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EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance for downstream users

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Guidance for downstream users

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1 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). The main drivers for the update are issues related to checking compliance with exposure scenario (including scaling) and communication of information on mixtures. 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 The format consisting in flowcharts with explanatory notes has been replaced by more user friendly and clear explanations of the main DU obligations. The update includes the following: - Revision of sections 0 and 1 in order to eliminate outdated information and reflect the new structure of the updated guidance. The introductory section 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-section on the explanation of the key terms has been included using part of the information originally in chapter 5. - Revision of section 2 by eliminating out of date information, moving sub-section of REACH overview to section 1 and restructuring the information in order to highlight first the identification of the DU role and DU activities and then other possible roles. - Elimination of original section 3; information considered still relevant was moved to section 1 and 2. - Creation of a new section 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 section addresses communication upstream with the aim to have the use(s) identified. The emphasis is on sector description of uses as it reflects the current best practice. - Elimination of original section 4. - Creation of new section 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 section gives an overview of the possible actions to be undertaken in case the use is not covered by the ES. - Elimination of original section 5. Information on key terms	XXX 2013

	moved to section 1 and information on compliance check moved to section 4. - Elimination of section 6; relevant information moved to new section 4. - Creation of a new section 5 where the option of preparing a downstream user CSR, introduced in section 4) is described in details. The section covers legal requirements, timeframes, difference with standard CSA and practical steps to carry out a downstream user CSA. - Creation of new section 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. - Elimination of section 7; relevant information on DU CSR updated and moved to new section 5. - Elimination of sections 8, 9, 10 and 11. Relevant information has been updated and used in the new sections 3, 4 and 6 according to the new structure and workflow of the guidance. - Creation of new section 7 covering the communication obligations in the supply chain related to mixtures. The section elaborates and provides principles to be applied by a 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. - Merging of sections 12 and 13 in a new section 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 subsection 8.3 to highlight the compliance with obligations related to substance in articles for DUs. - Elimination of section 14. Relevant information has been moved to the new section 7. - Transfer of original section 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. - 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. - 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. - Update of original Appendix 6 (moved to Appendix 4) on relevant EU legislation.	

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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).

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List of acronyms

DNEL	Derived No-Effect Level
DU	Downstream user
DU CSR	Downstream User Chemical Safety Report
ECHA	European Chemicals Agency
ES	Exposure Scenario
GES	Generic Exposure Scenario
Guidance on IR&CSA	(ECHA) Guidance on Information Requirements and Chemical Safety Assessment
OC	Occupational Condition
OEL	Occupational Exposure Limit
PNEC	Predicted No Effect Concentration
PPORD	Product and Processes Research and Development
RMM	Risk Management Measure
SVHC	Substance of Very High Concern

0 Objectives of this guidance

This guidance is intended for downstream users of chemical substances. A downstream user (DU) is a specific role under REACH, and refers to using a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A company can have many different roles under REACH, as a role under REACH is tied to the company's activities related to a given substance. Many different types of companies can have downstream user role, including formulators of 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 full range of obligations that a downstream user may face under REACH as well as the different circumstances that a downstream user may encounter. Once the principles of downstream user roles and obligations are clarified by reading this guidance, further, more practical information can be found in the Practical Guide on "How downstream users can handle exposure scenarios"[3] and, more generally, on the downstream users webpage of the ECHA web site[4]. The Navigator tool5 provides an additional form of help to identify roles and obligations under REACH with regard to the substances you are using.

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 2006. The Regulation aims at ensuring 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.

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 more than 1 tonne/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. If the substance is manufactured or imported in quantity of more than 10 tonne/year a **chemical safety assessment** (CSA) is required. Such assessment includes an assessment of hazards resulting from intrinsic properties of the substance (hazard assessment). If the substance is

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

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

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

[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).

hazardous, it is also required an assessment of the nature and extent of the exposure to demonstrate that the risks stemming from exposure can be controlled with a set of operational conditions and risk management measures 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.

How does registration affect you as downstream user? REACH will apply to most of the substances that you use today. Registration of so called phase-in substances, i.e. substances that have been already on the market, will take place gradually from 2010 to 2018 depending on the tonnage and hazardousness of the substance[7]. New substances need to be registered before they can be placed on the market.

This means that until 2018, your products may contain substances which are either:

- registered;
- pre-registered and have the registration deadline of 2018;
- produced/imported by the supplier in amounts below 1 tonne per year; or
- exempted from registration (as given in the scope and the exemptions in Annex IV and V of REACH).

Under REACH, the compliance of individual registration dossiers or single substances may be **evaluated** by the authorities. ECHA is required to assess testing proposals and 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 the Agency concludes that a dossier is incompliant, it will request the registrant to update his dossier. ECHA also scrutinises the testing proposals8 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 is a task carried out by the Member State Competent Authorities. It is undertaken if there are grounds 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. However, the further information generated via evaluation may change 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.

Additionally, certain substances, identified to be substances of very high concern (SVHC) 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 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

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

[8] 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 the Agency as part of their registration dossier.

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 needs to be made as soon as the substance is included in Annex XIV as the processing of the authorisation application takes time and it has to be completed before the sunset date.
If a substance used by a downstream user is subject to authorisation, it is communicated by the supplier in the SDS or in the other information supplied in line with Article 32 of REACH (the authorisation number shall also be included on the label).

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 covered by the restriction. The restriction process is not new under REACH and previous restriction under Directive 76/769/EC have been carried over into Annex XVII of 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 pose unacceptable risks to human health or the environment. For this, information on the intrinsic properties of substances as well as information on the uses and related exposures is needed.

The registrants are in a key position to compile this information together for individual substances, as 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. However, the information from downstream users is also crucial, as the supply chains may be long and complicated, and registrants themselves may have limited knowledge on the use of the substance further down in the supply chain. Therefore 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. 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. Only 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 innumerable 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 section 3). Sector organisations play a crucial role in the process, as a structured dialogue between downstream users and registrants is necessary. In short, 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. 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 the Agency, 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.

Just as today, downstream users will receive information on hazardous substances and mixtures, including risks from their use and measures to control these risks, in safety data sheets. The information gathered in the registration process may trigger a need to update them. After the substance has been registered, some safety data sheets will have one or more exposure scenario(s) as annexes. The exposure scenario will give more specific information on how to use the substance or mixture safely, and how the workers, customers, consumers and the environment can be protected from risks. These new, extended safety data sheets first reach mainly formulators.

When formulators (and, indeed, any downstream users) receive safety data sheets with exposure scenarios they need to check if their use and conditions of use are covered in it, and have thus been covered in the registrant's chemical safety assessment and assessed safe (see section 4). If not, they have several options, including contacting their supplier and asking him to include the use (see section 4.4), or to conduct their own downstream chemical safety assessment (see section 5). If they choose the last option, they also need to report their use to ECHA. In addition, formulators need to decide how to best convert the information they receive on substances into information concerning safe use of mixtures, so that they can pass this information along the supply chain to their customers. The best option depends largely on their customers' needs, and clarifying that beforehand is recommendable (see section 7).

The downstream users further down in the supply chain all receive safety information from their suppliers. They all need to check if their use is covered, and decide how to respond to it. Eventually the safety information reaches the end-users of the substance, that can be either industrial or professional ones. 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 is covered by it. A schematic representation of a simple supply chain with one formulator level only is presented in Figure 1.

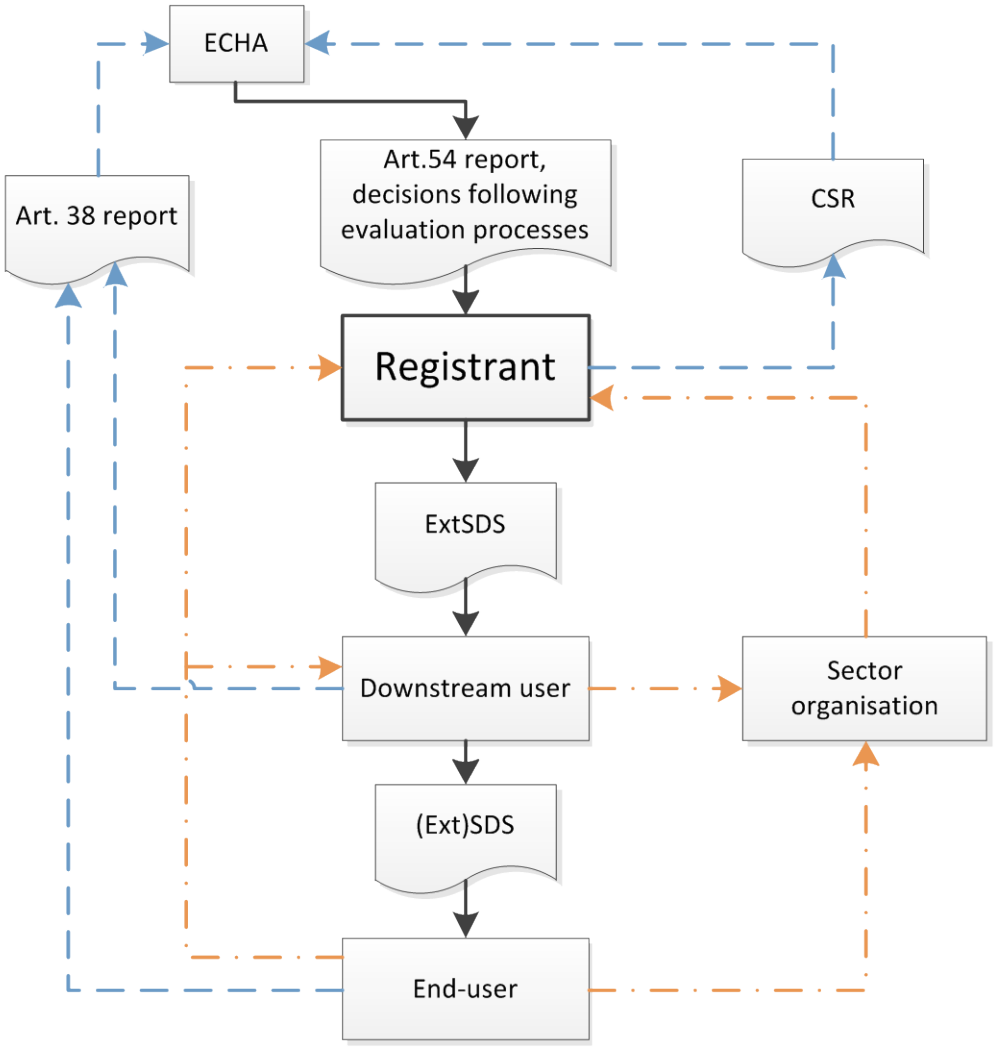

Figure 1 Simplified representation of communication flows in the supply chain under REACH

It is obvious from the simplified summary presented above that the first step in the communication in the supply chain 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.

1.3 Explanation of key terms

In order to be able to carry out the downstream user duties under the Regulation, it is important to understand the terminology, which is in part new.

The ECHA Guidance on Information requirements and chemical safety assessment, (IR&CSA) Part A[9] (Section 2.4.1 and subparagraphs) provides a comprehensive description of the key terms which are relevant for exposure scenario. To complement it, this section provides a summary of key terms which are significant for downstream users.

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

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 available to third parties, whether in return for payment or free of charge within the territory of the EU Member States and those EEA-EFTA countries which have implemented the CLP Regulation. In addition, import, defined as the physical introduction of a substance or mixture into the customs territory of the EU and those EEA-EFTA countries which have implemented the REACH Regulation, is deemed to be placing on the market.

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,
- is informed by one of his immediate downstream users in writing of an existing (or intended) use.

An exposure scenario always refers to one or more "identified uses" of a substance, which is indicated in its title as well as under Section 1 (sub-section 1.2) of the safety data sheet. Some examples of use are given in the table below.

Table 1 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 (mixtures) are used to cover metals. The use consists of several activities, such as the mixture 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 up and blown, the material is cooled and packaged.

1.3.3 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. OCs 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). Table 2 below provides practical examples of operational conditions.

Table 2 Examples of operational conditions

	Example 1	Example 2
Identified use	Industrial use of a hard surface cleaner Washing and cleaning product	Industrial use of a hard surface cleaner Washing and cleaning product
Type of activity/use	• Dilution of a concentrated solution • Spray onto surfaces to be cleaned. • Wiping off surface with a cloth.	• Dilution of a concentrated solution • Spray onto surfaces to be cleaned. • 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
Ventilation conditions	The application takes place indoor Normal air exchange of 0.5/hr	The application takes place outdoor
Containment	Open process	Open process

The term **'risk management measure'** means a measure that is introduced during manufacture or use of a substance (either in 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.

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

This guidance document provides support for downstream users in fulfilling their duties under REACH. Depending on the circumstances and sometimes also on your own choices, you as DU can have one or several of the following obligations:

- Follow the instructions in the safety data sheets you receive and in the exposure scenarios (when attached to the safety data sheets). If you receive an exposure scenario you should 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, develop your own chemical safety report or take another action.
- 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.
- If you place hazardous mixtures on the market (e.g. you are a formulator) you have to provide safety data sheets to your customers. In some cases, this may require you to consolidate or develop exposure scenarios covering uses of substances in your mixtures further down the supply chain and to attach them to the safety data sheet.
- Provide your own customers with information
  - on hazards, safe conditions of use and appropriate risk management advice for mixtures,
  - if the content of Substances of Very High Concerns (SVHC) exceeds the concentration of 0.1 %w/w in the articles you produce.
- Comply with the obligations related to the authorisation or restriction of the substance that you use. Relevant information and conditions to be respected are indicated by your supplier, usually in the safety data sheet.

In addition, to facilitate communication in the supply chain you (preferably via your sector organisation) 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.

1.4.1 Navigate through the guidance

The guidance is structured so that the main obligations and requirements for downstream users are dealt with in different sections. The main obligations and actions required from downstream users, as well as the relevant timelines are summarised in the table and the subsequent flowchart below. Reference to further information either in this guidance or elsewhere is included.

