

Guidance for downstream users



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LEGAL NOTICE

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

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PREFACE

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

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

The legal reference for the document is the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006¹

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

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0 HOW TO USE THIS GUIDANCE

This guidance is intended for downstream users of chemical substances. A downstream user is someone who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. Many different types of companies can be downstream users, including formulators of preparations, producers of articles, craftsmen, workshops and service providers or re-fillers.

This guidance is also aimed at 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 is structured in a series of chapters:

- the introductory chapters (chapters 1, 2 and 3) give the background (overview of REACH, roles and obligations of downstream users and how downstream users can prepare for REACH) and direct you to the main chapters of the guidance that help you to meet those obligations.
- the main chapters provide further detail to help you to meet your specific obligations under REACH. These sections are all similar in structure: 1) summary of content and explanation of the requirement; 2) charts – workflows – to outline the overall processes (compliance with REACH, communication upstream and downstream); 3) explanations of the workflow providing additional guidance, including references to sources of further information.

This guidance covers the full range of obligations that you may face under REACH as a downstream user and the different circumstances that you may encounter. Some of this information may be relevant to you only occasionally, if ever. Note that general information on REACH, as well as a tool to help you identify your role and obligations under REACH with regards to the substances you are using, is available at <http://reach.jrc.it/>.

The guidance is structured so that you only need to refer to the chapters that are relevant to you – you are not expected to read it through. The series of questions below will direct you to the right chapters of the guidance.

1. ***What is REACH and what does it mean for me?*** For a summary of REACH and its requirements go to [chapter 1](#).
2. ***Am I a downstream user and what are my obligations?*** Are you clear that you are a downstream user? Do you understand the obligations imposed on you by REACH and when you have to comply with these? **If not, go to [chapter 2](#)**
3. ***How should I prepare for REACH?*** Do you know what action you may have to take to comply with REACH and when? Do you know what information you will need and where to find it? Are you clear how and when you should contact your suppliers about REACH? **If not, go to [chapter 3](#)**
4. ***What should I do when I receive information from my suppliers?*** If you have received information with the substances you use, either on their own, in preparations or articles, you will need to act upon that information. **Go to [chapter 4](#)**
5. ***What if the information includes an exposure scenario?*** An exposure scenario describes ways in which to use a substance safely. You will need to check whether you comply with the exposure scenario. **Go to [chapter 5](#)**
6. ***What if the exposure scenario does not cover my use?*** In this case, you will have to decide what action to take. **Go to [chapter 6](#)**

7. ***How do I prepare a downstream user chemical safety assessment?*** If you decide to make a downstream user chemical safety assessment, **go to [chapter 7](#)**
8. ***How do I inform my supplier of my use?*** If you decide to make your use known to your supplier, so that he or another actor in the supply chain can include it in his exposure scenario, **go to [chapter 8](#)**
9. ***What information will my supplier need and how can I get it?*** If you decide to identify your use to your supplier, he will need information on how you use a substance. For advice on the type of information, and where you may find it, **go to [chapter 9](#)**
10. ***What if I have new information on substance hazards?*** You must pass this information on to your supplier; **go to [chapter 10](#)**
11. ***What if I have information that calls into question the risk management measures in the safety data sheet or exposure scenario?*** REACH requires you to pass this type of information on to your supplier. **Go to [chapter 11](#)**
12. ***What is authorisation and what does it mean for me?*** If a substance is subject to authorisation, specific requirements apply. **Go to [chapter 12](#)**
13. ***What are restrictions?*** Restrictions may be applied to the manufacturing, placing on the market and use of certain substances. **Go to [chapter 13](#)**
14. ***I am a formulator of preparations – what do I need to do?*** There are specific requirements relating to preparations. **Go to [chapter 14](#)**
15. ***I am a distributor – what are my duties under REACH?*** Although distributors are not downstream users, they have duties under REACH. **Go to [chapter 15](#)**

1 EXECUTIVE SUMMARY

REACH² is the new chemicals regulation that aims to ensure a high level of protection of human health and the environment from chemical substances, while enhancing competitiveness and innovation.

*One of the main elements of REACH is registration of substances, which obliges **manufacturers and importers** of substances to provide a defined set of information, in the form of a registration dossier, to the Chemicals Agency. This information concerns the hazards of the substances and whether they could pose risks when being used. Manufacturers and importers of certain dangerous substances need to assess the exact nature and extent of these risks in a 'chemical safety assessment'. Certain very dangerous substances will require authorisation before they can be used and restrictions may be placed on the use of certain substances.*

*Under REACH, **downstream users** must not place on the market or use any substances which are not registered in accordance with REACH. Downstream users will receive information on dangerous substances and preparations, including risks from their use and measures to control these risks, in safety data sheets, just as today. Some safety data sheets will have an annex, called an exposure scenario. This exposure scenario will give more specific information on how to use the substance or preparation safely and how you can protect yourself, your customers and the environment from risks. If your use is not covered, communicate with your supplier with the aim of having your use covered by an exposure scenario or you may need to develop your own chemical safety report. You must comply with the risk management measures and with any restrictions on the use of the substance. Downstream users must also communicate certain information upstream and downstream in the supply chain.*

1.1 Main obligations of downstream users

As a downstream user, your main obligations under REACH are to:

1. Follow the instructions in the safety data sheets you receive and in the exposure scenarios which will be attached to some safety data sheets. If your use is not covered by an exposure scenario, you can communicate with your supplier with the aim of having your use covered by an exposure scenario or you may need to develop your own chemical safety report.
2. Contact your suppliers if you have new information on the hazard of the substance or preparation or if you believe that the risk management measures are not appropriate.
3. Provide your customers with information
 - a. on hazards, safe conditions of use and appropriate risk management advice for your preparations, if you are a formulator
 - b. if the content of certain very dangerous substances, which are candidates for authorisation, exceeds a concentration of 0.1 %w/w in the articles you produce.

1.1.1 When do downstream users have to comply with REACH?

REACH entered into force on 1 June 2007, and from this date the obligations related to communication in the supply chain, for example, the duty to provide safety data sheets when supplying dangerous substances and preparations, started to apply. However, obligations linked to

² Registration, Evaluation Authorisation and Restriction of Chemicals. For more details see <http://echa.europa.eu>

the registration of substances will only apply after 1 June 2008. For instance, the obligation to comply with the exposure scenario developed by the supplier (or to develop them for uses not covered) applies twelve months after the downstream user has received a safety data sheet with a registration number.

Downstream users must not place on the market any substances which are not registered in accordance with REACH. This means that your products may contain only substances which are either:

- 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), or which
- have been pre-registered and have a later registration deadline, or
- have been registered.

In practice, you should make sure that your supplier is aware of REACH and complies with his requirements. You should obtain a statement confirming that your supplier knows his requirements, follows them and also checks that his suppliers are in compliance with REACH, and request a confirmation that pre-registration has taken place or is going to take place.

It is advisable that you start preparing for REACH by enquiring of your suppliers whether they are going to pre-register and register and by discussing your uses, so that they can be covered by the registration. In addition, if you have information about substances, e.g. test data, you may want to contact the Chemicals Agency with a view to be part of the substance information exchange forum (for more details see the Guidance on data sharing).

1.1.2 What should you do when you receive a safety data sheet?

Under REACH, you will need to comply with the conditions described in the safety data sheet or the exposure scenarios attached to some of the safety data sheets. In addition, if your use is not covered or if it is a use advised against, you may need to develop your own chemical safety report.

1.1.3 Checking and implementing the exposure scenario

Some safety data sheets will have an exposure scenario attached; this is a new feature under REACH. It will depend on whether the substance is dangerous and the quantity produced by the manufacturer or importer who registers it. If you receive an exposure scenario with the safety data sheet, you need to check whether you comply with it. The key steps are set out in Table 1 below. You should note that, as well as complying with REACH, you must continue to comply with existing legislation to protect workers' health and the environment.

1.1.4 What should you do when you do not receive a safety data sheet?

If your substance does not have a safety data sheet, you still need to implement (and communicate down the supply chain) the risk management measures which are communicated to you by the supplier by other means.

Table 1 Checking the exposure scenario

1.	Read the description of use in the first part of the exposure scenario; this is informative. If the description of use is very different from the way you use the product, you should contact your supplier and discuss it.
2.	The exposure scenario will contain information on how the substance or preparation may be used. Compare that to how you use it. If you use the substance or preparation in a way that leads to higher exposure, for example if you use it more often, in larger amounts or in a different way than described, you may not comply with the exposure scenario and you should contact your supplier.
3.	Risk management measures are also specified in the exposure scenario. Compare these to how you protect workers, consumers or the environment. Decide if your measures are as, or even more, efficient than those recommended in the exposure scenario. You should also inform your supplier if you think the risk management measures he recommends are inappropriate.
4.	If your use of the substance or preparation differs from the exposure scenario, it may pose risks to your workers, consumers or the environment. You have a number of options, such as contacting your supplier and asking him to prepare an exposure scenario that fits your use conditions, changing your working practices, assessing in more detail if there is actually a risk or not or looking for less hazardous substances or preparations to use.

1.2 Companies producing preparations

If your company produces preparations, you have to provide safety data sheets under REACH, just as today. In developing these, you will have to include the relevant information contained in safety data sheet and exposure scenario you receive from your supplier. It is important that the information in the exposure scenarios is consistent with the safety data sheets. This is a new task, as you need not only to combine information on the hazards of substances and preparations for your safety data sheet, but also to combine and forward information to your customers on exposures and conditions of use.

1.3 Importers of substances, preparations or articles from outside the EU

Regardless of the type of commercial activity you carry out, you should check whether you purchase chemical substances or preparations (including e.g. cleaning agents, solvents and similar products) from outside the EU. If you are responsible for the physical introduction of substances or preparations into the EU, you have the role of an importer under REACH and you may have to register the substances. If you import articles, you may also have to fulfil requirements under REACH.

If you purchase from a supplier in another EU³ country, you are not an importer and do not have to register. If you purchase substances or preparations from a non-EU supplier who has an ‘only representative’⁴, you are a downstream user under REACH and you do not have to register.

³ Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The Netherlands, United Kingdom. Suppliers in Switzerland are not EU-suppliers. Suppliers in Norway, Iceland and Liechtenstein will be considered as EU-suppliers once these countries have implemented REACH.

⁴ Ask your non-EU suppliers if they have an only representative

2 ROLES AND OBLIGATIONS

This section sets out the main aspects of REACH which are relevant to downstream users. It describes the consequences of registration for downstream users and provides guidance to assist them to identify their roles and obligations under REACH.

An alternative way for downstream users to identify roles and obligations is to use the web based Navigator tool (http://echa.europa.eu/reach_en.html)

2.1 The main aspects of REACH relevant to downstream users

The most important elements of REACH for downstream users are set out in Title V of REACH (articles 37-39). They are:

1. If you use dangerous substances and preparations, you will still receive **safety data sheets**, which, under REACH, may have one or more exposure scenarios attached. An exposure scenario describes how a substance or preparation can be used safely and the risk management measures which should be applied to control risks to humans or the environment. If you receive an exposure scenario, you must check whether your current use is covered and whether you comply with the conditions described in that exposure scenario.
If you use a substance or preparation **outside the conditions described in the exposure scenario**, or if your use is not covered by the exposure scenario, you have several options:
 - you may make your use/use conditions known to your supplier so that the supplier can prepare an exposure scenario covering your use conditions
 - you may change your conditions of use so they comply with the supplier's exposure scenario,
 - you may find another supplier who provides an exposure scenario covering your conditions of use,
 - you may prepare your own chemical safety report⁵, or
 - you can find an alternative substance, preparation or process and stop using the substance/preparation in question.
2. If you **place dangerous preparations on the market** (formulator) you will still 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 preparations further down the supply chain and to attach them to the safety data sheet (article 31 of REACH).
3. **Communication along the supply chain** on the use of substances and preparations **will significantly increase under REACH**:
 - REACH increases the extent of information to be communicated to you by your suppliers to enable you to use chemicals safely. In addition, REACH requires you to communicate new information you may have on hazards and possible inadequacy of recommended risk management measures to your suppliers.
 - You will need to communicate upstream and downstream, e.g. when pro-actively identifying your uses to a supplier, or collecting information on customers' uses.

⁵ Unless any of the exemptions of articles 37(4) (a) to (f) applies to you

- You may also be asked to forward information, e.g. upstream when a customer has new information on substance properties or downstream when registrants seek information on the end-use of their substances.
- 4. **The use of some substances may be subject to an authorisation** requirement. This will be indicated by your supplier, usually in the safety data sheet. You may use the substance provided that the use is in accordance with the conditions of an authorisation granted to an actor up your supply chain. If your use is not covered by such an authorisation, and you want to continue this use, you will have to apply for an authorisation for your own use and, if relevant, for your customers' uses (article 56 of REACH).
- 5. **Some substances may be subject to restrictions** on their use, placing on the market or to bans (article 67 of REACH). Restrictions that were in place under the Marketing & Use Directive (76/769/EEC) are carried over in REACH.
- 6. If you **produce or import articles**, you may have to register substances which are intended to be released from the articles. This is not required if that use of the substance is already covered by a registration. If the article contains above 0.1% (w/w) of certain substances of high concern, you may have to notify the Chemicals Agency and inform your customers on safe use of the article, depending on the quantity of the substance used and whether exposure can be excluded (article 7 and 33 (1) of REACH). Consumers of articles can also request information about these substances (article 33 (2) of REACH).

This list is deliberately simplified to provide an overall understanding of REACH. Further and more detailed information on REACH as a whole can be found on the website of the Chemicals Agency (<http://echa.europa.eu>). The new obligations you face and how to fulfil them are discussed in detail in the later sections; in particular, chapter 3 gives guidance on how to prepare for your obligations under REACH.

Most of the current legal requirements that apply to your use of substances and preparations, for instance those related to the protection of workers, consumers and the environment, will continue to apply alongside REACH⁶.

2.2 Consequences of registration for downstream users

You are not required to register the substances that you use, but the registration of these substances by their manufacturers and importers will affect you in a number of ways:

- Substances which are not registered will no longer be available on the EU market.
- The classification and labelling of some substances may change and, if you are a formulator using such substances, you will need to review the classification of your products and their safety data sheets accordingly.
- Safety data sheets will also be updated or extended with information generated through the registration process. If you receive an exposure scenario attached to a safety data sheet, this will trigger additional obligations for you.

2.3 Registration deadlines for manufacturers and importers

Manufacturers/importers of substances will begin to register substances manufactured or imported in

⁶ For a period of five years initially, the obligation to register does not apply to a substance manufactured or imported for the purposes of **product and process oriented research and development** by a manufacturer/importer or producer of articles. In such cases, the manufacturer/importer or article producer must notify the Agency. Further information on this is provided in the Guidance on registration.

quantities of 1 tonne or more per year and per manufacturer/importer, starting from 1 June 2008. Substances notified under Directive 67/548/EEC, which can be recognised by their ELINCS number, are regarded as already registered⁷ under REACH.

REACH allows manufacturers/importers to register most substances later, between 2010 and 2018, if they have pre-registered them. When pre-registering, they provide the Chemicals Agency with the substance name and the envisaged deadline for registration. The pre-registration period starts on 1 June 2008 and ends on 1 December 2008.

The pre-registration process applies to the following substances, known as 'phase-in substances':

- All EINECS substances (excluding polymers) (approximately 100,000 substances were notified to the inventory of substances in the EU market in 1981 but only about 30,000 of these are on the market above 1 tonne per year).
- All substances which have been manufactured in the EU (including the new member states) but have **not** been placed on the EU market since June 1st, 1992 – this means they have been produced only for export purposes. Documentation has to be available to show this.
- "No Longer Polymers" notified under Directive 67/548⁸

Substances that are not phase-in substances must be registered as of 1 June 2008, before they can be further manufactured, imported or placed on the market. Substances that are phase-in substances must be pre-registered between 1 June 2008 and 1 December 2008, in order to benefit from the delayed deadlines for registration according to Article 23 of REACH⁹.

The deadlines for the registration of phase-in substances that have been pre-registered depend on their volumes and classification. The tonnage thresholds relate to the total quantity of a substance manufactured or imported by an individual manufacturer or importer per year.

The deadlines are as follows:

- **30 November 2010**
 - substances produced/imported in volumes of 1000 tonnes per year or more;
 - known CMR substances (category 1 and 2) in volumes of 1 tonne per year or more
 - substances classified as R50/53 in volumes of 100 tonnes per year or more
- **31 May 2013:** for all other substances manufactured/imported in volumes of 100 tonnes per year or more

⁷ Manufacturers/importers may have to submit additional information if tonnage thresholds are exceeded. Active substances for use in biocides and plant protection products are also regarded as already registered.

⁸ Polymers were subject to special rules within Directive 67/548/EEC. The term "polymer" was further defined in the 7th amendment of Directive 67/548/EEC (Directive 92/32/EEC). As a consequence some substances which were considered to be polymers under the reporting rules for EINECS were no longer considered to be polymers under the 7th amendment. The Council of Ministers made it clear that these no-longer polymers should not, retrospectively, become subject to notification.

⁹ If a company fails (or does not wish) to pre-register on time, it will have to suspend its activities involving the substances concerned and register them without delay. All manufacturing and placing on the market of such substances between the start of the pre-registration deadline and the date of suspension of activities may be subject to penalties according to national law. This also means that the downstream uses of these substances may be at risk. Activities involving the substances concerned can then only be resumed three weeks after the submission date of the a complete registration dossier.

- **31 May 2018:** for all other substances manufactured/imported in volumes of 1 tonnes per year or more

2.4 Registration and downstream users

It is advisable that you contact your suppliers before pre-registration ends to make sure they will pre-register the substances that you are using. By 1 January 2009, the Chemicals Agency will publish a list of pre-registered substances on its website. There you can find out if and when a substance you use, as such or in preparations, is intended to be registered. If a substance you use is not on the list, you can express your interest in the substance to the Chemicals Agency (see chapter 3 of this guidance). The Chemicals Agency will then publish on its website the name of the substance¹⁰. On request from a potential registrant, the Agency will provide him with your contact details.

Note: as a downstream user, you are not required by REACH to register substances, unless you act as a manufacturer or importer of a substance as such or in a preparation, or a producer or importer of substances present in articles and intended to be released, in quantities of one tonne per year or more.

In parallel to REACH, the Globally Harmonised System for classification and labelling of substances and preparations will be implemented in the EU. This will replace the classification and labelling provisions of the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC). Guidance on the Globally Harmonised System will be developed separately and is not included in this guidance.

¹⁰ Any entity that manufactures or imports for the first time a phase-in substance may register in accordance with the extended registration deadlines of Article 23, even if it did not pre-register before 1 December 2008, provided it submits the information to the Agency within six months of manufacturing or importing the substance for the first time and no later than 12 months before the relevant registration deadline of Article 23 (Article 28.6 of REACH). If a downstream user decides to do so, he becomes a manufacturer or importer.

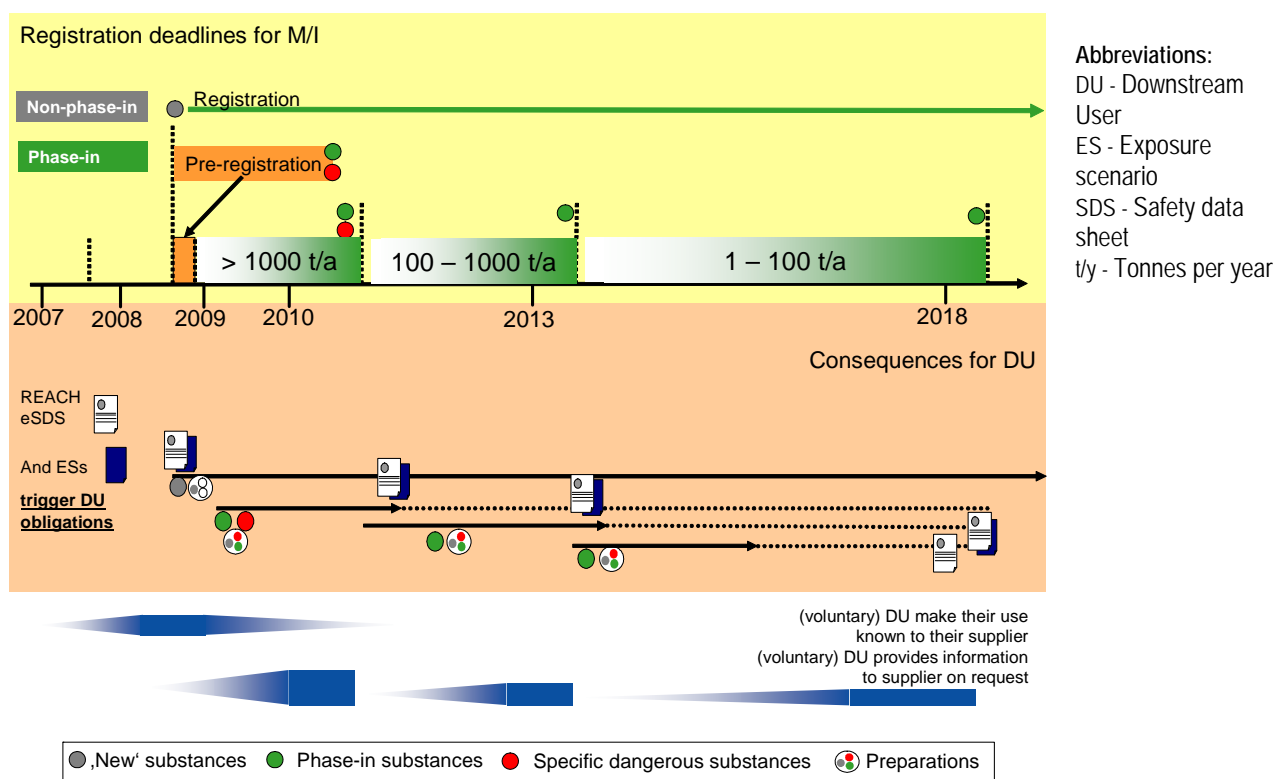


Figure 2-1 Registration deadlines and consequences for downstream users

Before registration, you may provide your suppliers with information about your uses and the conditions under which you are using the substance, including risk management measures, to allow these to be covered in the dossier your supplier will have to provide for registration. Whilst this is not mandatory, if the supplier covers your use it can significantly help you to fulfil your obligations. In addition, you can expect questions from your suppliers about your uses. More details on preparing for REACH are given in chapter 3 of this guidance.

2.5 Identification of roles and obligations

2.5.1 Who is a downstream user under REACH and how can I identify my roles?

A downstream user is defined by REACH as someone¹¹, other than a manufacturer or importer “who uses a substance, either on its own or in a preparation¹², in the course of his industrial or professional activities” (article 3(13) of REACH)

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 preparation or in an article. The following tables provide questions to assist you to identify of your role(s) under REACH. For each of your roles, you can then identify your obligations using Table 5 which directs you to the relevant chapters of this guidance.

Keep in mind that the requirements under REACH apply to you in relation to the individual

¹¹ Any natural or legal person established within the Community

¹² A preparation is a mixture (solid, liquid or gas) composed of two or more substances

substances that you use. Therefore, you may have more than one role and you should follow all the tables to the end in order to identify all of your roles. The starting points for identifying your roles are your activities and the information you receive from your suppliers. Firstly, it is important to check whether you are also a manufacturer or importer, as described below.

2.5.2 Identification of manufacturer/importer roles

This guidance is addressed to downstream users as defined by REACH. However, you may also have manufacturer/importer roles. The table below will assist you to identify whether you also act as a manufacturer or importer of substances. If so, you may have obligations to register substances and you will need to refer to other guidance documents to explain these.

Some substances are exempted from the scope of REACH altogether, some are excluded from specific Titles (including registration). The navigator tool on the Chemicals Agency's guidance website, and the Guidance on registration, will assist you to determine whether your substance is included or excluded from REACH (http://echa.europa.eu/reach_en.html).

Polymers are subject to specific rules. Separate guidance on this is provided in the [Guidance for polymers](#).

Table 2 Identification of roles – manufacturers/importers of substances as such, in preparations or articles

Question	Role	Supporting information, examples
Do you manufacture substances by synthesis, refining or extraction? This includes new substances created while making preparations	Manufacturer of substances, either on its own or in one or more preparation(s). See the Guidance on registration	The formation of ‘new substances’ during the normal use of a substance or preparation is, in principle, exempted from the registration requirement e.g. a substance resulting from a chemical reaction occurring upon use of other substances. ¹³ <i>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.</i> <i>But if you produce calcium sulphate, for example, 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).</i>
Do you import substances or preparations from outside the EU?	Importer of substances as such or in preparations See the Guidance on registration	Substances as such or substances contained in preparations are imported if you purchase them from a manufacturer or distributor who is located outside the EU. Countries belonging to the EEA will implement REACH in their national legislation; once they have done so, substances purchased from those countries will not be regarded as imports under REACH. If you import a polymer, you will need to check whether you have to register monomers or other substances in the polymer.
Do you import articles?	Importer of substances in articles See the Guidance for 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 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 the Agency. For more detailed guidance see the guidance document on requirements for substances in articles

Note: Non-EU manufacturers can appoint an only representative inside the EU, who is responsible for registration and communication on the substances, as such or in preparations.

2.5.3. Identification of downstream user roles

Two main downstream user roles can be distinguished: the formulator of preparations and the final user of substances as such or in preparations. There are also a number of other downstream user roles. The following table subdivides the role of end-user to make it easier for you to identify your roles and to better guide you to the relevant chapters of this guidance document explaining how to fulfill your obligations. To do this, the table includes descriptions of roles that are not included within the definitions set out in REACH.

¹³ This is called ‘reaction upon use’ and it is exempted under Annex V.

Table 3 Identification of roles – downstream user of substances as such or in preparations (all the roles identified in the table below are downstream users under REACH)

Question	Downstream user role	Supporting information, examples
Do you mix substances and/or preparations to make preparations to place on the market?	Formulator: actor producing preparations.	<p>If you only mix substances and/or preparations to make preparations, 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. However, mixing an acid and a base which results in a new substance (salt) is considered as manufacture.</p> <p>You may be contracted to make a preparation by a third party, who owns the formulation and places it on the market. When making a preparation, you are considered a downstream user. An example is a formulator of a detergent sold under a retailer's own brand¹⁴</p> <p>Your customers/recipients may also be producers of preparations if they use your preparations to make other preparations (e.g. if you supply a solution of an additive or a pigment paste).</p> <p>Your customers/recipients may be commercial actors or consumers, or may use your preparations to manufacture articles or apply them in other end-uses. This means that, once your customers have applied your preparation, 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.</p>
Do you use substances and preparations in the context of an industrial process or a professional activity, which you do not forward, as such or in a preparation to another actor?	End-user: actor using substances or preparations in an industrial or professional activity (e.g. not a consumer or a distributor) who does not supply it further downstream	<p>When you use a substance or preparation, it is either incorporated into an article or is consumed in the activity. You do not forward any substance or preparation to another actor.</p>
Do you use substances/preparations as processing aids in the context of an industrial	Industrial User: end user using substances/preparations which do not remain in the product (e.g.	<p>If the substance(s) as such or in a preparation do not form a part of the product you use, but facilitate the processing or are 'washed off' after the production is finished, you use them solely as processing aid. There may be incidental</p>

¹⁴ An actor ("contractor") 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 2). 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 Table 5). Sub-contractors performing the role of distributors under REACH must comply with the distributor obligations (see Table 4). The contractor 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	Downstream user role	Supporting information, examples
process?	is applied as a processing aid) in the context of an industrial process.	contamination of any articles produced by the substance(s), but this is not intended. Examples of industrial users are users of surface cleaners prior to electroplating or users of lubricants for chainsaws.
Do you incorporate substances / preparations into articles in the context of an industrial process or a professional activity?	Article Producer: end-user incorporating substances / preparations into articles, by which they become an integral part of such articles For obligations as an article producer see the Guidance for articles	Incorporation of a substance as such or in a preparation into an article means a) inclusion into the article matrix, e.g. dyeing of textile fibres or b) application onto the article's surface, e.g. lacquering of steel.
Do you use substances and preparations in the context of professional activities other than industrial use?	Craftsman, workshop, professional service provider: end-user using substances or preparations in the context of a 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. These users might not have specific expertise regarding dangerous substances or preparations. Examples of such users are flooring contractors, mobile cleaning companies, professional painters, construction companies.
Other downstream user roles		
Do you re-fill substances or preparations from one container to another?	Re-filler: actor who transfers substances or preparations from one container to another.	The transfer of substances or preparations 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 preparations in any other activity. A re-brander that applies a new brand while refilling, is also a downstream user ¹⁵ .
Do you import substances or preparations from a manufacturer or distributor outside the EU, who has an only representative in the EU?	Importer where supplier has an only representative: 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' ¹⁶ , 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'.
Have you evidence that a substance / preparation that you import from non-EU suppliers has been	Re-importer of substances: an actor who imports substances, as such or in preparations, which have	Can you prove that the substance as such or in an imported preparation has originally been produced and registered in the EU? You will need to have documentation showing that the substance is identical to

¹⁵ A re-brander is an actor who affixes his brand on a product that he has not manufactured. Affixing a brand to a product does not trigger the obligation to register, which applies to manufacturers and importers under REACH. If the operator only affixes his brand, he is a distributor under REACH and consequently has the obligation to transmit information down the supply chain. If, besides affixing his brand, he "uses" the product, as understood under REACH, e.g. by transferring the substance from one container to the other, he is a downstream user and has further obligations.

¹⁶ 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, preparations or articles) to fulfil the obligations as importer under REACH.

Question	Downstream user role	Supporting information, examples
originally produced and registered in the EU?	originally been produced in the EU. In terms of REACH, you will be considered a downstream user if you can prove that the substance was registered in the EU by you or someone in the same supply chain..	that registered in the EU by you or someone in your supply chain ¹⁷ . Furthermore, in order to avoid having to register the re-imported substance, you need to have available a safety data sheet, or similar information for a non-dangerous substance or preparation (Article 2.7).

2.5.4 Other roles under REACH

A number of other actors in the supply chain have obligations under REACH. The following table will assist you in identifying these roles.

