IED Directive 2010/75/EU, however its provisions remain applicable until 6 January 2014). | Establishes emission limit values for VOCs in waste gases and maximum levels for fugitive emissions. Gives industrial operators a possibility to be exempted from limit values provided that they achieve by other means the same reduction as would be made by applying them. This could be achieved by substituting products with a high solvent content for low solvent or solvent free products and changing to solvent free production processes. This will become part of the permit application process under 2010/75/EU. | The requirements of VOC directive are more difficult to meet in small enterprises, as many applications to collect VOC emissions are expensive. | Where you have already taken action in response to this Directive, this may provide good information and material for risk management measures for REACH. In particular, it may provide useful information on the use of process-integrated solutions and substitution rather than implementation of end-of-pipe techniques. |

| | | | |
|---|---|---|---|
| Directive 2006/11/EC of the European Parliament and of the Council of 15 February 2006 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (Codified version) | This Directive lays down rules for protection against, and prevention of, pollution resulting from the discharge of certain substances into the aquatic environment. It applies to inland surface water, territorial waters and internal coastal waters.<br>Two lists of dangerous substances have been compiled to combat pollution:<br>- discharge of substances in list I must be eliminated; while<br>- discharge of substances in list II must be reduced. | The discharges of any DUs using substances on List II, would be subject to prior authorisation by the competent authority. | By providing greater information on substances and their conditions of use, it would aid the DU is avoiding problems caused by discharging substances into the aquatic environment. |

A. REACH can also help you to comply with national legislation on occupational health, product safety and environmental protection.

B. Although REACH can assist with meeting the requirements of the legislation, compliance with an exposure scenario is not equivalent to compliance with the other legislation. You must still follow all aspects of the other legislation.

# Appendix 5 Structured overview of communication needs along the supply chain

The aim of this overview is to provide a checklist of "all" communication needs, both those between downstream users and others in the supply chain and between downstream users and the authorities. The checklist will help to ensure that appropriate tools and formats are developed for downstream users to assist with all of these communication needs.

| List of communication needs | | | | | | |
|---|---|---|---|---|---|---|
| | (A) Subject | (B) Sender | (C) Recipient | (D) Date | (E) Guidance's ch. | (F) Available tools and formats |
| ***Preparing for REACH*** | | | | | | |
| 1. | (Voluntary) request for information on uses to assist with registration | Supplier (M/I; distributors; DU) | Any DU | Any time before registration | 3 | |
| 2. | (Voluntary) provision of information on uses to assist with registration (Art. 37(1)) | Any DU | Supplier (M/I, distributor, other DU) | Any time before registration | 3 | Chapter R.12 (" Use descriptor system") and chapter R.13 ("RMMS and OCs") of *Guidance IR&CSA* |
| 3. | (Voluntary) provide relevant information on a substance | Any DU | SIEF members | Any time | 6 | *Guidance on data sharing* |
| 4. | (Mandatory) react to requests of information<br><br>(Art. 29(3)) | SIEF members | DU who participates in a SIEF | Without delay following a request | | *Guidance on data sharing* |
| 5. | (Voluntary) request to determine whether it is intended to seek registration for a substance | Any DU | Supplier (M/I, distributor, other DU) | Any time before registration | | List of pre-registered substances<br><br>List of registered substances |

| | | | | | | |
|---|---|---|---|---|---|---|
| 6. | (Voluntary) request to determine whether it is intended to include a use in a registration/exposure scenario | Any DU | Supplier (M/I, distributor, other DU) | Any time before registration | | |
| 7. | (Voluntary) expression of an interest in a substance not listed in the pre-registration list by ECHA | Any DU | ECHA | After publication of pre-registration list | | REACH IT |
| ***Actions triggered by information – substances on their own or in mixtures*** | | | | | | |
| 8. | (Voluntary) request for a REACH-compliant SDS if not received by due date | Any DU | Supplier (M/I, distributor, other DU) | First supply after registration | | *Guidance on the compilation of SDSs* |
| 9. | (Mandatory) provision of a SDS compliant with REACH when required<br><br>(Art.31) | Supplier (M/I; distributors; DU) | Any DU | When the substance/mixture is first supplied | | *Guidance on the compilation of SDSs* |
| 10. | (Voluntary) request for Art.32 information (SDS not required) if not received by due date | Any DU | Supplier (M/I, distributor, other DU) | First supply after registration | | |
| 11. | (Mandatory) information on the substance when SDS not required (Art.32) | Supplier (M/I, distributor, other DU) | Any DU | First supply after registration | | |
| 12. | (Mandatory) information to enable safe use and protection of human health and environment when supply of SDS not needed<br><br>(Art. 31(4)) | Supplier (M/I, distributor, other DU) | General public | When the substance/mixture is first supplied | | |
| 13. | (On request) information required to comply with REACH<br><br>(Art. 36) | Supplier (M/I, distributor, other DU) | Authorities | Without delay when requested | | |
| ***Actions triggered by information – substances in articles*** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 14. | (Voluntary) request for information on whether substances subject to restriction are contained in an article | DU recipients of articles | Supplier (producer/importer) of articles | Any time | 8 | |
| 15. | (Voluntary) request for information on whether SVHC are contained in an article at concentrations > 0.1% w/w | DU recipients of articles | Supplier (producer/ importer) of articles | Once the substance is included in the Candidate List | 8 | |
| 16. | (Mandatory) information on safe use of articles containing SVHC in concentration > 0,1% w/w (Art.33(1)) | Supplier (producer/ importer) of articles | Recipients of articles | Once the substance is included in the Candidate List | 8 | *Guidance on requirements for substances in articles* |
| 17. | (On request) information on safe use of articles containing SVHC in concentration > 0,1% w/w (Art.33(2)) | Supplier (producer/ importer) of articles | Consumer | Within 45 days of request being received | 8 | *Guidance on requirements for substances in articles* |
| 18. | (Mandatory) notify SVHC in articles under Art. 7(2) | Supplier (producer/ importer) of articles | ECHA | Once the substance is included in the Candidate List | 8 | *Guidance on requirements for substances in articles*<br><br>Data Submission Manual " How to Prepare and Submit a Substance in Articles Notification using IUCLID" |
| ***Checking compliance with the exposure scenario*** | | | | | | |
| 19. | (Mandatory) Reporting use of a hazardous substance outside the supplier's ES (Art.38(1)) (needs to cover the different exemptions and may therefore have different information needs) | DU | ECHA | Before commencing use after the substance has been registered and within 6 months after receiving the registration number in a SDS. | 4 | Data Submission Manual "How to Prepare and Submit a Downstream User Report using IUCLID 5"<br><br>Downstream user report web page |