Table 3 Main obligations / actions of downstream users and the relevant timelines

	Obligations / Actions	Timeline	Go to Chapter
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 safety data sheet or other information supplied with non-hazardous substances or mixtures	Within 12 months after receiving a safety data sheet 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 prepare a downstream user chemical safety report	4,5
	Communicate 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 labelling	Without delay	6
Additional obligations for formulators and re-fillers only	Provide information to your customers and to retailers / consumers to enable safe use of substances or mixtures Downstream users that supply substances or mixtures shall recommend appropriate measures to control risks, identified in safety data sheets, the information that is supplied to them in accordance with article 32 of REACH regulation, or in their own chemical safety report.	Within 12 months after receiving a safety data sheet for a registered substance	7
Obligations related to the substances subject to authorisation or restrictions	Your supplier or you need to apply for an authorisation for your use if you want to continue to use the substance after the sunset date. For substances subject to authorisation, comply with the conditions of the authorisation covering your use, and 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
	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	8 and Guidance on requirements for substances in articles

Additional obligations for re-importer	Document that substance(s) are identical to those registered in the EU 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	Guidance on Registration

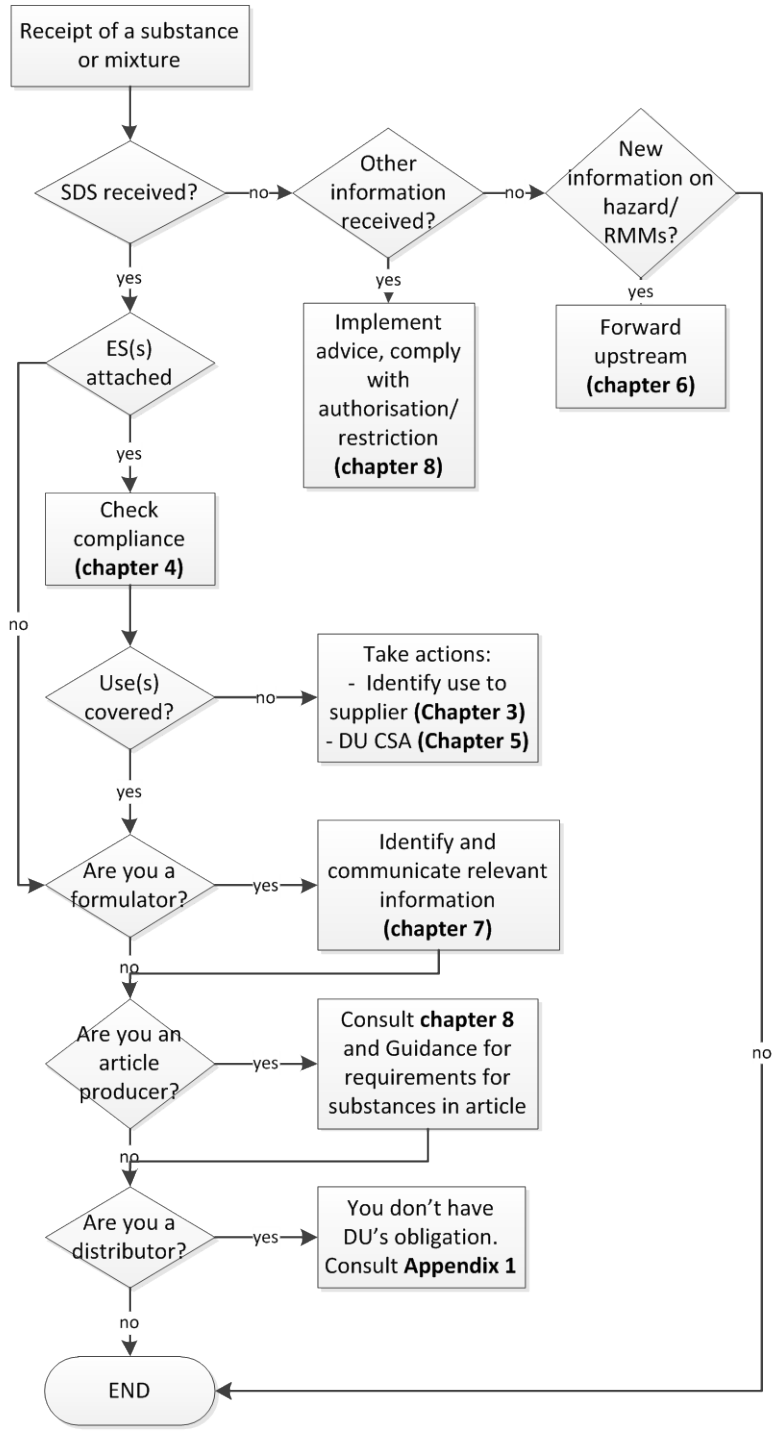

Figure 2 General overview of the actions triggered by information received by the downstream users under REACH.

2 Understanding your roles under REACH

This section provides guidance to assist downstream users to identify their roles under REACH. An additional way for downstream users to identify different roles and to get an overview of related obligations is to use the web based Navigator tool[10].

2.1 Identification of downstream user roles

Your obligations under REACH will depend on the exact activity you carry out in relation to a specific substance that you use, either on its own, in a mixture or in an article[11]. 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 section 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.

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 the table 4.

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

[10] echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/identify-your-obligations .

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

Table 4 Identification of your role – downstream user of substances

Question	Your role as a downstream user	Supporting information, examples
Do you mix substances to make mixtures that you place on the market?	**You are a Formulator**: Actor producing mixtures. 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). 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 substances. Dissolving a substance in water is not manufacturing a substance but a use. In contrast, mixing an acid and a base which results in a new substance (salt) is considered as manufacture. 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[12].
End-user activities		
Do you use substances which do not remain in the product in the context of an industrial process?	**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. You do not forward any substance or mixture to another actor.	If the substance(s) as such or in a mixture is not included in the product you use, but is used to facilitate the processing or 'washed off' after the production is finished, you use them solely as processing aids. Examples of industrial users are users of surface cleaners prior to electroplating or users of lubricants for chainsaws.
Do you incorporate substances into articles in the context	**You are an article producer**: user incorporating a substance	Incorporation of a substance as such or in a mixture into an article means

[12] 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 6). This is consistent with the concept of toll manufacturing under Directive 67/548/EEC (see Manual of Decisions of Directive 67/548/EEC). 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.

Question	Your role as a downstream user	Supporting information, examples
of an industrial process or a professional activity?	into articles. **For obligations of an article producer see the Guidance on requirements for substances in articles**[13]	a) inclusion into the article matrix, e.g. dying of textile fibres or 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. Examples of such users are flooring contractors, mobile cleaning companies, professional painters, construction companies.

Table 5 Identification of your role – other actors carrying out downstream users activities

Question	Your role as an actor with downstream user obligations	Supporting information, examples
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 import substances or mixtures from a non-EU supplier, who has nominated an only representative?	**You are customer of 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-EU supplier has an only representative[14], this only representative takes over the responsibilities linked to the import of that substance into the EU. Therefore you are regarded as a downstream user, even though you purchase directly from the non-EU supplier and not from the only representative. It is recommended that you ask your non-EU supplier whether he has such an only representative.
Do you know that a substance that you import from non-EU suppliers has been originally manufactured and registered in the EU up in your supply chain?	**You are a re-importer** of substances: Actor who imports substances, as such or in mixtures, which have originally been produced in the EU. In terms of REACH, you will be considered a downstream user if you	You will need to have documentation showing that the substance is identical 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.

13 Available at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

14 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. See Guidance for Registration for more information on only representatives (echa.europa.eu/web/guest/guidance-documents/guidance-on-reach).

	can prove that the substance was registered in the EU by someone in your supply chain.	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.

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 (also) something else. In the next two tables the following roles under REACH are explained

- Manufacturer of substances
- Importer of substances as such or in mixtures
- Importer of substances in articles
- 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 6 Identification of your role – manufacturers/importers of substances as such, in mixtures or articles[15]

Question	Your Role is…	Supporting information, examples
Do you produce 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. **See the Guidance on registration.**	The formation of 'substances' during the normal use of a substance or mixture is, in principle, exempted from the registration requirement under Annex V. *For instance, if you use a reactive textile dye, there is a chemical reaction in your process, but this need 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 EU?	**Importer** of substances as such or in mixtures **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 EU/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** **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". 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

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

Question	Your Role is...	Supporting information, examples
		the substance. 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 7 Identification of roles – roles other than downstream user or manufacturer/importer

Question	Role	Supporting information, examples
Are you established in the EU/EEA and only store or place substances, on their own or in a mixture, on the market, by supplying or making it available, whether in return for payment or free of charge, to a third party ?	**Distributor:** Actor who only stores and places on the market substances, on their own or in a mixture **You are not a downstream user, but you do have obligations under REACH** Go to Appendix 1 of this guidance.	To be a distributor as defined by REACH, you can only store and make substances and mixtures available to third parties (e.g. resell). If you undertake an activity with the substance defined as "use" under REACH (note, for example, that decanting or refilling is considered a use under REACH), 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. **You are not a downstream user. You are considered a distributor and you do have obligations under REACH.** 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 make substances, mixtures or articles available (e.g. sell) 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. **You are not a downstream user, but you do have obligations under REACH.** Go to Appendix 1 of this guidance.	Retailers are a sub-group of distributors. If you undertake an activity with the substance defined as a "use" under REACH (note, for example, that refilling or mixing paints in storage 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, communication on the safe use of a substance relies on characterising the uses in an unambiguous way. Therefore describing uses correctly in REACH terms is vital. The registrants of the substances used by downstream users need this information to prepare the chemical safety assessment for the whole life cycle of that substance. The better the uses are described, the more accurate and clearer the information for the safe use of the substance DU can expect to receive back in the extended safety data sheet from the supplier.

After explaining the life cycle approach to uses under REACH (section 3.2) this chapter describes the approaches to communicate DU's uses to the suppliers (the registrants). The default approach should be the collective communication via sector organisations (section 3.2), as only then can the mass flow of communication be handled in an efficient way. In exceptional cases, individual downstream users could communicate their uses directly to their suppliers (section 3.3). It is also explained how DU should handle information on the customers' uses (section 3.4) and what suppliers should do when they receive information about DU's use (section 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 his supplier. It is not an obligation, so you are also allowed not to communicate your use upstream, if you, for example for confidentiality reasons, do not want to make your use known to others. In this case you need to be prepared to carry out the chemical safety assessment yourself, if it is required for that substance (see section 5).

Identifying uses to the supplier is a crucial step for the whole process and is relevant in particular for substances where a chemical safety report is required for their registration (substances that are manufactured or imported in quantities of 10 tonnes/year or more by the registrant). If the substances fulfil certain hazard criteria, the registrants also undertake an exposure assessment, including the generation of exposure scenarios, and a risk characterisation. Exposure scenarios are attached to safety data sheets where applicable. As a downstream user you need to comply with the conditions of safe use communicated by your supplier (see section 4), and therefore it is in your interest that 1) your uses are known to the registrant and 2) the registrant's chemical safety assessement is based on the actual conditions of use down in the supply chain.

If you want to make your use known to your supplier, as a first step you should consider whether the substance is already registered or not yet registered. For substances that are yet to be registered, the collection and compilation on information on the uses should by default take place via sector organisations (see section 3.3).

Therefore as a downstream user your main contact point should be your own organisation, who may contact your for collecting information on your uses and the conditions of use for

substances. Furthermore, as the chemical safety assessment of the registrants must cover the whole life cycle of the substance, you might also be asked to inform your organisation about the known or foreseeable uses of the substance by your customers further downstream, as well as on the conditions of use for those uses.

In return, the 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 substance will be registered. If you still remain in doubt whether your supplier is going to register the substance of interest to you, you could discuss directly with him to gather further information on the likelihood of receiving an exposure scenario in the future.

If the substance is such that a chemical safety assessment is required for it, and it is already registered, you should receive an updated safety data sheet with the registration number and one or more exposure scenarios. When receiving extended safety data sheets, you need to react to them (see section 4). One possible outcome can be that you want to contact your supplier to have your use included into the scope of the chemical safety assessment and the resulting update of the extended safety data sheet (see section 3.4).

3.2 Life cycle of a substance

Under REACH, the registrants' chemical safety assessments must cover all life cycle stages of the substances they intend to register. Depending on the uses of the substance there can be one or more life cycle stages in between. When conducting their chemical safety assessments, the registrants need to consider whether the six life cycle stages beneath are relevant for their substance and hence for their chemical safety assessment of it. For this, they need information from their downstream users[16].

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: During formulation the 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. As a result of the use, the substance has reacted and hence transformed to another substance, has been incorporated into an article, has been released into air/waste water or has become waste. As the definition of use is wide under REACH, the substance can also stay the same e.g. if the use if re-filling. If the substance has been incorporated into an article, its subsequent use in that article must be considered (see step 6). 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

[16] For the roles referred to in the steps below, refer to section 2.1.

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. The use of a professional worker can also lead into incorporation of the substance into an article, which must then be followed by considering the use of that article (see step 6). This life-cycle stage covers the activities of professional end-users, including craftsmen, employees in public administration and self-employed professionals.

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.

The life cycle stages of a substance are depicted in Figure 3 below.

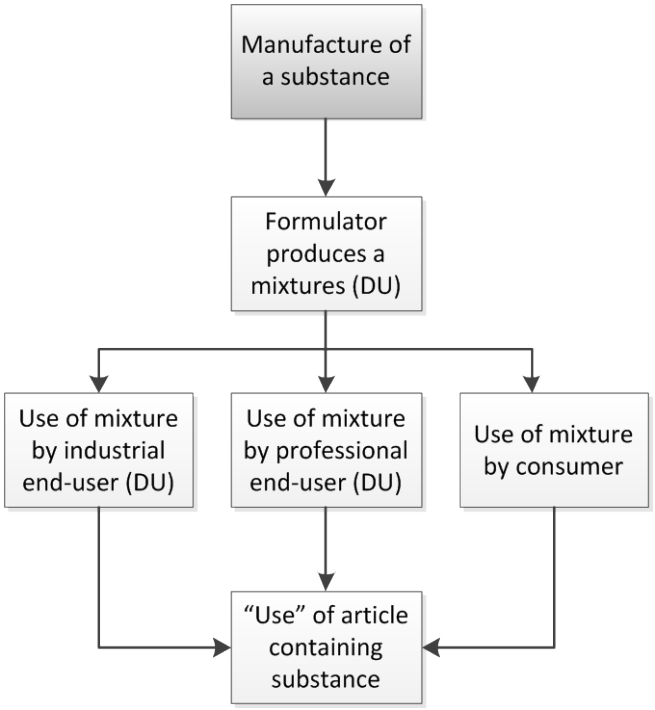

Figure 3 Schematic presentation of potential uses of a substance at different life cycle stages. The life cycle stages where downstream user uses can occur are marked with (DU).

3.3 Collecting information on uses via sector organisations

Many industry sector organisations have collected information from their members on the tasks and activities, i.e. uses and use patterns of substances within their sector. These use mappings should cover the whole life cycle of the substance, 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

- o A short verbal/technical description of the use; and
- o 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, environmental and consumer exposure. These include:
  - o A generic exposure scenario for worker exposure
  - o A specific environmental release category for that use; and
  - o 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 gather detailed information on your use.

You should contact your organisation to know whether such standardised descriptions of use exist for your sector. If yes, 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 be in contact with your sector organisation.

It may also be that such standardised descriptions for 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, and 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.

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 consumers 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[17]. 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.

[17] For use descriptor system, please see ECHA Guidance R.12 available at echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Therefore you should provide information on your conditions of use (see section 1.3.2) to your sector association, so that they can select the appropriate use descriptor set for the use at the sector level.

Generic exposure scenarios (GES)
Generic exposure scenarios document the typical conditions of use for a typical product or 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[18].

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.

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 industry sectors organisation to cover the majority of their membership.

3.4 Description of a single use directly to the supplier

Infrequent or exceptional uses will not be covered by sector mappings, and to have them included in the chemical safety assessment of registrants, you will need to describe your use and conditions of use directly to your supplier.

You can yourself collect information also 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 one go. This is particularly relevant if you are a formulator, and have to forward safety information to you customers, because then you need to consolidate the information you have received from your suppliers (see section 7 of this guidance) and may have to assess uses which are not covered in the suppliers' assessment (see section 4 of this guidance). The chemical safety assessment (or resulting identified uses) may include not only the uses of your immediate customers, but also uses further down the supply chain and related life-cycle stages, such as service life of articles or disposal of waste. In this case, you should involve your key customers in the collection of information on the uses further downstream.

When collecting information from your customers and even further downstream, you are advised to use the publicly available templates developed for the purpose of collecting information on uses, as they give orientation to which information is needed on the use and conditions of use for preparing a chemical safety assessment. In requesting that your use becomes an identified use, you must provide sufficient information on your own operational

[18] 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.

conditions and risk management measures to enable the supplier to develop an exposure scenario covering your use. This should include at least the following:

- Short description of process/activity
- Applicable use descriptors
- Applicable SpERC
- Physical state of substance (solid or not)
- Duration and frequency of exposure
- Outdoor or indoor activity
- For indoor activity, is local exhaust ventilation available
- Need for respiratory protection
- Need for eye protection (goggles)
- Need for hand protection (gloves)
- Concentration of the substance in a mixture
- Water solubility of the substance
- Octanol-water partition coefficient of substance
- Release from your processes to water, air and soil (if it takes place)
- Environmental risk management measures in place

For more hazardous substances and for uses where high exposure is expected, the standard set of information will probably not be adequate and refined information will be needed by the registrant to finalise the chemical safety assessment. You should make him aware e.g. 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.