Table 4 Identification of roles – roles other than downstream user or manufacturer/importer

Question	Role	Supporting information, examples
Do you obtain substances, preparations or articles from EU suppliers and make them available (e.g. sell) to actors who use these in commercial activities? Do you store substances and/or preparations for other actors and give them back to these actors, as a storage-provider?	Distributor: actor who stores and places on the market substances, preparations and articles inside the EU and makes available to third parties without further processing You are not a downstream user, but have obligations under REACH Go to chapter 15 of this guidance first	To be a distributor as defined by REACH, you can only store and make substances and preparations 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 2 will apply.
Do you make substances, preparations or articles available (e.g. sell) to consumers?	Retailer: actor who stores and places on the market substances, preparations or articles to final consumers and/or professional users in retail stores. You are not a downstream user, but have obligations under REACH Go to chapter 15 of this guidance first	Retailers are a sub-group of distributors. If you undertake an activity with the substance defined as "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 2 will apply.

¹⁷ 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. You can then obtain the safety data sheet or other information (Article 32 of REACH) supplied with it, from the original registrant.

2.5.5. Overview of the possible obligations

Table 5 Identification of the possible obligations related to different roles¹⁸

Roles	Obligations	Chapter
Obligations of downstream users and distributors (including retailers and storage providers)	Identify roles and obligations	2
	Inform suppliers of any new information on hazards, including classification and labelling	10
	Communicate information that might call into question the appropriateness of the risk management measures in any exposure scenario received	11
	Distributors shall pass on relevant exposure scenarios and use the relevant information in the safety data sheet received when compiling your own safety data sheet. Furthermore distributors shall provide customers with the information that is supplied to him in accordance with Article 32 of REACH regulation. Downstream users that supply substances or preparations have additional obligations, as described below.	4, 15
Additional obligations for downstream users (formulators, end-users, refillers)	Identify and apply appropriate measures to control the risks communicated in safety data sheet or other information supplied with non-dangerous substances or preparations	4
	Check compliance with an exposure scenario, if you receive one from your supplier, and take further action in case of non-compliance	5,6
	For substances subject to authorisation, comply with the conditions of the authorisation covering your use. You may need to apply for an authorisation if your use is not covered by an authorisation granted to a supplier and you want to continue this use.	12
	Check compliance with any restrictions on the substance	13
Additional obligations for formulators and re-fillers only	Provide information to your customers and to retailers / consumers to enable safe use of substances or preparations Downstream users that supply substances or preparations 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.	14
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).	Guidance for articles
Additional obligations for distributors only	Forward requests to make a use an identified use to the next actor or distributor up the supply chain.	15
Obligations of Re-importer	Document that substance(s) are identical to those registered in the EU by you or someone in your supply chain. Have documentation according to Article 31 (safety data sheet and exposure scenario where applicable) or Article 32 of REACH	

¹⁸ Although REACH only distinguishes between manufacturers/importers, distributors and downstream users, there are obligations that apply only to specific types of downstream users/distributors. This depends on the role in the supply chain and activity carried out. This table combines various types of supply chain roles with their obligations, in order to facilitate identification of the relevant guidance section.

3 PREPARING FOR REACH

This section sets out voluntary actions that are recommended for downstream users to prepare for REACH. It covers:

- *The benefits of preparing early for REACH*
- *What may happen if you do not prepare*
- *The information needed to prepare*
- *Understanding the substances you use and how you use them, so you can communicate appropriately*
- *What and how to communicate to suppliers and how to prioritise communication*

3.1 Introduction

REACH will apply to most of the substances that you use today. As REACH is implemented, you will only be able to continue to use these substances if the manufacturer or importer registers them. This applies both to the substances you use on their own and to those you use in preparations or in articles. For certain substances, a chemical safety report needs to be compiled and, for the uses that are identified, suppliers must communicate specific information on the safe use of the substance to downstream users¹⁹.

Registration of phase-in substances under REACH will have to take place from 2010 to 2018, provided the substances are pre-registered²⁰. Manufacturers and importers of substances, though, will begin to decide at an early stage whether to register their substances and what uses to include in the registration. Many have already begun this process. You are advised to start preparing and communicating with your suppliers and customers as soon as possible. By preparing early for REACH, you will ensure that you, as a downstream user, become aware of any potential problems with the future supply of your substances or of tasks that you need to carry out under REACH.

REACH relies on communication along the supply chain. Your suppliers may seek information from you to help them to prepare for their registration. If you are also a supplier (of a substance, preparation or article) to further recipients, your customers may also seek information from you about REACH and whether or not the supply can be ensured in the future. Early communication of your uses with your suppliers will help your suppliers to include your uses in their registration.

This section aims to help you to prepare for REACH, by identifying and prioritising your in-house preparation and communication needs. Key dates in preparing for REACH are summarised in Table 3.1.

¹⁹ A Chemical Safety Report needs to be prepared for all substances subject to registration in quantities of 10 tonnes or more per year per registrant. For substances classified as dangerous, or which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), the chemical safety report shall include exposure scenarios according to REACH Annex I.

²⁰ For more details about this see chapter 2 of this guidance

Table 6 Key dates in preparing for REACH ²¹

Date	Activity	Downstream user
From 1 June 2007	Suppliers must provide a safety data sheet compiled in accordance with Annex II of REACH ²² , which may include an exposure scenario. Suppliers must update their safety data sheets as soon as new information on risk management measures or on hazards becomes available to the suppliers.	You will need to identify, apply, and if you are supplying, recommend measures to control risks. If exposure scenarios are attached your use conditions should be according to the conditions described. If not, you must decide what action to take (see section 3.3). Downstream users must apply the appropriate conditions in the safety data sheet within 12 month after receiving the registration number of a substance.
From 1 June 2008	Manufacturers and importers must register non phase-in substances or not pre-registered phase-in substances	Contact suppliers before this date to ask whether substances that you use are phase-in substances and will be pre-registered (see section 3.4)
Deadline 1 December 2008	Manufacturers and importers to complete pre-registration of phase-in substances	Contact suppliers to check whether phase-in substances that you use have been pre-registered (see section 3.3 and 2.3)
1 January 2009	The Chemicals Agency will publish a list of pre-registered substances on its web site.	Check whether substances that you use are included on the list. If not, you may inform the Chemicals Agency of your interest in the substance (see section 3.3)
From 1 January 2009	All potential registrants who have pre-registered will become part of a Substance Information Exchange Forum	You may participate in a forum for a substance you use, if you wish to contribute data for the purpose of registration (see the Guidance on data sharing).
1 June 2009	The Chemicals Agency will make its first recommendations for substances to be included in Annex XIV. The candidate list will be available before this date, probably in the second half of 2008.	Check the list to see if you use any of the substances on the list. If so, contact your supplier as a priority (see section 3.6)
Deadline 30	Substances produced/imported in	Contact suppliers of any such

²¹ A graphical presentation is provided at the end of this chapter.

²² Where no safety data sheet is required (see article 31 of REACH), the supplier must provide the registration number(s) of the substance(s), indicate whether the substance is subject to authorisation or any restriction and any other available and relevant information to enable risk management measures to be applied (see article 32 of REACH)

Date	Activity	Downstream user
November 2010	volumes over 1000 t/y, CMR category 1 and 2 substances in amounts of 1 t/y or more, and substances classified as R50/53 in amounts of 100 t/y or more must be registered by their manufacturers/importers	substances that you use, as a priority, to make sure that they are aware of your use and are able to include it in their registration dossier (see section 3.6)
From 1 June 2011	Producers or importers of articles must notify the Chemicals Agency if an article contains a substance identified according to Article 59.1 above a concentration of 0.1%	Notify the Agency if you produce an article containing more than 0.1% of a substance which is on the candidate list and which has not been registered for that use, and the quantity of substance is over 1 tonne per year
Deadline 31 May 2013	All other substances produced/imported in amounts of 100 tonnes per year or more must be registered by manufacturers/importers	Contact suppliers of any such substances that you use, to make sure that they are aware of your use and able to include it in their registration dossier (see section 3.6)
By first delivery after 1 June 2013 of a substance to be registered by 2013	Manufacturers/importers must provide a revised safety data sheet, which may include an exposure scenario	Check that your use of the substance is included. If not, you must decide what action to take (see section 3.3)
Deadline 31 May 2018	All other substances produced/imported in amounts of 1 tonnes per year or more must be registered by manufacturers/importers	Contact suppliers of any such substances that you use, to make sure that they are aware of your use and able to include it in their registration (see section 3.6)
By first delivery after 1 June 2018 of a substance to be registered by 2018	Manufacturers/importers must provide a revised safety data sheet, which may include an exposure scenario	Check that your use of the substance is included. If not, you must decide what action to take (see section 3.3)

3.2 The benefits of preparing early

3.2.1 What are the benefits of contacting suppliers early?

If you contact your suppliers early, they may be able tell you whether or not they plan to register the substance, whether a chemical safety report will be required and whether your use²³ will be included. Knowing this will help you to prepare more effectively for REACH and to plan for any changes that you may need to make to your use of substances.

²³ Under REACH, ‘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”. Therefore a “use” refers not only to process conditions and how the substance is handled, but also to the applications for which it is utilised (for example ‘screen printing with UV curable inks’).

Contacting suppliers before they have made a decision on registration can help to ensure that the registration takes proper account of the applications for which you use the substance, your conditions of use (such as how much of the substance you use and for how long each day) and risk management measures (e.g. local exhaust ventilation, wearing of protective equipment such as gloves). Provided the supplier considers that these are safe, this may avoid a situation where the exposure scenario specifies conditions of use or risk management measures that are costly or impractical for your process or which do not cover your use, so that you may have to prepare your own chemical safety report. Under REACH, you may choose to provide information to assist in the preparation of a registration (article 37(1)). You may also request (article 37(2)) that a use becomes an identified use, which will involve providing your supplier with the relevant safety information ([see chapter 8 of this guidance – Requesting that a use becomes identified](#)).

3.2.2 What are the benefits of early contact with customers?

Under REACH, your customers also have the right to make their use known. It may be difficult for them to adapt to use conditions specified in an exposure scenario attached to the safety data sheet within the required 12 month period (article 37.5, article 39 of REACH), especially if changes to the process or substitution of the substance are needed. If you make early contact with your customers, and encourage them to make their use an identified use, this can help to ensure that their uses are also taken into account in registration, maintaining important markets for your products.

Guidance on the type of information your customers may need to provide to ensure that their use becomes identified is given [in chapter 9 of this guidance](#).

3.3 The consequences of failing to prepare for REACH

Failing to prepare for REACH could mean that the substances you use, on their own or in preparations, are not registered or that your use is not covered in the supplier's registration dossier or exposure scenario.

3.3.1 What happens if a substance is not registered?

If a substance is not registered under REACH, it cannot be manufactured, imported or supplied to the EU market at or above 1 tonne per year. You cannot continue to use it, unless it is specifically exempted from registration (see chapter 2 of this guidance). If you find that a substance you use is not on the list of pre-registered substances, you can express your interest in the substance to the Chemicals Agency. The Agency will then publish on its website the name of the substance²⁴. On request from a potential registrant, the Chemicals Agency will provide him with your contact details.

3.3.2 What happens if a substance is registered, but the exposure scenario does not cover my use?

If a substance is registered, but the exposure scenario does not cover your use, you may need to:

²⁴ Any entity that manufactures or imports for the first time a phase-in substance may register in accordance with the extended registration deadlines of article 23 of REACH, even if it did not pre-register before 1 December 2008, provided it submits the information to the Chemicals Agency within six months of manufacturing or importing the substance for the first time and no later than 12 months before the relevant registration deadline of article 23 (article 28.6). If downstream user decides to do so, he takes over the role of a manufacturer or importer.

- make your use known to your supplier, with the aim of obtaining an exposure scenario covering your use;
- change your conditions of use to comply with your supplier's exposure scenario;
- find a supplier who provides an exposure scenario covering your use;
- prepare your own chemical safety report (see chapter 7 of this guidance); or
- find an alternative substance or process, and stop using the substance in question.

All of these changes could take time, and may involve significant costs. For this reason, it is important to begin preparing as soon as possible. Waiting until your suppliers have made their decisions, and supplied you with a new safety data sheet or other information, could leave you with only 12 months to comply.

3.3.3 What are the implications of authorisation?

Authorisation obligations only start after a substance is put on the candidate list as a substance of very high concern. If a substance requires authorisation, you can only continue to use it if the authorisation covers your use. An application for authorisation can be made by you or your supplier, or jointly. If the application for authorisation is not successful, you must stop using the substance by a specified date (the 'sunset date'). For more information, see chapter 2 of this guidance.

3.4 The information needed

3.4.1 What information do I need and how can I prepare for this?

Manufacturers and importers may seek information from you to prepare their registrations and to develop exposure scenarios. Early communication with your supplier is advisable, because otherwise the supplier may be unable to include your use correctly in his registration. This could mean that the safety data sheet and exposure scenario where provided, are not appropriate for you. Guidance on the type of information to be provided is given in chapters 8 and 9 of this guidance.

Initial requests for information may be made through industry associations, with more detailed information only sought from individual downstream users later, if needed. (If you are not a member of an association, it may be even more important for you to contact your supplier directly). Detailed requests for information from suppliers may be accompanied by a tailored questionnaire. Appendix 1 of this guidance sets out the types of information required to prepare an exposure scenario.

3.4.2 What about confidential business information?

You may be concerned that providing information to suppliers may risk the loss of confidential business information. There are a number of ways to overcome this problem. One is to use a general description of conditions of use and risk management measures in your sector. This is described further in [chapter 8](#) of this guidance – Requesting that a use becomes an identified use. Another is to prepare your own chemical safety report; guidance on this is given in [chapter 7](#) of this guidance. This requires considerable effort, so it is advisable to contact suppliers at an early stage to determine whether or not it is likely to be necessary.

3.5 Understanding which substances you use and how you use them

Preparing for REACH involves:

- understanding the substances that you use, how and what they are used for and where they are sourced from;
- gathering the available information that might be needed;
- deciding who to contact, when and how; and
- making contact and deciding on your future course of action.

3.5.1 Understanding the substances you use

Substances that need to be registered under REACH may be present in a wide variety of products that you purchase. This includes substances, on their own and in preparations, which are used in your manufacturing process as well as those with other uses, such as cleaning or office use.

You may not have full information on the substances contained within the preparations and articles that you use. For example, the composition of preparations may be withheld from safety data sheets by your suppliers, on the grounds of confidentiality, and labels on articles may include only limited information on the substances intended to be released. In these cases, early contact with your suppliers may be even more important, to ensure that the substances contained within the preparation or article are registered for your use.

3.5.2 Sources of information

The first step is to gather available information on the substances and preparations you use, how you use them and who supplies them. Information may be available from a number of different sources within your company. This could include:

- inventories of the chemicals that you use, gathered to meet the requirements of the Chemical Agents Directive or as part of your environmental management system;
- procurement databases;
- safety data sheets supplied with substances and preparations, technical data sheets provided by suppliers and labels on packaging;
- risk assessments and other information prepared for workers' health protection;
- information held by your transport department to comply with transport regulations;
- environmental permits.

It may be helpful to set up a team or working group, including people from different departments, to bring together the information required. This could include people responsible for purchasing, manufacturing, operations, warehousing, transport and sales as well as technical, safety and environmental experts.

3.5.3 Gathering the data together

You may find it useful to compile a list of all the substances and preparations that you use, together with information on the supplier and how you use the substance or preparation. Table 7 (at the end of this chapter) gives an example of how you might bring this information together. Staff from different departments in your company could be asked to review the list, to make sure that it is comprehensive. As the various obligations in REACH start applying, such an inventory could also help you to keep track of what substances have been registered, which have an exposure scenario and which are subject to restrictions or authorisation.

You should also consider your products. If you make preparations that are placed on the market,

you have specific obligations under REACH (see chapter 14 of this guidance). You may therefore wish to go further and prepare an inventory of the individual substances contained within the preparations that you use. Table 8 (at the end of this chapter) gives an example of the types of information you could begin to gather on the substances you have identified.

If you produce articles containing substances that are intended to be released (or substances on the candidate list for authorisation present in concentrations over 0.1% by weight, in volumes of 1 tonne per year or more), you may also have obligations under REACH. These are described further in the [Guidance for articles](#). You may, therefore, wish to prepare an inventory of such substances.

3.6 Communicating information to suppliers

When next contacting your suppliers, you should ask whether they plan to pre-register and register all the substances you use for your uses, including those in the preparations you receive. You may wish to provide brief descriptions of your use and conditions of use to all of your suppliers. If you use a number of substances and preparations in similar ways, this information can be sent to all relevant suppliers. If your supplier is a distributor, he must pass the information to the next actor up the supply chain. If he is another downstream user, he may pass the information to the next actor up the supply chain or he may prepare an exposure scenario for your use.

If you use a large number of substances in different uses or under different conditions (e.g. you are a formulator), it may not be feasible to contact all of your suppliers at once. You may wish to focus your resources first on the most important substances.

An overview of factors that might lead you to prioritise a substance for communication is given in the following work flow.

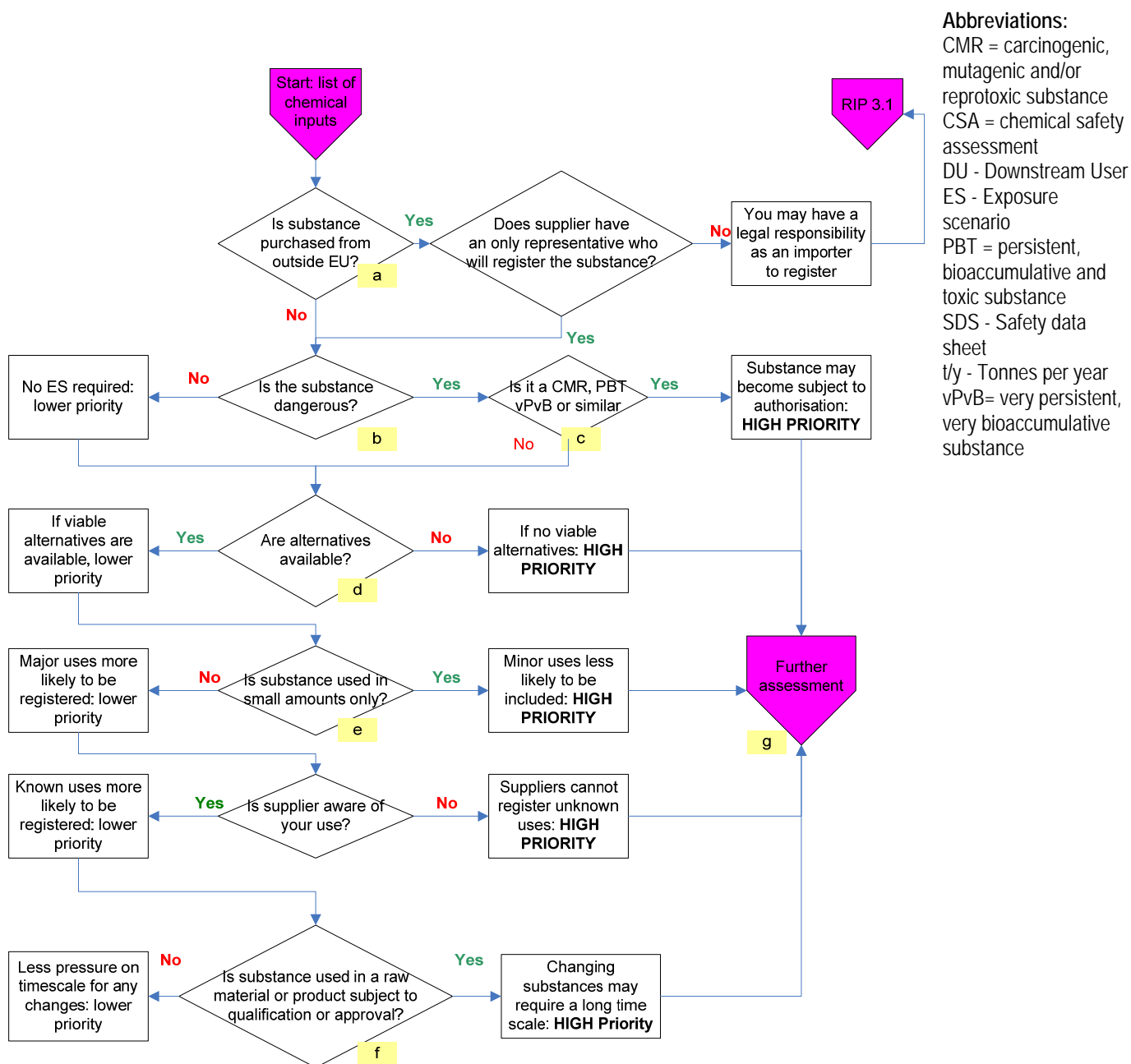


Figure 3-1 Workflow triggers for prioritising communication

Note a - Imported substances / preparations

Substances imported from outside the EU or EEA²⁵, in amounts of 1 tonne per year or more per importer, either on their own or in preparations, must be registered (see chapter 2 of this guidance).

²⁵ The European Economic Area includes the 27 EU Member States plus Iceland, Liechtenstein and Norway. Iceland, Norway and Liechtenstein plan to implement REACH and, when they have done so, substances from these countries will not be treated as imports for the purposes of REACH

Substances imported in articles in amounts of 1 tonne per year or more per importer, and which are intended to be released, also need to be registered (unless they have already been registered for that use by anyone).

If you import the substance directly, registration will be your responsibility, unless the non EU manufacturer has appointed an only representative in the EU who will register it (see chapter 2 of this guidance – Roles and obligations).

If you import polymers, including polymers in preparations, you may have to register the monomers or monomer units, as well as other substances contained in them. You should therefore include polymers imported as such or in preparations in your inventory.

Note b – Dangerous substances

If a registrant manufactures or imports a substance in amounts of 10 tonnes or more per year, he will have to carry out a chemical safety assessment. If it is a dangerous substance (or a PBT or vPvB – see note c) he will also have to prepare an exposure scenario, which will require more information on downstream uses. Early contact with your supplier will help to establish what information will be needed to include your use in his exposure scenario.

Note c – Substances of very high concern (SVHC)

Substances of very high concern include those classified as Category 1 and 2 carcinogens, mutagens and toxic to reproduction (CMRs category 1 and 2); those that are persistent, bioaccumulative and toxic (PBTs); those that are very persistent and very bioaccumulative (vPvBs) and those of equivalent concern to all the previous. Such substances may be subject to authorisation (see chapter 12 of this guidance – compliance with authorisation). The Chemicals Agency will make its first recommendations for substances to be included in Annex XIV by 1 June 2009. The candidate list will be available before this date, probably in the second half of 2008.

It is the manufacturer/importer's responsibility to determine if a substance meets the criteria for substances of very high concern. The existing safety data sheet should indicate if a substance is a CMR, but it may not be possible for you to determine whether a substance is a PBT or vPvB. If the substance is classified as R50/53, this may be an indication. From 1 June 2007, PBT and vPvB substances will be listed in Section 3 of safety data sheets; however, this will only apply to non-phase in substances or once substances are registered and a new safety data sheet has been issued.

Note d – Availability of alternatives

If there are no alternatives to a substance, or if any alternatives have a higher price or lower performance or would require changes to your process or product, it is particularly important for you to know as soon as possible whether or not the substance will be registered for your use.

Note e – Substance used in small amounts

Some downstream users are concerned that substances which they use in small quantities may be of low value to their manufacturers/importers, who could therefore decide not to register them. In many cases, though, there are other, larger, markets for the same substance which make it important to the supplier's business. In addition, if your substance is only manufactured or imported in lower quantities (below 1 tonne per manufacturer or importer) it is not subject to registration.

You should note that you are not required to prepare a downstream user chemical safety report, even when your use is outside the exposure scenario, if you use less than 1 tonne per year of the substance or preparation.

Note f – Substance in a raw material or product subject to qualification/approval

A change to a substance that you use may trigger a qualification/approval process, either through a legal requirement concerning its use as a raw material (for example, use in a cosmetic product of ingredients subject to a positive list) or because your customers require it for the products that you sell to them (for example, coatings used in the aerospace sector). If this is the case, you need to know as soon as possible if there will be any changes to the availability of these substances.

Note g – Further assessment

Once you have identified substances of high importance to you, you can then decide what action is most appropriate. This might include:

- Contacting your supplier to find out whether he plans to pre-register and register/apply for authorisation of the substance and to include your use in his exposure scenario. You could also contact all suppliers, using the use description system in the [Guidance on the Chemical Safety Report](#). You can then follow-up with more detailed information if needed;
- Making a formal request that your supplier includes you in his registration or application for authorisation, if he does not plan to do so (see chapter 8 of this guidance). For this, you must provide sufficient information on your use and conditions of use. You could also try to identify alternative suppliers who plan to include your use;
- If you wish your use to remain confidential, you could contact your industry association (if you are a member of one) to identify whether it is preparing generic information for suppliers that may include your use, or you could develop your own general description. Finally, you could consider preparing a downstream user chemical safety report; see chapter 7 of this guidance;
- Examining the options for substitution of the substance with one that is less dangerous and will be registered for your use by your supplier;
- Contacting customers to obtain additional or more detailed information on their uses; see [chapter 9](#) of this guidance.

Table 7 Listing chemical inputs (substances and preparations) used

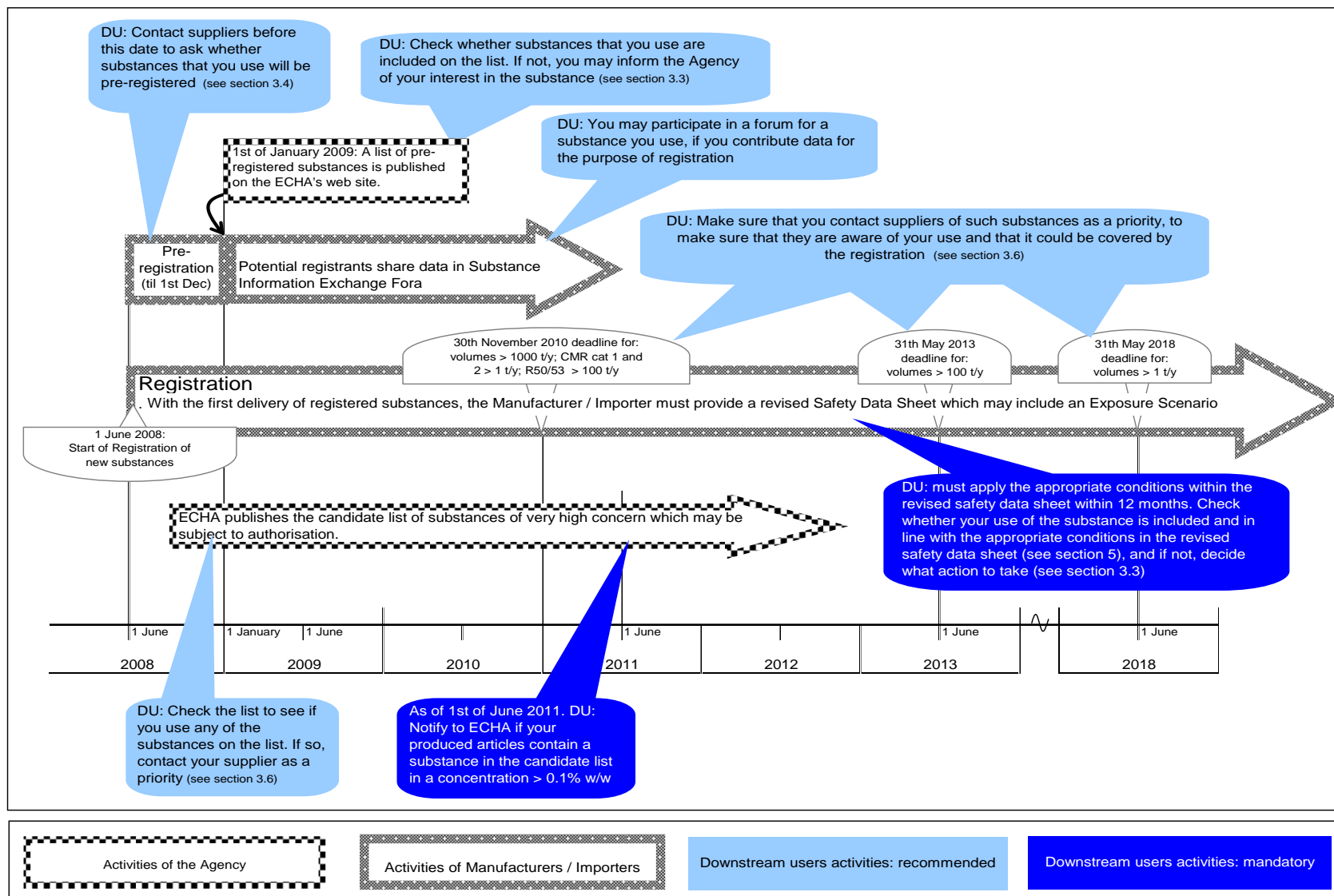
Name of input	Substance or preparation?	CAS/EINECS number (if known)	Classification (if known)	Supplier name	Is supplier outside EU? ¹	Use ²

1. If supplier is outside EU, you may have obligations as an importer
2. A standard descriptor system for uses is available in the [Guidance on the Chemical Safety Report](#).

Table 8 Example of a substance inventory

Name	CAS/ EINECS number	Properties		Supplier information		Use (amount and purpose)				Priority for communication ? (see flow chart)
		Classification (according to Directive 67/548/EEC)	CMR category 1 or 2, PBT, vPvB?	Name of supplier	EU/non-EU company	Tonnes per year	Function	Qualification/ approval required as raw material or in finished product?	Customer use (if known/ relevant)?	

Figure 3-2 Key dates in preparing for REACH



4 ACTIONS TRIGGERED BY INFORMATION RECEIVED WITH SUBSTANCES, PREPARATIONS OR ARTICLES

This chapter sets out how to meet your requirements in response to information received from suppliers. It provides an alternative entry to the guidance than chapter 2 on roles and obligations. It directs you to the more detailed sections of the guidance.