| | | | | | | |
|---|---|---|---|---|---|---|
| 20. | (Voluntary) Documenting compliance with the ES, in particular if conditions are not exactly the same. | Any DU | Authorities | Once supplier's SDS/ES is received | 4 | |
| ***Preparing a downstream user chemical safety report*** | | | | | | |
| 21. | (Voluntary) Checking whether a generic ES has been prepared (by an industry association) | DU considering preparing DU CSA | Industry association, other | Before commencing use after the substance has been registered | | |
| 22. | (Voluntary) Obtaining additional information from supplier in order to carry out a DU CSR | DU considering preparing DU CSR | Supplier (M/I, distributor, other DU) | Before commencing use after the substance has been registered and within 12 months after receiving the registration number in a SDS. | | |
| 23. | (Voluntary) Obtaining information on substance properties in order to carry out DU CSR | DU preparing DU CSR | Own supplier, other M/I of a substance or SIEF | Before using after substance has been registered and within 12 months after receiving the registration number in a SDS. | | SIEF to be checked if possible, may be IT-based. |
| 24. | (Voluntary) Obtaining information on customers' use of a substance to prepare DU CSA | Any DU, but primarily formulator | Downstream users (customers, distributors) | Before commencing use after the substance has been registered and within 12 months after receiving the registration number in a SDS. | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 25. | (Mandatory) notify that the DU CSA is to be prepared | DU | ECHA | Before commencing or continuing a particular use and within 6 months after receiving the registration number in a SDS. | 5 | Data Submission Manual "How to Prepare and Submit a Downstream User Report using IUCLID 5"<br><br>Downstream user report web page |
| ***Requesting that a use becomes an identified use*** | | | | | | |
| 26. | Requesting that a use becomes an identified use<br><br>(Art.37(2)) | Any DU | Supplier (M/I, distributor, other DU) | At least 12 months before the deadline for registration | 3 | Chapter R.12 of *Guidance IR&CSA* " Use descriptor system" |
| 27. | Informing that a use cannot be included as an identified use for reasons of protection of human health or the environment and reason for this | Supplier (M/I, distributor, other DU) | DU requesting that a use becomes identified<br><br>ECHA | 'without delay' | | |
| ***Collecting information on uses*** | | | | | | |
| 28. | (Voluntary) Obtaining information on own use of a substance | Any DU, but primarily industrial users | [other departments/ entities within own company] | Any time before registration or before preparing DU CSA | 3 | *Guidance IR&CSA* chapter R.12 "Use descriptor system" |
| 29. | (Voluntary) Obtaining information on customers' use of a substance to prepare DU CSR | Any DU, but primarily formulator | Downstream users (customers, distributors) | Before commencing use after the substance has been registered and within 12 months after receiving the registration number in a SDS. | 3, 5 | *Guidance IR&CSA* chapter R.12 "Use descriptor system" |
| ***Informing suppliers about new information on hazards*** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 30. | (Mandatory) Communicating any new information on the hazardous properties<br><br>(Art. 34) | Any DU | Supplier (M/I, distributor, other DU) | Any time (not specified) | 6 | No prescribed format |
| 31. | (Mandatory) Informing if a classification of a substance is different to that of the supplier<br><br>(Art. 38(4)) | Any DU | ECHA | Any time (not specified) | 6 | Downstream user report web page<br><br>Data Submission Manual "How to Prepare and Submit a Downstream User Report using IUCLID 5" |
| ***Informing suppliers about information calling into question the appropriateness of risk management measures*** | | | | | | |
| 32. | (Mandatory) Passing on information that may call into question the appropriateness of risk management measures<br><br>(Art. 34) | Any DU | Supplier (M/I, distributor, other DU) | Any time (not specified) | 6 | No standard format, exposure scenario including exposure assessment if appropriate |
| ***Compliance with requirements related to authorisation*** | | | | | | |
| 33. | (Mandatory) Notifying use of a substance subject to authorisation<br><br>(Art. 66(1)) | DU | ECHA | Within 3 months of first supply of the an authorised substance | 8 | To be implemented in the REACH IT |
| 34. | (Voluntary) Request to determine whether a supplier plans to apply for authorisation of a use of a substance | Any DU | Supplier (M/I, distributor, other DU) | Once a substance has been included in Annex XIV | 8 | *Guidance on the preparation of an application for an authorisation* |
| 35. | (Voluntary) Contacting potential partners about the possibility of making a joint application for authorisation of use of a substance | Any DU | Supplier (M/I, distributor, other DU); customers; competitors | Once a substance has been included in Annex XIV | 8 | *Guidance on the preparation of an application for an authorisation* |

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU

LOREM IPSUM DOLOR SIT AMET

ISBN