A generic format for collecting information on specific uses has been developed and presented in Appendix 3. It is recommended that you use this template when compiling information on your use for your supplier as it represents the commonly agreed good practice. It is also possible that some suppliers use their own questionnaires to request information on your use.

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 Section 3.2 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[19] describe specific processes or emission scenario documents may be available[20]. The Technical Notes for Guidance prepared under the Biocidal Products Directive[21] may be helpful for substances used in biocides and in similar application types or processes.

3.5 Incorporating information on your customers' uses after the substance has been registered

It can happen, that a customer, to whom you supply substances on their own or in mixtures[22], contacts you to make their use known to you with the aim of making it an identified use. Such a contact signifies that your customer's conditions of use may not be covered by the exposure scenario you have supplied. You should check this and, if so, consult further guidance on options to proceed (see section 4.4 of this guidance).

Such information on a use (be it prior to registration or after your customer has received information in the form of a safety data sheet or Article 32 information) from your customers should either be forwarded to your supplier or dealt with at your level. The latter results in updating the information you provide to your customers, such as the safety data sheet or Article 32 information.

If you are assessing a use yourself, you will be able to judge whether the information gathered from your customers is sufficient to carry out the assessment or not. In other cases, information collection and discussion about 'sufficient level of detail' will be based on interaction with your own suppliers.

3.6 Response when receiving information on use

A supplier has several options to react to a use made known to him by a downstream user. In a typical case the supplier will assess the use and include it in the chemical safety assessment and registration (if the supplier is a manufacturer or importer). If applicable, the supplier then provides the resulting exposure scenario to the customer. If the supplier to whom the use is made known in writing is a downstream user, he can also forward the information to his own supplier, so that the use can be covered by an exposure scenario developed by a supplier or the registrant further up in the supply chain.

The registrant can also decide not to assess your use because he considers for example that assessment of the use is not feasible or not economically justified, and in addition does not forward the request up the supply chain. In this case, you should be prepared to carry out the chemical safety assessment for your use yourself (see section 5) or switch to a supplier who

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[19] Best Available Techniques (BAT) reference documents are designed to demonstrate best available techniques for each sector covered by IPPC (http://eippcb.jrc.es/reference/).

[20] 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.

[21] ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents.

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

has assessed or is willing to assess that use. In order not to run the risk of losing your supply, you could first ask informally whether your supplier intends to cover your use in his chemical safety assessment. It is recommended that your supplier replies in writing, so that you as a downstream user can decide the best option forward.

If a supplier of a substance/mixture decides to cover uses in their chemical safety assessment, he has to respect the following timeframes for generating the chemical safety report:

- For phase-in substances which have not yet been registered (see section 1 of this guidance and Guidance on Registration[23]): the use must be included in the chemical safety report and the resulting extended safety data sheet before the deadline for registration, provided that the downstream user has made his request at least 12 month before that deadline.
- For registered substances: the use must be included in the chemical safety report and the resulting extended safety data sheet before they next supply 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 is also possible that after having assessed your use in accordance with Article 14 of REACH, your supplier concludes that he is unable to include your use as an identified use because it is not safe for human health or the environment. In this case, your use becomes a use he advises against, and he must provide you with the reason(s) for that decision in writing without delay. Through discussions with your supplier, you should establish which aspects of your use of the substance make it unsafe in his view. It is possible that his assessment is based on incomplete or incorrect information, for example not taking into account the risk management measures that you have implemented or the specific operational conditions that are in place at your site. If this is the case, you should provide additional information that will enable him to revise his assessment. If the supplier concludes that your use is still unsafe, the supply of the substance can continue if you carry out a downstream user chemical safety assessment and are able to demonstrate that the use is safe (see section 5).

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

4 Downstream users and Exposure Scenarios

This section contains a summary of key checks that a DU should undertake in order to assess whether the descriptions of safe use contained in exposure scenarios received as annexes to the safety data sheet with a substance or mixture cover the conditions under which the substance or mixture is actually used. The contents of this section, with the exception of scaling, are explained in detail in the Practical Guide "How DUs can handle exposure scenarios" [24]. The principles of scaling are explained in appendix 2 of this guidance, while examples on scaling will be published, in a later stage, in the Practical Guide.

4.1 Legal requirements related to downstream users' compliance with the exposure scenario

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 DU you may receive an exposure scenario as an annex to the safety data sheet of a substance that you use. An exposure scenario describes the conditions under which a substance as such or in mixtures can be used safely. The exposure scenarios are normally[25] developed by the manufacturer or the importer as part of their registration dossier for the substances which meet the criteria to be classified for any of the hazard classes or categories listed in Article 14(4) of REACH or assessed to be a PBT or vPvB, and produced/imported in amounts of 10 tonnes per year or more[26]. The exposure scenario(s) cover all life cycle stages of a substance, from manufacture to disposal[27]. The exposure scenarios are forwarded along the supply chain as annexes to the safety data sheet. Safety data sheets for mixtures may have exposure scenarios attached that refer to the mixture, or to the individual hazardous substances contained in the mixture, or both (section 7 of this guidance is dedicated to information to be communicated on mixtures). Key terms relevant for exposure scenarios are explained in section 1.3.2 of this guidance but detailed information about exposure scenarios is provided in Part D of the Guidance on IR&CSA[28].

As downstream user of a substance or mixture who is supplied together with a safety data sheet and attached exposure scenario(s), you have 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 scenario that you have received from your suppliers.

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[24] The full list of ECHA Practical Guides is available at echa.europa.eu/web/guest/practical-guides.

[25] Exposure scenarios can also be prepared by downstream users, either to meet the requirement to conduct a downstream user chemical safety assessment (see chapter 7 of this guidance) or when making an exposure scenario for a mixture by merging and consolidating exposure scenarios received (see chapter 14 of this guidance).

[26] Cases when exposure scenario is required in the chemical safety report are indicated in art 14.4 of REACH.

[27] Although waste is exempt from registration, the safety assessment has to include the disposal.

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

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 section 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 section 4.2.5 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. Section 4.4 of this guidance provides more information.

An explanation on how to check use and use conditions is provided in the following section 4.2 and in the Practical Guidance "How Downstream users can handle exposure scenarios"[29].

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[30], compliance with environmental permits under the Industrial Emission Directive[31]), 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 section is explained in section 1.3.2 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 SDS. Identified uses are named in the safety data sheet, under section 1.2 and in the title section of the attached exposure scenarios. The naming should be consistent with the title of the exposure scenario. 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[32].

29 echa.europa.eu/web/guest/practical-guides.

30 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).

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

32 Chesar manuals are available at chesar.echa.europa.eu/web/chesar/support/manuals-tutorials.

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 the exposure scenario in a short text and/or list. The activities relating to the identified use will only include those where exposure to the relevant substance or mixture is expected. Assess whether you carry out activities with the substance or mixture that are not listed and may cause higher or different exposures than those listed. Note that activities such as loading or unloading vessels are usually included in the 'main activity' described.

4.2.3 Checking the conditions of use (OC and RMM)

A Comparison of operational conditions

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 section 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.

B Comparison of risk management measures

Compare the information given on risk management measures, including their effectiveness, with those you apply. To document your assessment you may use appendix 3 of this guidance.

Effectiveness is the key information related to risk management measures. It is the degree of exposure or emission reduction achieved by application of the RMM (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 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 8 Checking risk management measures

Information in exposure scenario	Your own practice
• Half mask (protection factor 10 assumed)	• Appropriate half masks are worn
• Gloves (nitrile) should be worn.	• Appropriate gloves are used
• No environment related measures needed	• No environmental measures are implemented

under given operational conditions of use	
Residual paints and empty cans should be disposed of via municipal collection system.	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 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, have different break-through times for different substances 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 RMM defined in worker legislation[33] 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[34]), can be taken into account when assessing the effectiveness of a RMM. If you adopt a RMM that is considered higher in hierarchy by other applicable legislations and more effective compared to the RMM in the ES you may conclude that your conditions of use are covered. For example the exposure scenario indicate use of PPE with 90% effectiveness and you have an enclosed system where residual releases are <3% (equal 97% effectiveness). In this case your RMM can be considered higher in hierarchy and also more effective and therefore your conditions of use are covered.

4.2.4 Scaling

In order to be in compliance with REACH you, as downstream user, must either:

- be exempted from preparing your own CSR under any of the letters contained in Article 37(4) of REACH, e.g. implement “as a minimum” the conditions of use described in the exposure scenario, or

- be able to demonstrate, that your own conditions of use are as a minimum as strict as those in the exposure scenario.

If some of your conditions of use differ from the exposure scenario of your supplier, it is not always clear whether the use is covered by the exposure scenario or not. In these cases, your supplier may indicate rules in the exposure scenario itself to help you to determine if your use is covered by scaling the determinants of exposure.

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 DU 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 to prepare a Downstream User Chemical Safety Report (DU CSR) (REACH Article 37(4) (this option is detailed in section 5).
This method should 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 data.

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

[34] BREF documents can be downloaded at eippcb.jrc.es/reference.

When scaling is applied, modification of one factor can be compensated by modification of another factor.

Scaling options are meant to provide you with a simple tool aimed to check if their conditions are "equivalent" to the conditions defined in the exposure scenario meaning that DUs levels of exposure (for humans and the environment) are equivalent or lower than levels of exposure resulting from the application of the conditions described in the ES.

NOTE: 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 SDS 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 if your supplier has prepared an exposure scenario which is in line with ECHA Guidance on IR%CSA Part D and Chesar.

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

1. the mathematical method which has to be applied (i.e. the algorithm: it could be a formula, an IT tool or a web interface);
2. the (determinants of exposure) parameters which can be scaled;
3. the boundaries of scaling (to what extent changes in some parameters can be compensated by variation in other parameters).

When you are able to apply the scaling rules provided by your supplier according to the instruction received, you can conclude that your own use is covered because this proves that your conditions are 'as a minimum as strict' as in the exposure scenario.

If your own conditions of use differ from the description in the exposure scenario and minimum implementation cannot be demonstrated via scaling, your own use is not covered.

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[35].

4.2.5 Uses advised against

If the safety data sheet specifies that your use is advised against, it is advisable to stop this use of the substance or mixture. However, you may be able to show that your use, although advised against, is safe by carrying out a DU CSR. This will require you to assess the use of the substance or mixture and, where necessary, modify your conditions of use and therefore, potentially, coming to a different conclusion on the risk. Guidance on the DU CSR is provided in section 5 of this guidance.

35 echa.europa.eu/web/guest/practical-guides.

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 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. This can be relevant for example to facilitate checking the use of other mixtures that you use in the same application. A format is provided in appendix 3 of this guidance. You may also consider integrating compliance checking in your health, safety and environmental management system.

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

This subsection aims to assist DU 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

If the conditions of use of your substance or mixture are not covered by the exposure scenario, in general you are required to make a DU CSR unless the exemptions in Article 37(4) of REACH apply. Other options may also be available under REACH, as alternatives to the DU CSR. The following list summarizes the key options that you have in case the conditions of use of your substance are not covered by the exposure scenario that you received from your supplier:

1. make your use known to your supplier with the aim of having it an “identified use” and included in the supplier’s chemical safety assessment (see section 3 of this guidance); or
2. implement the conditions of use described in the exposure scenario you have received; or
3. substitute the substance either with a different substance for which an exposure scenario is not required or where the exposure scenario(s) cover your conditions of us or with process techniques not requiring the substance; or
4. find another supplier who provides the substance or mixture with an exposure scenario that covers your use; or
5. prepare a DU CSR (unless this is exempted).

Table 9 Options if exposure scenario does not cover the use

Option	This option could be best if	Advantages	Risks
Exemptions apply (see details below 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 - 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	Your supplier may be unwilling to do the assessment for you
Implement conditions of use (see 4.4.4)	- your use is not covered by the (similar) conditions of use in several exposure scenarios - your have problems in complying with other legislation and consider modifying your risk management in these areas too	Certainty that the use is assessed and does not pose any risks Synergies for compliance with other legal obligations	Upgrading existing or introducing new risk management measures can be costly
Substitute your substance or mixture (see 4.4.5	- you have very few substances or mixtures which are not covered by the exposure scenario - you want to substitute the substances / mixtures also for other reasons	Several risks can be eliminated or reduced Product quality may improve	Substitution may require time and resources Assessment may be complex for mixtures
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	Safe use is demonstrated and documented You can continue using the substance / mixture	Resource and some expertise are required. Changes in the process may be needed if adequate control of risks cannot be demonstrated with existing conditions of use

4.4.2 Do the general exemptions of Article 37(4) letters (a) to (f) apply?

If your use is not covered by the exposure scenario you should first check if any of the exemptions of Article 37(4) letters (a) to (f) of REACH apply to you. If you are exempted, you only have to report this fact to ECHA if you rely on the exemptions contained in Article 37(4)(c) or (f). If you are not exempted, you should continue checking the options described below before making a DU CSR. Table 10 lists the exemptions of Article 37(4) and more explanations are provided below where necessary.

Table 10 Checking if the exemptions from the duty to prepare a downstream user chemical safety report apply

Exemption	Explanation - your own use	Explanation - customer's use[36]
(a) No safety data sheet required for substance or mixture	If your supplier is not obliged to provide you with a safety data sheet, you do not have the obligation to prepare a DU CSR It is possible that you may receive a safety data sheet and exposure scenarios on a voluntary basis; here, also, the requirement to make a downstream user chemical safety assessment does not apply.	If you supply your customer with a mixture not requiring a safety data sheet, you do not have to provide an exposure scenario either. You therefore do not have to consider whether the use of your customer is covered by the exposure scenarios of your suppliers (in case they were not exempted as well). Nevertheless, you should consider whether information according to Article 32 needs to be forwarded (see also section 7)
(b) No chemical safety report is required to be completed by the supplier	A DU 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 section 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.
(c) Use is less than 1 one tonne per year	See "criterion c" discussion below this table.	
(d) As a minimum the conditions of use are covered	See chapter 4.2 of this guidance for details on coverage of as a minimum the conditions of use	
(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 for that substance is not required. Nevertheless, you do have to consider all information in compiling your SDS.	
(f) Substance is used for PPORD	See "criterion f" discussion below this table.	

[36] 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. in the SDS). In order to prepare such information, you have to assess if the ES you have received from your suppliers covers 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 downstream user chemical safety report to cover these uses or you may consider other options (see section 4.4.1 of this guidance). Please check section 5 of this guidance for more information on DU CSR and section 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".

Criterion c – Do you use less than 1 tonne per year of the substance or mixture?

If you use the substance or the mixture in total amounts of less than one tonne per year, you do not have to make a chemical safety report (Article 37(4) c of REACH). The amount considered as "used" is not limited to that actually applied, but includes the amount stored as well. Furthermore, the tonnage limit applies to the total amount used, regardless of the supplier and whether or not an exposure scenario was received.

If this exemption applies, you are still required to identify and implement measures to ensure control of risk to humans and the environment based on information received from your supplier or your own chemical safety report. If you are a formulator, you must communicate appropriate measures to your customers in the safety data sheet, if one is required. You also have to report to ECHA (see section 4.4.2.1 below on what has to be reported).

Criterion f - Use in product and process oriented research and development

If you are using the substance or mixture in process and product oriented research and development (PPORD[37]), you are not required to make a downstream user chemical safety report, 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 of June 1st 2008.

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 by your supplier (including any conditions imposed by ECHA). It is your obligation to implement these conditions[38]. 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 assure that your use of the substance has been registered (in such case you have to receive a SDS 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.

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[37] 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;*" 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 .

[38] 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). 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.