4.1 Introduction

REACH will increase the amount of information you will receive. The receipt of a registration number, as part of a safety data sheet or other information supplied to you, triggers obligations. This chapter is structured according to the order of reading such information. [Section 4.2](#) explains how to act on information supplied with substances or preparations and [section 4.3](#) covers articles²⁶.

4.2 Workflow on actions from information on substances or preparations

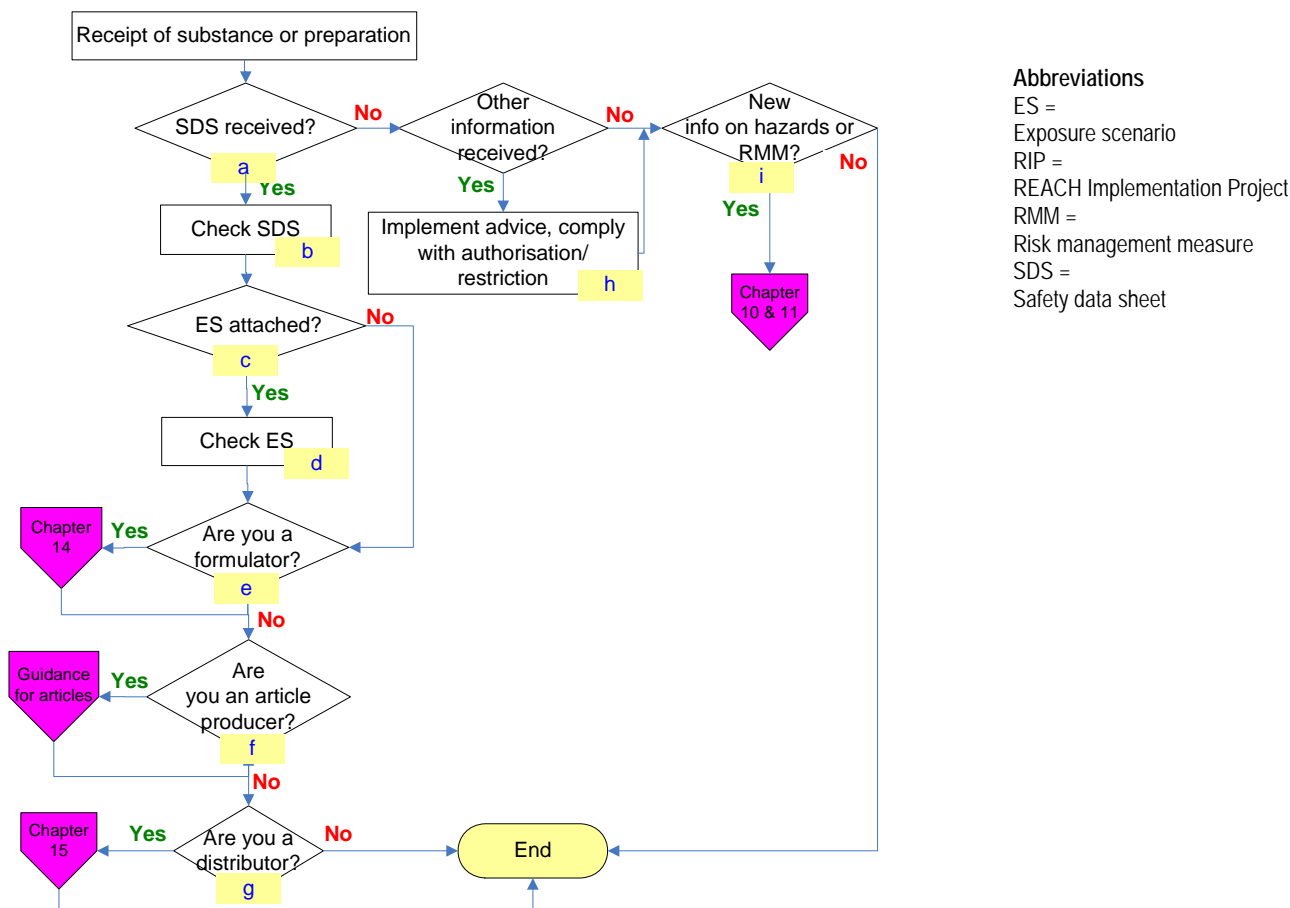


Figure 4-1 Actions triggered by information on substances or preparations

Note a - Information received

If you purchase a substance on its own, your supplier must provide a safety data sheet if the

²⁶ Note: Some objects are not regarded as articles with intended release of substances, but as preparations in special containers or on special carrier materials, e.g. pens, printer cartridges, wet tissues. As a consequence you will receive safety data sheets for these preparations or may have to provide them yourself. See the Guidance on articles.

substance is classified as dangerous, or if it is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative or if it is included on the candidate list for authorisation (article 31.1 of REACH). You may receive other information from your supplier, if the substance is not classified as dangerous but you should take special precautions to ensure safe handling.

If you purchase a preparation, your supplier must provide a safety data sheet if the preparation is classified as dangerous. You may request a safety data sheet where the preparation is not classified as dangerous, but contains at least one substance posing health or environmental hazards, or for which there are community workplace limits²⁷ (article 31.3 of REACH).

If a safety data sheet is not required, your supplier is required to provide information on any substances subject to authorisation or restriction and any information necessary to enable you to identify and apply appropriate risk management measures. This is what is meant by 'other information' in the flow chart (article 32 of REACH).

Note b – Check safety data sheets

Updated safety data sheets should be provided from 1 June 2007. They will at the latest be updated when a substance has been registered by the manufacturer or importer, to include the information gathered in the registration process.

You must not place on the market any substance, as such or in your preparations or articles, which is not registered or pre-registered in accordance with REACH unless it is exempted from registration. This means that you have to be sure that your suppliers are in compliance with REACH (see chapters 1 and 2).

Check whether registration numbers are given under heading 1 (substances) or 3 (preparations). If so, you can assume that some testing has been performed and classification and hazard descriptions are based on that information.

Once you receive a registration number, a countdown of 12 months starts for you to meet your obligations as downstream user under REACH. If a substance is not yet registered and you do not receive a registration number, you should follow the advice given in the safety data sheet, as before.

You should check the hazard and risk management information, as well as the implementation of risk management measures and whether any substances as such or contained in preparations are subject to authorisation or restrictions. Table 9 lists the headings of the safety data sheet in column 1, their relevance for compliance with your obligations, relevant action needs and the guidance chapters providing further details.

²⁷ Where the substance is in an individual concentration of 1% or more by weight for non-gaseous preparations or 0.2% or more by volume for gaseous preparations. Note that if you request a safety data sheet for a preparation containing a substance for which a chemical safety report has been made, you may receive an exposure scenario with the safety data sheet.

Table 9 Information in the safety data sheet relevant for compliance with downstream user obligations

SDS heading	Information relevant for meeting your obligations under REACH	Action	Chapter
1. Identification of substance / preparation and of company	Registration number of the substance if registered. Known uses of the substance; where a chemical safety report is required, all identified uses Contact information for the supplier	Obligations start to apply as of 1 st June 2007. Requirements of article 37 of REACH apply at the latest one year after you receive a registration number ²⁸ Voluntary: If your use is not listed, you may wish to identify it to your supplier	8
2. Hazards identification	Most important adverse physicochemical, human health and environmental effects of the substance as such or of the preparation	Supply any new information on hazards to the next actor up the supply chain Report to the Chemicals Agency if you classify differently	10
3. Composition / information on ingredients	Hazards of the components of the preparation	Supply any new information on hazards to the next actor up the supply chain Report to the Chemicals Agency if you classify differently	10
4. First aid measures	Measures to treat the effects of accidents	No changes to current practice	
5. Fire fighting measures	Measures to ensure safety in case of fire	No changes to current practice	
6. Accidental release measures	Measures to address the risks of accidental releases	No changes to current practice	
7. Handling and storage	Information to help devise suitable working procedures and organisational measures to manage risk	No changes to current practice	
8. Exposure controls/personal protection	Exposure limit values and risk management measures. The information must be consistent with the information set out in the exposure scenario, if one is attached to the safety data sheet.	Implement appropriate risk management measures Inform your supplier if you have information calling into question the risk management measures	11
9. Physicochemical properties	Important health, safety and environmental information	Supply any new information on hazards to the next actor up the supply chain	10
10. Stability and reactivity	Conditions and materials to avoid	Supply new information on hazards to the next actor up the supply chain	10
11. Toxicological information	Information on potential risks to health	Supply new information on hazards to the next actor up the supply chain	10
12. Ecological information	Information on potential risks to the environment	Supply new information on hazards to the next actor up the supply chain	10
13. Disposal considerations	Appropriate methods of disposal	Check if there is information that should be passed on to your waste disposal organisation	
14. Transport information	Any special precautions for transport	No changes to current practice	
15. Regulatory information	Whether the substance as such or in a preparation is subject to authorisation or to restrictions Indication of whether a chemical safety assessment has been carried out.	Check compliance with authorisation Check compliance with restrictions	12 13
16. Other information	Recommended (non-statutory) restrictions on use	Check compliance with restrictions Supply any new information on hazards to the next actor up the supply chain	13 10
Annex	Exposure scenario(s) for the identified uses relevant for you	You are to implement the conditions of use described in the exposure scenarios unless you have developed your own chemical safety report and relevant exposure scenario, or exemptions for this apply to you.	5

²⁸ See article 39.1 of REACH

Note c - Exposure scenario(s) received

Your supplier should provide you with one or more exposure scenarios for all dangerous substances which are produced or imported in volumes of 10 tonnes or more per year per registrant. If such substances are contained in a preparation and are listed under heading 3, the safety data sheet for this preparation will also have an exposure scenario attached.

Note d - Check exposure scenario

If you receive an exposure scenario for a substance or preparation, you have to check whether you comply with it. Detailed information on how to check compliance with exposure scenarios is provided in chapter 5 of this guidance.

Note e - Formulators

If you formulate preparations, you may have to supply information (safety data sheets or other information) to your customers. The obligations which are to be fulfilled under REACH, in addition to the existing requirements, are described in chapter 14 of this guidance.

Note f - Article producers

If you produce articles, you may have to register or notify substances you use. Guidance is provided in the guidance document on requirements for substances in articles.

Note g - Distributors

If you are a distributor of substances or preparations, you have a duty to pass on the safety data sheet or any other information received, to the next actor in the supply chain. Details of the obligations of distributors are provided in chapter 15 of this guidance.

Note h - Other information

You may receive ‘other’ information, according to article 32 of REACH, on whether or not a substance is subject to authorisation or restrictions and on specific measures to control risks from its use, e.g. in the framework of a product and process oriented research and development notification. This information must be implemented.

REACH does not specify the format in which this information should be supplied. Every supplier of a substance or preparation should consider which information instrument may be best for each customer. Thus, you could receive Article 32 information, for example:

- in the format of a safety data sheet
- as separate section in the technical data sheet
- as a separate information leaflet
- or in other formats

Your supplier should ensure that the information clearly stands out as Article 32 information, in particular where it is included in a technical data sheet, for example.

If you are informed that a substance²⁹ is subject to authorisation, you may have to check whether your use is exempted, or whether an authorisation has been granted to an actor up the supply chain covering your use and whether you comply with the respective conditions or if you yourself could apply for an authorisation (see chapter 12 of this guidance). If you are informed that a substance²⁹ is restricted, you have to comply with the conditions of the restriction (see [chapter 13](#)).

²⁹ Registration number must be supplied.

You may receive other information that your supplier regards as necessary to enable appropriate risk management. This could, for example, include information on risks of damage resulting from the physical form of a substance or information on conditions of use that should be avoided³⁰.

If you receive information from your supplier, you should also check whether you have to forward the information to your customers. This is explained in chapter 14 of this guidance if you are a formulator, in chapter 15 if you are a distributor and in the Guidance for substances in articles if you are a producer of articles.

Note i - Other information on hazards

If you have carried out testing, or have observed that a substance poses hazards which are not reflected in the information you received or which would require a safety data sheet for the substance or preparation, you must report that to your supplier.

4.3 Workflow on actions from information on articles

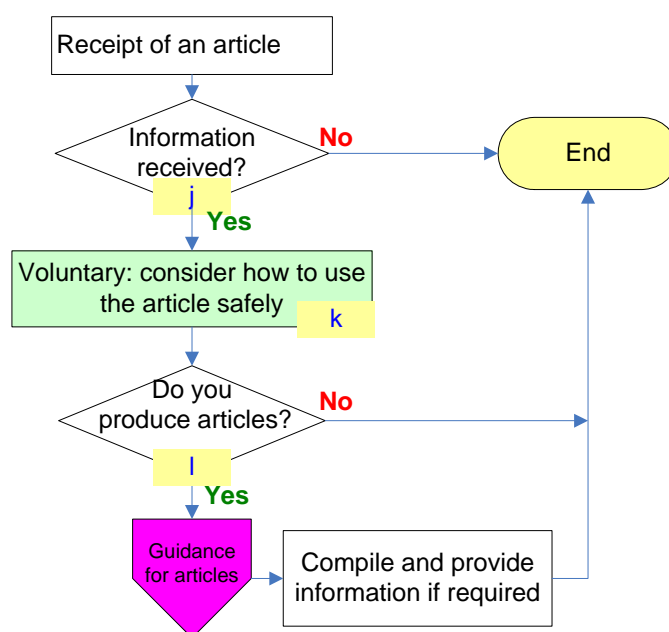


Figure 4-2 Actions triggered by information on articles

Note j - When to expect information supplied with articles

Your supplier of an article shall provide you with information if the article contains substances of very high concern which are included on the candidate list for authorisation in concentrations above 0.1 %. The candidate list will probably be published in late 2008.

Note k - Information on safe use

It is obligatory that your supplier provides you with all the information necessary to ensure safe use of the article. If applicable, as a minimum, he must specify the name(s) of substance(s) of very high concern contained in the article in concentration above 0.1% w/w. He may provide any additional information on a voluntary basis.

³⁰ Registrants may refrain from testing certain substance properties (called waiving) if they exclude exposure of humans or the environment. One way to exclude exposure would be to communicate relevant conditions of use.

Note 1 - Forwarding information with articles

If you produce an article using as input material an article containing substances on the candidate list, in concentrations of 0.1 %w/w or more in the article, you may be obliged to forward information to the recipients of the article you produce (article 33 of REACH). These recipients may be other enterprises that use the article but also retailers, which provide articles to consumers. All actors, article producers, importers or distributors/retailers, must provide this information to consumers on their request, within 45 days and free of charge³¹. Use the Guidance for articles to check whether you have to forward information.

REACH does not specify a format for providing information with articles. You should choose a format that will ensure that the recipient can readily become aware of the information. Potential information items to include are shown in Table 10.

Table 10 Information on substances in articles

Item	Obligatory	Example
Substance name	Yes	Diarsenic trioxide
CAS Number	No	1327-53-3
Registration number (if provided by supplier)	No	01-1234567-49-00
Classification	No	Carc. Cat. 1; R45; T+; R28; C; R34 ; N; R50/53 May cause cancer
Concentration in the article ³²	No	1% w/w
Information on safe handling	(Yes) ³³	Prevent from heating up above 60 °C Keep article out of reach of children
Safe disposal	No	This article should be disposed of as hazardous waste. Please do not put it in your normal household waste

³¹ Article 33(2) of REACH

³² Concentration ranges could be considered in order to preserve confidential business information

³³ If the information is necessary to ensure safe handling by the user of the article, it is obligatory to forward.

5 CHECKING COMPLIANCE WITH THE EXPOSURE SCENARIO

This section explains how to assess whether the descriptions of safe use contained in exposure scenarios received as annexes to the safety data sheet with a substance or preparation cover the conditions under which the substance or preparation is actually applied.

5.1 Requirements related to 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.

An exposure scenario describes the conditions under which a substance as such or in preparations can be used safely. Each downstream user of a substance or preparation which is supplied together with a safety data sheet and attached exposure scenario(s), must ensure that his use conditions are covered by that scenario. This means that you are to compare the conditions described in the exposure scenario with your own practices. Three cases can be distinguished:

1. Your use is covered: your actual operational conditions and risk management measures correspond to those specified in the exposure scenario. You do not need to take further action.
2. Your use differs from the exposure scenario: the type and/or scale of your operational conditions and risk management measures do not correspond to the exposure scenario. You have to make a more detailed compliance check.
3. Your use conditions are not covered by the exposure scenario: you apply different operational conditions or risk management measures, resulting in different or higher exposure levels than those in the exposure scenario. You will need to check section 6 of this guidance to decide what action to take.

Exposure scenarios are normally³⁴ developed by manufacturers and importers as part of their registration dossier for substances which are dangerous and produced/imported in amounts of 10 tonnes per year or more. The exposure scenario(s) cover all life cycle stages of a substance, from production to disposal³⁵. Exposure scenarios are forwarded along the supply chain as annexes to the safety data sheet. Safety data sheets for preparations may have exposure scenarios attached that refer to the preparation, or to the individual dangerous substances contained in the preparation, or both. More detail about exposure scenarios is provided in the [Guidance on the Chemical Safety Report](#), and in appendix 1 of this guidance.

³⁴ 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 preparation by merging and consolidating exposure scenarios received (see chapter 14 of this guidance).

³⁵ Although waste is exempt from registration, the safety assessment is to include the disposal.

5.2 Explanation of key terms

5.2.1 Use

In general, a 'use' is any activity carried out with a substance as such or in a preparation, which could lead to an exposure to that substance. Activities carried out with articles are not a use of a substance. Some examples of uses are given in the box below.

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;

Example 1 Examples of uses

Formulation of a paint	Substances and preparations 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 (preparations) are used to cover metals. The use consists of several activities, such as the preparation of the electroplating baths (filling and adjustment), the immersion of parts into the baths and the drying of parts. Cleaning and maintenance activities are also part of the use.
Blowing of plastic films	Raw materials of polymer compounds are mixed, filled into the extruder, heated up and blown, the material is cooled and packaged.
Re-distillation of cleaner	Cleaning agents are regenerated, by distillation and removal of contaminants from the cleaning process, for further use in production. This activity is not covered by waste legislation and is thus regarded as a downstream use.

Article 3(26)

Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, 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;

'Identified uses' are uses which are intended by an actor in the supply chain. This may include his own uses, and uses made known to him in writing with the aim of making the use an identified use

An exposure scenario always refers to one or several identified uses of a substance or preparation, which is indicated in its title as well as under heading 1 of the safety data sheet. A standard system for the brief general description of a use is given in the Guidance on the Chemical Safety Report.

5.2.2 Conditions of use

The conditions of use specify which parameters determine the exposure in a use. They include:

- the operational conditions,
- the risk management measures,
- concentration in a preparation or an article and the physical state (powder, liquid etc) and
- information on the surroundings in which the substance is used

It may not always be possible, and is also not necessary, to differentiate unambiguously between these types of information, in particular between the operational conditions and risk management measures in the exposure scenario. However, it is important that the information necessary for checking if safe use can be ensured is given in the exposure scenario.

5.2.3 Operational conditions

The operational conditions are part of the exposure scenario and aim to specify the circumstances of use of a substance or preparation. In particular, they describe the types of activity to which the exposure scenario relates, how frequently, how often and for how long a substance is used and in which type of process, at which temperatures etc. Only parameters influencing the exposure level are included in the exposure scenario. Some examples are given in the box.

Example 2 Examples of operational conditions

Operational condition	Example 1	Example 2
Identified use	Use of a hard surface cleaner Washing and cleaning product, air dispersive techniques	Coating Low energy spreading (brushing, rolling)
Type of activity/use	Delivered product is a concentrated solution, which is diluted by the user Diluted product is spray applied onto surfaces to be cleaned. Product is wiped off surface with a cloth. Cleaning equipment	Preparation of paint. Manual application of paint indoors with brush or roller Cleaning equipment
Duration	4 hrs/day	8 hours per application (per day)
Frequency	5 workdays/week	5 workdays / week
Temperature, capacity of receiving environment etc.	The application takes place at normal room temperature - 20°C Room size 100 m ³ - height 2.5 meters Surface area: 40 m ² Normal air exchange of 0.5/hr	Room temperature, 20°C 50 m ³ Room Air exchange of 0.8/hr Less than 1% emitted to waste water during cleaning;
Containment	Open process	Open process

5.2.4 Risk management measures

The term ‘risk management measure’ means an activity or device that reduces or controls the exposure of humans or the environment to a substance during its use as such, in a preparation or an article. Risk management measures applied in industrial uses include exhaust ventilation, waste gas incinerators or on-site waste (water) treatment. The use of personal protective equipment, such as gloves or masks, is also a risk management measure. Municipal sewage treatment plants are also risk management measures, as they reduce the environmental exposure.

5.2.5 Scaling

The aim of scaling is to allow flexibility in checking if your own or your customers’ uses are covered by an exposure scenario. In principle you should comply with the conditions of use indicated in your supplier’s exposure scenario. However, if you have another combination of operational conditions and risk management measures which allow you to achieve the same level of safety, you can use scaling to demonstrate that you are in compliance. Options and limitations of scaling are to be communicated by the supplier. Detailed guidance is provided in the Guidance on the Chemical Safety Report.

Scaling allows demonstrating that a use covered by an exposure scenario, although not all parameters are directly covered by the conditions of use in that exposure scenario. Your supplier

should specify how the conditions of use which can be scaled influence the risk characterisation ratio. He can provide algorithms describing the relation between a condition and the risk or point out which exposure assessment tools could be applied.

Scaling is only possible for the parameters specified by the supplier and only in accordance with his scaling instruments (algorithm, IT-tool etc.). Scaling is definitely not possible if:

- different routes of exposure would result from the adjustment of an exposure determinant,
- different target groups would be involved and/or
- the exposure duration and frequency are significantly changed, resulting in a different type of exposure (e.g. from acute to chronic exposure).

5.3 Checking compliance with the exposure scenario

In order to compare your conditions of use with the information in the exposure scenario, you may need to collect information on your operational conditions, risk management measures and the surroundings in which you use the substance or preparation. Information sources include documentation prepared for other legislation (e.g. the Chemical Agents Directive, compliance with environmental permits under the Directive on Integrated Pollution Prevention and Control), 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 in the exposure scenario.

In the following, an example exposure scenario is used to illustrate the type of information needed for compliance checking. If you are checking whether your customers' uses are covered, the same workflow can be applied and the relevant information will need to be collected from the customer.

5.4 Workflow on checking compliance with the exposure scenario

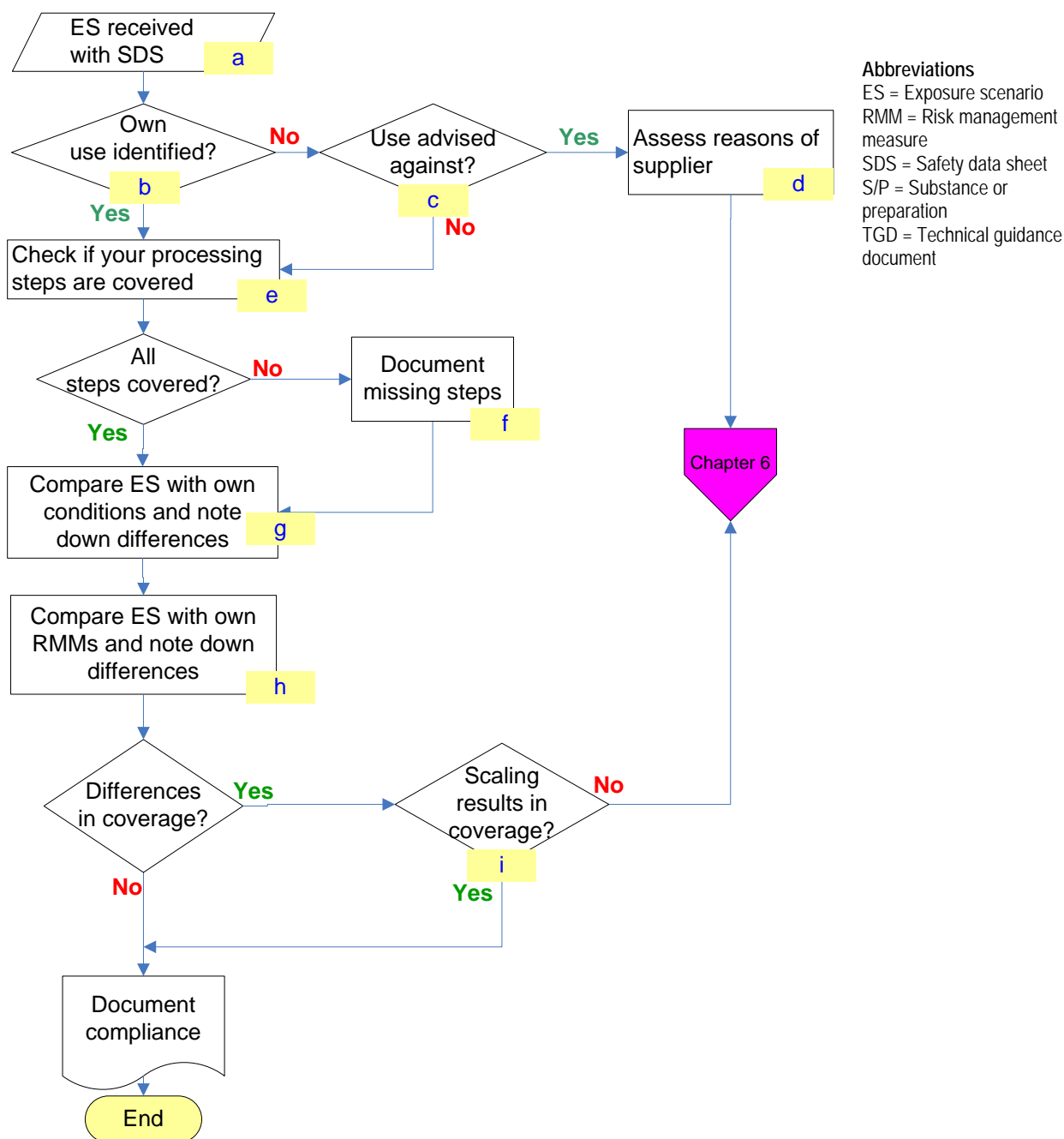


Figure 5-1 Workflow checking compliance with the ES

Note a - Exposure scenarios received with safety data sheet

If you purchase the same substance from different suppliers, you may receive different exposure scenarios with them and at different times. They may not be comparable, as they could differ in scope (number and types of identified uses addressed) or define different conditions of use. You have to check your compliance with each exposure scenario separately.

You may 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.) and assess your compliance. If you comply with this, you can argue that the conditions in place are more strict than those of the other exposure scenarios. This does not mean that you necessarily

have to implement the most stringent risk management measures, but you have to make a decision with regard to the most stringent scenario and continue assessing compliance for the other exposure scenarios.

If you use preparations which are classified as dangerous, you may receive exposure scenarios relating to the preparation as such or to (some of) the classified substances in it, or both. If you receive an exposure scenario for the preparation, you should use that as the basis for checking your compliance. If you receive exposure scenarios only for the substances contained within the preparation, you must check compliance for each substance separately. It should be noted that any supplier is obliged to communicate relevant exposure scenarios that are consistent with the information in the safety data sheet.

If you incorporate substances or preparations into articles, you are responsible for assessing that any information regarding the article and its service life is also complied with. This means e.g. if you produce an article for indoor use, like a table, but the exposure scenario specifies that the substance or preparation may be used only in articles for outdoor applications, the scenario does not cover your article.

As the exposure scenarios describe the conditions of safe use of a substances or preparation, they may provide valuable input to assist your compliance with workers protection and environmental legislation. You may consider how exposure scenarios could be integrated in your health, safety and environmental management routines.

Note b - Identified use

Identified uses (see also the definition of terms in section 0) are named in the safety data sheet, under heading 1. Their naming should be consistent with, but not necessarily the same as, in 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 part of the Guidance on the Chemical Safety Report.

If your use is not named in the safety data sheet or in the title of the exposure scenario, this does not necessarily mean that you are not in compliance with the obligations. You may use a substance or preparation for a use that is not identified, as long as you comply with the conditions of use described in the exposure scenario.

Example 3 Comparing the identified use with your own use

	Example 1	Example 2
Short title of exposure scenario	Professional Construction works, solvent in coating, low energy spreading (brushing, rolling)	Professional, Scientific And Technical Activities Solvent in Washing and Cleaning Products Air dispersive techniques
Lifecycle step in exposure scenario	Application of product	Application of product
Your practice	Manual coating of metal parts by brushing and rolling	Manual surface cleaning by rubbing as pre-treatment for electroplating
Consequences	Your own use is covered by the identified use.	Your own use is not part of the identified use (cleaning with cloths by rubbing is different from air dispersive techniques). This does not trigger any legal obligations, but you need to check that your conditions of use are the same as the ones recommended in the exposure scenario, even if the name of the

		use is not the same.
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Note c - Uses advised against

If your supplier advises against specific uses, for reasons of protection of human health or the environment, he has to indicate this in Section 16 of the safety data sheet or in the information provided according to Article 32. If no reasons are given, you have the right to request them. Examples of reasons may be that adequate control of risks was assessed and could not be demonstrated in the chemical safety report. A use advised against is clearly outside the supplier's exposure scenario.

Note d - Reasons for 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 preparation. However, you may be able to show that your use, although advised against, is safe by carrying out a downstream user chemical safety report. This would require you to assess the use of the substance or preparation in more detail than your supplier and, where relevant, modifying your conditions of use and therefore, potentially, coming to a different conclusion on the risk. Guidance on a downstream user chemical safety assessment is provided in chapter 7 of this guidance.

Note e - Checking processes/activities of the exposure scenario

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 preparation is expected. Assess whether you carry out activities with the substance or preparation 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.

Example 4 Checking processes and activities

	Example 1
Short title of exposure scenario	Professional Construction works Solvent in coating Low energy spreading (brushing, rolling)
Activities / processes covered	Preparation of paint. Manual application of paint in-door with brush or roller Cleaning equipment
Your practice	Same steps performed. In addition, painted metal parts are dried in an oven
Action	Drying metal parts in an oven is not listed as activity in the exposure scenario. The drying process may cause a different emission rate to the air and you should ensure that this does not lead to environmental risks or risks to the neighbourhood of the plant.