4.4.2.1 Report to ECHA (Article 38(2))

You have to report to ECHA, at the latest 6 months after you have received an exposure scenario that does not cover your use, if you rely on the two exemptions described above. The report must include the following information:

- your identity and contact details
- the registration number of the substance(s), as such or in mixtures, which are not covered by the exposure scenario, where available
- the identity of the substance(s) concerned
- the identity of the manufacturer, importer or supplier of the substance(s) concerned
- a brief general description of your use.

More information about the report obligation in accordance to Art 38 of REACH are available in section 5.5 of this guidance, in the Practical Guide "How downstream user can handle exposure scenarios"[39] and in the DUs pages of the ECHA website[40]. You will find information on the substances' registration numbers and identity, as well as your supplier, in the safety data sheet. In the brief general description of use, you are expected to describe the purpose for which you and your customers apply the substance or mixture. You can use the system for standard description of uses (see Chapter R.12 of the Guidance on IR&CSA).

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, or that your conditions of use are not covered. If this is the case, you have the option to make your use known in written to your supplier, with the aim of making it an identified use. See sections 3.3 and 3.4 of this guidance for more detail.

4.4.4 Implement the conditions of the exposure scenario

If your conditions of use are not covered by the exposure scenario, you could also change your production process 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 and mixtures 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;

39 echa.europa.eu/web/guest/practical-guides.

40 echa.europa.eu/web/guest/regulations/reach/downstream-users.

- changing the process (for example, enclosure of machinery) or product design (for example, reducing the concentration of the substance or mixture in your product) according to the information in the exposure scenario.

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

4.4.5 Substituting the substance or 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 (for example, omitting cleaning steps). If you, as DU 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. When planning a substitution of a substance with another substance (substitute), you should look at the phys chem 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;
- costs for substitution (e.g. tests, qualification/certification, change of processes/equipment etc.);
- ease and practicability of change;
- if a substance (contained in the mixture) is listed on the candidate list (see REACH Article 59), it may have to be authorised in future.
- availability of alternatives.

The Guidance on the preparation for an application for authorisation[41] 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

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

4.5 Your use is confidential

You may want to consider that your use of the substance or mixture is confidential. In this case you have same three options described above to achieve compliance with REACH: you can substitute the substance or mixture with one that has no exposure scenario or one that covers your use, you can adapt your process design to the exposure scenario provided by your supplier or you can carry out a downstream user chemical safety report that shows adequate control.

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

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

Following the check described in section 4, a downstream user may establish that his use (including the use(s) further downstream) is not covered in the exposure scenario received from the supplier. One option is to undertake a downstream user chemical safety assessment. This section provides guidance on carrying out this assessment and on documenting it in the DU CSR. The issues discussed in this section include:

- what are the requirements and scope of the DU CSR;
- what other obligations are there;
- what are the timelines;
- how to carry out the assessment and prepare the DU CSR;
- how to communicate with ECHA and your customers.

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

Article 37(4) of REACH states that:

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.

Before commencing a DU CSR it is advisable to check all your options and if any of the exemptions in Article 37(4), described in section 4.4 apply.

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

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.

As mentioned in section 4.4.2.1 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;
- 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.

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 to 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.

This is illustrated with the examples below:

Example 1: as a downstream user, you use a registered substance of total 5 tonnes per year (total use >1 tonne/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, because your supplier and the other actors up the supply chain do not attach an ES to the SDS to cover your spray application process. However, you do not have to report to ECHA, because the particular use not covered (spraying) is less than 1 tonne/year and your total use is more than 1 tonne per year.

Example 2: as a downstream user, you use a registered substance of total 0.8 tonnes per year and use all of it in a spray application process, and your use is not covered in the exposure scenarios you receive. You do not have to prepare a DU CSR because your total use is < 1 tonne/year. However, you do have to report to ECHA that your use is not covered.

Details on how to report to ECHA are provided in section 5.5 and on the Downstream User pages of the ECHA website[42].

5.1.2 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.

[42] echa.europa.eu/web/guest/regulations/reach/downstream-users.

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 your use is outside the conditions described in the received exposure scenarios 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
- prepare a DU CSR (unless you qualify for an exemption from undertaking a DU CSR).

The time period starts on receipt of the SDS with the registration number, however it is not possible to check if your use is not covered without the receipt of exposure scenarios.

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 (see section 5.1.1) within 6 months after having received a safety data sheet containing a registration number.

5.2 What is a chemical safety report (CSR)

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, 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.

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

Where a downstream user has decided to perform a chemical safety assessment, a downstream user chemical safety report 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 downstream user chemical safety report is a different and generally much smaller undertaking than one 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 carries 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, and do not have to gain familiarity with any complex software. However, you need to feed the outcome of any assessment into your system for generating and maintaining safety data sheets.
- The downstream user chemical safety report is not submitted to ECHA.

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.

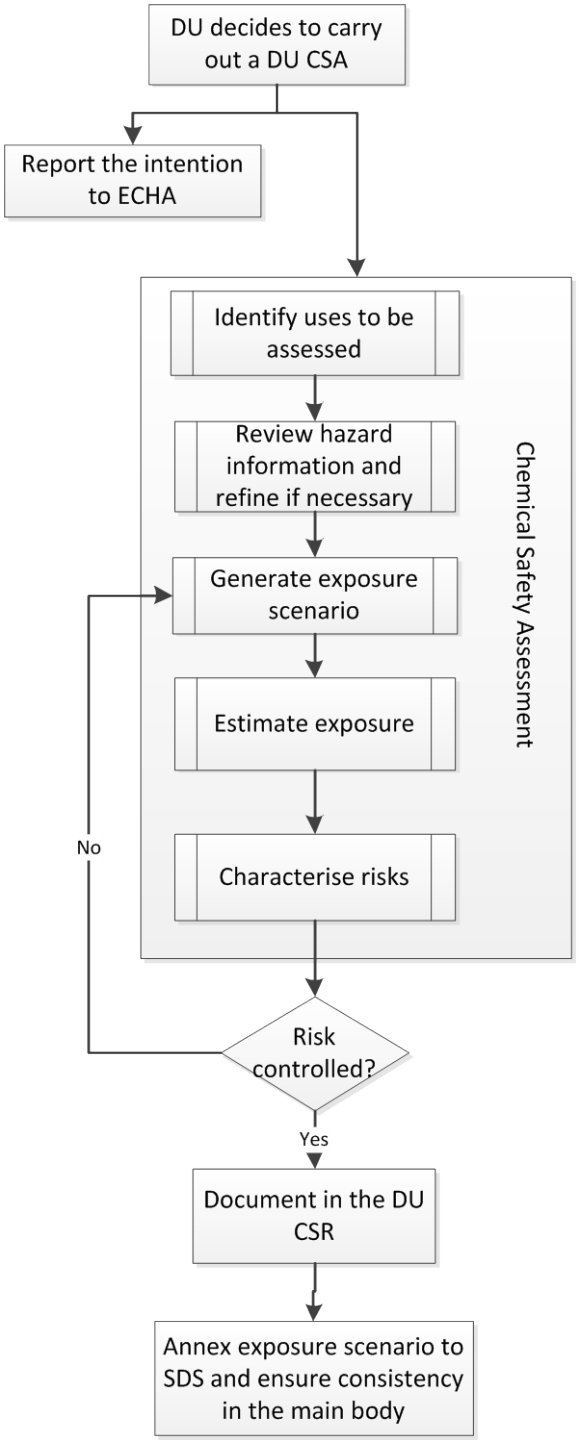

Figure 4 Work process for downstream user chemical safety assessment

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 hereinafter. It is expected that the person undertaking a DU

CSR has some expertise and competence in undertaking risk assessment. The Guidance on IR&CSA[43] provides additional and in depth guidance.

1. 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.

2. Review the hazard information provided by your supplier

   Determine if the hazard information provided in Section 8 of the SDS received from your supplier is adequate for the identified use(s). If you do not agree with it, consult section 5.4.1 for how to proceed.

3. 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 section 5.4.2.

4. 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 data, exposure estimation tools or control banding. Section 9 of the SDS provides physical and chemical properties of the substance which a DU might find useful for carrying out the exposure estimation.

5. 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.

6. Document in the DU CSR

   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 SDS, if applicable.

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

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

Safe threshold values are likely to be provided either by your supplier (Section 8, sub-section 8.1 of the SDS (REACH Annex II)) or the ECHA database.

However, you may have to adapt the hazard information either:

(i) because safe threshold values (DNELs/PNECs) have not been provided, or

(ii) because the supplier's hazard assessment is not appropriate.

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

(i) DNEL's/PNEC's not provided

This may be the case if the DNELs/PNECs have not been derived, in which case you may consider:

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

- deriving the value yourself using the Guidance on IR&CSA[44] and the Practical Guide "How to prepare toxicological summaries in IUCLID and how to derive DNELs" [45] (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 the Practical Guide "How to undertake a qualitative human health assessment and document it in a chemical safety report"[46]. This practical guide assumes some knowledge of risk assessments of chemicals.

(ii) Supplier's hazard assessment is not appropriate

If you decide that the hazard information received is not appropriate you may consider the following approaches:

- assess if additional or more relevant information is available (e.g. from substance testing found online or in literature) and use it to derive a new DNEL/PNEC[47] (as described previously). As a first step, you should find out if this information is held by other actors up your supply chain.
- conduct tests and generate the base information to derive the safe threshold value. You have to decide which type of test would be needed and find a laboratory which

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

45 echa.europa.eu/web/guest/practical-guides.

46 echa.europa.eu/web/guest/practical-guides.

47 See Guidance on IR&CSA at echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

undertakes such tests. Which tests are needed to improve the data base is described in the Guidance on IR&CSA.

Please note the requirements and deadlines with regards to testing proposals, and your obligations for communicating up and down the supply chain in cases where you do generate / collect new information on a substance's hazards.

5.4.2 Develop exposure scenarios (for uses not covered)

For a DU CSR, it is normally quite straightforward to develop exposure scenarios. They are generally for a use onsite, or a use that a customer has informed you about. Exposure scenarios should include article service life and waste stages if relevant.

If you communicate 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[48]).

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.

It may also be relevant to consider the risks for consumers and the environment, and when the substance is part of an article, the life-cycle of the article should be taken into consideration. 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.

Such arguments could be:

- The use of the substance in a certain application, and the related exposure routes, is explicitly not supported. For example, the indoor use of an article is not supported and thus exposure via indoor air can be excluded.
- It can be demonstrated in the assessment that the substance properties and/or physical form make certain exposure routes very unlikely. For example, low volatility, low water solubility and/or low mobility of the substance in matrices argue for low probability of evaporation or elution of the substance. However, it is important to consider that, in later life cycle stages, releases over time may represent a risk.
- Common sense arguments based on documented experience. For example, a consumer will only touch a coated wooden wardrobe sometimes and only briefly. Thus dermal exposure to substances contained in (the coating of) the wardrobe is expected to be low.

The Guidance on IR&CSA contains further arguments and examples.

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

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 data

B. Exposure estimation tools

C. Control banding

A. Measured data

Measured 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 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 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). This should be documented in the DU CSR. Further information is provided in the Guidance on IR&CSA, Chapter R.14: Occupational exposure estimation[49].

If measured 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 substances. 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. Ecetoc TRA
b. Stoffenmanager
c. Advanced Reach Tool (ART)
d. EUSES
e. ConsExpo

These tools are publicly available, and are free of charge. 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 COSHH-BAuA tool, can be used for inhalation exposure calculations. This is an exposure predictive tool which is based on the assumption that the

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

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 COSHH-BAuA tool can be downloaded from the Internet[50]. Its application in chemical safety assessment is described further in section D 5.3.5 of Guidance IR & CSA, Part D.

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 sphere 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.

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

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 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"[51].

Site-based risk assessments carried out due to the requirements of other legislation may also be applicable.

5.4.5 Documenting the downstream user chemical safety assessment in the report

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

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50 reach-helpdesk.de/en/Exposure/Exposure.html.

51 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/web/guest/practical-guides.

The downstream user chemical safety report 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

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 downstream user chemical safety report to ECHA. You are, however, required to keep the chemical safety report up to date and available.

5.5 Reporting to ECHA

When required to report to ECHA (by submitting a so called Downstream user report), two options are available:

(i) a Webform via the downstream user pages of the ECHA website[52]: 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.

If you need to report that classification 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[53], 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 annex the relevant exposure scenarios (for commuication) to the safety data sheet you supply to them

52 echa.europa.eu/web/guest/regulations/reach/downstream-users.

53 echa.europa.eu/web/guest/regulations/reach/downstream-users/downstream-user-reports.

(Article 31(7)). Detailed information is provided in the Gudiance on the compilation of safety data sheets[54].

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.

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

6 Communicating new information on hazards and risk management measures upstream

This section 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 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.

Examples of new information are observations on acute human health effects at workplaces, 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 11 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 11 Forwarding information on classified substances and preparations

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.
		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
3: Composition		The classification reflects the information on hazards. It's obligatory to forward new information on hazards
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 downstream user chemical safety report to refine a PNEC/DNEL value, it is obligatory to forward the information upstream.
		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		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.
10: Stability & reactivity		
11: Toxicology		
12: Ecotoxicology		
(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.

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'. Note also that this type of supply chain communication does not involve any reporting to ECHA. The requirements relate to the main body of the safety data sheet, as well as the exposure scenario.

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 section 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 risk management measures in the attached exposure scenarios, where information is consistent with the main body but more detailed. Therefore, the possibility to react is limited to risk management measures which are clearly inappropriate. This section gives some examples of when you may consider the risk management measures recommended under Section 8 of the SDS 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, if a substance as such or in a mixture is always used in closed processes and full-time use of gloves is recommended as risk management measure, this is clearly inappropriate.
- The recommended measures relate to exposure routes that do not occur: an example would be that effluent treatment is recommended in the safety data sheet, although your process produces no wastewater. Another example would be that dust

masks are recommended to be worn, although the substance or mixture is provided as a liquid and no aerosols are formed during the use.

- The recommended risk management measures contradict the classification and labelling of the substance or mixture or conflict with existing environmental, workers or installation related legislation: if a certain risk management measure is triggered by the classification and labelling information and the recommended risk management measures are clearly contradictory, this is an obvious case of inappropriateness. This case could also arise from new information on hazards which could change the classification and corresponding labelling (see previous chapter).

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 or 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, 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 section 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 section 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 any 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. If the reason for differences in classification is based on a different interpretation of existing data, you only need to report to ECHA. However, if you use new data for classification that was not considered by your supplier, you also need to inform your supplier about this new information (see section 6.2).

In general, 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"[55].

[55] echa.europa.eu/web/guest/support/faq/questions-and-answers-on-downstream-user-reports.

7 Communication in the supply chain related to mixtures

This section provides guidance to downstream users who formulate mixtures. It presents the main obligations under REACH relating to mixtures and describes how information on 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, and in the "Guidance on the compilation of safety data sheets"[56].

A mixture is defined in the 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). The physical state of the mixture may affect the level of exposure to a substance in the mixture for an identified use, and should be considered when establishing the conditions of use such that the risk is adequately controlled. Formulators are one of the downstream users of chemical substances identified in section 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 is included to relevant requirements under CLP Regulation. 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 12.

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

1. **Classify, label and package mixtures.**
   - i. Until 1 June 2015 - 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;
   - ii. After 1 June 2015 - in accordance with the CLP Regulation. However, any mixtures which are on the market before 1 June 2015 can continue to be labelled and packaged in accordance with DPD until 1 June 2017 (Article 61 of the CLP Regulation).
2. **Provide safety data sheets** compiled in accordance with Annex II of REACH:
   - i. provide safety data sheets for all classified mixtures to downstream users and distributors;
   - ii. provide safety data sheets on request for non-classified mixtures which contain substances above specified concentration limits;
   - iii. include relevant exposure scenarios and use other information from the safety data sheets supplied to you when compiling these safety data sheets.