Note f - Documentation

You should document your assessment of, and compliance with, the conditions of use in the exposure scenario, for example to facilitate checking the use of other preparations 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.

Note g - 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.

Example 5 Checking operational conditions

Information in exposure scenario	Your own practice
Preparation of paint. Manual application of paint in-door with brush or roller Cleaning equipment	Preparation of paint. Manual application of paint in-door with brush or roller Cleaning equipment Drying of paint on metal parts in drying oven
Duration and frequency: 8 hours per application (per day), 5 workdays/week	Duration and frequency of use: 2 hrs /day; 5 workdays / week (documentation: risk assessment at workplace) <u>Assessment:</u> duration of use is lower, frequency the same as in the exposure scenario → covered by exposure scenario
Amount used per day	Amount used per day: 20 kg/day (documentation: risk assessment at workplace) <u>Assessment:</u> used amount less than in exposure scenario → covered by exposure scenario
Other operational conditions determining exposure, <ul style="list-style-type: none"> Room temperature, 20°C 50 m³ Room Air exchange of 0.8/hr Less than 1% emitted to waste water during cleaning; 	Operational conditions <ul style="list-style-type: none"> Application at normal room temperature; drying in oven at 50°C Room size where paint is applied > 100 m³ Normal air exchange (app. 0.8 / hr) during application Much higher air exchange in drying oven with exhaust to outdoors No emissions to waste water at all <u>Assessment:</u> your use conditions related to workers health are covered by the exposure scenario. The drying process is not completely covered, as one activity and thus its operational conditions are not described in the exposure scenario. This process may cause different emission rates of the substance to the air. Whether or not these emissions cause an environmental risk is not clear: the total amount emitted is not increased but the exposure concentration is higher than during drying at normal temperature. This should be discussed with the supplier. It may be helpful to document the outcome of that discussion → further checking necessary

Not every difference between the description of conditions of use in the exposure scenario and your own practice means that the use is not covered. If your operational conditions are the same or similar (e.g. different material of gloves or membrane filtration is used instead of reverse osmosis for wastewater treatment) to those described, and the quantitative values (such as the temperature range or amounts applied) are within the given ranges, they are covered by the exposure scenario. If the quantification of parameters differs, you are covered if this results in lower exposures. For example, if you apply half the amount per day specified in the scenario, your exposure will be lower and your use is covered; whereas if you apply double the amount per day, your exposure will be higher and you will need to assess in more detail whether the use is covered or not. Parameters for which lower values in your practice compared to the exposure scenario result in lower exposures (and thus your use is covered) include the amount used, frequency and duration of use, the operating temperature or pressure. Parameters for which higher values would result in lower exposures include the air volume at the workplace or the volume of the receiving surface water

(higher dilution of the substance).

The exposure scenario may also specify factors which are not directly related to the use, but describe 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. If the actual receiving surface water volume exceeds that given in the exposure scenario, the environment is exposed at a lower level, because the resulting concentration is lower (higher dilution volume). If the actual dilution in the receiving surface water is lower or other conditions differ, then you can ‘compensate’ in a similar way³⁶, as explained in **note i**.

Note h - Comparison of risk management measures

Compare the information given on risk management measures, including their efficiencies, with those you apply. For documentation of your assessment you may use appendix 3 of this guidance. To find out how efficient your risk management measures are, you may discuss with the technical staff, consult maintenance instructions or measurement protocols of technical devices. Furthermore, producers of these devices could provide information on functioning and efficiency.

Example 6 Checking risk management measures

Information in exposure scenario	Your own practice
<ul style="list-style-type: none"> • Half mask (protection factor 10 assumed) • Gloves (nitrile) should be worn. • No environment related measures needed under given operational conditions of use 	<ul style="list-style-type: none"> • Appropriate half masks are worn • Appropriate gloves are used • No environmental measures are implemented
Residual paints and empty cans should be disposed of via municipal collection system.	Wastes are disposed off as hazardous waste

The key information related to risk management measures is their efficiency - the degree of exposure reduction achieved at the target (for example local exhaust ventilation reduces the substance concentration in workplace air by 50%, gloves reduce dermal exposure by 80%). You may have difficulty in comparing the efficiencies 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. Difficulty in comparison may also arise when you combine risk management measures.

You can be sure that your risk management measures are covered if their efficiency is equal to, or higher than, 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.

If you have measurement results, for example that you generated for an environmental permit application or for assessing chemical risks at the workplace, it may be helpful to use them to support checking compliance with the exposure scenario.

Note that a given risk management measure may have a different efficiency for different (groups of)

³⁶ An exception is conditions at the workplace where the available air volume is significantly higher or lower than specified in the exposure scenario, as the air flow in the rooms may be irregular and, thus, peak concentrations could occur. Here, expert advice should be sought.

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 device.

Note i - Scaling of the conditions of use

If several of your conditions of use differ from the exposure scenario, it is not always apparent whether the use is covered by the exposure scenario or not. In these cases, and if your supplier has specified relevant scaling rules or assessment instruments in the exposure scenario, you may assess the coverage of your use by scaling the determinants of exposure. Details about scaling should be communicated by your supplier. Specific guidance is given in the Guidance on the Chemical Safety Report. The following table illustrates the type of information on scaling which could be given in the exposure scenario.

Table 11 Type of information in exposure scenario related to scaling

Where relevant: a set of variables (and a suitable algorithm) which together indicate safe use, but allow for scaling	Human Exposure: Concentration and ventilation rate can often be scaled based on linearity. Amounts and room size/application area are interdependent and cannot be changed independently. Exposure predictions have been made using the following models: Inhalation: ConsExpo Dermal: Generic exposure values from BPD use models Environment: EUSES
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In cases where your actual operational conditions lead to higher emissions from your process, compared to the exposure scenario, you may be able to compensate this by applying more efficient risk management measures or by higher dilution volumes³⁷. Vice versa, less efficient risk management measures could be compensated by stricter operational conditions or higher dilution volumes (e.g. having a closed system instead of a semi – open one, using only half the amount specified in the exposure scenario or having work take place in larger areas with higher diluting air volumes).

Table 12 Relationships between exposure determinants and exposures

Type of parameter	Description in ES	Implementation at DU	Linearity	Reason
Physical state of substance	Liquid	Powder	No	The substance behaves differently as a liquid than as a solid particle. This leads to different exposure routes for the powder form.
Process / type of application	Brushing	Spray painting	No	Spraying leads to the formation of aerosols (inhalation and dermal exposure), which does not occur during brushing (dermal). Exposure routes and related risk management measures are different.
Local	Efficiency of	Encapsulation	Yes	The type of risk management measure differs from

³⁷ The exposure of workers and the environment can be diluted in time, (intermittent release to the environment is defined as once every 30 days (Guidance on the Chemical Safety Report, section on environmental exposure assessment) and allows use of a lower application factor). In addition, the environmental compartments themselves can dilute a substance emitted, e.g. the higher the receiving water volume the lower is the concentration of the substance in it.

exhaust ventilation	70%	of process releasing 5% to workplace		the exposure scenario, but it has the same effect and is even more efficient, without changing the exposure of other targets.
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When you can apply the scaling rules provided in or together with the exposure scenario, or when you can use IT-tools specified by your supplier to adapt the conditions of use, your own use is covered because this proves that your conditions are ‘as a minimum as strict’ as in the exposure scenario.

In order to be in compliance with REACH you must either be exempted under article 37 of REACH, or implement the conditions of use described in the exposure scenario, or be able to demonstrate via scaling tools supplied with the exposure scenario that your own conditions of use are as a minimum as strict as those 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. This is true even if you have measured concentrations of substances at the workplace and in the environment indicating that the measured exposure levels are below the derived no effect levels (DNELs) or predicted no effect concentrations (PNEC) communicated in the safety data sheet. This may be an indication that you implement ‘as a minimum’ the conditions of use of the exposure scenario (Article 37.4(d) of REACH). However, you would have to demonstrate this via a chemical safety report and make a notification to the Chemicals Agency or make your use known to your supplier with the aim of identifying your use.

5.5 Substances or preparations incorporated into articles

The registrant’s chemical safety report must include all life stages, also service life of articles, if relevant, and waste stages and relevant exposure scenario. As a downstream user, you can only check the steps that apply to you, e.g. your own waste management measures, and article life-cycle steps that are relevant to you. You are not responsible for determining whether others down the supply chain comply.

If you are a producer of articles and use substances as such or in preparations to produce these, you have to check whether their use in your article is covered. You should forward information on safe disposal with your article, if needed.

6 DECIDING IF THE USE IS NOT COVERED BY THE EXPOSURE SCENARIO

This section aims to assist you in deciding what to do if your use is not covered by the conditions of use set out in the exposure scenario.

6.1 Introduction

If the conditions of use of your substance or preparation are not covered by the exposure scenario, in general you have to make a downstream user chemical safety report. However, this may not be necessary if certain exemptions apply (Article 37.4 of REACH) or if you choose one of the following options to act:

1. make your use known to your supplier with the aim of having it identified and included in the chemical safety assessment (see chapter 8 of this guidance), or
2. implement the conditions of use in the exposure scenario, or
3. substitute with a substance or preparation without exposure scenario(s) or with exposure scenario(s) covering your conditions of use
4. find another supplier, who provides the substance or preparation with an exposure scenario that covers your use.

There is no standard guidance on ‘the best solution’ and the decision has to be taken case-by-case, considering the various arguments relevant for your business strategy. The following workflow aims to help in your decision making. Table 13 provides additional indications of which option may be best in which situation and gives examples of advantages and disadvantages.

Table 13 Options if exposure scenario does not cover the use

Options	This option could be best if	Advantages	Disadvantages
Exemptions apply 6.a	Case-by-case	No changes in process or substances / preparations needed	No certainty about adequate control of risk Situation may change when you increase production
Make your use known to your supplier 6.e	- this does not raise confidentiality concerns for you - the exposure scenario you received is rather general / 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
Find supplier with exposure scenario covering your use		No changes to current practice, except sourcing of raw materials	Change of source
Implement conditions of use 6.g	- your use is not covered by the (similar) conditions of use in several exposure scenarios - you 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 6.g	- you have very few substances or preparations which are not covered by the exposure scenario - you want to substitute the substances / preparations 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 preparations.
Downstream user chemical safety report 6.h	- you do not want to disclose information on your use - only a few exposure scenarios do not cover your use - you have enough information and expertise to do the assessment	Safe use is demonstrated and documented You can continue using the substance / preparation	Work is resource intensive Not clear if adequate control can be demonstrated with existing conditions of use

6.2 Workflow and explanation on decision taking if the use is not covered by the exposure scenario

Note a – Do the general exemptions of Article 37.4 apply?

If your use is not covered by the exposure scenario, you may have to make a downstream user chemical safety report. You should first check if any of the exemptions of article 37(4) of REACH apply to you. If you are exempted, you only have to report to the Chemicals Agency. If you are not exempted, you should continue checking the options described below before making a downstream user chemical safety report.

Table 14 lists some of the exemptions of Article 37. Further exemptions are explained below.

Table 14 Checking if exemptions from the duty to make a downstream user chemical safety report apply

Exemption	Explanation - your own use	Explanation - customer's use³⁸
(a) No safety data sheet required for substance or preparation	<p>If your supplier is not obliged to give you a safety data sheet, you do not have the obligation to make a DU CSR</p> <p>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.</p>	If you provide your customer with a preparation not requiring a safety data sheet, you do not have to supply 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. Nevertheless, you should consider whether information according to article 32 needs to be forwarded (see also chapter 14)
(b) No chemical safety report is required for supplier	<p>If an exposure scenario of a preparation does not cover your use, this exemption only serves to focus your chemical safety assessment on the relevant substances, in case you decide to make one, but does not fully exempt you from this duty.</p> <p>A chemical safety assessment is only required for those substances in a preparation for which the manufacturer or importer had to complete one, or which have not been diluted in the preparation you use below the concentration thresholds in article 14 (2) of REACH. You will find relevant information in section 15 of the safety data sheet. Further detail is given in chapter 7 of this guidance.</p>	If you make a chemical safety assessment for the use of a substance in your preparation, you only have to consider it if your suppliers had to make a chemicals safety report.
(c) As a minimum the conditions of use are covered	See chapter 5 of this guidance for details on coverage of as a minimum the conditions of use	
(d) Substance is diluted below concentrations of Article 14(2)	If you use a preparation containing a substance below the lowest of the concentration thresholds in Article 14(2) of REACH, you do not have to make a chemical safety assessment 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 chemical safety assessment for that substance is not required. Nevertheless, you do have to consider all information in compiling your safety data sheet.	

Note b – Do you use less than 1 tonne per year of the substance or preparation?

If you use the substance or the preparation 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 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

³⁸ It is not required that you assess the use of your customers. However, if you are a formulator, you will frequently do so to prepare information for your products. If the use of your customer is not covered by one or more exposure scenarios received from your suppliers, you could make a downstream user chemical safety report for his use. The exemptions listed in this table apply to this situation. They are described in more detail in chapter 7 of this guidance.

control of risk to humans and the environment based on information received from supplier or 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 the Chemicals Agency.

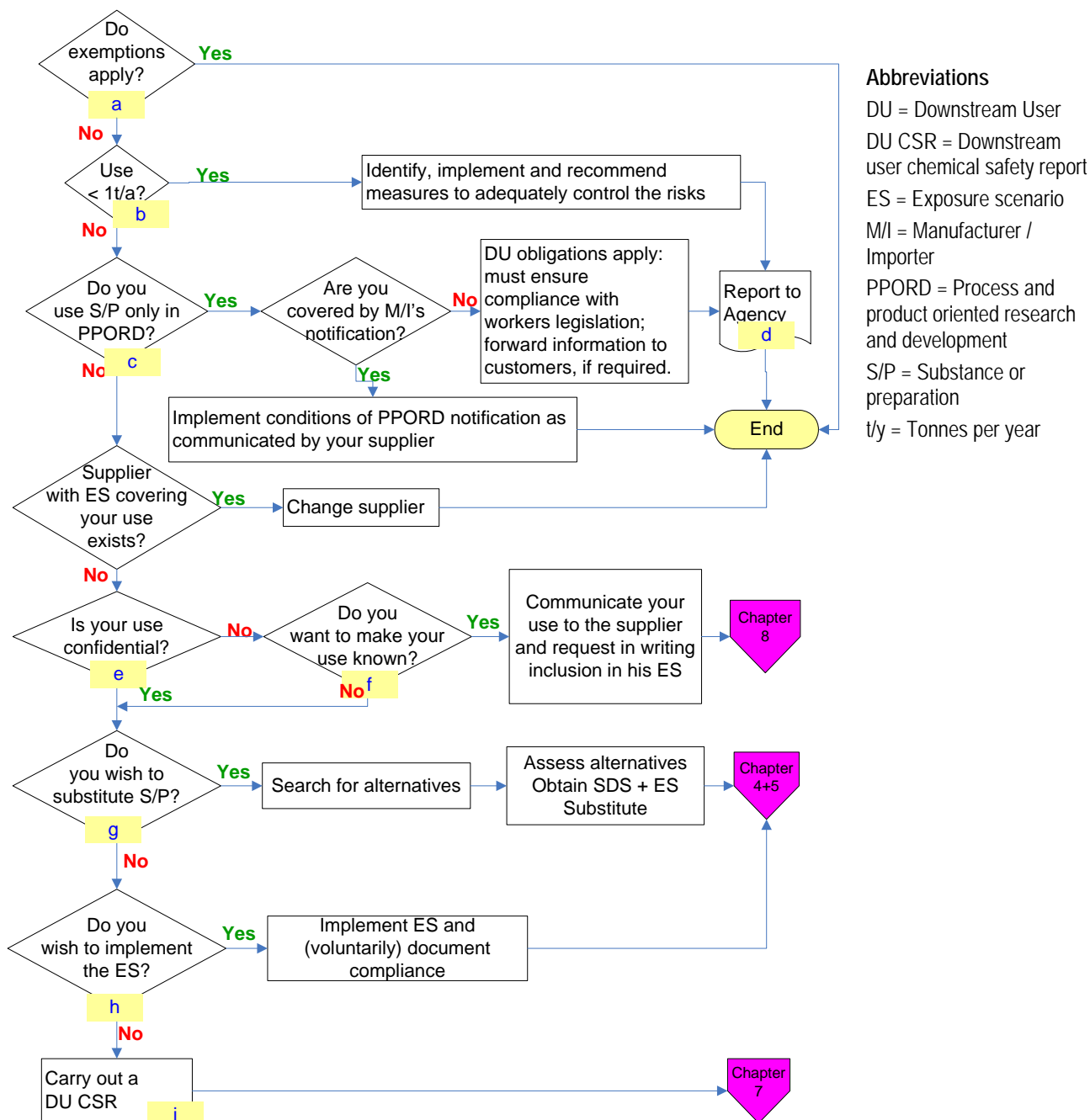


Figure 6-1 Decision tree in case use is not covered by the ES

Note c - Use in product and process oriented research and development

If you are using the substance or preparation in process and product oriented research and

development (PPORD³⁹), 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 the Chemicals Agency. 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 authorisations or restrictions (see chapters 12 and 13).

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 the Chemicals Agency). It is your obligation to implement these conditions⁴⁰. If you start using the substance for other purposes than process and product oriented research and development, you need to inform your supplier of this.

If you are using a substance or preparation 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. However, if you have determined that your conditions of use are not covered by the exposure scenario, you do not have to make a downstream user chemical safety report. You do have to report to the Chemicals Agency, however, even if you use the substance or preparation in amounts below 1 tonne per year. Check whether your activities are covered by the definition of process and product oriented research and development and ensure that you implement as far as possible the conditions of safe use communicated to you.

Note d - Report to the Chemicals Agency (Article 38 paragraph 2)

You have to report to the Chemicals Agency, 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:

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

The report will be created and submitted via the REACH – IT system. 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

³⁹ 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 preparations 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 Guidance Document on obligations pertaining to scientific Research and Development and Product and Process Oriented Research and Development (PPORD).

⁴⁰ A safety data sheet must be supplied if the substance or preparation is classified as dangerous. 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.

your customers apply the substance or preparation. You can use the system for standard description of uses (see Guideline of Chemical Safety Report).

Note e - Your use is confidential

If you consider that your use of the substance or preparation is confidential, you have three options to achieve compliance with REACH: you can substitute the substance or preparation 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.

Note f - 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. You could make your use known to your supplier, if you believe that he will re-assess it and provide you with a new exposure scenario that covers your use; see section 0 of this guidance for more details.

Note g - Substituting the substance or preparation

Substitution of the substance or preparation may be achieved not only by exchange of raw materials but also by optimising process design in such a way that the substances or preparations under question become superfluous (for example omitting cleaning steps). If it has one, the exposure scenario of the substitute must of course cover the conditions of use. Further relevant factors may be:

- Availability of alternatives
 - Are there suitable alternatives available that provide the same performance?
 - Can it be demonstrated that the alternative does not introduce higher risks for human health or the environment?
 - Has it already been registered and assessed?
 - If the substance has not yet been registered and there is no information comparable to that on the substance to be replaced, it is possible that the substitute may turn out to be even more dangerous and, therefore, care should be taken.
- Costs for substitution should be acceptable
- Ease and practicability of change:
- Are processes / equipment adequate for the alternative substance or preparation, or would reformulation / re-engineering be required?
- Raw materials and products as well as customers’ products may have to undergo special qualification / certification
- Customers may not agree with changes to substances and preparations and changes would have to be discussed and potentially tried out with the downstream users
- Is the substance, or does the preparation contain, a carcinogen, mutagen or reprotoxicant or are they classified R50/53? If a substance (contained in the preparation) is listed on the candidate list (see REACH article 59), it may have to be authorised in future.

The Guidance on authorisation application contains advice on how to assess the availability and feasibility of substitution and could help you in organising substitution.

Note h - 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 and implement the exposure scenario. You should ensure that you consider all exposure scenarios that do not cover your use conditions, in order to bring you into compliance with all of them in one action. This option is particularly worth considering when:

- Exposure scenarios of several substances and preparations 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:

1. adding new risk management measures and/or
2. upgrading existing risk management measures and/or
3. changing the operational conditions according to the information in the exposure scenario
4. changing the process (for example, enclosure of machinery) or product design (for example reducing the concentration of the substance or preparation 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).

Note i - Downstream user chemical safety assessment

Preparing a downstream user chemical safety report means that you yourself assess whether the risks from your use of the substance or preparation are adequately controlled. Further information is given in chapter 7 of this guidance.

7 MAKING A DOWNSTREAM USER CHEMICAL SAFETY REPORT

This chapter provides guidance on conducting a downstream user chemical safety assessment for your and/or your customers' uses. It should give an overall understanding of the methodology described in more detail in the guidance on the chemical safety report. Issues specific to the downstream user chemical safety assessment are discussed in this guidance such as:

- How to identify substances for which the downstream user chemical safety report is actually required, when an exposure scenario of a preparation does not cover the use*
- How to identify and define the scope of the assessment*
- How to find out if additional hazard data are needed*
- How and what information to collect on your own or your customers' uses to carry out the assessment,*
- How to make a chemical safety report for a preparation*

7.1 What is a downstream user chemical safety assessment

The chemical safety assessment aims to identify the conditions of use under which a substance can be used safely throughout its entire life-cycle. It is normally the task of the substance registrant to carry out the assessment and to document it in the chemical safety report. Exposure scenarios are a core instrument in the chemical safety assessment. If the exposure scenario of a substance or preparation does not cover your use or your customer's use, you may be required to carry out such an assessment yourself. This is called a downstream user chemical safety assessment.

The chemical safety report must document 'safe use', which means that the exposure of humans (workers and consumers) and the environment remain below the levels regarded as safe, or exposures should be minimised. The safe levels are called the derived no effect level (DNEL) for human health and the predicted no effect concentration (PNEC) for the environment. Exposure levels and safe levels should be expressed numerically, if possible. If a downstream user uses a substance in quantities of 1 tonne per year or more and carries out downstream user chemical safety assessment, he must report certain information to the Chemicals Agency. The chemical safety report is not submitted to the Agency, but is to be updated and kept available.

The principle of chemical safety assessment is similar to that for risk assessments at workplaces, where exposure levels are estimated by using exposure models or measuring substance concentrations at workplaces and are compared to occupational exposure limit values. However, the chemical safety assessment considers not only risks for workers, but also for consumers and the environment and it covers all steps in the life-cycle of a substance. This means that not only exposures in your own installation must be considered but also those resulting from the identified uses of your customers (see chapter 8) or, when the substance is part of an article, the life-cycle of the article.

A downstream user chemical safety assessment entails several (iterative) steps, which need to be carried out for each exposure situation that could occur at your own site and further downstream: development of an exposure scenario, selection and/or generation of information on safe thresholds, assessment of exposure levels and checking if there is a risk.

You may be required to carry out an assessment because your own use is not covered by your supplier's exposure scenario. It is also possible that a customer may make his use known to you and you decide to make the assessment for him rather than forwarding the information to your supplier so that the assessment can be made by another actor up the supply chain.

The following figure shows the steps of a downstream user chemical safety assessment.

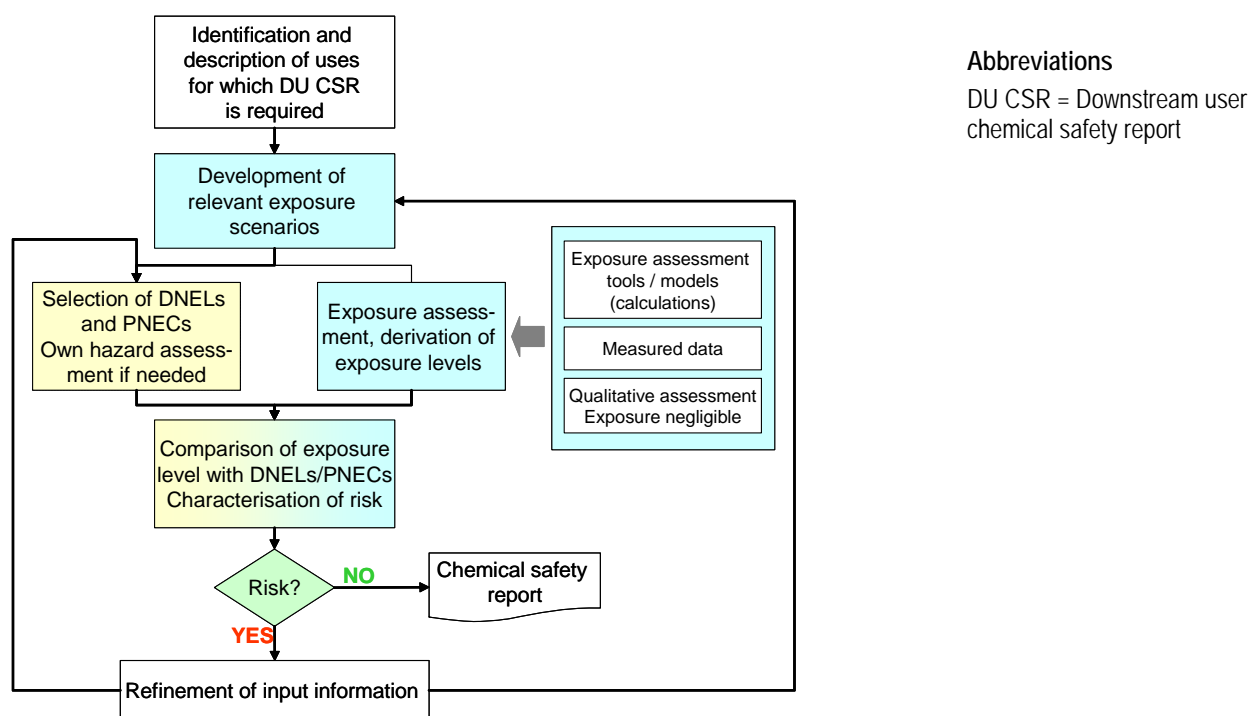


Figure 7-1 Process for downstream user chemical safety assessments

The extent and specific activities to be carried out in the downstream user chemical safety assessment depend on your specific case. You can assume that you will need to undertake the following types of work.

Table 135 Tasks and expertise for a downstream user chemical safety assessment

Task	Expertise needed in 'easy' cases	Expertise needed in more complicated cases	Help
Define uses for chemical safety assessment	Business decision on which uses to assess Common sense		Discussion with customers, this guidance and the guidance on the Chemical Safety Report
Collect information and develop exposure scenarios	General understanding of exposure assessment method and uses	Knowledge of the process parameters, use situation and risk management measures applied.	
Assess if hazard information is insufficient	Knowledge of exposure routes and types and which DNELs/PNECs to apply	(Eco-)toxicological knowledge to either search for information in data bases or to decide on testing and derivation of safe levels	Guidance on the Chemical Safety Report and Guidance on data requirements
Deriving exposure levels	Use of exposure assessment tools	Use of complex exposure models, assessment of exposures from many sources	Exposure models, guidance document on preparing a chemical safety report

If you do not plan to carry out the assessment yourself, but plan either to contract external experts or to ask your supplier to do the assessment for you, see chapter 8 of this guidance.

If you are planning to carry out a downstream user chemical safety assessment using your own expertise and personnel, it is recommended that you read the following sections to get a better understanding of the process. You will, in addition, need to use the guidance on the Chemical

Safety Report, as this contains the actual methodological guidance.

The last section of this chapter describes the principles of making a chemical safety report for a preparation, in order to develop an exposure scenario for a preparation. This approach can streamline your efforts, in cases where several substances in a preparation you use require a chemical safety assessment.

7.2 Requirement for a downstream user chemical safety assessment

- Downstream users can be required to make their own chemical safety assessment with regard to substances classified as dangerous, or substances which are persistent, bioaccumulative and toxic (PBTs) or very persistent and very bioaccumulative (vPvBs).

This means that a chemical safety report is not required for substances for which you do not receive a safety data sheet. In addition, an exemption also applies in the following cases:

1. Your supplier is not required to make a chemical safety report for that substance.
2. Your use of the substance or preparation in total is below 1 tonne/year (this refers to all the uses of that substance or preparation)⁴¹.
3. Your conditions of use are at least as protective as the ones recommended in the safety data sheet.
4. You use the substance for product and process oriented research and development (PPORD) and you implement risk management measures in accordance with relevant worker protection and other environmental legislation⁴².

In the case of preparations, the obligation only applies for substances in a concentration level above those listed in article 14.2 of REACH if:

- the exposure scenario(s) or use and exposure categories of substances or preparations provided by the suppliers do not cover the conditions of use of the downstream users; or
- the information in a safety data sheet under heading 16, or provided according to Article 32, establishes that the use for which the substance or preparation is applied is advised against.

Producers or importers of articles that are required to register a substance in accordance with article 7 of REACH are considered as registrants and, therefore, they are required to make a chemical safety report if they use that substance in amounts of 10 tonnes or more per year (regardless of whether or not the substance requires a safety data sheet).

If you carry out a downstream user chemical safety report you may cover either your own uses only or also uses communicated by your customers. When you are notified of a use by a customer, you may decide if you want to cover it in your chemical safety report (unless it is a use advised against) or to notify it up the supply chain.

If you are required to make a downstream user chemical safety report, you must comply with this obligation within 12 months after having received a safety data sheet containing a registration number.

⁴¹ Downstream users relying on this exemption must consider the uses of the substance or preparation and identify and apply any appropriate risk management measure to ensure the risks to human health and the environment are adequately controlled. The downstream user will also need to report to the Chemicals Agency (see article 37.4.(c) of REACH)

⁴² You need to report to the Chemicals Agency if you rely on this exemption. This is also the case if you are using less than 1 tonne of a substance for this particular use (see article 38(5) of REACH).

7.2.1 Making the assessment for single substances

A chemical safety assessment generally refers to a single substance. The duty of downstream users to perform a chemical safety assessment also refers to single substances: downstream users may need to carry out a chemicals safety assessment if the substance is used outside the conditions in supplier's exposure scenario. If a preparation is used, the downstream user needs to ensure that his conditions of use of individual substances, and, if applicable, the conditions of use he recommends to his customers, are as a minimum as those specified in the exposure scenario(s) he received.