[56] Available at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

An exemption applies to obligation (i) above. If the mixture is offered or sold to the general public, a SDS need not be supplied if sufficient information for safe use is provided.

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.

4. **Prepare a Chemical Safety Report** in accordance with Annex XII for any use outside the conditions described in the exposure scenarios received or any uses the supplier advises against. In this case you have to attach the exposure scenarios resulting from this assessment to your safety data sheet.

5. **Comply with general obligations relating to downstream users**. These are detailed elsewhere in this guidance. In particular, you should:

   i. communicate information about the uses of the mixtures to your supplier with the aim to make these identified uses. This is optional. Refer to section 3 for more details.

   ii. check whether your uses (and the foreseeable uses of your customers) are covered in the exposure scenarios they receive. Refer to section 4 for more details;

   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 section 6 for more details;

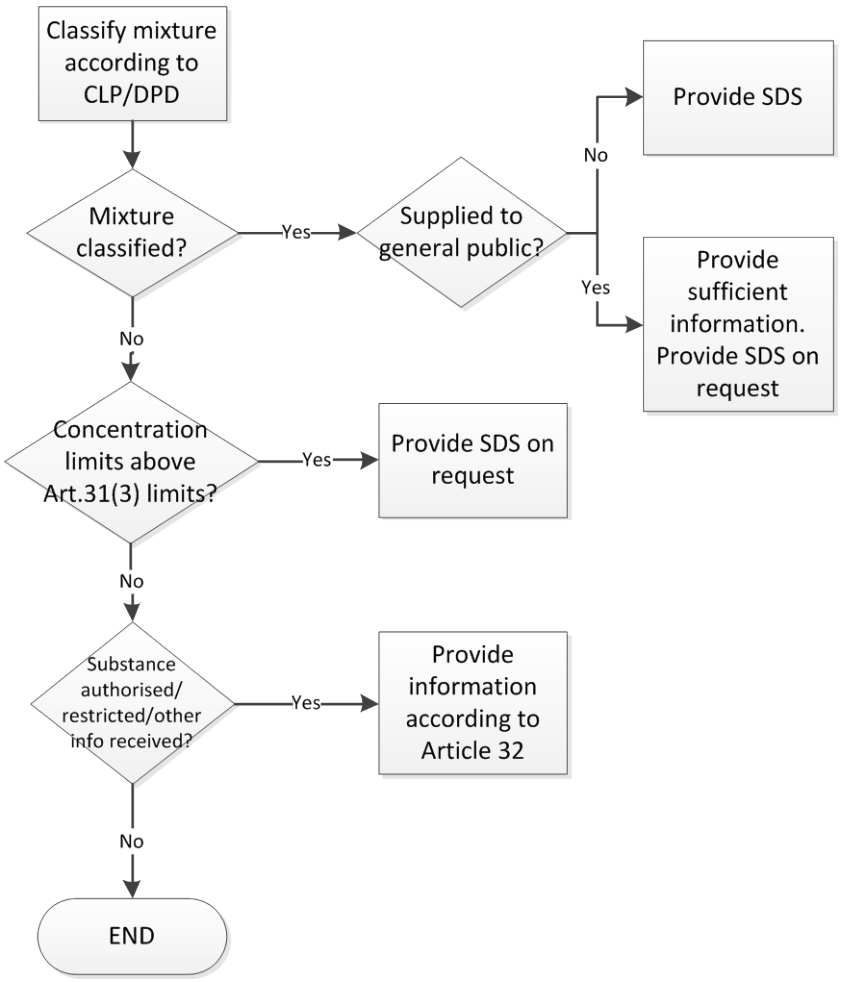

Fig 5 Workflow summarising when a safety data sheet or other information on the mixture needs to be forwarded to downstream users and distributors

1 **Table 12 Legal references in 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:* *(a) where a (…) mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC;* *(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or;* *(c) where a substance is included in the list established in accordance with Article 59(1), for reasons other than those referred to in point (a) and (b).*	An SDS is required if the mixture is classified as dangerous according to DPD or, from 1 June 2015, classified as hazardous according to CLP. The requirements for the SDS are presented in Annex II of REACH. A detailed guidance is provided by the Guidance on the compilation of SDSs. 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. Note that this article applies to all substances and mixtures, and not only those that are registered under REACH.
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.* *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*	If a CSA is prepared for a whole mixture, in addition to the single substance(s) in a mixture, the SDS can be based on this CSA. Please note: Annex 1 and Annex XII of REACH refer to CSA/CSR for single substances. A CSA for whole mixture is not defined in REACH. Nevertheless Table 12 includes an overview of assessment approaches that may be applicable to mixtures.
31(3)	*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:* *(a) in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one*	An SDS shall be provided on request even if the mixtures is not classified as dangerous but contains individual substances that are hazardous or PBT/ vPvB above specified concentrations.

REACH Article	Regulation	Clarification
	substance posing human health or environmental hazards; or *(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* *(c) a substance for which there are Community workplace exposure limits.*	An SDS shall be provided, on request, if an OEL is assigned to any substance in the mixture (regardless of classification and concentration). 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[57].
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 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.*	If you supply mixtures that are classified, article 31(1) requires you to provide an SDS to downstream users or distributors (recipients). However, if these mixtures are also available to the general public, the requirement to provide an SDS to recipients is waived if you provide 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. A recipient (including a retailer) is, however, entitled to request an SDS, if preferred. The SDS should be provided without undue delay, allowing for the time required to prepare the SDS if necessary. This situation will normally apply at the last stages of the supply chain, when the supplier can clearly establish (i) the information that is sufficient to provide to the recipient, and (ii) that the mixture is provided to the general public. A member of the general public is not entitled

[57] Article 59 of Regulation No 1272/2088 (CLP Regulation).

REACH Article	Regulation	Clarification
		to request an SDS.
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.*	The safety data sheet has to be translated into the national languages of the recipients. Exposure scenarios are part of the safety data sheet and the translation requirement also applies to them. This provision is introduced to ensure that all members of the supply chain, including end users, have equal access to the information in a language they understand. It avoids the unnecessary cost of all end users undertaking their own translation and promotes consistent translation. Formulators may prefer to receive exposure scenarios in English, to facilitate collation of information from a number of countries.
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 (i) he is registering the substance and the requirements of Articles 14 apply [substances > 10 tonne, concentration limits for mixtures] or if (ii) he is a downstream user whose use is outside conditions of exposure scenario (Article 37). He shall include the relevant exposure scenarios in an annex to the safety data sheet. If a formulator has prepared a CSA for a whole mixture, the relevant exposure scenario(s) related to the whole mixture may be annexed to the safety data sheet (instead of the ES for the single substances).
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 should convey relevant information through the supply chain. Information is obtained from exposure scenarios and the SDS provided. Note also: (i) The relevant ESs included may be for the

REACH Article	Regulation	Clarification
		individual substance(s) or for the mixture. (ii) When there are a small number of uses and/or conditions of use, it may be appropriate to incorporate the relevant information in the main body of the SDS. (iii) When information from an ES is incorporated in the body of the SDS, such as a risk management measure, it should be clearly identified that it was sourced from an exposure scenario. This is because specific legal obligations apply to recommendations from exposure scenarios (Article 37(4)).
31(9)	*Suppliers shall update the safety data sheet without delay on the following occasions:* *(a) As soon as new information which may affect the risk management measures, or new information on hazards becomes available* *(b) ….*	For formulators, it is likely that when they receive an extended SDS for a registered substance, it will include new information on hazards. This may be DNELs/ PNECs, new classification or additional risk management measures. Consequently, a formulator is likely to have to update the safety data sheet without delay.
31(10)	*(..)* *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. However, if the substances or mixtures are classified *and* labelled according to CLP Regulation prior to 1 June 2015, classification in the SDS shall be provided in accordance with both CLP and DSD/DPD.

REACH Article	Regulation	Clarification
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:* *(a) the registration number(s) (..), for any substances for which information is communicated under points (b), (c) or (d) of this paragraph;* *(b) (..) details of any authorisation granted or denied (..);* *(c) details of any restriction imposed (..);* *(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied (..)*	If an SDS is not required for the mixture but it contains a registered substance that was (i) considered for authorisation, (ii) is restricted, or (iii) other information is relevant to the user, the registration number and relevant information shall be provided to the recipient. According to Article 32(3), this information shall be updated without delay, under circumstances the same as Article 31(9) above. Note that this requirement does not apply to mixtures for consumer use only.
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) new information on hazardous properties, regardless of the uses concerned;* *(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 the substance or a mixture, they have to notify their supplier. 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 mixture, even though the recommendations presented in the ES were followed). 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).

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7.2 Communicating information on 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)). The objective is to convey information that helps to protect human health and the environment in a way the user can easily understand.

This subsection 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 work (Section 7.2.1);
- identify the information that is relevant to communicate downstream (including an overview of assessment approaches to mixtures) (Section 7.2.2);
- communicate this information effectively (Section 7.2.3).

Table 13 includes an overview of assessment approaches to mixtures.

7.2.1 Collating information on a substance or mixture from different suppliers

As a formulator you typically purchase a given substance or mixture from more than one supplier. The information received from different suppliers can differ markedly, and be received at very different times. You need to collate the information received from the different suppliers before you can communicate information on your mixtures to your own customers.

A first step is to identify the relevant exposure scenarios and align these as much as possible. This could include determining similar identified uses, standardising the terminology, and matching the conditions of use. Scaling may be useful when aligning the conditions of use (see section 4 and appendix 2).

The exposure scenarios may still deviate significantly. The approach taken is likely to depend on both commercial and technical considerations. Typical situations you may encounter are illustrated below.

Situation 1: The operational conditions and risk management measures in the exposure scenarios for the same use differ from different suppliers. How do I decide which to include in my collated information?

You have three main approaches. All are valid and the preferred approach will depend on the situation. You could:

i. select the exposure scenario with the most stringent conditions of use (lowest use amounts, lowest frequency and duration of use, most efficient risk management measures etc.). This is straightforward, but it may result in the propagation of overly precautionary risk management measures;

ii. select the exposure scenarios with conditions of use most appropriate to your customers. If this approach is taken, you need to ensure your conditions of use are

covered. You could ask suppliers of more stringent exposure scenarios to include your preferred exposure scenario;

iii. perform a DU CSR to verify that the preferred exposure scenario provides adequate control of the risk.

Situation 2: I receive exposure scenarios for a relevant use from one supplier but not from another supplier. Can I forward on the exposure scenario for that use to my customers?

Yes. This has the advantage that all information available on uses remains in circulation. However, it is advisable to inform suppliers who have not included that use to ensure that they have not deliberately omitted that use for valid reasons.

Situation 3: I receive exposure scenarios for a relevant use from one supplier but another supplier states this is a "use advised against". What should I do?

If a use is advised against by one supplier, but not by another, then it is the responsibility of the formulator to establish if the use is safe for his customers. This could be by a downstream user CSR or by communication with your suppliers.

Situation 4: I haven't received exposure scenarios from all my suppliers, so how can I forward information on to my customers?

If exposure scenarios have not been provided, but would be expected, contact your supplier. If all the expected information is still not received, communicate information downstream based on other information available to you.

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 when new information has been received by you.

7.2.2 Identifying information to communicate to downstream users

Identifying the information to communicate downstream can be a straightforward task for many mixtures. It may be obvious which are the necessary operational conditions and risk management measures to protect human health and the environment.

For some situations however, it can be technically demanding. When there are several hazardous substances, identifying the critical component of the mixture for each health or environmental effect or can be challenging, as can identifying any potential interactions between individual substances in the mixture.

The appropriate methodology depends on the substances, the hazards and the identified uses:

- It may be based on consolidating the information provided in the supplier exposure scenarios and integrating information on other components of the mixture into this consolidation. This may also include exposure scenarios that are based on a formulator's DU CSR for a single substance. The formulator needs to ensure that the risk management advice provided to customers ensures safe use of all components in the mixture.

- For certain assessment situations a "chemical safety assessment" or "risk assessment" for the whole mixture may be appropriate. Please note: The term "chemical safety assessment for mixtures" is used in article 31(2), although not described in any further detail in REACH. The term "risk assessment for mixtures" does not exist in REACH at all.

Examples of applicable methodologies are in development during the drafting of this guidance. There is considerable work being undertaken in industry sector organisations, in regulatory science and at policy level on how to assess chemical mixtures. As this work is not finalised at the time of publication, details do not form part of this guidance.

An important basic aspect is the assessment of the risk from the mixture. Formulators are likely to have experience in conducting risk assessments for mixtures on-site in accordance with environmental and health and safety legislation, and many of the approaches are applicable here. Also, sector organisations have developed generic exposure scenarios for mixtures based on an assessment for the mixture.

There are further examples on approaches from other regulatory schemes (e.g. for biocidal products, plant protection products, veterinary medicines etc.). Some are in development and some are already established. These approaches may be useful in dealing with chemical mixtures, and defining the RMM-related information to communicate. Such sophisticated methodology, which requires professional judgment and expertise, is unlikely to be necessary in normal circumstances.

It is important to keep in mind that the purpose is to examine RMMs that should be applied to protect humans and the environment when the mixture is used so that the supplier can advise their customer. Therefore the use of the mixture determines human and environmental exposure. The effects on human health and on the environment from such exposure to the mixture depend on its properties:

- For some properties (e.g. irritation) it is most appropriate to examine the properties of the mixture itself. There may be existing studies on the mixture. However it is more common to estimate the properties from the component substances. In estimating the properties of the mixture from the components, it may be necessary to take account of interactions between substances in the mixture; i.e. affecting the chemical properties (e.g. pH of the mixture) or biological properties (e.g. one component may enhance the dermal absorption of a second component).
- For other properties (e.g. PBT/vPvB) what matters are the properties of the individual component substances in the mixture; hence in effect they are assessed separately as resulting from exposure due to use of the mixture.

Although these methodologies to assess risks from mixtures will change and develop, some core principles that apply to all of them have been identified. These core principles, presented in Table 13, contain the fundamental concepts that underpin all methodologies. The principles are not prescriptive but require case-specific expert judgement to be applied. The approaches can be tailored to suit the needs of different users.

The core principles are listed in approximate order of increasing ‘sophistication’. Simple situations, which may be applicable in a limited, but significant, proportion of cases, are near the beginning of the table. Rare and complex cases, that may need a risk assessment, are at the end of the table.

Table 13 Core principles for identifying information to communicate for mixtures

Ref no.	Principle
	General considerations
1	A simple 'editorial' approach may be adequate: the RMMs for the individual substances can be combined into an equivalent form that applies to the mixture, under the OCs applicable to the mixture; i.e. the RMMs for the mixture fully correspond to the various RMMs for the component substances recommended for the same OCs.
2	RMMs for the mixture can be derived by use of the most stringent RMMs recommended for the individual substances of the mixture and used as a 'worst case' approach. This is a simple yet conservative method that may be applied in many cases. However, expert judgement is required to ensure that the RMMs recommended are not over-precautionary and impractical.
3	The precautionary statements from the classification of the mixture (Annex V of Guidance on the Application of the CLP Criteria) can be a useful basis for the selection RMMs for the mixture, at least as a starting point in simple cases.
	Hazards linked to physicochemical properties
4	Where individual substance(s) have physicochemical properties – they are explosive, flammable or have oxidising properties - intimately linked to physical hazards, the properties of the whole mixture must be determined (in principle by testing the mixture or otherwise determining its properties), in order to decide on the combination of OCs and RMMs to adequately control the risk from using the mixture (unless a worst case approach is appropriate, as in core principle 2).
	Human health (toxicological) hazards
5	When the mixture presents a risk due to the toxicological hazardous / properties (i.e. due to the mixture as a whole or from the individual component substances in the mixture), the potential risk should be assessed based on exposure to the mixture as a whole.
6	For local effects (i.e. skin and eye irritation and corrosion) and acute toxicity, the hazardous properties of the mixture as a whole are relevant for assessing the risk resulting from exposure and deciding on the most appropriate RMMs. The hazardous properties of the whole mixture can be estimated from the properties of the component substances, taking into account their concentration (percentage) in the mixture. The CLP methodology is one of the tools that can be used. Alternatively, existing test data on the whole mixture may be used. New studies should not be conducted. The assessment of risk for human health is then conducted for exposure to the mixture as a whole.
7	a) For mixtures which contain substances that are carcinogens, mutagens, toxic to reproduction (CMRs) or sensitisers (dermal or respiratory), the risk assessment and recommendations related to safe use of the mixture should be based on the component substances themselves. The human exposure to each of these substances is estimated from the use of the mixture. b) For mixtures containing substances with general, systemic long-term toxicity (other than CMR and sensitisation), there are different possible approaches. It may be appropriate to consider that the component substances exert their toxic effects independently of each other; hence the risk associated with each such hazardous component substance in the mixture should be assessed separately (as in core principle 7a above). Alternatively, it may be appropriate to estimate the general long-term toxicity of the mixture as a whole, conduct the risk assessment (when appropriate) and recommend RMMs for the mixture as a whole (along the lines of core principle 7). c) If the toxicity of an individual substance in a mixture is affected by the presence of other substances, i.e. either accentuated or diminished, this is addressed in the risk assessment: indeed the classification may be affected, hence this is an alert to deal with this in assessing the risk.
	Ecotoxicological hazards
8	a) The environmental risk results from the release of the mixture to one or more of the environmental compartments – air, water, soil. The long term (i.e. time-averaged) exposure in the different environmental compartments, and hence the resulting effects in these compartments, will be affected by possible differences in environmental fate and distribution of the individual substances composing the mixture. The environmental release pathway associated to each use triggers the assessment for the mixture; two main situations should be considered: direct environmental emissions of the mixture as such, and emissions through wastewater treatment plants and waste management activities. Direct release of mixtures to environmental compartments may trigger adverse effects at the local level based on the combined hazard of the mixture; in such a case fate

Ref no.	Principle
	and distribution factors are of relative low concern for the local short term risk assessment. In release through wastewater treatment plants or as a consequence of disposal and waste management, the physicochemical and fate properties of the components of the mixture may be different, and the individual components of the mixture released to water, soil and air should be considered in the PEC and PNEC calculations. The influence of these environmental releases on the different compartments should be considered independently of each other. If a first tier, screening assessment considering the mixture as a whole is conducted, worst-case values instead of averages should be used. b) There are different possible approaches to the assessment of the ecotoxic effects of the mixture on the environmental compartments, ranging from assuming that the substances act independently (hence separate risk assessments apply for each substance) to assuming that the effects are additive. It should be noted that the level of protection for the environment is at the population level, thus substances with different modes of action at the individual level may still produce relevant combined effects if acting on the same ecological receptor. In general, the use of additivity principles serving as basis for the classification and labelling of mixtures under the CLP Regulation is considered a suitable alternative, and can be applied to aquatic, sediment and soil organisms. If as implied by (a), the mixture as such is not released but a different pool of components is released to each environmental compartment, the estimation should consider the expected compositions of the fraction of the mixture reaching each compartment. c) If the ecotoxicity of substances in a mixture may be affected by the presence of other substances in the same mixture, i.e. either accentuated or diminished, this is addressed in the risk assessment. d) The PBT or vPvB properties of substances are intrinsic to the individual substances, i.e. they are not properties of the mixture, so they should be treated on a substance basis, even though their release to the environment will occur from the release of the mixture. The released component substances may undergo environmental fate and distribution. However, the risk for secondary poisoning should address the combined effects of all components in the mixture with bioaccumulation potential.

7.2.3 Options for communicating information 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 mixtures to users further downstream.

There are two options, as follows:

(i) annexing relevant exposure scenarios; or
(ii) integrating the exposure scenario information in the main body of the SDS.

The exposure scenario shall be annexed to the SDS if you prepare a chemical safety report. Otherwise, the option selected will depend on aspects such as the uses, the recipient and business considerations.

The information requirements differ for different customer groups. For example, customers who are formulators or who have expertise are likely to require a lot of detail. Other customers using mixtures, such as lubricants, adhesives, cleaning agents and coatings, may have limited familiarity with chemicals. This customer group needs information that is accessible and understandable.

In practice, the customers for a given mixture often fall within a spectrum of needs and abilities. If so, you should 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 at the end of this section. Aspects to consider are discussed in the following sections.

7.2.3.1 Annexing relevant exposure scenarios

Annexing exposure scenarios is the more suitable approach when useful information cannot be readily communicated in the main body of the SDS. 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.

There are four main types of exposure scenarios which can be annexed to the safety data sheet:

a. exposure scenarios derived from the downstream user CSR;

b. exposure scenarios received from the supplier;

c. generic exposure scenarios for the substances/mixture;

d. consolidated exposure scenarios for the mixture.

a. Exposure scenarios received from the downstream user CSR

If a chemical safety assessment has been performed by you, either in the role of registrant or as a downstream user, the relevant exposure scenarios shall be attached (Article 31(7)).

This is the only situation where there is no option available to the formulator.

b. Exposure scenarios received from the supplier

The relevant exposure scenarios that you have received from your supplier for the substance(s) and/or mixture(s) can be annexed to the safety data sheet for your mixtures.

This approach is likely to be the most suitable 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 clearly presented exposure scenario for each identified use. It is usually more suitable if there is a short, well-structured supply chain.

c. Generic exposure scenarios (GES)

GESs are likely to be most suitable in an industrial sector where the uses are clearly identified, and where the hazardous properties of the substances in the mixtures can be readily categorised.

When generic exposure scenarios are used, it should be kept in mind that you “recommend an exposure scenario which includes as a minimum the conditions described to you in the safety data sheet” (Article 47(4)(d)).

To avoid checking that your customer use is covered on a case by case basis, you may choose to forward all the generic exposure scenarios you use to the relevant suppliers and request they be covered in the safety data sheets provided.

If you undertake a downstream user chemical safety report and derive the exposure scenarios for communicating information to your customer from this CSR, it is necessary to report to ECHA. If the exposure scenarios are based on generic exposure scenarios and your customer use is covered, it is not required to report to ECHA.

d. Consolidated exposure scenarios

Consolidated exposure scenarios refer to building an exposure scenario for a given use of the mixture based on the supplier's exposure scenarios for the substances contained in the mixture, and any additional information that may be relevant. The objective is to identify the conditions of use that are appropriate and proportionate using a methodology that is transparent, reproducible and efficient.

As mentioned in 7.2.2, this can be a simple or a complex undertaking. Methodologies for consolidating information on mixtures are being developed and are not detailed further in this guidance.

Consolidated exposure scenarios are suitable when the recipient is an end user, and also when the mixture is relatively complex.

7.2.3.2 Integrating information in the main body of the SDS

The necessary information can be provided in the main body of the SDS, rather than in the form of an exposure scenario.

This is likely to be a suitable approach when communicating simple conditions of use to end users, especially to small and medium sized enterprises (SMEs). It is applicable when there are a relatively small number of identified uses and/or conditions of use, and the conditions of use are applicable to all uses.

Integrating information is usually not suitable if extensive advice on the operational conditions and risk management measures is necessary.

If a chemical safety assessment has been performed by you, either as a registrant or as a downstream user, the relevant exposure scenarios shall be attached (Article 31(7)) and only integrating information in the main body of the SDS is not an option.

When you integrate information sourced from an exposure scenario of your supplier into the main body of the safety data sheet, it should be clearly indicated as an identified use. Risk management measures derived from an exposure scenario should be clearly flagged, as specific legal obligations associated with Article 37(4) are attached to these risk management measures.

7.2.4 General guidelines when communicating information

Some general guidelines to consider when communicating information are the following.

a) **Conflicting information is resolved as far as possible**. If conflicting information has been obtained from different suppliers for a given use and substance, either specify the more precautionary OC/RMM, based on the hierarchy of controls and effectiveness, or specify the most appropriate OC/RMM. If the latter option is selected, contact your suppliers to request your conditions of use are covered or prepare a downstream user CSR.

b) **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.

c) **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.

d) **The OCs and RMMs 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.

e) **Important information is easy to retrieve and to understand.** Include tools such as a table of contents to aid retrieval of information. Avoid an overload of information which "hides" the information that is necessary to ensure the conditions of use are safe.

f) **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 (such as EScom phrases[58]) and generic exposure scenarios 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.

g) **The supplier exposure scenarios for substances are grouped into relevant identified uses or use and exposure categories, as far as feasible.** A "use and exposure category" is an exposure scenario covering a wide range of processes or uses. If such grouping is applied, it would promote clarity and convenience, without losing information necessary to adequately control the risks. Limit the exposure scenarios to the foreseen uses of the substance.

h) The information in the exposure scenario is consistent with the information in the main body of the SDS. The exposure scenario needs to be considered together with (and be consistent with) the information within the SDS main body. Appendix 2 of the ECHA guidance on the compilation of safety data sheets contains a list that allows for a consistency check between exposure scenario information and the respective sections of the SDS.

i) SDSs and exposure scenarios are provided in the local language. This applies unless provided otherwise by the member state concerned (Article 31(5)). Use of ESCom/EuPhraC phrases or equivalent help to promote harmonisation and good

58 cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/.

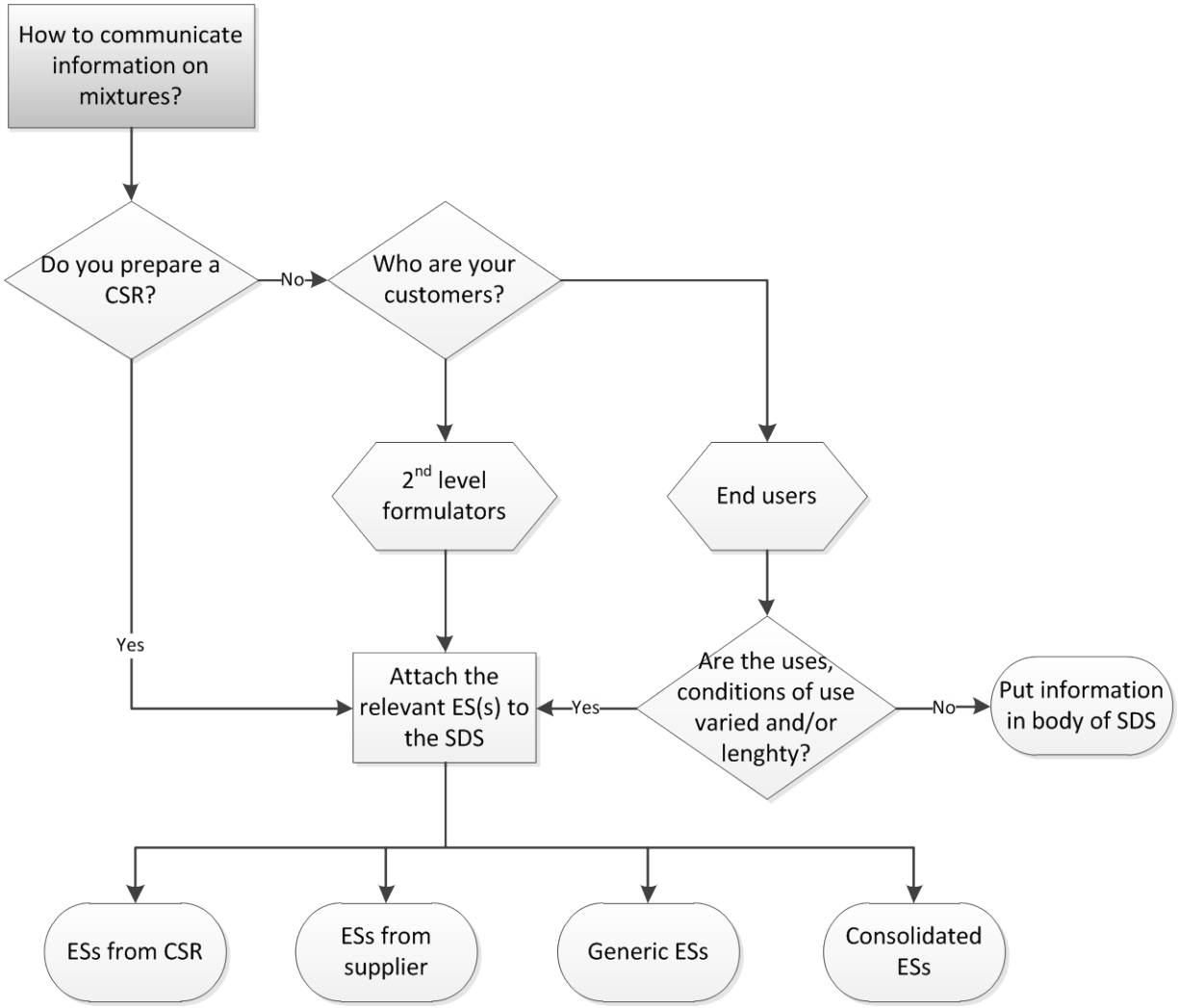
translations. They also assist any of your customers who may need to generate SDS's for their mixtures.

j) **The actions should be undertaken within the time periods specified within the legislation.** You should ensure that any actions required to be undertaken on receipt of an extended safety data sheet for a registered substance are completed within 12 months (and if a DU CSR is required, this should be reported to ECHA within 6 months).

k) **The safety data sheet is updated 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 sufficient information is received, you should update your own SDS. For substances for which ESs are not yet available, use existing information from the SDS to identify appropriate RMMs. If an exposure scenario becomes available after publication of your SDS, an update is only required if the hazard information or safety advice needs to be changed. 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.

Figure 6 Simplified decision tree to identify how to communicate information downstream



8 Requirements related to authorisation, restrictions and substances in articles

8.1 Authorisation requirements and downstream users

This section 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". Only if an authorisation is granted to the company or an actor up its supply chain, can the substance be used or placed on the market after the sunset date. 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-EU manufacturer can also submit an application for authorisation.

Authorisations will be granted for (specific) uses 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 authorisations. You can make an application for an authorisation for your use or for uses by your DUs, 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 applications for authorisation[59]. More details on the authorisation procedure are provided on the dedicated section of the ECHA website[60].

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 his the downstream users before the application is submitted to insure that all concerning uses are covered. Once authorization is granted the DU 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. The authorisation number has also to be mentioned in the label in accordance with Article 65 of REACH, and the recipient must informed pursuant to Article 32 of REACH.

8.1.1 Uses exempted from authorisation

The REACH Regulation foresees exemptions from 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. Nevertheless, you

[59] Available on the ECHA web site at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

[60] echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation.

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 14 lists the exemptions from authorisation requirements according to REACH. Further information on exemptions can be found in the section on Q&A on application for authorisation[61].

Table 14 Generic exemptions from the authorisation requirement

Exemption (short)	Description of the exemption:	REACH Article
Out of scope	Substances not within the scope of REACH See also scope of REACH in the navigator and the guidance on registration[62]	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: - 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; - 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 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; - 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; - in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition.	2 (5) (b)
Scientific research and development	Use in scientific research and development	56(3)
Plant protection products	Use on plant protection products within the scope of the Council Regulation (EC) No 1107/2009	56(4)

61 Available on the ECHA web site at echa.europa.eu/web/guest/support/faq/questions-and-answers-on-applications-for-authorisation.

62 You can start a Navigator session at echa.europa.eu/web/guest/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/web/guest/guidance-documents/guidance-on-reach.

Biocidal products	Use in biocidal products within the scope of the Biocidal Products Regulation (BPR 528/2011)	
Motor fuel	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)	
Fuel in combustion plants	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)	
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) 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)

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 oriented 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 the 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 the need for authorisation in order to have it ready for inspectors.