Article 37

Downstream user chemical safety assessment and duty to identify, apply and recommend risk reduction measures

Paragraph 4

"A downstream user of a substance on its own or in a preparation 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."

7.2.2 Making the assessment for a preparation

A downstream user chemical safety assessment for one substance can cover also other substances in the same preparation, or even all of them, when the assessment carried out for that substance is sufficient to assess and document that risks are controlled for (the) other substances as well. This can be useful where several substances in a preparation require a downstream user chemical safety report. A similar approach to that described in section 7.13 could then be used, i.e. the critical component methodology, applied to the set of substances used outside the conditions described in the received exposure scenario(s)). This needs to be justified.

It is also possible to make a chemical safety assessment for a preparation. The downstream user chemical safety assessment for a preparation is voluntary and may be particularly useful for preparations with less severe hazards than those of the individual substances they contain. It may also be helpful if an assessment is required for several substances in the preparation. Making an assessment for a preparation means that you can:

- develop the exposure scenario for the preparation,
- assess safety of the use of the critical component(s) and
- provide argumentation, that all substances requiring a chemical safety report are covered by the assessment.

When a downstream user chemical safety report has been prepared for a preparation, you are required to indicate in Section 15 of the safety data sheet which substances are covered by the assessment.

Article 31

Paragraph 2

[...]If the safety data sheet is developed for a preparation and the actor in the supply chain has prepared a chemical safety assessment for that preparation, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

In making a chemical safety report for the preparation, you must assess and document that the risks from all substances in the preparation requiring a chemical safety assessment are controlled by the conditions specified in the exposure scenarios. Thus, by making a chemical safety report for the preparation, you can avoid having several chemical safety reports for the individual substances in a

preparation. Details on the method for making the assessment for a preparation are given in section 7.13.

7.3 Cases where formulators may assess chemical safety

Two cases can be distinguished:

- Your own conditions of use are not covered by the exposure scenario(s) you receive and you make the assessment to demonstrate that your formulation process with the substance or preparation is safe. You can prepare your safety data sheet and exposure scenario – if required – for your preparation based on the information you received from your suppliers.
- If the conditions of use down the supply chain indicated by your customer⁴³ are not covered, you make the chemical safety assessment for and in cooperation with him for his use and the uses further down the supply chain.

In both cases, you could receive one or more exposure scenarios for the substances and preparations you use to make your preparation, of which you could use one or more.

Figure 7-2 shows what a formulator could do when his customers' use(s) are covered by some but not all of the exposure scenarios of the substances for which a chemical safety assessment is required.

There may be five situations for the formulator

- Situation 1: there are few, very similar, exposures scenarios recommending the same risk management measures for the substances in the preparation and the formulator simply forwards them⁴⁴ to the customer (see chapter 14 of this guidance). The formulator may not be aware of all uses along the supply chain and some exposure scenarios may not cover the uses further downstream. The customer may thus be required to make a downstream user chemical safety assessment.
- Situation 2: the formulator consolidates the information in the exposure scenarios he receives into one scenario for the preparation (see chapter 14 of this guidance). He may not be fully aware of the uses downstream and it is possible that they are not covered by the scenario he prepares. The customers may thus be required to make a chemical safety assessment.
- Situation 3: the formulator is aware that some of his customers' uses are not covered by one of the exposure scenarios he receives and he carries out a downstream user chemical safety assessment for that substance. This is described in the remaining sections of this chapter. The derived exposure scenario will be used for developing the exposure scenario for the preparation, if the downstream user makes one (see chapter 14 of this guidance).
- Situation 4: the formulator is aware that some of his customers' uses are not covered by at least one of the exposure scenarios he receives and he carries out a downstream user chemical safety assessment for this set of substances, or a downstream user chemical safety assessment for the preparation to develop the exposure scenario for his customers.

⁴³ Non-covered uses could be those of your direct customer or of customers further down the supply chain and include formulating processes and end-uses, including the incorporation of substances and preparations into articles.

⁴⁴ For customers who are end-users, the formulator should merge and consolidate exposure scenarios rather than just forwarding them. However, if the formulator supplies another formulator, forwarding the scenarios without changes could be the preferred option, as it provides the customer with sufficient information to carry out a chemical safety assessment, if required, or merge the information for the end-user, if necessary.

- Situation 5: the formulator is aware of that an exposure scenario does not cover the use of a customer and asks his supplier to assess that use of that substances, by making the use known and providing relevant information (see chapter 8 of this guidance).

In all cases, the safety data sheets and exposure scenarios communicated must be consistent and allow the customers to identify and further recommend appropriate measures to control risks.

The figure also shows the relation between this chapter and chapter 14 of this guidance - on fulfilling the obligations for preparations

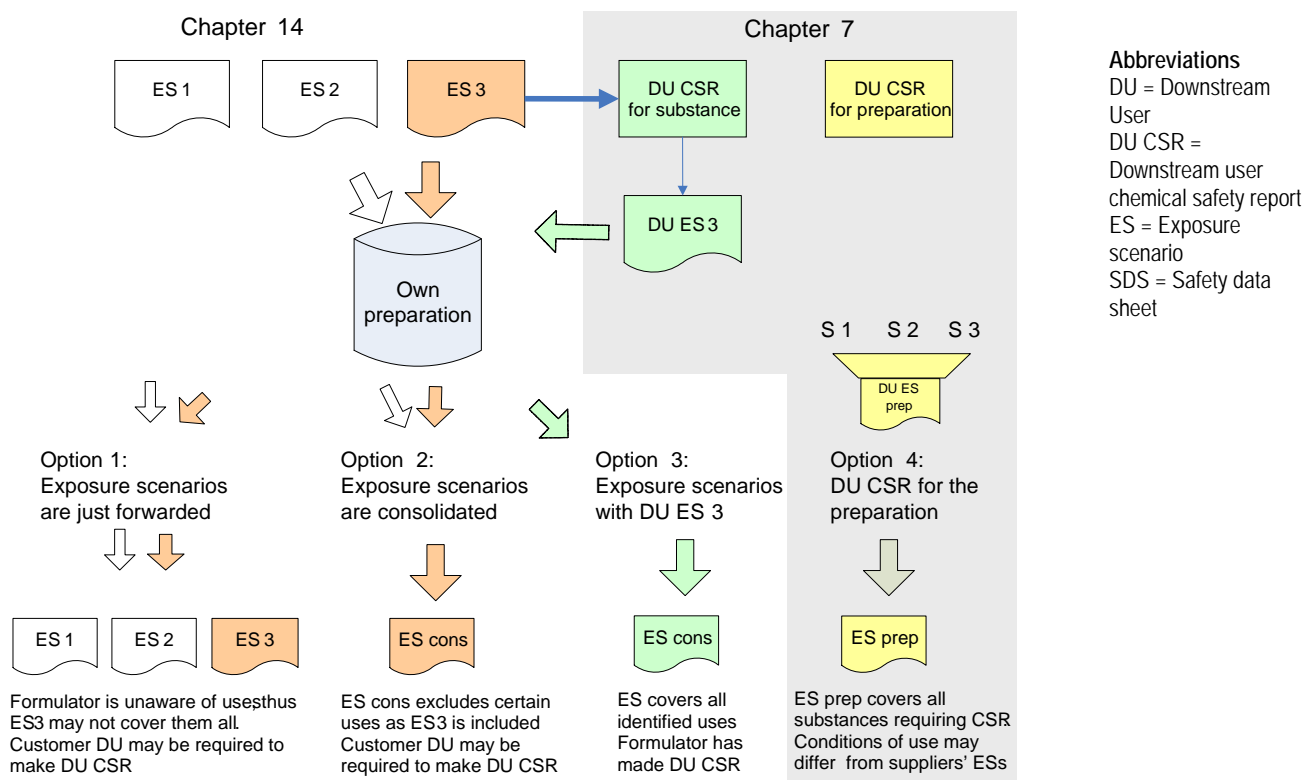


Figure 7-2 Downstream user chemical safety report for preparations

If a customer makes his use known to you in writing, you can decide to include it in your chemical safety report or to forward that information up the supply chain to have it covered by the chemical safety report of your supplier. If you do not do either, you should not further supply your preparation to that customer.

If the chemical safety report is required because your or your customer's actual conditions of use are not covered by those in the exposure scenario received, you may frequently be able simply to refine the parameters determining the exposure level to demonstrate adequate control of risks. If your or your customers' uses as such are not included in the suppliers' assessments, you may have to develop entirely new exposure scenarios and related assessments. This may also involve generating new hazard information.

If your or your customer's use is advised against, you may first assess the reasons of your supplier before starting your own assessment.

7.4 Demonstrating safe use

The aim of the assessment is to demonstrate that the conditions of use described in an exposure scenario result in adequate control of risk, by showing that the actual exposure levels remain under the threshold concentrations below which no adverse effects are expected. This means comparing the quantified exposure of humans and the environment (predicted exposure level – PEL - for humans and predicted environmental concentration – PEC – for the environment) to the safe thresholds (DNEL and PNEC). Normally, DNELs and PNECs are derived by the registrant and communicated with the safety data sheet. Details on the derivation of safe levels can be found in the Guidance on the Chemical Safety Report.

If a threshold cannot be determined, the conditions of use must demonstrate that exposure is minimised, according to Annex I. 6(5) of REACH.

7.5 Workflow for downstream user chemical safety assessments

The downstream user chemical safety report is described in Annex XII of REACH. The difference to the chemical safety report required from manufacturers and importers for registration is that downstream users do not have to make a hazard assessment, but can use the available information. The downstream user chemical safety report does not have to be submitted to the Agency.

If you receive an exposure scenario for a preparation which does not cover a use, it is possible that only the use of some of the hazardous substances it contains is not covered. It may be necessary to identify in detail for which substances and uses the assessment is actually required.

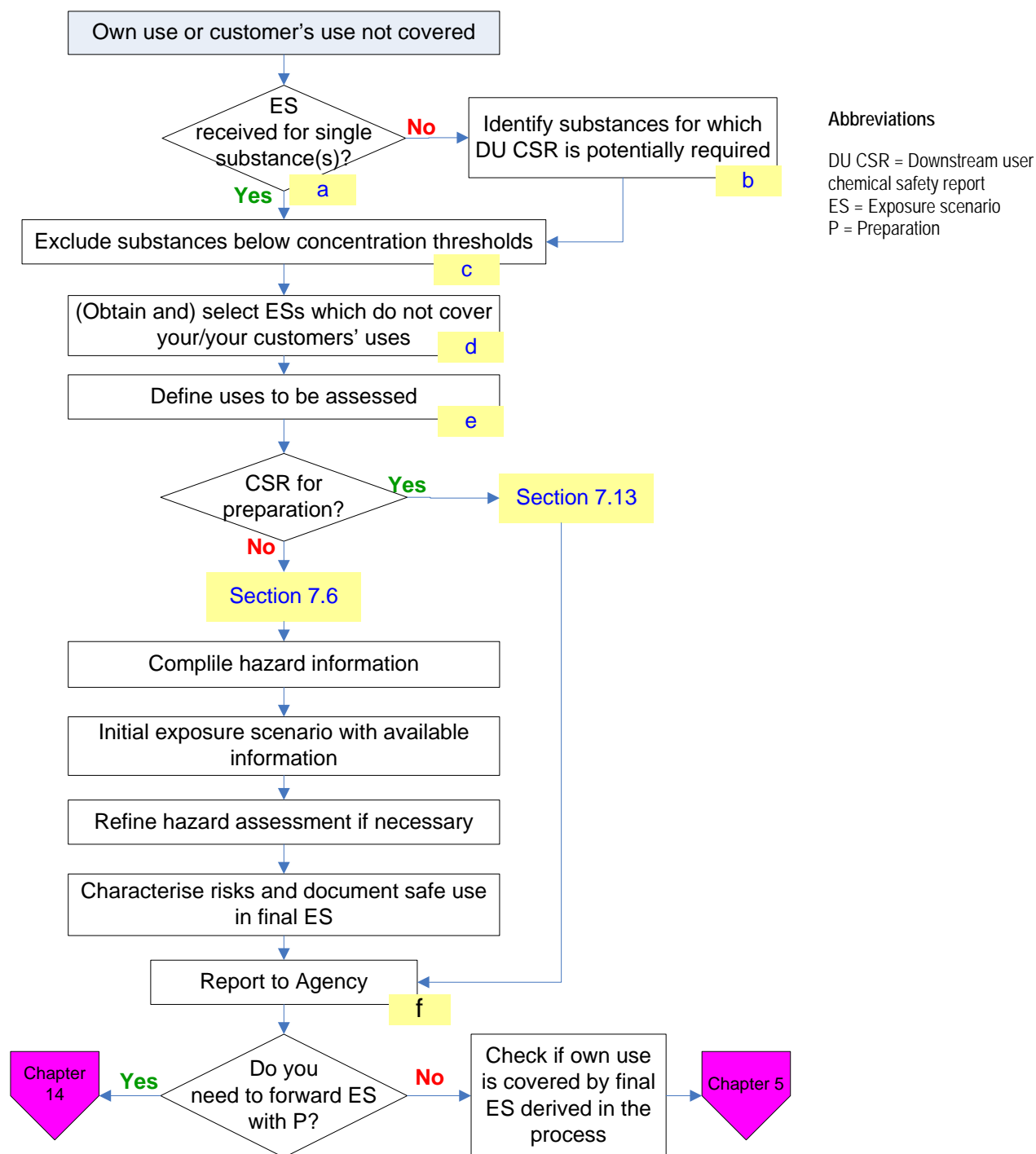


Figure 7-3 Work process for downstream user chemical safety assessment

Note a: Information received

If you use a preparation, you may receive:

- exposure scenarios relating to single substances contained in it, or
- one exposure scenario for the entire preparation, or
- one exposure scenario for the preparation and several exposure scenarios for the individual substances contained in it.

Receiving exposure scenarios for individual substances enables you to check coverage for each of them separately and to identify which require a downstream user chemical safety assessment.

Note b: Identification of substances requiring assessment

If you only receive an exposure scenario for the preparation, you can find information in section 15 of the safety data sheet on for which of the substances it contains a chemical safety assessment has been prepared by the registrant⁴⁵. In principle, an assessment may be required only for these substances⁴⁶. Checking if the substances' (original) exposure scenarios cover the conditions of use is not immediately possible, as these are not supplied.

Note c: Concentration of substances in the preparation

For substances contained in a preparation below the lowest of the concentration thresholds specified in article 14(2) of REACH, no downstream user chemical safety assessment is required. Consequently, if you are a formulator, you should assess your recipes and check which substances the assessment is not needed for, because they are diluted in your preparation.

If you are an article producer, there is no such cut-off for the concentration of a substance in the article. This means that, if the supplier's exposure scenario does not cover the conditions under which the substance is included in the article and/or for the article's service life or waste phase, you have to include the substance and the life-cycle stages downstream in your assessment.

Note d: Obtaining information

If you only received an exposure scenario for a preparation, you have two options to proceed: you could either assume that all substances on your list require a downstream user chemical safety assessment and include all of them in your assessment, or you could communicate with your supplier and try to find out which substances are not actually covered. For this you would need to obtain the original substance exposure scenarios or get confirmation by your supplier on the coverage of the conditions of use.

Note e: Scoping of the assessment

You only have to assess the uses from the receipt of the substance as such or in a preparation (your own use) and the identified uses downstream which you assume are not covered by the conditions of use of your suppliers' exposure scenario(s).

Note f: Provide information to the Agency

For each substance used outside the conditions described in an exposure scenario you received, you need to provide the following information to the Agency, at the latest 6 month after you received the exposure scenario not covering your identified use:

1. your identity and contact details
2. the registration number of the substance(s), as such or in preparations, which are not covered by the exposure scenario, where available
3. the identity of the substance(s) concerned
4. the identity of the manufacturer, importer or supplier of the substance(s) concerned

⁴⁵ You can only be required to make a downstream user chemical safety assessment if a chemical safety report was prepared by the manufacturer or importer up your supply chain who registered the substance.

⁴⁶ There may be classified but not yet registered substances in the preparation. Although you are not required to include these in your assessment, you may want to do so, to ensure safe use of the whole preparation. No guidance is provided here for these cases, as it is a voluntary action.

a brief general description of your use.

It is possible that only the uses occurring at specific life-cycle stages are not covered by the exposure scenario. If, for example, you produce a window frame by a specific technological process, it is possible that the incorporation of the substance in the window frame (article as such and its service life) is covered but your own production process is not. In that case, you only need to make an assessment of the lifecycle stages of your use that are not covered and you may use your supplier's assessment of those that cover your use (in this case the service life).

You may have to make several exposure scenarios or compile exposure scenarios for several substances in the preparation for one life-cycle stage. You may use Table 16 to list the assessment needs for each substance.

Table 16 Life-cycle stages to be considered in scoping the assessment

Life cycle stage	Substance 1	Substance 2	Substance 3
Formulation			
End-use as processing aid			
End-use by incorporation in article			
End-use as service provider			
Article service life			
Waste phase			

7.6 Process of the downstream user chemical safety assessment

[Guidance on the Chemical Safety Report](#) provides the main guidance for making the assessment. Therefore, the following section explains only the main principles and provides some examples to give a better understanding of the process.

7.6.1 Title(s) of the exposure scenario(s)

All exposure scenarios shall have a title, sufficiently describing the use(s) of a substance. Particularly if you are a formulator and communicate the exposure scenarios to your customers, it is advisable that you work with the standardised use descriptor system (see the Guidance on the Chemical Safety Report). This system consists of a set of four descriptors that work together. Not all descriptors are always needed and sometimes the information from two or more descriptors is redundant. For each descriptor, there are pick-lists⁴⁷ to select from. The descriptors process category and article category can be directly linked to standard exposure assessment tools. The four descriptor types are:

1. sectors of use
2. product category
3. process category
4. article category

Example 7 Applying the use descriptor system

⁴⁷ See Guidance Document on preparing a Chemical Safety Report, Part D1

	Sectors of use	Product category	Process category	Article category
Manufacturer of chairs, preparation is a wax	Manufacture of furniture	Polishes and wax blends	Low energy spreading	Wood and wood furniture: furniture
Cleaning of metals	Manufacture of fabricated metal products, except machinery and equipment	Washing and cleaning products (including solvent based products)	Immersion operations	not applicable

7.6.2 Compiling information for exposure scenarios (s)

All parameters which have an influence on the exposure levels need to be described in an exposure scenario and, where possible, quantified. If you have to assess several uses, you may have to develop several exposure scenarios or you may be able to include them in one.

Assessment tools can be used to model exposure levels, based on the exposure scenario information and/or the brief general description of use. For the first assessment, the ECETOC TRA is recommended for workers, EUSES for the environment, and ConsExpo for consumer uses⁴⁸. Here, pre-set broad exposure settings are integrated, which can be selected for the assessment and also modified to an extent. If they are used, information collection for exposure scenarios may be targeted towards the data needed to carry out the first assessment.

Generic exposure scenarios may be developed by industry sectors or single companies, applying to various substances / preparations and covering a broader range of conditions of use. If 'your sector' has developed such generic exposure scenarios that are applicable for your use, you should use these as a starting point. You should check whether the conditions of the use(s) you assess correspond to the generic exposure scenario and modify / adapt it if necessary.

A format with explanation for structuring the information in an exposure scenario is provided in Appendix 2 of this guidance. It also contains a list of determinants of exposure. Chapter 9 of this guidance provides information on how, and from where, to collect the relevant information. Chapter 5 of this guidance contains some additional examples of what the information could look like.

You may have to quantify the exposure level of all exposure routes and for all target groups potentially exposed to the substance. This applies even if a substance is not classified for a specific end-point or has no or very high derived no effect levels (DNELs) or predicted no effect concentrations (PNECs). In these cases, you may be able to use generic data, because risks would only occur at very high exposure levels. Furthermore, you may be able to show, based on qualitative considerations, that certain exposure routes are negligible and do not have to be quantified to make a statement on the risk.

7.6.2.1 Exposure scenarios for processes

Exposure scenarios for industrial or professional processes describe only the exposures of workers and of the environment as a result of emissions from the process. If the use of a substance by consumers, as such or in a preparation, is assessed, similar information is needed, except that the consumer has less potential to reduce his exposure.

To begin your assessment, it may be helpful to visualise the use, to get a better understanding of

⁴⁸ See the Guidance on the Chemical Safety Report for further details and where to get access to the tools.

where exposures of humans or the environment could occur and what would determine the exposure levels. Figure 7-4 shows an example of a polymer extrusion process, where the emission points from the process are indicated.

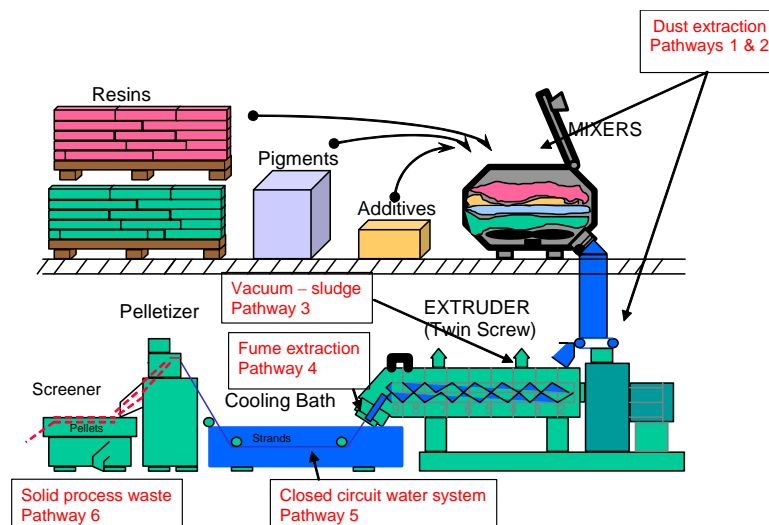


Figure 7-4 Extrusion process with emission pathways and risk management

7.5.2.2 Exposure scenarios for articles

The main difference between exposures from the use of articles and exposures from the use of preparations is that substances are released at a much slower speed at normal temperatures from articles. This means that release of substances from the article and related exposures of humans and the environment are more difficult to quantify.

Although the exposure levels from articles need to be assessed as part of a substance's life-cycle, and you therefore need an exposure scenario, there is no requirement to communicate the final exposure scenario down the supply chain with an article. If you determine that certain measures are required for safe use of the article, this information could be communicated with the article, e.g. in the use instructions or on the package. Communication on instructions may be required under article 33 of REACH for substances on the candidate list for authorisation.

7.6.2.3 Exposure scenarios for waste

For the assessment of the waste phase, you need to consider waste containing the substance that results from all uses that you assess – this means any process and, if relevant, the article in which the substance is included. The principle of quantifying exposure levels is the same for the waste phase as for the other uses of a substance. Handling of preparation wastes would usually require the same risk management measures as recommended for the actual use of the preparation. Handling of article waste containing the substance would require different measures, but may be covered under existing legislation, such as the IPPC Directive and waste legislation. For the assessment of risks from the waste phase, you should consider mainly the specific risks from the waste management processes, which have not been covered by another downstream user process. Further information is provided in the [Guidance on the Chemical Safety Report](#).

7.7 Quantification of exposure levels

Using the information in the exposure scenarios, you can determine the exposure levels for each

relevant exposure pathway and target group (workers, consumers, and environment). The main way to do this will be to use software tools that model the exposure levels. Several of these tools are introduced and described in the [Guidance on the Chemical Safety Report](#).

7.7.1 ‘Negligible’ or ‘unlikely’ exposure pathways

Before you start to quantify exposure levels, you may consider whether some of the possible exposure routes could be declared as ‘negligible’ or irrelevant, based on qualitative arguments. Considering quantification of exposure on certain pathways as being not relevant requires documented arguments and clarity as to whether the argument refers to “no exposure to be expected” or “exposure likely to be very small”. The 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’s 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 is expected to substances contained in (the coating of) the wardrobe to be low.

The [Guidance on the Chemical Safety Report](#) contains further arguments and examples.

7.7.2 Relevant exposure pathways

For exposure pathways identified as relevant, you need to quantify the exposure levels to demonstrate safe use. You need to decide case-by-case which method is best, taking into account the level of detail needed and the information available. In principle, you can use exposure models, measured data or a combination of both.

7.7.3 Measured data

If you use measured data to predict an exposure level under the described conditions of use, it is important to compare these data with the prediction from exposure assessment tools and to provide information on the statistical background for the data presented. This is in order to make transparent the extent to which the measured data are representative for the situation under assessment.

Examples of measured data are:

- measurements of workplace air conducted in the framework of risk assessments at workplaces under the Chemical Agents Directive
- measurements of substance concentrations in waste water or exhaust gases carried out in the framework of environmental permits or emission monitoring
- measurements of emissions to indoor air from construction products,
- measurements in the framework of ‘sweat tests’ for textiles,
- measurements to prove product safety for children’s toys,
- migration models for plastic materials,
- emission measurements for car indoor air etc.

Example 8 Measured data for acetone at the workplace

Example: a company makes a downstream user chemical safety report for acetone used in a preparation. Acetone is the only component dangerous via the inhalation route. Measured data from risk assessments at workplaces are available and the measurements were conducted under conditions which correspond to those set out in the exposure scenario.

The measurement result of 55 mg/m³ can be directly used in the risk characterisation

You could also use these measurements for substances with lower vapour pressures than acetone and argue that, as a worst case, these would be present at the workplace at the same concentration.

Example 9 Using measured data from other substances

Example: the same company makes a downstream user chemical safety report for xylene used in a preparation. Xylene is the only component dangerous via inhalation. Measured data from risk assessments at workplaces are available for acetone, which is used in a different preparation but in the same process and the measurements were conducted under conditions which correspond to the exposure scenario compiled by the company. The vapour pressure (20°C) of acetone is 24 kPa and that of xylene is 3.7 kPa.

The measurement result of 55 mg/m³ obtained for acetone could be use as a worst case assumption for xylene.

7.7.4 Modelled data

There are several exposure models available to estimate exposures at the workplace, for consumers or for the environment based on the information compiled in the exposure scenario. These tools are described in the Guidance on the Chemical Safety Report.

7.8 Compiling information on hazards

Compile the safe threshold values for the substances you need to assess from the safety data sheet of your supplier. You should find the derived no effect levels⁴⁹ (DNELs) and predicted no effect concentrations (PNECs) under heading 8. You can use the following tables for structuring your list. Note that the tables list all possible DNELs/PNECs and that you should carefully decide which ones you need, based on your exposure scenario and the likelihood of exposure routes⁵⁰.

Table 17 Compilation of hazard data

Human health values	DNEL Workers	DNELs General population ³
---------------------	-----------------	--

⁴⁹ For non-threshold effects, like mutagenicity, no DNEL can be derived. However, in order to be able to characterise risks, a derived minimal exposure level can be established. This value describes a threshold, accepting a certain level of risks, and it is therefore not comparable to a DNEL. When it is not possible to determine a DNEL or a PNEC, a qualitative assessment that the likelihood of effects can be avoided when implementing the exposure scenario shall be carried out. For PBT and vPvB substances, the recommended risk management measures should minimise exposure to humans and the environment.

⁵⁰ Note that the information on systemic and local effects is needed to derive the values. The lower value should then be used for the assessment. If a substance is, for example, a respiratory irritant (local effect) and also affects the central nervous system via inhalation (systemic effect), DNELs could be derived for both effects. For targeting the risk management measures for acute exposures, only the lower value should be communicated and used in the assessment, as it covers the other effect.

Acute – dermal , systemic effects ¹		
Acute – inhalation, systemic effects ¹		
Acute – oral, systemic effects ¹		
Acute – dermal, local effects ²		
Acute – inhalation, local effects ²		
Long-term – dermal, systemic effects ¹		
Long-term – inhalation, systemic effects ¹		
Long-term – oral, systemic effects ¹		
Long-term – dermal, local effects ²		
Long-term – inhalation, local effects ²		

¹ Units are mg/m³ for inhalation, and mg/kg bw for oral and dermal exposure

² Units are mg/m³ for inhalation, and mg/cm² or ppm for dermal exposure

³ General population includes consumers and humans via the environment. In rare cases, it may also be relevant to derive a DNEL for specific sub-populations, such as children.

Environment	PNEC value
Freshwater, single instance / short- term	
Freshwater, continuous	
Marine water	
Sediment freshwater	
Sediment marine	
Soil	
Micro-organisms in STP	
Secondary poisoning (oral)	

If no such values are given for the substances, this could be for several reasons:

- The substance is registered in the lower tonnage bands and hazard data for certain end-points is therefore not available for deriving safe thresholds
- The PNECs/DNELs did not have to be listed by the supplier, as the supported uses do not lead to relevant exposures.
- The effects have no threshold and, therefore, no PNEC/DNEL can be derived.
- No PNEC/DNEL was derived, as respective hazard data has been waived by the registrant.

In order to assess the exposure levels, you will also need information on the substance's mobility and fate in the environment. This relates in particular the

- vapour pressure,
- molecular weight,
- log K_{ow},
- water solubility, and
- biodegradability.

When you lack a safe threshold value that you need to make the assessment, or information on physicochemical properties, you should first contact your supplier. If your supplier cannot help you, check the substance data base of the Chemicals Agency for this information. Information on substance properties that has been generated and/or derived by the registrants will be made publicly available there (<http://echa.europa.eu>). If you don't find the information needed, you may have to generate that information yourself. Turn to section 0 for further guidance.

7.9 Risk characterisation

Characterising risks means comparing exposure levels determined in the exposure assessment with

the safe threshold values. You can use Table 17 to carry out the risk characterisation.

Compile the DNELs/ PNECs and the exposure levels for each of the uses, target groups and exposure types. Divide the exposure level derived in the exposure assessment by the relevant DNEL/PNEC to obtain the risk characterization ratio. If the ratio is greater than 1, there is a risk and you need to iterate your assessment for this exposure pathway. You could extend the table to include safe threshold values for this, as shown below. For more details see the Guidance on the Chemical Safety Report.