8.1.2 Fulfilling authorisation requirements

If you use a substance on Annex XIV you should:

- check the latest application date of the substance[63];

[63] 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.

- 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, and
- report to ECHA if you use a substance under the authorisation granted to an actor up the supply chain[64].

It is important to check the Authorisation List as it develops to see whether any of the substances that you use are on it.

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 the 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 controlled and/or minimised. It also needs to include an analysis of alternatives and, where these exist, a substitution plan. Applications for substances for which no DNELs/PNECs exist shall include a socio-economic analysis.

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[65].

64 If you have applied for the authorisation yourself, no notification of the Agency is required.

65 Both available in the "Support" section of the ECHA website at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

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 authorisation process. 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 apply for an authorisation with a group of actors who have the same use of the substance. For example, you could consider:

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

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, must not be supplied to your customers after the sunset date.

8.1.2.2 – Sunset date

In case the substance you use is subject to authorisation and none of the exemption 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, but is not obliged to, 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 web site[66].

The supplier will 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 SDS.

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66 At echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list.

Checking if a use is covered by an authorisation is similar to the 'normal' checking of coverage of an exposure scenario (section 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, 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 in REACH-IT and will require as a minimum the following information:

- your identification and contact details;
- the authorisation number, which you will find on the label and/or in the SDS of the substance or mixture;
- 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, when 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).

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 section 8.3 and, in more detail in the Guidance on requirements for substances in articles[67].

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[68] and on ECHA website[69].

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

68 eur-lex.europa.eu/JOIndex.do.

69 echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list.

Holders of authorisations must submit a review report at least 18 months before the expiry of the time-limited review period[70].

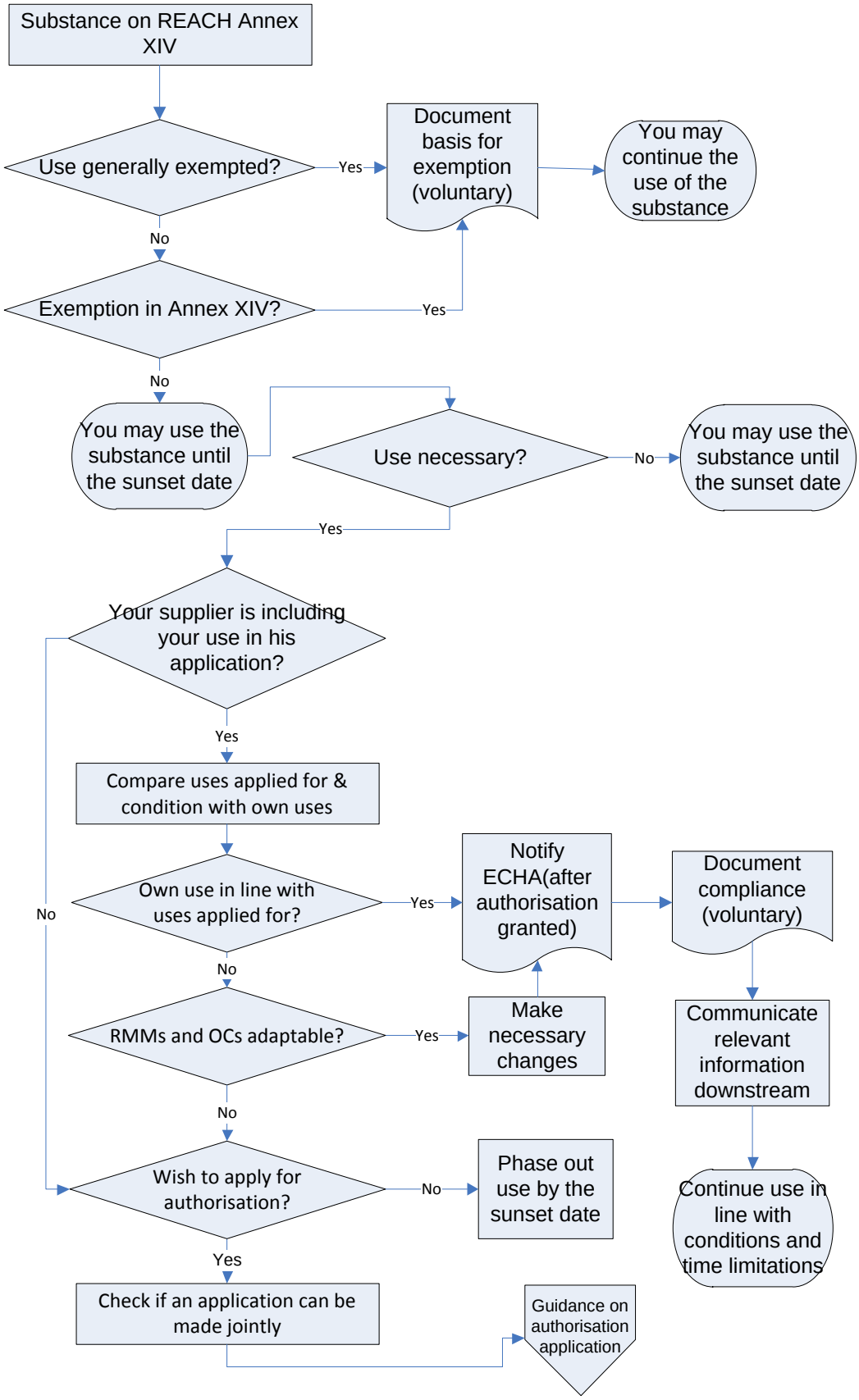
8.1.3 Contributing to public consultations

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

- when a proposal for identification of SVHC has been submitted;
- when the SVHC is recommended by ECHA for inclusion in Annex XIV (comments from DU are expected to be given on the wide dispersive uses and quantities used, exempted uses, alternatives),
- when the application for authorisation is under evaluation by the Committees during the opinion making phase (public consultation on alternatives to specific uses of the Annex XIV substance);
- after the decision has been made (e.g. new information on alternatives becomes available) on the specific application for authorisation.

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

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[71].

8.2 Downstream users and restriction requirements

This section 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, either on its own or in a mixture or in an 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 are carried over into Annex XVII of REACH.

Your 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 web site[72].

More information on the restriction procedure is available on the ECHA website[73]. There you can find out also which substances are considered for restriction, and the type of restriction proposed.

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.

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71 echa.europa.eu/web/guest/support/faqs.

72 Available at echa.europa.eu/web/guest/addressing-chemicals-of-concern/restrictions/list-of-restrictions

73 At echa.europa.eu/web/guest/regulations/reach/restriction.

8.2.2 General exemptions 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.

These general exemptions 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[74]. Further information on interpretation on restrictions can be found on the support page of the ECHA website[75], where the FAQs and "Questions and Answers on restriction" 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 section 7 of this guidance.

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74 At echa.europa.eu/web/guest/addressing-chemicals-of-concern/restrictions/list-of-restrictions.

75 Available at echa.europa.eu/web/guest/support/faqs.

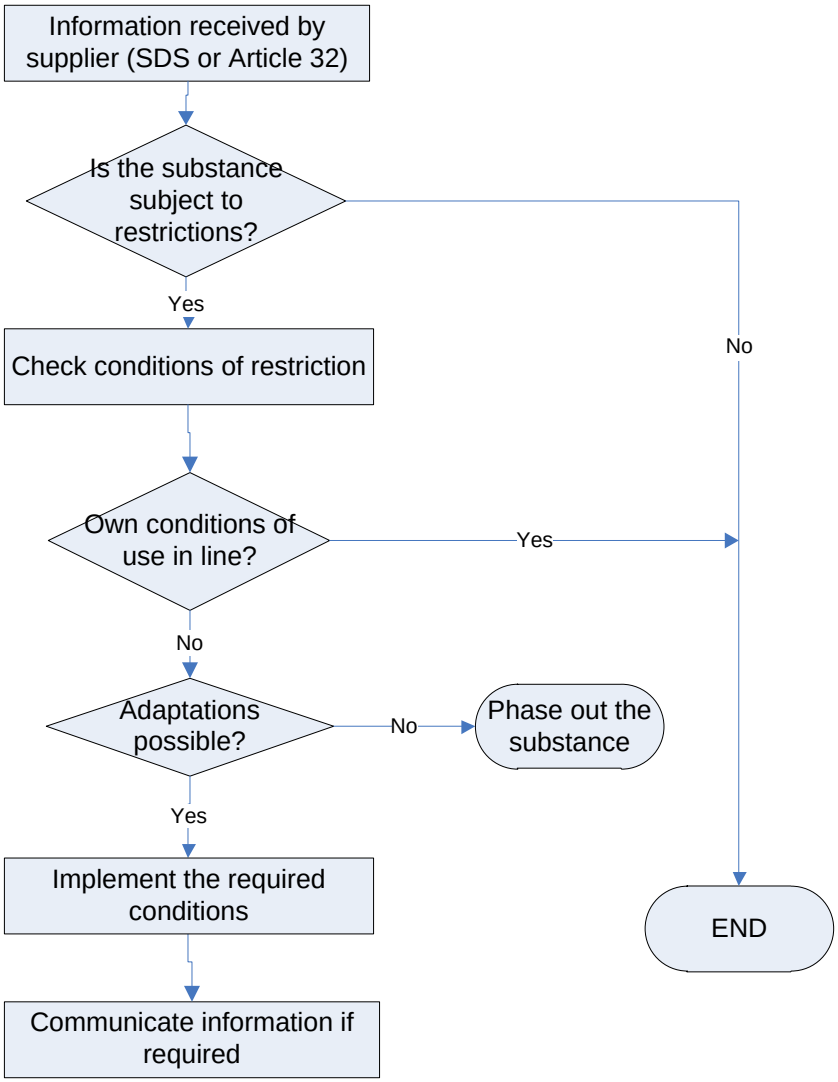

Figure 8 Workflow checking compliance with restrictions

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[76].

In general, please refer to the dedicated page on the ECHA website[77].

8.3 Compliance with requirements related to substances in articles

Companies producing articles 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 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 use78. 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 section 3 of the 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 may have to notify ECHA (Article 7(2) of REACH).

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).
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 website79. In this section 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 incoporation 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.

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 be normally covered by the exemption if the communication through the supply chain and the assessment of all identified uses have been properly carried out.

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[76] Available at available at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

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

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

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

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.

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 section 8.3.3). The Candidate List is updated regularly and the updates can be followed on the ECHA website[80]. 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 be 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.

80 At echa.europa.eu/web/guest/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, consult section 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 EU (or the EEA), including retailer, who only stores and places on the market a substance, on its own or in a mixtures, for third parties[81] (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, their obligations are limited to forwarding information in the supply chain as described in this section.

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[82].
- **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 section 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 section 2 of this guidance. To obtain general information on the aims and functioning of REACH, you could also use the REACH Navigator[83] or the introductory information on REACH on the ECHA website[84].

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81 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.

82 All the Guidance documents and other supporting material are available in the "Support" section of the ECHA web site at echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation.

83 Available at echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/identify-your-obligations.

84 echa.europa.eu/web/guest.

A1.2 Obligations for distributors under REACH

As a distributor, your main obligation is to pass on information on the goods you distribute from one actor in the supply chain to another. This includes SDS for substances and mixtures. Furthermore, there is a requirement for certain information to be provided for substances, mixtures or articles when a SDS 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 illustrate 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.

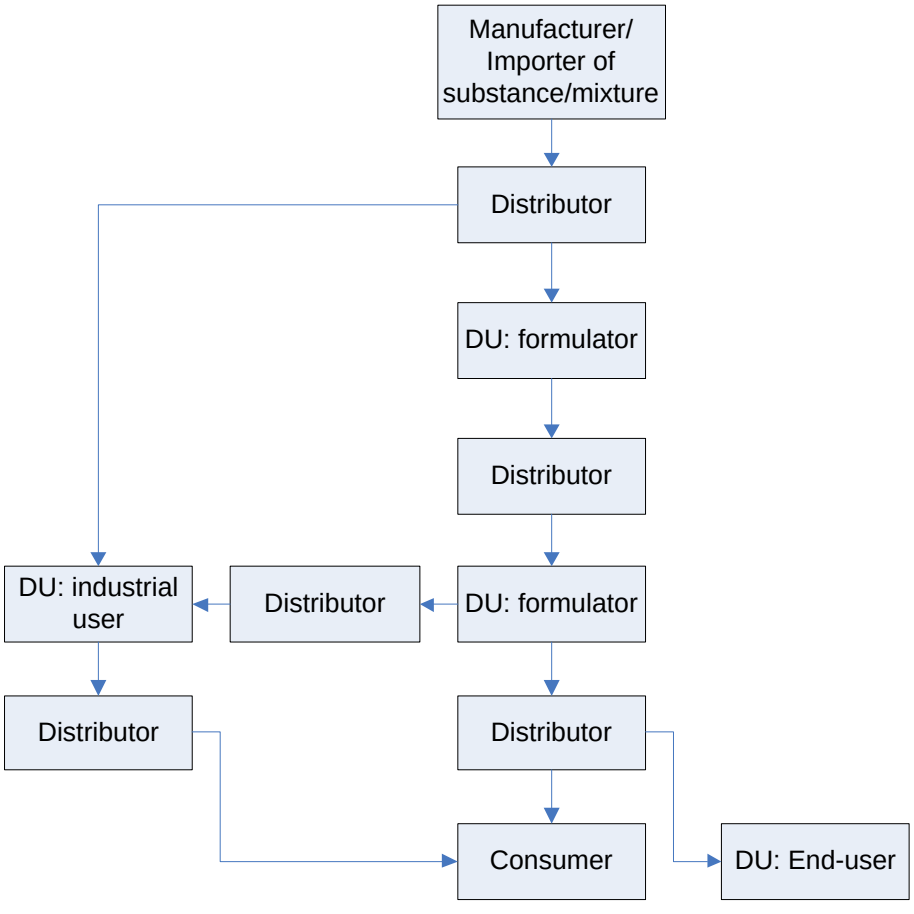

Figure 9 The distributor and the supply chain

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 and/or his customers' use(s) of a substance or a mixture (as described in section 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[85] (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 downstream user chemical safety report.

- 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 15.

85 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 heading 1 of the safety data sheet e.g. an emergency number. See also Table 28 Information flow in the supply chain.

Table 15 Information flow in the supply chain

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).	Responds 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[86]	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[87].	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. New information on hazards and information questioning recommended risk management measures have to be forwarded.
Safety data sheet for a mixtures and downstream user chemical safety report[88]	Delivery of information for making a safety data sheet and /or a chemical safety report for a mixture, on request from downstream user.	Requests for additional substance information needed for making a downstream user chemical safety report. Requests for a safety data sheet when concentration of hazardous substances in a mixture is above a threshold value for	If a customer makes a downstream user chemical safety report for a substance or mixture, he may request information on substance hazards. You may receive requests from customers for safety data sheets for non-classified mixtures. If hazardous substances

86 See section 3 this guidance.

87 See section 6 of this guidance.

88 See section 5 and section 7 of this guidance.

Subject	Type of information received	Type of information to be forwarded	Remarks
		providing of safety data sheet[89].	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: - On a substance subject to authorisation or restriction. - Needed for identifying appropriate risk management measures.	Information: - On a substance subject to authorisation or restriction. - 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. A non-classified mixture may contain, e.g. a substance subject to authorisation. 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: - the classification, as a minimum. - Recommendation on safe conditions of use should also be included.	Information on: - the classification, as a minimum. - Recommendation on safe conditions of use should also 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[90]			
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 for authorization
Information on substances in articles[91] (Article 33)			
Information in the supply chain for articles	For articles with a substance on the Candidate List for authorisation present in a concentration > 0.1 %	Downstream user may request information on the content of 'substances of very high	You have to pass the information from your supplier of an article to your customers (downstream users and

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

90 See section 8 of this guidance for more information on compliance for downstream users with the authorisation and restrictions.