Table 18 Risk characterisation for all exposure pathways

Human health values (one is needed for workers, one for the general population)	DNEL value	Exposure level	Risk characterization ratio
Acute – dermal			
Acute – inhalation			
Acute – oral			
Long-term – dermal			
Long-term – inhalation			
Long-term – oral			

Environment	PNEC value	Exposure level	Risk characterization ratio
Freshwater, single instance / short- term			
Freshwater, continuous			
Marine water			
Sediment freshwater			
Sediment marine			
Soil			
Micro-organisms in STP			
Secondary poisoning (oral)			

If all risk characterisation ratios are below 1, the use you assess is considered as safe and your initial exposure scenario becomes final. If there are no DNELs/PNECs to compare with because of non-threshold effects, exposures should be minimised as far as possible. You can document the assessment in the chemical safety report. If the risk characterisation ratio for one or more exposures exceeds the value of 1, a refinement of the assessment may be needed.

7.10 Iteration of the assessment

There are two options to iterate the assessment: either the hazard information is refined, or the information on the use – in particular the risk management measures - has to be changed.

7.10.1 Refinement of the hazard information

You may have to refine the hazard information either:

- because you lack safe threshold values (DNELs/PNECs) to characterise risk, or
- because you find it more efficient to refine the values communicated to you than to refine the exposure assessment.

If you cannot obtain missing DNELs/PNECs from your supplier or the Chemicals Agency data base (section 0), it is likely that nobody has yet derived them. You could ask your supplier to forward an inquiry to the substance information exchange forum (or ask his supplier to do so) to ask if there are other members in the substance information exchange forum interested in, or currently deriving, that value. If this is not successful, you will have to derive the value yourself.

DNELs/PNECs are based on test results to which ‘application factors’ are applied. These application factors take account of uncertainties in the data base and the extrapolation of animal test information to humans. Refining DNELs/PNECs means decreasing the uncertainty about the safe level by providing better data. This usually leads to higher numerical values.

If you have to derive the values yourself, use the [Guidance on the Chemical Safety Report](#). The concise guidance introduces the principles and the reference document advises more specifically on how to derive and refine DNELs and PNECs. This guidance requires a high level of toxicological and ecotoxicological expertise.

The level of uncertainty of the data base is reduced by collecting additional or more appropriate information on the substance’s dangerous properties, for example by

- assessing if additional or more relevant information is available and using it to derive a new DNEL/PNEC⁵¹. As first step, you should find out if this information is held by other actors up your supply chain. The registrant of the substance(s) in question may have access to additional data (e.g. via the substance information exchange forum). If you find information from substance testing for example on the internet or in literature, you can use this data to refine the values. As your suppliers have to take into account existing information it is however unlikely that you will find such information.
- conducting tests and generating 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 undertakes such tests. Which tests are needed to improve the data base is described in the Guidance on the Chemical Safety Report.

Before carrying out tests or investing in the generation of new data, you should pre-assess the extent to which you can influence the threshold value by reducing the safety factors, to get an idea of the likelihood that you will be able to demonstrate adequate control of risk. In cases where you are considering conducting tests with vertebrate animals, you need to submit a testing proposal to the Chemicals Agency and wait for the reply before you start testing. Until such time as the testing proposal is executed (after having been validated by Chemicals Agency) and your exposure scenario is complete, you are required to identify and record in your chemical safety report the risk management measures intended to manage those risks. Note that in cases where you do generate / collect new information on a substance’s hazards, you have to communicate this to your supplier⁵² (see chapter 10 of this guidance).

If you have refined the values, you have to document this part of the chemical safety assessment in your chemical safety report. For hazard data that you simply copy from your supplier’s safety data sheet, this is not required. The new values have to be communicated in your safety data sheet, if one is required.

⁵¹ See Guidance on the Chemical Safety Report

⁵² You are required to forward new information on hazards to your supplier. However, you do not have to communicate any results directly and should ensure that, if data are shared, your costs are also shared.

7.11 Refinement of the exposure assessment

In developing the exposure scenario and making the assessment of exposure levels, you may have made assumptions on the conditions of use. You could refine these assumptions with more precise information and/or reasoning. You could also carry out measurements to verify your assumption; for example, if you modelled the concentration of a substance in your waste water, you could measure its actual concentration in your effluent and use this to refine your exposure estimation.

You could also refine the information on risk management measures or operational conditions of use in your scenario. The risk management measures could be made more stringent, that means their prescribed efficiency increased, either by upgrading existing measures or by adding additional ones.

Another way of refining the exposure assessment is to exclude certain uses. If, for example, you identify a risk to consumers when assessing their application of paint, you could decide not to supply the paint to consumers.

If you modify your conditions of use in your scenario, use this new quantification in your exposure assessment tools. Derive the respective new exposure levels and use them in your risk characterisation. If you can demonstrate safe use, the new exposure scenario will be the final one and has to be communicated downstream, if an exposure scenario needs to be communicated to your customers.

7.12 Documentation of the downstream user chemicals safety assessment

To document the downstream user chemical safety assessment, you must use the relevant sections of the chemical safety report format given in Annex I of REACH.

The content of the downstream user chemical safety assessment is the documentation of:

1. the implementation of the risk management measures for your own use, according to the final exposure scenarios, as well as the communication of risk management measures to the customers, if required (Part A)
2. the results, any argumentation and supporting documents for the exposure assessment and risk characterisation for all assessed uses (Part B, section 9 (exposure assessment) and 10 (risk characterisation) of the format in section 7 of annex I)
3. references to the DNELs/DMELs/PNECs taken from the supplier and additional information your own hazard assessment, if performed.

You are not required to submit the downstream user chemical safety report to the Chemicals Agency. You are, however, required to keep the chemical safety report up to date and available. In addition, if you make your own chemical safety report, you are required to inform the Chemicals Agency of the fact, unless the use to which the chemical safety report refers represents less than 1 tonne per year (see chapter 6, note c of this guidance).

7.13 Downstream user chemical safety report for a preparation

By making a chemical safety report for a preparation, a downstream user can develop exposure scenarios for a preparation, including appropriate recommendations for risk management, and fulfil his legal obligations to prepare downstream user chemical safety assessments for one or more substance for which this is required. A downstream user chemical safety report for a preparation may be more resource efficient than making several assessments for different substances separately. Furthermore, the specific properties of the preparation can be taken into account. As stated before in

paragraph 7.1, the obligation of making chemical safety report relates to single substances, therefore performing a chemical safety report for a preparation is voluntary.

In practice, the development of the exposure scenario for the preparation can be focused on the critical components in the preparation, if it can be documented that the risks from all other substances are covered by this. To identify the critical component(s) within a whole preparation, also information on substances for which no exposure scenario is received or which are not yet registered but are known to be dangerous, need to be taken into account. Additivity rules should be applied in the same way as is done for the classification of preparations and matrix effects of the preparation can be considered with regard to the mobility of the substances. The final exposure scenario derived in the assessment may cover a range of substances, with different properties, in the preparation.

The assessment of physicochemical risks from a preparation can, and in many cases must, be based on testing of the preparation. The assessment of risks for human health and the environment is based on the properties of the single substances, that means the DNELs and PNECs are used in the risk characterisation. To assess exposure levels, in some cases the properties of the preparation influence the mobility of the substances, such as rubber or alloys, and this should be taken into account. DNELs and PNECs can not be derived for the preparation.

7.13.1 Workflow on downstream user chemical safety report for preparations

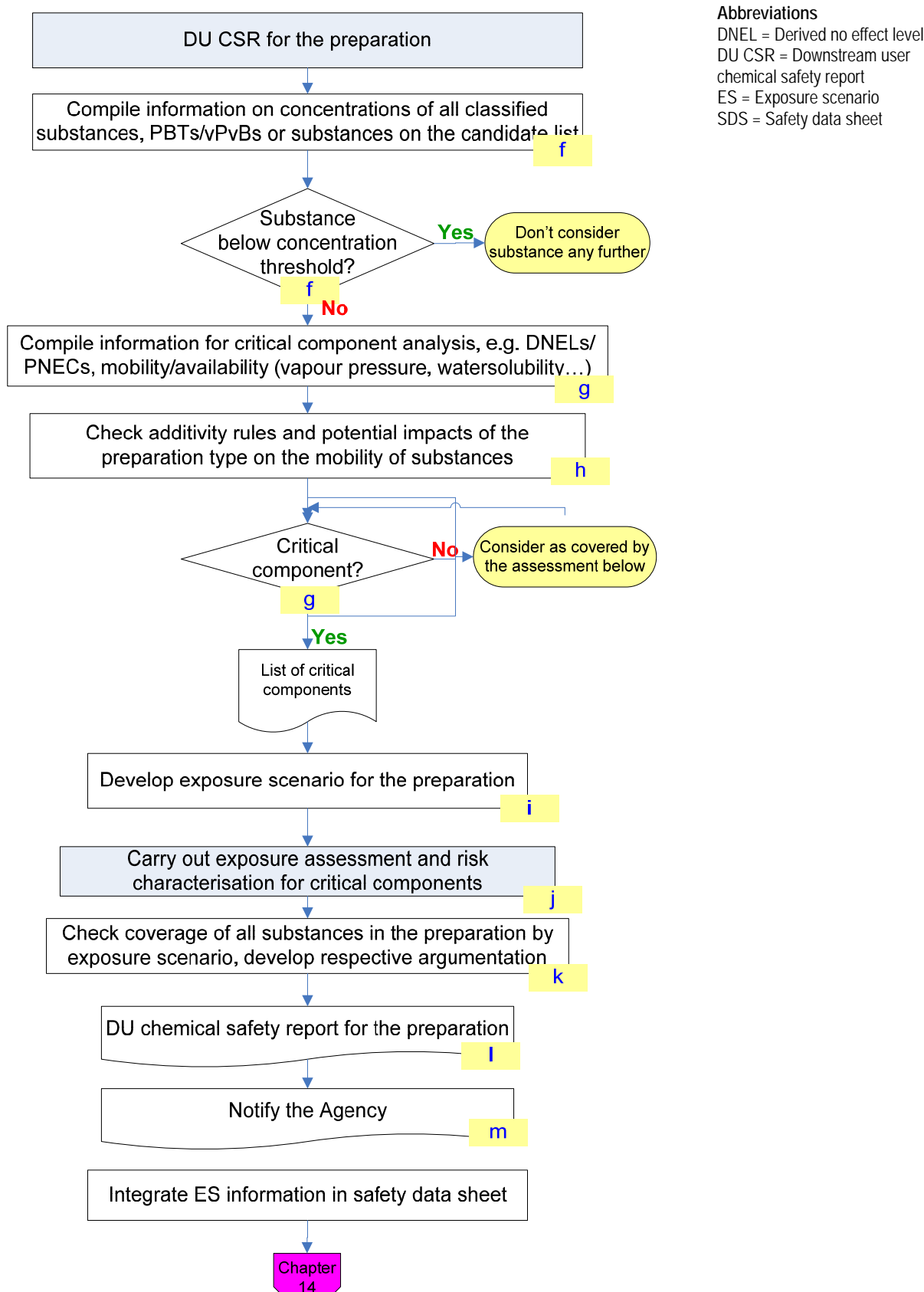


Figure 7-5 Downstream user chemical safety report for preparations

Note f: Compile information on concentrations and amounts

Check the recipe of your preparation and determine the concentration of each substance that is classified as dangerous, a PBT or vPvB or a substance on the candidate list and which is contained in your preparation in concentrations exceeding the thresholds listed in article 14(2) of REACH. Substances in concentrations below these thresholds do not need to be considered further.

If you know that the same substance is contained in several of the preparations you use, you should sum up the amounts, to verify that your use is above 1 tonne (of the substance or preparation).

In preparing a chemical safety assessment for the preparation, you have to consider all available and relevant information. Thus, you have to take into account not only the information on substances for which a chemical safety report has been made by an actor up the supply chain, but also the safety data sheet (or maybe even article 32 information) you receive for substances which are not yet registered or which do not require a safety assessment or a safety data sheet.

Note g: Compile information to identify critical components

The critical components are those substances that determine the risk for one or more adverse effects via one or more exposure pathways. To determine whether or not a substance is 'critical', a comparison of the substance's risk potential is necessary, taking into account its hazardousness (DNELs/PNECs), mobility, vapour pressure, water solubility etc.) and its concentration in the preparation. The risk characterisation ratios of your suppliers in section 8 of the exposure scenario of the substances, as such and contained in preparations, may also give an indication of which components are critical. The lower the risk characterisation ratio, the less critical the substance may be.

Further guidance on performing the critical component analysis is given in appendix 4 of this guidance and in the Guidance on the Chemical Safety Report.

Check whether each substance (consider additivity) is a critical component in relation to any of the end-points. The chemical safety assessment needs to justify that the conditions in the exposure scenario for the preparation, which is based for each target and exposure route on the most critical components, actually covers the other substances in the preparation.

Note h: Assess preparation related parameters

In the downstream user chemical safety assessment for preparations, you should apply the rules of additivity as you do for the classification of preparations. Thus, in determining the critical components and later in developing the exposure scenario setting out safe conditions of use, the nature of the preparation may influence the mobility of substances in/from the preparation. For example, use of a substance in an alloy could reduce its exposure potential. This should be taken into account in the assessment, remembering that releases may occur in later life stages as long term releases. Furthermore, extreme conditions of use may occur which influence the stability of the matrix (in the case of alloys, e.g. casting processes), where the mobility is changed.

The physicochemical hazards of the preparation may differ significantly from those of the single substances it contains. Here, also the classification rules for preparations should be followed for.

Note i: Develop exposure scenario for the preparation

Develop one or more exposure scenarios for the preparation that ensures safe use of all critical components in the preparation. You may have to develop more than one scenario, if there are several uses of the preparation, or if exposures could be controlled using different risk management measures. Use the tools and information given in section 0.

Note j: Carry out exposure assessment and risk characterisation for critical components

In general you have to determine exposure levels for all exposure pathways resulting from the use of the preparation, including its service life and disposal, where relevant and applicable. If you can demonstrate qualitatively that certain exposure pathways can be neglected for all substances in your preparation and all life-cycle stages, a quantification of exposure levels may not be necessary (see section 0).

For the remaining exposure pathways and toxicological and ecological endpoints, you have to assess the exposure level of that substance which is critical for that exposure route, taking into account possible additivity of several substances. If you are unsure which of the components in a preparation is critical for an exposure pathway, you should determine the exposure and make a risk characterisation for all potentially relevant substances.

Characterise the risks from the preparation by characterising the risks from the individual critical components; compare the exposure levels with the DNELs/PNECs of the individual substances. If all risk characterisation ratios are below 1, the exposure scenario(s) covers all critical components. All less critical substances are regarded as covered by this as well, provided that there is plausible argumentation.

If the risk characterisation is performed for substances for which it is not possible to derive DNELs/PNECs, exposures should be minimised.

Note k: Check coverage of all substances

Make sure that all of the components in the preparation are covered by the exposure scenario, thus ensure that control of the critical components would also cover the other substances in the preparation. Develop and document plausible argumentation of why the chosen components are critical. Guidance can be found in the Guidance on the Chemical Safety Report as well as in the appendix 4 of this guidance.

Note l: Compile chemical safety report

The results of the assessment have to be documented in a downstream user chemical safety report for the preparation. This report should document the entire assessment, highlighting for which substances the chemical safety assessment is actually required. The hazard information taken into account for all substances needs to be part of the report. The source of that information (e.g. reference to the safety data sheet of the supplier or the Chemicals Agency data base) should be specified. Furthermore, the critical component analysis should be thoroughly documented, including the argumentation as to why substances have been selected as critical. Whereas the exposure scenario can cover all substances in the preparation, the exposure assessment needs to be documented substance-by-substance. The risk characterisation should show adequate control of risks on all exposure pathways for the critical components.

Note m: Report to the Agency

Although you have prepared only one chemical safety report for the preparation, you need to inform the Agency about all substances covered by your report and which are used outside the conditions of the supplier's exposure scenario. You do not need to send the chemical safety report to the Agency.

8 REQUESTING THAT A USE BECOMES AN IDENTIFIED USE

REACH gives downstream users the right to make a use known in writing to their immediate supplier of a substance or preparation, with the aim of having their use covered in the registration. This is particularly important for substances which are supplied with an exposure scenario. This section shows the steps to be taken by a downstream user to make a use known.

8.1 Introduction

Article 37.2 of REACH gives downstream users the right to make a use known:

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 preparation 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 Art 37.2)

A supplier has several options to react to a use made known to him:

1. The supplier assesses the use and include it in the chemical safety assessment and registration (if the supplier is a manufacturer or importer) and provide a relevant exposure scenario to the customer
2. The supplier assesses the use and identifies it as 'not safe'. The fact that the use is regarded as not safe must be communicated to the Chemicals Agency and the customer. Supply can be continued; however, the downstream user will need to decide what other action to take (see chapter 6 of this guidance)
3. If the supplier to whom the use is made known in writing is a downstream user, he can forward the request to his own supplier, so that the use can be covered by an exposure scenario developed by a supplier up the supply chain.
4. The supplier does not assess the use (e.g. because he considers that assessment of the use as not feasible or not economical), and does not either forward the request up the supply chain. In this case, he should stop supplying the substance for that use. In order not to run the risk of losing your supply, you could first make informal inquiries regarding inclusion of your uses as identified uses by your upstream supplier.

How to request that a use becomes an identified use is explained in the following workflow.

8.2 Workflow and explanation requesting that a use becomes an identified use

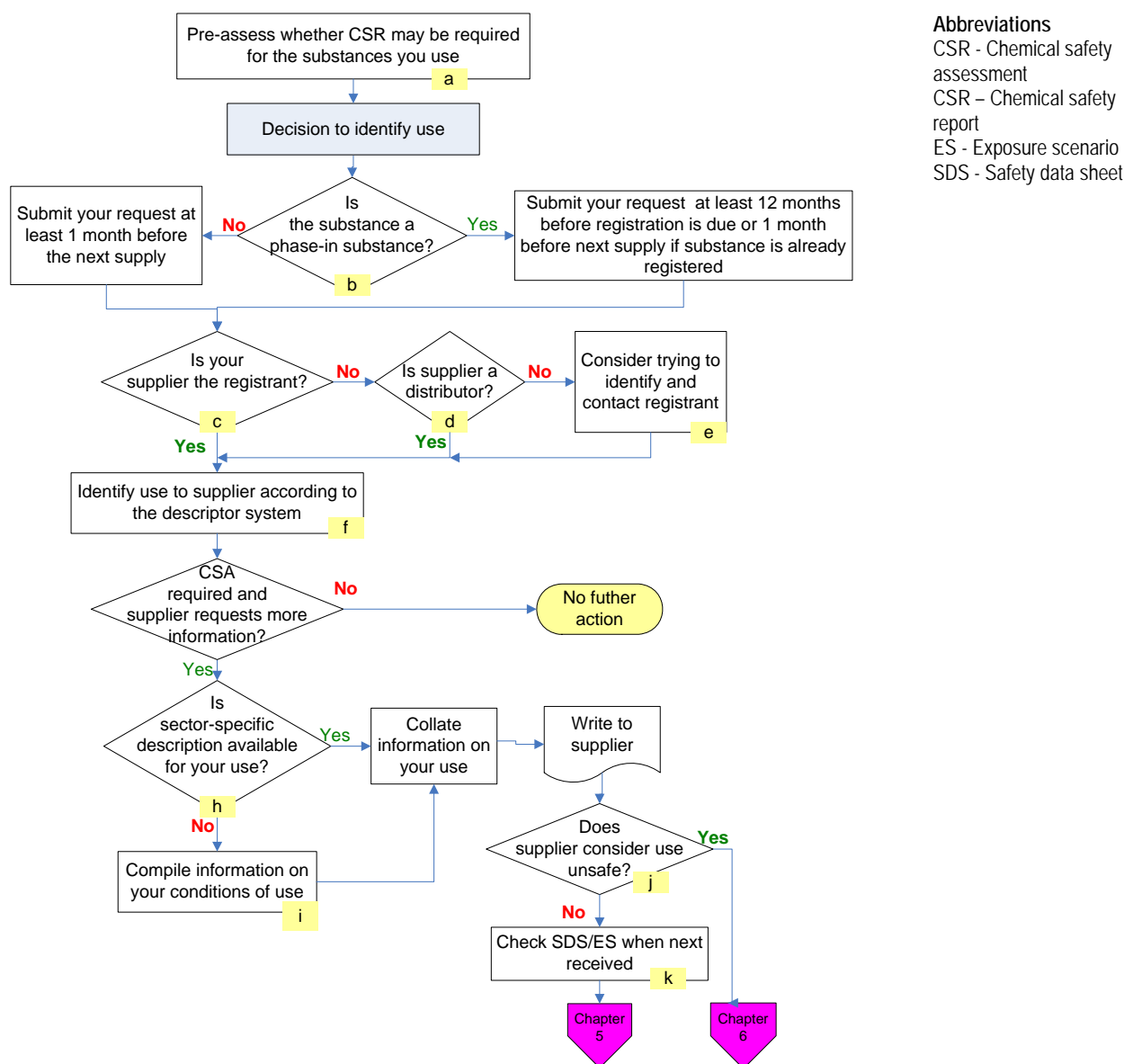


Figure 8-1 Workflow on requesting that a use becomes identified

Note a – Pre-assess whether a Chemical Safety Report may be required for your use

Identifying uses to the supplier is most relevant for substances requiring a chemical safety report for their registration. This is due to the fact that exposure scenarios, the conditions of which have to be complied with by the downstream user, will only be communicated for these substances. Therefore, it is essential to identify the substances for which your uses should be identified and those for which it is not necessary. Chapter 3 of this guidance gives advice on how to prioritise such communication needs.

You could screen your substances for classification⁵³, but may have difficulty finding out production or import volumes of substances. You could discuss with your suppliers, to gather further information on the likelihood of receiving an exposure scenario in the future.

Note b - When to submit a request for a use to be identified

Suppliers of substances and preparations have to cover identified uses in their chemical safety report within the following timeframes:

- For phase-in substances which have not yet been registered (see chapter 2 of this guidance): before the deadline for registration, provided that the downstream user has made his request at least 12 month before that deadline.

How to find out about this deadline? By 1 January 2009, the Chemicals Agency will publish a list of pre-registered substances and first envisaged deadlines, which will be accessible on its website. You can find out if a substance you use, as such or in preparations, is intended to be registered. However, as the list will not indicate who the pre-registrant is, you may want to contact your supplier and enquire whether he (or anyone upstream) has pre-registered and the envisaged registration deadline.

- For registered substances: before they next supply the substance or preparation, provided that the request was made at least one month before the supply (or within one month after the request, whichever is the later).

Note c - Your supplier is the registrant

If your supplier is the registrant, he must assess the use as part of his chemical safety assessment. If he is unable to include it as an identified use for reasons of protection of human health or the environment, this is called a 'use advised against'. Your supplier can continue to supply you, but he must provide you and the Agency with the reasons for his decision in writing without delay. In this case, you will need to decide what other action to take (see chapter 6 of this guidance).

Note d - Your supplier is a distributor

If your immediate supplier is a distributor, he should pass your request on to the next actor or distributor up the supply chain.

Note e - Your supplier is a downstream user

If your immediate supplier is another downstream user, he may decide to prepare a downstream user chemical safety report (DUCSR, see Section 7) for the identified uses or pass the information to the next actor up the supply chain. Your supplier may also advise against the use, if he cannot identify safe conditions of use (see also note c). Finally he may decide not to include your use in his CSR, then he should pass your request upstream or he cannot continue to supply you.

Note f- Use identifier system

Provide your supplier with the brief general description of use, if you expect him or his supplier to make a chemical safety assessment for the registration, in order to ensure that the communicated exposure scenarios cover your use. A descriptor system for uses, based on four pick-lists, is provided in the [Guidance on the Chemical Safety Report](#). If your supplier needs to make a

⁵³ Note that, due to the change to a new classification system and the additional data collection under REACH, different and more substances will be classified in the future and might require a chemical safety assessment. Thus, current classification is only an indication.

chemical safety report, he may ask you for additional information in order to prepare an exposure scenario.

Note g - Sector-specific description of uses

During the phase-in period (see chapter 2 of this guidance), industry sector associations may collect information on applications and use patterns within their sector and draft one or more standard description(s) of use for the sector. Such descriptions could be used to support a request for a use to become an identified use, without having to disclose confidential business information or to gather detailed information on your use. It may be useful for you to check whether such standard descriptions exist which cover your conditions of use.

Note h - Information on conditions of use

In requesting that your use becomes identified, you must provide sufficient information on your own operational conditions of use and risk management measures to enable the supplier to develop an exposure scenario covering your use. Sector-specific description may be available that will help you to compile this information. A list of the types of information that are needed to enable your supplier to develop an exposure scenario is given in appendix 2. Chapter 9 of this guidance provides guidance on where you may find the information that your supplier needs to make an exposure scenario covering your use.

Note i - Your supplier considers your use unsafe

Your supplier may conclude, having assessed the use in accordance with article 14 of REACH, 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, he must provide you with the reason(s) for that decision in writing without delay.

Through discussions with your supplier, you may be able to establish which aspects of your use of the substance make it unsafe in his view. It is possible that his assessment could be based on incomplete or incorrect information, for example not taking into account the risk management measures you use or the specific operational conditions in place at your production site. In this case, you may be able to provide further information that would enable him to revise his views. However, if the supplier continues to conclude that your use is unsafe, you will need to take one of the alternative courses of action discussed in chapter 6 of this guidance.

Note j - Checking the safety data sheet

After your use had been included as an identified use and a chemical safety assessment has been done, you should receive an updated safety data sheet. Check that the exposure scenario attached to it covers your use.

8.3 Receiving information from customers making a use known

A customer, to whom you supply substances on their own or in preparations⁵⁴, may have informed you of his use, with a request to make it an identified use. There may be several situations in which you could receive such request. If you have supplied your customer with a preparation, accompanied by a safety data sheet and an exposure scenario, such a request may signify 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 0 of this

⁵⁴ This right does not apply to recipients of articles

guidance).

Any request, be it prior to registration or after your customer has received information in the form of a safety data sheet or article 32 information, should either be forwarded to the supplier or dealt with at your level, which could result in updating your own information, such as the safety data sheet or article 32 information.

9 COLLECTING INFORMATION ON USES

This section applies primarily to substances supplied with an exposure scenario. You may need to collect information on your own uses of a substance, and those of further recipients, for a number of activities under REACH:

1. *for your own information and to send to your suppliers when preparing for REACH (see chapter 3 of this guidance),*
2. *to send to your supplier with a request that a use becomes identified (see chapter 8 of this guidance),*
3. *to check that you comply with an exposure scenario that you receive from a supplier (see chapter 5 of this guidance) or*
4. *to prepare a downstream user chemical safety report (see chapter 7 of this guidance).*

This chapter provides guidance on how to obtain the information needed on your own uses (section 9.1) and on the uses of your customers (section 9.2)

9.1 Information on your own use(s)

The amount of detail that you need to collect on your own use(s) of a substance depends upon the nature of the substance and what the information will be used for:

- When contacting a supplier while you are preparing for REACH, a brief general description of your use may be sufficient as a starting point (see the Guidance on the Chemical Safety Report).
- More details will be needed to prepare a chemical safety assessment and exposure scenarios (see chapters 5 and 7 of this guidance). Appendix I to this guidance describes the information needed to develop an exposure scenario. Table 19, at the end of this chapter, sets out possible company internal and external information sources. It uses the same headings as the exposure scenario format proposed in the Guidance on the Chemical Safety Report.
- Some suppliers may use questionnaires to request information on your use. Sources of information to complete these questionnaires will be similar to those set out in Table 19.

In collecting information on your own use, you may tier your information collection, depending on which level of detail is needed. You may wish to follow these steps:

1. Identify, which exposure assessment tools, e.g. ECETOC TRA and EUSES, may be applied for your use and what information would be needed as an input. Guidance on these tools and what information is needed to work with them is given in the Guidance on the Chemical Safety Report.
2. Collect information that is readily available within your organisation, for example process descriptions, risk assessments at workplaces, environmental permits or measurements of emissions, exposures or related to your products. Appendix 8 to this guidance lists EU legislation from which information relevant to REACH may be available.
3. If this information is not sufficient, you may be able to fill the gaps by talking to technical experts, sales people and others within your organisation. This task will be easier if you have set up a REACH working group (see chapter 3 of this guidance)

4. If gaps remain, you may wish to consult external sources. Standard process descriptions may be available from industry associations or from regulators. BREF notes⁵⁵ describe specific processes or emission scenario documents may be available⁵⁶. The Technical Notes for Guidance prepared under the Biocidal Products Directive (<http://ecb.jrc.it/biocides>) may be helpful for substances used in biocides and in similar application types or processes.

9.2 Information on customers' uses

REACH requires that a chemical safety assessment shall include identified uses at all stages of the life-cycle, from manufacture to disposal (see appendix 1 of this guidance). Although you may receive exposure scenarios for uses downstream, there is no obligation for you to check whether your customers' uses are covered by your supplier's exposure scenario, even if you are a formulator.

It may nevertheless be necessary or advisable to collect information from your customers, to provide the necessary use information to your supplier when requesting that your customers use becomes identified. This is particularly relevant for formulators, who have to forward safety information to their customers and need to consolidate the information received (see chapter 14 of this guidance) or may have to assess uses which are not covered in the suppliers' assessment (see chapter 7 of this guidance). The following workflow provides guidance on how to do this.

⁵⁵ Best Available Techniques (BAT) reference documents are designed to demonstrate best available techniques for each sector covered by IPPC (<http://www.jrc.es/pub/english.cgi/0/733169>)

⁵⁶ 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.

9.3 Workflow and explanation –on obtaining information on uses

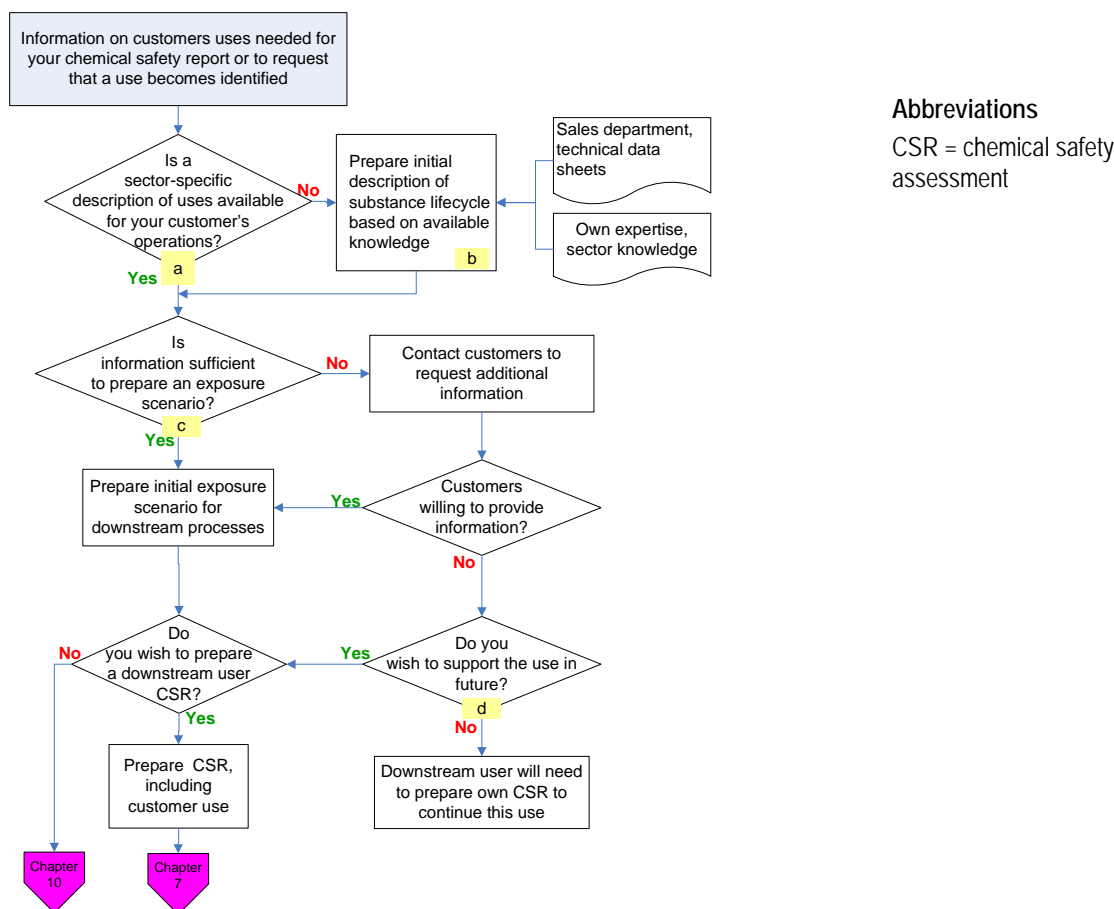


Figure 9-1 Workflow obtaining information on uses

Note a - Downstream user descriptions of operational conditions

You may not have full information on the operational conditions under which your customers use the substance as such or in a preparation. If they are available, descriptions of average operational conditions of use and standard risk management measures for different processes, developed by downstream user industry organisations, are likely to be the most appropriate source of information. Contact your key customers, or their industry associations (either directly or through your own association), to find out if such standard descriptions have been developed.

Note 9b - Initial description of life cycle

Outline the stages in the life-cycle⁵⁷ of the substance and describe what you already know of the processes and activities carried out with the substance at each life-cycle stage. You may have to contact your customers to identify what happens to the substance after they have used it.

Note c - Is the information sufficient?

If you are assessing a use yourself, you will be able to judge whether the information is sufficient or not. In other cases, information collection and discussion about 'sufficient level of detail' will be

⁵⁷ 'Life-cycle' means the different types of uses of a substance. Depending on the type of substance, these may be: manufacture, formulation, use in a preparation, inclusion in an article, use of the article and disposal.

based on interaction with your suppliers.

Checking if information is sufficient could entail comparing it to the input requirements of exposure assessment models, the list of standard information for exposure scenario building, your own assessment needs or the suppliers' request.

You may interview some of your key customers to verify your assumptions or to collect further information. As the exposure scenario is also a tool to influence how a substance is used downstream, you may wish to recommend changes to your customers' current way of handling the substance or preparation, to reduce risks further.

The chemical safety assessment (or identification of use) 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.

Note d - Supporting the use in future

This question is only relevant for downstream users (e.g. formulators) selling their products to other downstream users.

Your customer may refuse to provide you with information on his process, for example to protect confidential business information. In this case, your exposure scenario may not cover his use and the customer will need to prepare his own chemical safety assessment or to take another course of action (see chapter 6 of this guidance). If you still wish to include his use, you may be able to draw on other information and/or make the exposure scenario more general, if possible, so that his use is covered. More details of this process are given in chapter 7 of this guidance.

A supplier is required to provide guidance on safe use to his customer. He also has the right not to include a use in his exposure scenario if he does not consider that it is safe (see section 0 of this guidance).

Table 19 Sources of information on your own use(s) of a substance to complete a supplier questionnaire

Information type	Explanation	Internal sources	External sources
1. Short title of exposure scenario	Should include a reference to the industry sector, function of preparation, technical processes and article type, if relevant	If necessary, discuss this with your technical staff	Descriptor system for brief general description of use in guidance for the preparation of the chemical safety report
1a. Life cycle step (not explicitly part of exposure scenario format)	May also include an indication of which life cycle stages are covered by the exposure scenario (e.g. application of the product)	If necessary, discuss this with your technical staff	A diagram and explanation in guidance for the preparation of the chemical safety report
2. Description of activities/process(es) covered in the exposure scenario	Sets out the different steps covered, e.g. dilution of delivered product, spraying of product onto surface to be cleaned, wiping product off surface, cleaning of equipment	If necessary, discuss this with your technical staff	Process descriptor of use descriptor system, BREF notes, emission scenario documents and sector information
Operational conditions			
3 Duration and frequency of use for which the exposure	How frequently and for how long do you use the substance? How many workers/consumers are	Descriptions from workers' health risk assessments, discussions	Standard values may part of sectors' generic exposure scenarios or use descriptions.

COLLECTING INFORMATION ON USES

Information type	Explanation	Internal sources	External sources
scenario ensures adequate control of risk	exposed to the substance/preparation. Frequency and duration of environmental exposure	with technical and sales staff. Information from environmental permits, technical documentation Product information	
4.1 Physical form of substance or preparation provided to you	Is it gas, liquid, powder, granules, massive solids? Will it be contained in articles (surface area?) Does the physical form change during use?	If necessary, discuss this with your technical staff	-
4.2 Concentration of substance in preparation or article	Maximum concentration in preparation or article for which the conditions of use ensure adequate control of risks	If you produce preparations or articles containing the substance, this may be part of your product specification Assume or set values depending on your assessment	Supply chain
4.2 Amount used per time or per activity [...]	How much of the substance is used each time or per year	Descriptions from workers' health risk assessments, technical staff. Information for consumer products, if relevant.	Standard values may be developed by industry association.
5 Other operational conditions determining exposure	Other factors that affect the extent of exposure to the substance, e.g. temperature, capacity of the receiving environment (water flow, room size and ventilation rate); emission or release factors to relevant compartments (e.g. how much of the substance ends up in waste water, how much is inhaled by workers)	Environmental permits, discussions with technical staff, environmental reports or assessments under environmental standards Descriptions from workers' health risk assessments, technical staff (for example, the air volume can be calculated from the room geometry)	BREF notes, emission scenario documents. Information on the water flow to absorb discharges can be provided by the competent authorities responsible for discharge consents.
Risk management measures			
6. Risk management measures for occupational settings, environmental and consumer use	<u>Technical measures</u> including process-related measures (open/closed processes, automated processes, etc.), ventilation and waste treatment systems. <u>Organisational measures</u> , such as limiting the time of operations/activities. <u>Personal protection measures</u> , e.g. gas/dust filter masks, goggles/gloves, protective clothing. <u>Consumer related measures</u> added to the product to limit or prevent exposure, e.g. form of packaging, migration-preventing coating	Descriptions from workers' health risk assessments, advice from technical staff Environmental permits, discussions with technical department, environmental reports or assessments under environmental standards Discussions with the technical staff, sales literature, product descriptions	Your own or suppliers' safety data sheets and technical support materials. BREF notes; emission scenario documents. Information on the efficiency of measures may be available from equipment suppliers Guidance on risk management measures is available in the Guidance on the Chemical Safety Report Information on the efficiency of external measures (e.g. sewage treatment plant) may be available from suppliers,

Information type	Explanation	Internal sources	External sources
			operators of municipal waste water treatment and competent authorities databases Industrial associations may also have good knowledge of risk management measures
7. Waste related measures	Your internal handling of the substance in material to be disposed off as waste and treatment of substances in waste (including operation aiming at recovery) by companies authorised under waste legislation.	Environmental permits, discussions with technical staff, environmental reports or assessments under environmental standards	BREF notes; emission scenario documents. Information on the efficiency of measures outside your control may be available from waste disposal organisations, competent authorities databases
References on exposure prediction and guidance on scaling			
8. Prediction of exposure resulting from the conditions described.	These values are normally results of the exposure assessment but could also stem from measurements.	Measurements at workplaces or points of discharge to the environment.	Exposure scenarios of suppliers
Guidance on checking compliance using scaling	Downstream users may implement as a minimum the conditions of use in the exposure scenario. They are allowed to prove this using assessment tools recommended by the supplier, and for those parameters for which scaling is allowed.		Exposure scenario

10 INFORMING SUPPLIERS ABOUT NEW INFORMATION ON HAZARDS

This section provides guidance on how to comply with the obligation placed on downstream users by REACH to:

- *communicate new information on the hazardous properties of substances up the supply chain to suppliers;*
- *report to the Chemicals Agency if his classification of a substance is different to that of his suppliers.*

10.1 Introduction

Articles 34 and 38 of REACH require you to communicate certain specific information that you may hold about the hazardous properties of substances that you use.

Article 34 (a)

Any actor in the supply chain of a substance or a preparation 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;

Article 38(4)

A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.

‘New’ information means information that is not communicated to you by your supplier with a substance or preparation that you use and that is not available in public data bases or literature. For non-classified substances and preparations, you may not receive any information from your supplier at all. In this case, the obligation to inform suppliers about ‘new information’ also applies. Examples of new information are observations on acute human health effects at workplaces, or if you have carried out testing of substances and preparations.

Any actor in the supply chain, including a distributor, who receives such information from customers, is required to pass the information to the next actor up the supply chain.

If you classify a substance, and conclude with a different classification than your supplier, you should report this to the Chemicals Agency. If the reason for differences in classification is a different interpretation of existing data, you only need to report to the Agency. However, if you use new data for classification that was not considered by your supplier, you should also inform your supplier of it. Any reporting to the Agency will be via REACH-IT.

The requirement to report on differences in classification only applies to substances that you use, as such or in preparations, in quantities of 1 tonne per year or more (Art. 38(5) of REACH). If you have benefited from the exemption from developing a downstream user chemical safety report on the basis that you use less than 1 tonne per year of the substance or preparation (see chapter 6 or 7 of this guidance)⁵⁸, you need to make a report, even though you use less than 1 tonne per year of the substance.

⁵⁸ [...]A downstream user need not prepare such a chemical safety report in any of the following cases: [...] (c) the downstream user uses the substance or preparation in a total quantity of less than 1 tonne per year; (Article 37 (4))

10.2 Workflow and explanation on communicating new hazard information

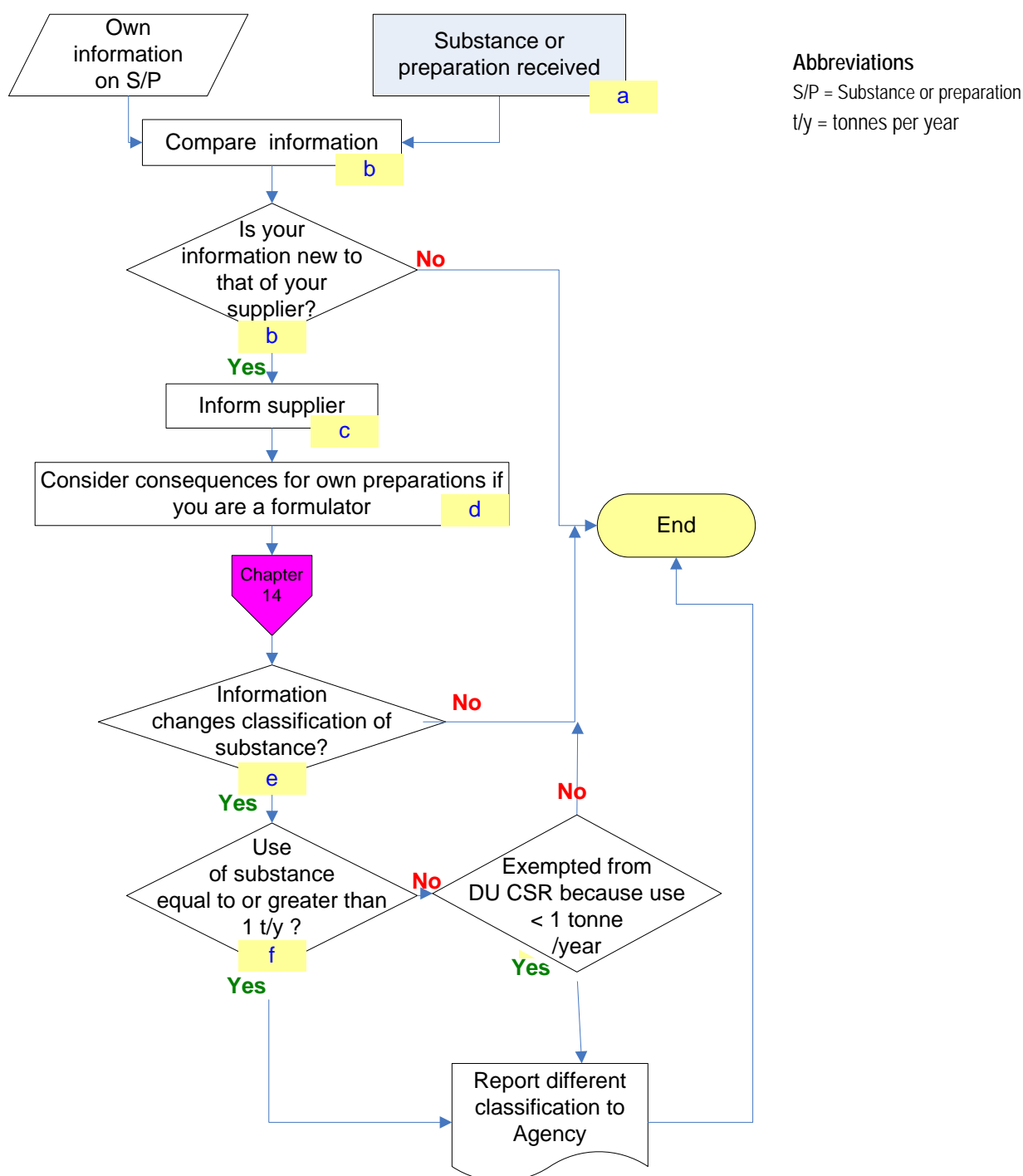


Figure 10-1 Workflow - new information on hazards

Note a - Substance or preparation received

With any substance or preparation you receive, you may receive information from your supplier, either in form of a safety data sheet or information according to article 32 of REACH. If you receive no specific information, this means that the suppliers assume that the substance or preparation is not hazardous.

Note b - Compare your own information on hazards with that of your supplier

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 preparations. 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 relevant for the substance or preparation you receive from the supplier;
- you have good evidence for the information;
- the information could have consequences for management of the risks of the substance.

If you have an indication that a substance or preparation for which you have received no information (neither according to article 32 nor a safety data sheet) is dangerous, this is considered new information and you should inform your supplier of this.

If you hold information that is different from that in a safety data sheet you receive, but which supports the hazard conclusion from your supplier, this is not regarded as ‘new’ provided it would not have consequences for the risk management of the substance.

Table 20 lists the headings of the safety data sheet that are relevant for indicating the existence of new information up the supply chain.

Table 20 Forwarding information on dangerous substances and preparations

Information received under Heading of safety data sheet	Substance / Preparation	‘New information’ and requirements / conditions to forward it up the supply chain
2: Hazards identification		<u>Substances</u> : new information from testing obligatory to forward.
		<u>Preparations</u> : if you test the preparation 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	Not applicable to substances	New information from substance testing is obligatory to forward
8: Exposure limit or biological values		Different limit values apply to you as specified in national or Community legislation and/or workplace risk assessments
8: Derived no effect levels (DNELs) and predicted no effect concentrations (PNECs)	DNELs & PNECs in Preparation 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, the information is obligatory to supply 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 should be forwarded to your supplier, if relevant to the substance or preparation you obtained from him.
10: Stability & reactivity		
11: Toxicology		
12: Ecotoxicology		
16: R-phrases		Either your supplier has classified differently or it is simply a mistake in the safety data sheet

Note c - To whom, how and when to inform

Any actor holding such information should report to his immediate supplier, regardless of whether or not he is the registrant of the substance. You may first want to communicate only the fact that you have new information on a substance or preparation, 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.

There are no specific deadlines for communicating information on hazards upstream. You should do so as soon as you become aware that, compared to the information received from your supplier, you have 'new information'.

Note d - Consequences of having new information on hazards

New information on hazards may influence your supplier's recommendations on risk management measures. If you supply hazard information upstream which suggests that a substance or preparation is more or less dangerous than communicated, you should also check chapter 11 of this guidance.

If you are a formulator, you should assess whether the new information warrants that new safety information is communicated with your preparation to your customers (see also chapter 14 of this guidance).

Note e - Reporting on classification and labelling

If you have new information that influences the classification and labelling and you thus classify the substance differently than your supplier (as communicated in the safety data sheet under heading 2 or heading 3), you have to report this to the Chemicals Agency. A format for reporting will be made available by the Agency.

Note f and g - Use of less than 1 tonne per year

A report to the Chemicals Agency is not required if you use less than 1 tonne per year of the substance as such or contained in a preparation for that particular use. However, if you have relied on the exemption from making a downstream user chemical safety report on the basis that you are using in total less than 1 tonne per year of the substance or preparation (in this case, you need to sum up the total amount used, including if it is used in other applications and/or purchased from other suppliers), then you do need to report.

11 INFORMATION ABOUT APPROPRIATENESS OF RISK MANAGEMENT

This chapter provides guidance on the requirement for downstream users to communicate up the supply chain any information that might call into question the appropriateness of risk management measures identified in a safety data sheet. It covers:

- *The obligations set out in REACH (section 11.1)*
- *When risk management measures might be considered inappropriate (section 11.2);*
- *What information to communicate (section 11.3);*
- *The process to follow to meet your obligations (section 11.4).*

11.1 Introduction

REACH Article 34

Any actor in the supply chain of a substance or a preparation 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 to ensure that the risk management measures communicated to you in a safety data sheet and exposure scenario, and which you are required to implement, are adequate to control the risks. It should also help to avoid recommendation of measures which are not technically feasible. 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.

Communication in accordance with these provisions does not involve any reporting to the Chemicals Agency. The requirements relate to the main body of the safety data sheet, as well as the exposure scenario.

11.2 When risk management measures may be considered inappropriate

11.2.1 Risk management measures communicated via an exposure scenario

Compliance checking with an exposure scenario includes the assessment of risk management measures (see [chapter 5](#) of this guidance), thus information indicating that the recommended risk management is inappropriate can be based on compliance checking. Inappropriateness of risk management measures includes both quantitative and qualitative considerations. Information to forward could be the documentation of compliance checking, measurement results or any other type of information supporting the conclusion that the measures are inappropriate.

11.2.2 Risk management measures communicated under heading 8 of the safety data sheet

Information on risk management measures under heading 8 of the safety data sheet addresses measures for all identified uses. They are described in a more general manner and it will, in most cases, not be possible to link a specific measure to specific conditions of use. Therefore, the possibility to react is limited to risk management measures which are clearly inappropriate based on a qualitative assessment. This section gives some examples of when you may consider the risk management measures recommended under heading 8 to be inappropriate:

- The recommended measures are not effective for the type of substances: for example, your supplier recommends waste gas incineration for a preparation containing metals. The incineration will destroy organic compounds but metals will be released unchanged.
- The recommended measures are overprotective: for example, if a substance as such or in a preparation is normally 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 preparation 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 preparation 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 risk management measures under heading 8 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 respective labelling (see chapter 10 of this guidance).

11.3 What information to communicate

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.

11.4 Workflow on providing information calling into question the appropriateness of risk management measures

The workflow shows the steps you should take to check whether you have information that might call into question the appropriateness of risk management measures. It distinguishes between recommendations in the safety data sheet and recommendations in the exposure scenario.

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

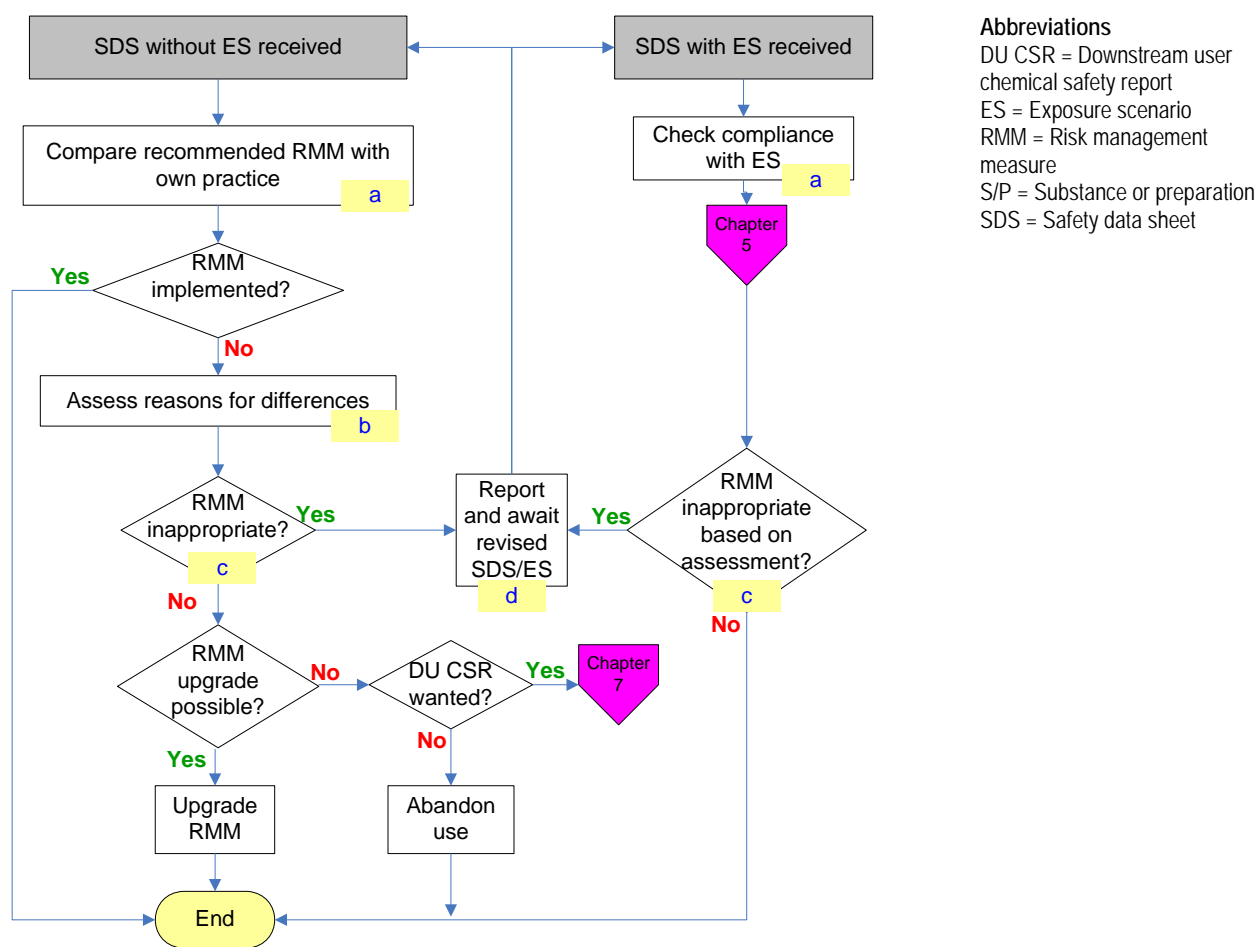


Figure 11-1 Communicating information on risk management measures

Note a - Compare safety data sheet with your current practice

Compare the risk management measures recommended under heading 8 of the safety data sheet with your current practice. If you find that you follow the recommended risk management measures, there is no obvious reason to call into question the recommendations.

If you receive an exposure scenario, you have to assess whether your conditions of use are covered by it, which includes an assessment of the recommended risk management measures. See chapter 5 of this guidance for details.

Note b - Assess reasons for differences in risk management

If your current practice differs from the recommendations, it may mean that the recommended measures are inappropriate, that the measures are applicable for other identified uses but not for yours, or that your current use of the substance or preparation is not safe. Other reasons may be that your installations are adapted to other and more hazardous substances. Check why you use the substance or preparation differently. You may wish to 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.

Note c - Inappropriateness of risk management measures

You have to inform your supplier if you regard the recommended risk management measures as inappropriate. If the inappropriateness is a result of new hazard information that you hold, you need

to inform your supplier of this as well (see chapter 10 of this guidance). If you do not apply the risk management measures indicated by your supplier in the safety data sheet or in other form, you should talk to your supplier with a view to adapt these risk management measures. You may need to upgrade your risk management, or you can consider substituting the substance or preparation, or, if you have received an exposure scenario and you are using a substance outside its conditions, you may prepare your own downstream user chemical safety assessment. Note that you may have more strict conditions of use than proposed by your supplier and that this does not necessarily mean that the recommended RMM are inappropriate.

Note d - Change of the recommendations in the safety data sheet or exposure scenario

When your supplier receives your information, he should reassess his recommendations for risk management measures, whether part of the main body of the safety data sheet, the exposure scenario 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 a new safety data sheet.

12 COMPLIANCE WITH REQUIREMENTS RELATED TO AUTHORISATION

This chapter describes the actions that downstream users are required to take in relation to substances subject to authorisation. It:

- *Introduces the system of authorisation and explains the limitations that apply to the use of substances subject to authorisation (section 12.1);*
- *Describes how applications for authorisation will be made and the types of information that will need to be provided (section 12.2);*
- *Provides a work flow to assist downstream users in meeting their requirements relating to authorisation (Section 12.3);*
- *Explains how to check if a use is exempt from authorisation, how to comply with the authorisation conditions if a substance is not exempt and how to decide on what to do if the authorisation conditions cannot be met (Section 12.4).*

12.1 Introduction

The authorisation system (REACH Title VII) addresses substances of very high concern with the aim of ensuring they are properly controlled and progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. Substances of very high concern will first be identified and put on a so-called “candidate list”, then gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set (the so-called “sunset date”), unless the company is granted an authorisation. There is no tonnage trigger for this requirement.

The candidate list of substances will be available, probably in the second half of 2008. Third parties, including downstream users, have the opportunity to comment e.g. on the inclusion of a substance on the candidate list according to REACH art 59(4). You should check this list, and Annex XIV as it develops, to see whether any of the substances that you use are on it. The Agency will make its first recommendations for substances to be included in Annex XIV by 1 June 2009.

Authorisations shall 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-limitation being decided case-by-case. You can make an application for an authorisation for your use, either on your own or together with the manufacturer/importer or other downstream users. How to apply for an authorisation is explained in the [Guidance on authorisation application](#). If a substance is subject to authorisation you should receive information from your supplier, either in section 16 of the safety data sheet or as information in accordance with article 32 of REACH.

Under REACH, as a downstream user using a substance on Annex XIV, you are obliged to:

- ensure an authorisation was granted to you or an actor up your supply chain, for your use (otherwise you need to abandon this use before the “sunset date” for that substance)
- comply with the conditions of authorisation, and
- report to the Chemicals Agency if you use a substance under the authorisation of an actor

up the supply chain⁵⁹.

More detailed information on the authorisation procedure is given in the [Guidance on authorisation application](#). If you incorporate such substances into preparations, 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 use of your preparation or to ask for an authorisation that covers their use.

12.2 Applications for authorisation

An application for authorisation needs to specify the use for which authorisation is requested and document control of risks in a chemical safety report. It also needs to include an assessment of alternatives and, where these exist, a substitution plan. Applications for substances for which no DNELs/PNECs exist shall include a socio-economic analysis.

If you apply for an authorisation, you could ask your supplier for his chemical safety report to include it in your dossier. If your supplier makes an application, 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 authorisation application](#) and in the [Guidance on Socio Economic Analysis](#).