91 See section 8 of this guidance and the Guidance on requirements for substances in articles for more detailed information.

Subject	Type of information received	Type of information to be forwarded	Remarks
	(weight/weight): - Available information on safe use of the articles. Name of the substance as a minimum	concern' in articles.	distributors/retailers). Furthermore, you should pass any requests upstream.
Information to consumers for articles	For articles with a substance on the Candidate List for authorisation present in a concentration of 0.1 % or more (weight/weight): - 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*: in this appendix the word "registrants" is used also to indicate 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 OCs and RMMs. If the calculated exposure levels are based on the recommended OCs and RMMs or even stricter, the DU 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 SDSs, the DU can use scaling to check if his combination of OCs and RMMs (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, DUs do not develop new exposure scenarios with the same equations, but they calculate whether their situation is within the broad 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. Only those who have undertaken a chemical safety assessment and prepared a CSR may know to what extent the conditions of use of DUs 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 may sometimes identify and recommend OCs and RMMs 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 DUs.

Scaling options defined by registrants should be easy to implement by DUs. 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 DUs condition) is the same or lower than the level of exposure resulting from strict application of the exposure scenario as received from the suppliers. DUs 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 DU 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 should consider to prepare a DU CSR or to check for other options (see section 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 DUs in order to guarantee that a substance is used safely. This means that if such conditions are implemented by a DU, 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 DU (see guidance on IR and CSA part D for further information on exposure scenario building and definition of safe use)

If, instead, one or more conditions of use at DU 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 DUs have to be considered outside of the exposure scenario boundaries.

If scaling options are provided in the SDS, DUs 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 DUs 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[92];
- scaling cannot be used by DUs to justify absence of RMM or a different RMM from the exposure scenario they have received for a substance even if resulting levels of exposure are the same or lower than expressed in the exposure scenario. In some cases, RMM can differ from the ES (see par 4.2.4).

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 DUs 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 annex to SDSs 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 DUs, registrants 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 DU) needs to:

Step 1

Determine a set of OCs and RMMs (key determinants of exposure) for which control of risk for the exposure route can be demonstrated. This is the set of OCs and RMMs to be communicated in the exposure scenario.

[92] Some exposure assessment tools use bands of input parameters (such as 5 bands for concentration of substance and 5 bands for duration of activity). The concentration and duration is connected in a non-linear way with the exposure estimation for the exposure to workers. There may be cases when scaling up one band of one parameter and scaling down of another band to reflect downstream user (DU) conditions results in a “numerical” increase of in the level of exposure determined. This increase may be an "artefact" resulting from the setting of the bands rather than indicating that a higher level of exposure is expected.

Step 2

Assure that Risk Characterisation Ratio (RCR_{ES}) and/or exposure/release levels are communicated in the section 3 of the exposure scenario (check Guidance on IR&CSA Part D: exposure scenario format). 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 RMM 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 ES could be described with a broader set of OCs and RMMs that ensure control of risks and allows, in the meantime, for more flexibility at the DU 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:
  - o workers: exposure duration, concentration per activity, RMM effectiveness;
  - o consumer: concentration/amount;
  - o environment: amount, release fractions/RMM effectiveness[93],
- List the OCs and RMMs, which are likely to be different in the actual use situations.
- Check that only mutually independent determinants OCs and RMMs are used for scaling purposes. The assumption of mutually independency often holds only in a limited range, e.g. in the consumer exposure via inhalation the concentration in the air may be expressed as a function of amount used, room volume and ventilation rate[94]. If the ventilation rate is expressed as hr-1, then it is actually a function of the air exchange rate (m^3/hr) and room volume (m^3). Therefore, in this case the determinants to use for scaling are either both air exchange rate (m^3/hr) and room volume or only ventilation rate expressed as hr-1. Example (for the environment): the exposure concentration and thus the RCR in the environment are proportional to the actual amount used (M_{Actual}). Thus the algorithm for scaling is: RCR_{Actual} =

[93] 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: $f_1*(100-f_2)$.

[94] Please notice that room volume should only be used for consumer exposure estimation and not for worker exposure situations. In normal workplace situations, both in process industry and manual work, the highest concentration of air impurity and the highest exposure is at the place of emission, and the concentration decreases quite rapidly with the distance from the source. As workers very often work close to the emission source, their exposure is much higher than the average in the room.

$RCR_{ES} \cdot M_{Actual} / M_{ES}$, where RCR_{Actual} is the calculated RCR for the actual situation.

- Start the scaling with the methodology used for exposure assessment for the target group and exposure route. This can be an available Tier 1 tool, an algorithm, or a higher tier tool. The DU can use, for scaling, a Tier 1 tool if it is publicly available and is reliable also for non-expert users. In this case, the registrant should use the exposure scenario to communicate the input parameters that are needed for the calculations.
- Linear scaling can be used, if the tool or the algorithm expresses linearity between the relevant OCs/RMMs and the derived exposure level. Otherwise, either consider applying non-linear scaling or check in which range of the OC/RMM, the assumption of linearity between derived exposure level and used OC/RMM still holds.
- Find the range in which the OC/RMM can vary. These ranges are determined by the possibility to demonstrate that:
  - 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 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 algorithm and the determinants in the exposure scenario

The algorithm and the determinant ranges for which the scaling can be used should be communicated in Section 4 of the exposure scenario. Further, 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) Linearity

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 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. This concept of linear scaling assumes that there are linear relationships between the determinants and the exposure level and thus the RCR. When the linear scaling applies, the DU 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. An example of parameters that can be assumed to be independent in a limited range is duration and amount.

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 determinant and the exposure level still holds, have to be specified in the exposure scenario, by the supplier.

Examples, where the assumption of linearity only holds in a limited range, are:

- Amount used: Linearity between environmental releases to waste water and amount used only holds as long as the water solubility is not exceeded.
- The temperature: has a non-linear impact on vapour pressure, which is a key determinant for inhalation exposure.
- The pH: can have an impact on the release factor to waste water e.g. from an electrolytic treatment, but the impact is not linear.

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.

If the OCs and/or RMMs differ qualitatively from the conditions described in the exposure scenario, an iteration of factors that could compensate each other is not possible.

B) Non-linearity

In cases where a simple linear relationship between determinant and exposure level cannot be used, the registrant may prepare a tool enabling the DU 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. It can also be the exposure tool, which the registrant used for exposure calculations, e.g. ECETOC TRA and EUSES. In this case, the registrant needs to communicate via the ES, which input parameters have been or can be used for the calculations.

Industry associations have provided some web-based scaling tools for DUs (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 DU sector organisations.

Appendix 3 Documentation format for exposure scenarios, where as a minimum the conditions of use are implemented

This template can be used to document compliance with the exposure scenario, in case coverage is not obvious (quantitative differences). The template can be used for checking exposure scenarios of substances, mixtures and articles. The format guides the assessment and documentation of compliance. The items listed in each of the tables are not exhaustive but cover the most frequent elements in an exposure scenario. Where necessary, further items should be added during checking as they are introduced in the respective exposure scenarios.

The tables should be completed with information on deviations from the exposure scenario and consideration should be given on whether differences are quantitative or qualitative (see Section 4 of this guidance, on compliance checking). If any of the deviations are of qualitative nature, you should turn to Section 4.4 of this guidance, on decision making in cases where the conditions of use are not covered by the suppliers' exposure scenario.

If only quantitative deviations are noted, and in case the supplier has indicated a scaling option, you should assess which factors affecting the exposure differ from those communicated in the ES. If the scaling rules are applicable you should conclude whether or not as a minimum the conditions of use described in the exposure scenario are implemented.

The documentation should be kept and updated for own use and potential inspections.

Table 16 Identification of use, exposure scenario title and coverage of processes

Item	Information in exposure scenario	Present situation	Conclusion	Action need
Short title of exposure scenario				No immediate need for action, as deviations from the use description does not trigger legal obligations, if you comply with the conditions of use indicated.
Description of activities/processes covered				
Processing steps at own site not explicitly covered (not mentioned in Section 2 of the exposure scenario)				
Considerations on exposures from missing activities and whether or not they are covered by the other activities or require more detailed assessment				

Table 17 Operational conditions

Item [95]	Operational conditions in the exposure scenario	**Present operational conditions**	**Consequence for exposure level**[96]	**Action need**
(Maximum) duration of use event				
(Maximum) frequency of use event				
(Maximum) amount used per time				
(Maximum) processing temperature				
Concentration of the substance in the mixture / article				
Physical form of the substance				
Other indicators such as maximum surface area of articles per substance content…				
pH – value during use				
…				
Capacity of receiving environment • Water flow • Soil area • …				
Capacity of receiving workplace • Air volume/room size • Ventilation rate • …				
Capacity of consumer environment • Room size •				
Emission or release factors specified				
Specific conditions related to wear and tear of articles, e.g. abrasive conditions				
Containment of process				

95 Not all of the items listed may be relevant for each exposure scenario and additional exposure drivers may be of relevance which has not been listed here. Information should be filled in only for differences!

96 In the case of quantitative differences, the possibility of scaling should be assessed. For this, the supplier should specify which determinants are linear and can be scaled and which method can be applied for calculation.

...				

Table 18 Risk management measures

Item[97]	Risk management measures (and efficiencies) in the exposure scenario	Risk management measures (and efficiencies)	Consequence for exposure level[98]	Action needs
Occupational health				
Organisational measures				
Process controls				
Technical risk management measures, e.g. ventilation (specified efficiency)				
Personal protective equipment				
Environment related measures				
Organisational measures				
Process controls				
Technical risk management measures, e.g. waste water treatment (specified efficiency)				
Consumer related measures				
Product related risk management measures (e.g. pellets instead of powders, protective layers etc.)				
Waste related measures				

Table 19 Predicted exposure levels

Predicted exposure level per exposure route as specified in the exposure scenario	Exposure levels available from measurements or modelling obtained in the framework of other legislation
Workers	
Environment	

97 Not all of the items listed may be relevant for each exposure scenario and additional exposure drivers may be of relevance which have not been listed here. Information should be filled in only for differences!

98 In the case of quantitative differences, the possibility of scaling should be assessed. For this, the supplier should specify which determinants are linear and can be scaled and which method can be applied for calculation.

Consumers	

Table 20 Scaling of conditions

In case your supplier has provided information on how to scale the conditions of use and in which way, document your assessment with the information listed above.

Predicted exposure level per exposure route as specified in the exposure scenario	**Exposure levels available from measurements or modelling obtained in the framework of other legislation**
Tool or algorithm to be used	Documentation of modification of parameters and argumentation on coverage

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. Where a national occupational exposure limit value (OEL) is exceeded, the employer must remedy the situation through preventative and protective measures. 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 difficult to implement, especially if you use many different chemical agents. 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 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. 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 difficult to implement at small and medium-sized enterprises. Resources for control are required.	Extended 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	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	The provisions are important risk reduction tools in specific work scenarios but may be difficult to implement at small and medium-sized enterprises. Resources for control are required.	Information in extended SDS may assist SMEs to identify the risks associated with substances and give clear guidance on the RMM required to address them

EU Directive[A]	Main Elements with respect to chemicals	How does it affect DUs	How does it link with REACH[B]
who have recently given birth or are breastfeeding	taken.		
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. The provisions for risk assessment may be difficult to implement, especially if you are a small company.	Information in extended 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	It may be difficult for you 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 extended SDS may assist you to identify the presence of any ototoxic substances, the risks associated with such 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 not have the relevant expertise or experience 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. 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	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.

EU Directive[A]	Main Elements with respect to chemicals	How does it affect DUs	How does it link with REACH[B]
	comply with requirements on risk assessment, emergency planning, land-use planning etc.		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[99]			
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 may be difficult, in the absence of reliable information from suppliers.	Information in extended 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. 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.
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).	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	Information in extended 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.

99 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)

EU Directive[A]	Main Elements with respect to chemicals	How does it affect DUs	How does it link with REACH[B]
	The amount of certain chemicals that may be contained in materials used for toys is specified.	to children. Satisfactory assessment of the risks posed by chemicals within products may be difficult, in the absence of reliable information from suppliers. Lack of data from suppliers may make it difficult to assess the concentration of substances within inputs.	
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.	Extended 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, whenever an exposure scenario is needed (for example for the manufacturing and use of active substances prior to their inclusion and use in a biocidal product, and for non-biocidal uses), then Article 31 of REACH requires that these exposure scenarios be attached to the safety data sheet.	Hazardous 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, (to be replaced on 7 January 2013 by IED Directive	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	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	Extended SDS may provide useful information on the nature and concentration of substances contained within raw and auxiliary materials, which will help in

EU Directive[A]	Main Elements with respect to chemicals	How does it affect DUs	How does it link with REACH[B]
2010/75/EU, however its provisions remain applicable until 6 January 2014).	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.	addition, applicants have to identify and assess emission reduction possibilities, which may require a lot of work.	determining foreseeable emissions. They may also provide useful information on emission control measures.
Directive 2002/95/EEC of 27 January 2003 on the restriction of use of certain hazardous substances in electrical and electronic equipment, 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
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". 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.	Extended 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. 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 (to be replaced on 7 January 2013 by IED Directive 2010/75/EU,	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	The requirements of VOC directive are 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

EU Directive[A]	Main Elements with respect to chemicals	How does it affect DUs	How does it link with REACH[B]
however its provisions remain applicable until 6 January 2014).	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.		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. Two lists of dangerous substances have been compiled to combat pollution: - discharge of substances in list I must be eliminated; while - 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 section**	**(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 (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 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 the Agency	Any DU	Agency	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 (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	Supplier (M/I,	General public	When the		

List of communication needs						
	(A) Subject	**(B) Sender**	**(C) Recipient**	**(D) Date**	**(E) Guidance 's section**	**(F) Available tools and formats**
	use and protection of human health and environment (Art. 31(4))	distributor, other DU)		substance/mixture is first supplied		
13.	(On request) information required to comply with REACH (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 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	4	Data Submission Manual "How to Prepare and Submit a Downstream User Report using IUCLID 5" Downstream user

List of communication needs						
	(A) Subject	**(B) Sender**	**(C) Recipient**	**(D) Date**	**(E) Guidance 's section**	**(F) Available tools and formats**
						report webpage
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		
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		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 F	Downstream users (customers, distributors)	Before commencing use after the substance has been registered		
25.	(Mandatory) notify that the DU CSA is to be prepared	DU	ECHA	Before commencing or continuing a particular use	5	Data Submission Manual "How to Prepare and Submit a Downstream User Report using IUCLID 5" Downstream user report webpage
Requesting that a use becomes an identified use						
26.	Requesting that a use becomes an identified use (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 ECHA	'without delay'		
Collecting information on uses						

List of communication needs						
	(A) Subject	**(B) Sender**	**(C) Recipient**	**(D) Date**	**(E) Guidance's section**	**(F) Available tools and formats**
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	Chapter R.12 of Guidance IR/CSA " 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	3, 5	Chapter R.12 of Guidance IR/CSA " Use descriptor system"
Informing suppliers about new information on hazards						
30.	(Mandatory) Communicating any new information on the hazardous properties (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 (Art. 38(4))	Any DU	ECHA	Any time (not specified)	6	Downstream user report webpage 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 (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 (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	Gudiance on the preparation of an application for an authorisation
35.	(Voluntary) Contacting potential partners about the possibility of making	Any DU	Supplier (M/I, distributor, other DU); customers;	Once a substance has been included in	8	Gudiance on the preparation of an

List of communication needs						
	(A) Subject	**(B) Sender**	**(C) Recipient**	**(D) Date**	**(E) Guidance 's section**	**(F) Available tools and formats**
	a joint application for authorisation of use of a substance		competitors	Annex XIV		application for an authorisation

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