⁵⁹ If you have applied for the authorisation yourself, no notification of the Agency is required

12.3 Workflow on fulfilling authorisation requirements

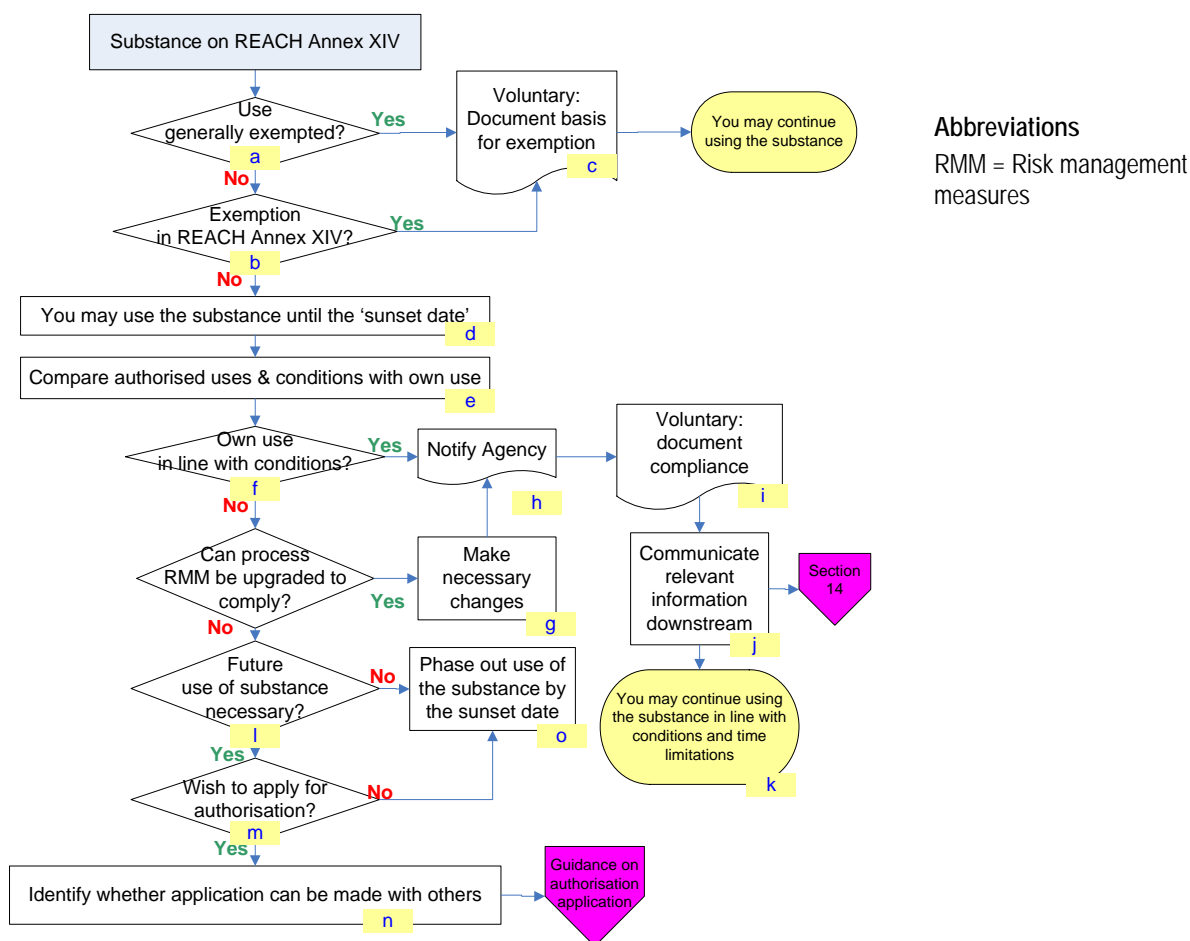


Figure 12-1 Fulfilling authorisation requirements

Note a – General exemptions from authorisation

A substance 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 have to implement the conditions of use and risk management measures communicated to you.

Exemptions from authorisation do not have to be communicated by your suppliers. Therefore, you should check whether your particular use is exempted.

Table 21, Table 22 and Table 23 list the exemptions. Further information on exemptions is given in the guidance on authorisation application.

Table 21 Exemptions of uses from authorisation

Exemption (short)	The substance does not have to be authorised if:	REACH Article
Out of scope	The substances are not within the scope of REACH See also scope of REACH in the navigator and the guidance on registration	2
Intermediates	All types of intermediates are exempted from the authorisation requirement. An intermediate is defined in REACH as a substance which is produced solely for the purpose of reacting with another substance (Article 3.15 of REACH) See also Guidance on intermediates	2.8
Medicinal products for human and veterinary use	It is used in medicinal products which are in the scope of Regulation 726/2004, Directive 2001/82/EC and Directive 2001/83/EC	Article 2.5.a
Food or feedingstuffs	It is used in food or feedingstuffs as specified in Regulation 178/2002 including uses as food additive, food flavouring, additive to feedings stuffs and animal nutrition. See the References to regulations and directives in REACH	2.5.b
Scientific research and development	It is used in scientific research and development	56(3)
Product and process oriented research and development	Check in Annex XIV if there are special provisions that PPORD is NOT EXEMPTED. Furthermore, there may be a limitation of the amount that may be used in PPORD. If PPORD is not exempted or you use more than the maximum quantity allowed, proceed with the workflow.	56(3)
Plant protection products	It is used in plant protection products within the scope of Directive 91/414/EEC	56(4)
Biocidal products	It is used in biocidal products within the scope of Directive 98/8/EC	
Motor fuel	It is used in motor fuels within the scope of Directive 98/70/EC	
Fuel in combustion plants	It is used as a fuel in mobile or fixed combustion plants of mineral oil products or used as a fuel in a closed system.	

Table 22 Exemptions depending on concentration in a preparation

Exemption of substances that are	if:	REACH Article
PBTs, vPvBs or substances of similar concern⁶⁰	They are contained in preparations in concentrations below 0.1 % (w/w)	56.6.a
CMRs category 1 and 2⁶¹	If they are contained below the lowest concentration limit specified in Directives 1999/45/EC or 67/548/EEC (on the classification, packaging and labelling of dangerous substances). This may be as low as 0.01%	56.6.b

⁶⁰ Article 57(d), (e) and (f); you may have to ask your supplier.⁶¹ Article 57 (a), (b), (c) you may have to ask your supplier

Table 23 Exemptions for specific situations

Exemption of substances in	if:	REACH Article
Cosmetic products under Directive 76/768/EEC	The substance meets the criteria for classification as a CMR category 1 or 2 ⁶¹ according to Directive 67/548/EEC or an endocrine disrupter ⁶² and is subject to authorisation only because of hazards to human health	56.5
Food contact materials under Reg 1935/2004		

Note b – Exemptions included in Annex XIV

Your supplier shall inform you via safety data sheet or information according to article 32 if a substance you use, as such or in a preparation, is listed on Annex XIV and thus may require an authorisation. Substances will be added to the Annex over time, as they are assessed by the Chemicals Agency. Some specific uses may be exempted from the need for authorisation in Annex XIV itself. In the Annex (which will be available on the Agency web site) 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 followed, or you cannot regard the use as exempted.

Note c – Document basis for exemption (voluntary)

You may wish to document the basis on which your use is exempt from the need for authorisation in order to have it ready for inspectors.

Note d – Sunset date

You can continue using a substance as such, or in a preparation or article, until its so-called “sunset date” is reached. The sunset date is specified in Annex XIV. After the sunset date, you may only use the substance as such or in a preparation or incorporate it into an article if an authorisation has been granted and you comply with the conditions of the authorisation, or if you or your supplier has applied for an authorisation but the decision is pending. Contact your supplier to find out whether an application has been made by him or another actor up your supply chain. In addition, you may want to check the Chemicals Agency’s website, where information about the uses for which an authorisation application has been made will be made available (however, you will not be able to find out who applied for an authorisation)

Contact your supplier to find out whether he has applied for an authorisation and which conditions of use he has specified in the application. The precise use may be confidential (article 118(2b) of REACH), but broad information on uses should be made available (article 64.2 of REACH).

Note e – Compare authorised uses and conditions with your own use

Your supplier should provide enough information to enable you to use the substance according to the conditions of an authorisation that has been granted to an actor up the supply chain. He may, but is not obliged to, provide additional information related to the authorisation, e.g. when the sunset date has been set or whether an application for authorisation has been made but has not yet been decided upon, or until when the authorisation will be reviewed. This information can in any case be found on the Chemicals Agency web site.

The supplier will communicate the conditions under which the substance can be used according to

⁶² Article 57 (f), you may have to ask your supplier

the authorisation in an exposure scenario attached to the safety data sheet.

Checking if a use is covered by an authorisation is similar to the ‘normal’ checking of coverage of an exposure scenario (chapter 5 of this guidance). However, exposure scenarios for the use of authorised substance are likely to be more specific in their description of the use conditions.

Note f – Own use in line with conditions?

For substances used under an authorization, the conditions in the exposure scenario are to be applied strictly. This means that thorough consideration needs to be given to checking whether scaling of the exposure scenario is appropriate. It could be the case if your conditions of use correspond as a minimum to those described in the exposure scenario. Thus you may deviate from the conditions if you apply stricter risk management measures or have lower exposure due to your operational conditions of use (shorter durations, less frequent use, lower temperatures, more tightly encapsulated processes etc.)

Note g – Upgrading process/risk management measures to comply with authorisation

To comply with the conditions of the authorisation, upgrade your process to implement the conditions of use and risk management measures described in the exposure scenario.

Note h – Reporting to the Agency

If you are relying on the authorisation granted to your supplier, you must report to the Chemicals Agency at the latest 3 months after first receiving an authorised substance as such or in a preparation (article 66 of REACH). A notification format is provided in REACH-IT and will require the following information:

1. Your identification and contact details
2. The authorisation number, which you will find on the label of the substance or preparation
3. Brief general description of use

Note i – Documentation of compliance

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 your process, when you will need to re-check your compliance).

Note j – Communicating relevant information

If you are a formulator and supply preparations 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 should be provided on the label.

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 the guidance for articles.

Note k – Time limitations

Authorisations are subject to a time-limited review. This will normally be noted in the safety data sheet or in 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 and on the Chemicals Agency website. A subsequent application may refer to previous applications, provided the previous applicant has allowed the applicant to do so.

Note l – Future use of substance

If no suppliers have applied for and received an authorisation for your use, consider whether substituting the substance may be a better option than continued use. Guidance on assessing alternatives and making substitution plans is provided in the Guidance on authorisation application.

Note m – Applying for authorisation

Check the Chemicals Agency website to identify whether an actor up the supply chain has applied for an authorisation for your use. If not, 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 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.

Note n – Applying with others

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:

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

Note o – Phase-out of the use

If no application for authorisation is made, you must stop using the substance by the sunset date and the substance as such or in a preparation must not be supplied to your customers after the sunset date. You may want to review information on alternatives that is available at the Chemicals Agency.

13 COMPLIANCE WITH REQUIREMENTS RELATED TO RESTRICTIONS

This chapter sets out the steps that a downstream user should take to ensure that he is in compliance with any restrictions on the substances that he uses. It covers:

- *The requirements of REACH concerning restrictions (Section 13.1);*
- *What a downstream user should do to ensure compliance with restrictions (Section 13.2)*

13.1 Introduction

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 preparations 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 preparation or 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 in line with REACH article 32 (see chapter 4 of this guidance). 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 Chemicals Agency web site.

Proposals for restrictions can be made either by the European Chemicals Agency (on request from the Commission) or by Member States; the Chemicals Agency or the member state will then prepare a dossier on the substance concerned. You can find out which substances are being considered for restriction, and the type of restriction proposed, by consulting the Chemicals Agency web site. You may 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.

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.

13.2 Workflow and explanation on ensuring compliance with restrictions

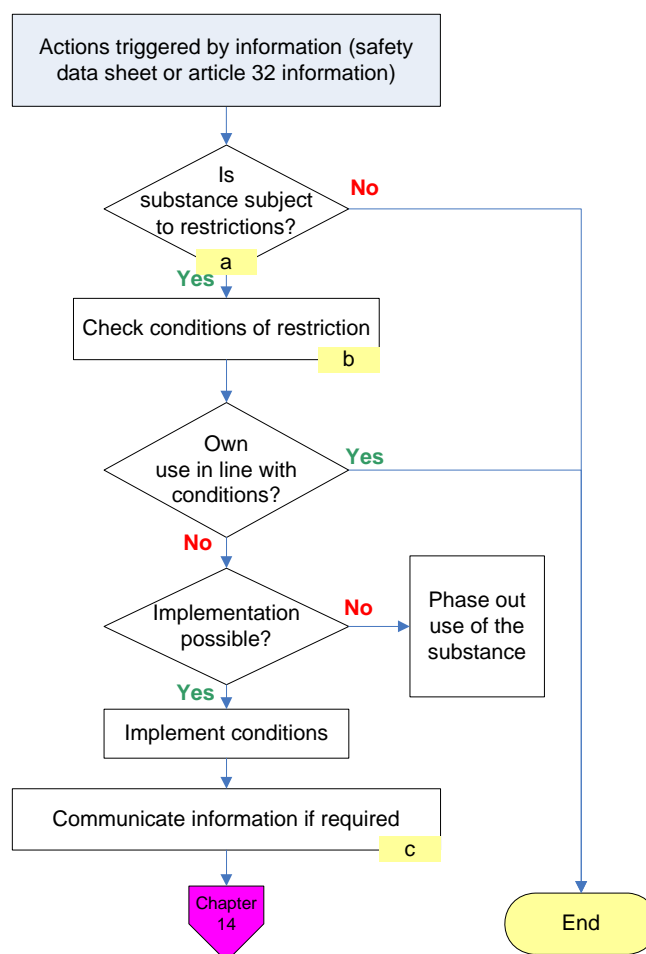


Figure 13-1 Workflow checking compliance with restrictions

Note a - Information on restrictions

Your supplier must specify, under heading 15 in 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.

Note b - Comparison of 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 preparations or articles you produce.

Note c – Communication downstream

If you are a formulator, and you include a substance subject to restrictions in a preparation 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 is given in chapter 14 of this guidance.

14 INFORMATION ON PREPARATIONS TO BE DELIVERED BY FORMULATORS

This chapter provides guidance on the requirements for formulators of preparations^{63, 64} to gather and communicate information on the preparations they supply down the supply chain.

The guidance:

4. *Gives advice on how to structure the information received from suppliers of substances/preparations*
5. *Provides a workflow enabling the formulator to work with exposure scenarios received from his suppliers of substances and preparations and to prepare exposure scenarios for his own preparation*
6. *Explains the type of information to be delivered by a formulator in different situations*
7. *Describes the additional information to be included in the safety data sheet as a result of the REACH Regulation*

14.1 Legal obligations relating to preparations under REACH

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

- a. To provide safety data sheets in accordance with article 31 of REACH to your customers (with the exception of consumers). This obligation applies to all substances in a preparation fulfilling the requirements laid down in articles 31 (1) and 31 (3) of REACH; this means also to substances which do not have to be registered under REACH.

Article 31 (1) applies to preparations meeting the criteria for classification as dangerous. Article 31 (3) applies to preparations not meeting the criteria for classification as dangerous and describes the rules for when a safety data sheet shall be provided on request. The safety data sheets should be compiled in accordance with the format and guide provided by Annex II of REACH.

- b. To communicate information to the recipient of a preparation when no safety data sheet is required (article 32):
 - a. If a substance in the preparation is subject to authorisation
 - b. If a substance in the preparation is subject to restriction
 - c. The obligation also applies in situations where other available and relevant information is needed to enable appropriate management measures to be identified.

This obligation includes information describing the specific conditions of use that allow safe use of the preparation when testing has been omitted, based on the exposure assessment made by the manufacturer or importer of a substance or a downstream user's own chemical safety assessment (article 32 (1d)).

The obligations to communicate information also apply when preparations are offered or sold to

⁶³ A preparation may be in a liquid, a gas or a solid phase such as alloys and plastic pellets. The phase of the preparation for an identified use may effect the exposure level of a substance in the preparation. This has to be considered by the manufacturer/importer of the substance when making his chemical safety assessment and communicated to the formulator in the exposure scenario.

⁶⁴ The term preparations will be replaced by the term mixtures under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

the general public. The general public has to be provided with sufficient information for safe handling of the preparation (article 31(4)), not necessarily in the form of a safety data sheet, unless requested by a downstream user or distributor.

3. To identify, apply and, where appropriate, recommend appropriate measures to adequately control risks identified in any of the documents listed in article 37(5):
 - a. The safety data sheet(s) supplied to you
 - b. Your own chemical safety assessment, if you have performed one
 - c. Any information on risk management measures supplied to you in accordance with article 32.
4. When compiling own safety data sheet for identified uses any downstream user shall include relevant exposure scenarios and use other relevant information from the safety data sheets supplied to him (article 31(7)).

In order to fulfill this requirement, a formulator cannot just forward exposure scenario(s) received from his supplier without considering if the communicated information provides consistent recommendations to the customer on how to adequately control risks. Although REACH does not specifically require that the exposure scenarios for the individual substances in a preparation have to be merged or consolidated, it places responsibility on the supplier to identify and communicate “appropriate measures to control risks”. In this regard, risk management measures and operational conditions needed for adequate control of risks included in the main body of a safety data sheet and in exposure scenario(s) annexed to the safety data sheet have to be consistent.

The supplier of a preparation also has the responsibility to assess whether any exposure scenario of the individual substances are relevant for the use of the preparation by his customers.

In some cases, the supplier of the preparation may need to consolidate the exposure scenarios covering all or some of the substances in the preparation into a single exposure scenario by using the procedure described further in this chapter (including and the critical component approach, if needed). In any case, the exposure scenario or exposure scenarios submitted should be consistent with the information provided in the safety data sheet of the preparation.

14.2 Information received and information to be communicated

You can expect to receive new information from your suppliers of substances and preparations from June 2008. Chapter 4 of this guidance explains the type of information, the format and when you can expect to receive the different information. The different types of information you can get from your suppliers will to a large extent determine the information that you are obliged to communicate to your customer of the preparation. An overview of the information to be communicated down the supply chain for a preparation is given in Figure 14-1.

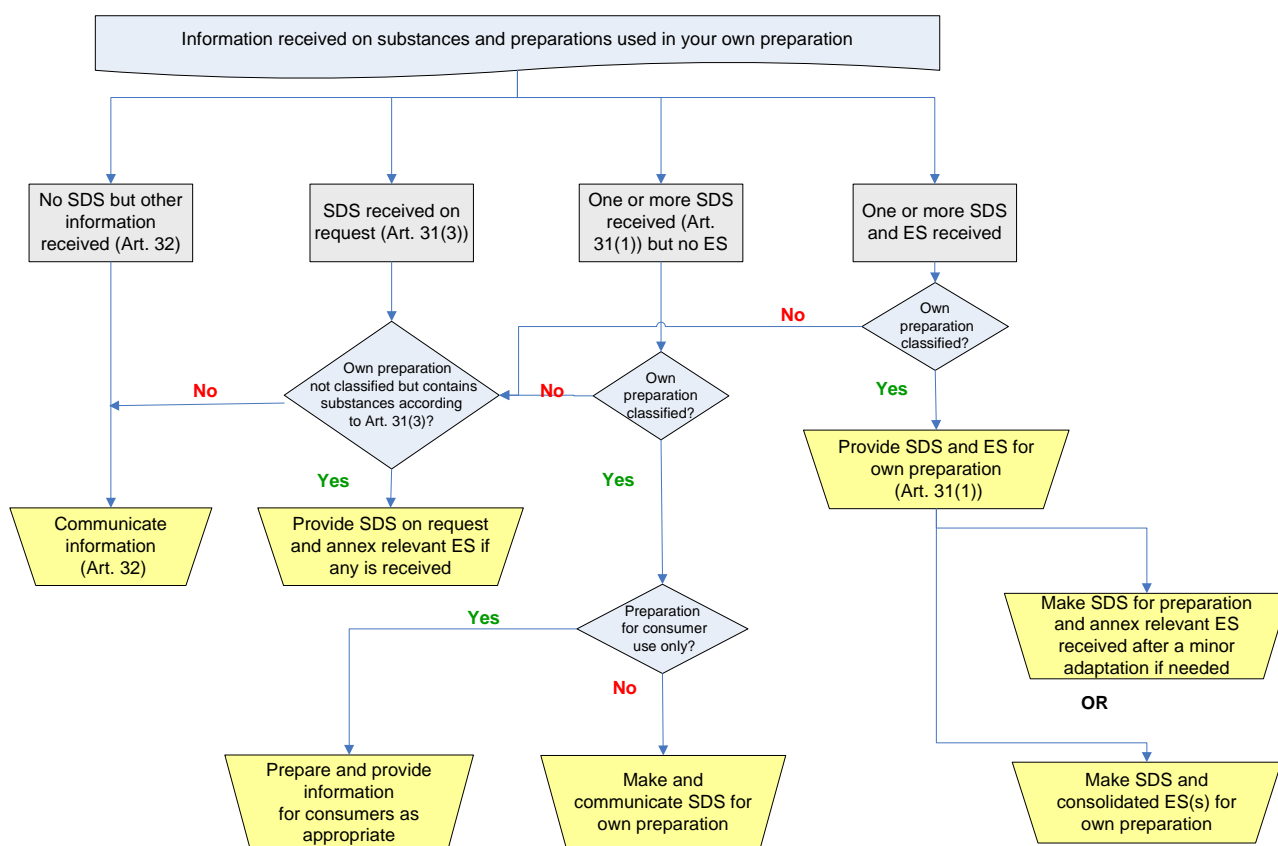


Figure 14-1 Information to be communicated down the supply chain by the formulator

The workflow in the following chapter explains how to work with the information and produce the safety data sheet, the exposure scenario(s) and other information for your preparation.

14.3 Workflow on actions to prepare information on preparation to be communicated downstream

The outlined steps of the workflow with correspondent notes include (Figure 14-2):

- | | |
|---------------|--|
| Notes a to d: | Initial work with all received information and classification of the preparation |
| Notes f to o: | Work with exposure scenarios including compliance checking, selection of operational conditions, compiling of risk management measures and consolidating of exposure scenarios |
| Notes p to s: | Compiling of safety data sheet and communication of information. |

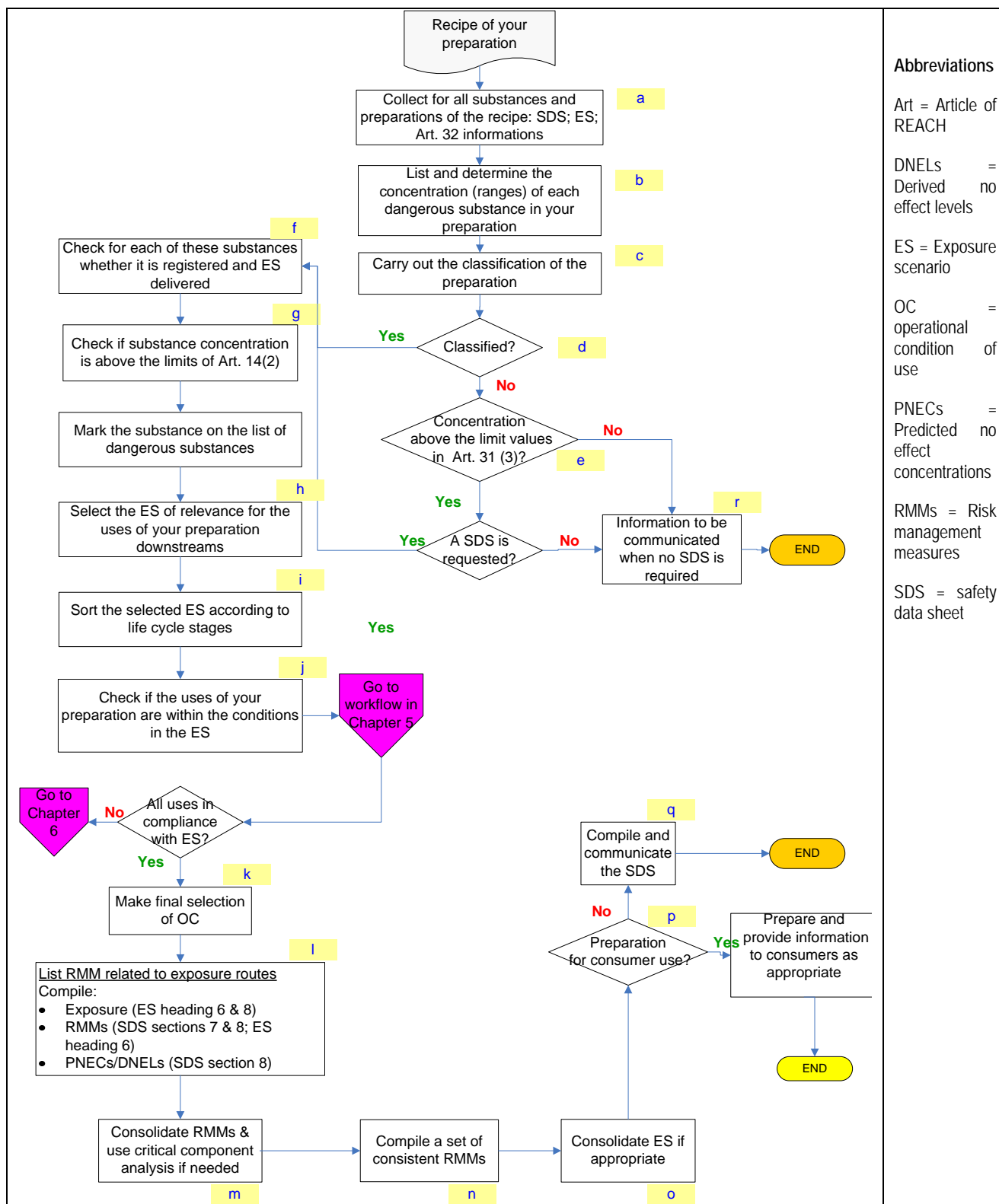


Figure 14-2 Actions to prepare information on preparations to be communicated downstream

Note a – Information for all substances and preparations

Collect all the safety data sheets, exposure scenarios and other information you have received for the substances and preparations you mix to make your own preparation. Include your own exposure scenario, if you have prepared a downstream user chemical safety report.

Note b – List and determine the concentration of dangerous substances

If you use a preparation to formulate your preparation, you may have to repeat this process, as the concentration or concentration range of a dangerous substance may not be known accurately enough. A possible approach is the following:

1. List all the dangerous substances in your preparation.
2. Begin calculation of the substance concentration, using the top end of any ranges given in the supplier's safety data sheet. You shall add up the same substances.
3. If the concentration minimum limits referred in articles 31(1), 31(3) and 14(2) of REACH are exceeded for a substance, and you are using a preparation as ingredient calculate which concentration of the substance in the preparation delivered to you would result in a concentration in your own preparation remaining under these concentration limits.
4. Contact the supplier of the preparation and ask if the substance is contained below the concentration limit you have calculated; if so, obtain written confirmation; if not, the concentration may be determined analytically.

Note c – Carry out the classification of the preparation

The classification of your preparation has to be carried out in accordance with the Dangerous Preparations Directive (1999/45/EC). Include all the dangerous substances in your list when establishing the classification and labelling of the preparation. When you have performed the classification and labelling, mark the classified substances for which the addition rules in the Dangerous Preparations Directive apply.⁶⁵

Use a different mark for each hazard category, making it possible to distinguish the different groups in your further assessment. The grouping in categories may be applied when preparing an exposure scenario which is consistent with the safety data sheet of your preparation (see note m).

The result of this step is a hazard classification of the whole preparation, allowing for the identification of the dominating hazards to be addressed by risk management measures. The safety phrases (S phrases) which have to be assigned to your preparation, based on the classification and the uses of your preparation, give instructions on the risk management measures you have to use for each exposure route in order to minimise human and environmental exposure.

Note d – The preparation is not classified

Even if the conclusion of the former step is that your preparation shall not be classified as dangerous, you may have an obligation to deliver a safety data sheet on request.

Note e – Concentration limits of article 31(3) of REACH

You have an obligation to deliver safety data sheet on request for a non-classified preparation:

1. If a substance in your preparation poses human health or environmental hazards and the concentration is 1% or more (by weight) for non-gaseous preparations and 0.2% or more (by volume) for gaseous preparation.
2. If the substance meets the criteria for Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances as described in Annex XIII of REACH or has been included at the candidate list for inclusion in Annex XIV of REACH, and the concentration is 0.1% or more.

⁶⁵ See Annex II, "Methods for the evaluation of health hazards of preparations in accordance with article 6", of the Dangerous Preparations Directive (1999/45/EC)

3. If there are community workplace exposure limits for a substance contained in your preparation. Compare the concentration of each substance in your preparation with the concentration limits above, to identify whether a limit is exceeded. If this is the case, or if the preparation contains a substance which has a community workplace exposure limit, you shall continue, assessing possible exposure scenarios and developing a safety data sheet for your preparation if a safety data sheet is requested.

If you come to the conclusion that it is not required to provide a safety data sheet on request, the next step is to assess whether you have any duties to communicate article 32 information (see note r) or if needed to prepare information for consumers (see note p).

Note f – Check registration and delivery of exposure scenario

If a substance has been (already) registered, registration number should be indicated on the safety data sheets (heading 1 for single substances and heading 3 for preparations). If this is the case, you can assume that the information on hazards has been based on testing and assessment according to REACH.

If a registered dangerous substance is produced or imported in a volume of 10 tonnes or more per year per registrant, you will receive either one or more exposure scenarios for the substance itself or for a preparation containing the substance. The exposure scenarios may include the uses of the substance or a preparation under different conditions, including the uses of your preparation.

Note g– Check if substance concentration is above the limits of article 14(2) of REACH

You may omit exposure scenarios for substances in your preparation below the lowest value of the concentration limits given in article 14(2) in the further steps of the assessment:

1. Applicable concentrations defined in the table of article 3(3), Part B of Annex II or Part B of Annex III of the Directive of Dangerous Preparations (1999/45/EC)
2. Concentration limits given in Annex I of the Directive of Dangerous Substances (67/548/EEC)
3. Concentration limits in the labelling inventory established under REACH Title XI
4. If the substance meets the criteria for PBT or vPvB given in Annex XIII of REACH and the concentration is below 0.1%.

Compare the calculated or measured concentration of each dangerous substance in your preparation with the different concentration limits to identify which could be excluded.

If a substance is registered, an exposure scenario is delivered and the concentration of the substance in the preparation is above the limits of article 14(2) of REACH, mark the substance in the list you have generated.

Note h – Select the exposure scenarios of relevance for the uses of your preparation

Select the exposure scenarios of relevance for the identified uses of your preparation including any consumer uses, for each substance marked on your list. These are intended uses, or uses made known to you in writing by an immediate downstream user (also see chapters 5 and 8 of this guidance). If you have received exposure scenarios of no relevance for the uses of your preparation, they can be disregarded. For example, if you have an exposure scenario for a solvent with the short title “Coating” and one with the short title “Hard surface cleaning” and your application is for “Hard surface cleaning” you should disregard the “Coating” exposure scenario.

Set aside all the selected exposure scenarios.

Note i – Sort the selected exposure scenarios

Sort the selected exposure scenarios according to the corresponding life-cycle stage. You will find the life-cycle stage under heading 1 of the exposure scenario. The sorting will result in sets of exposure scenarios of relevance for e.g. formulation, end-use of the preparation, service life of substances in reacted preparations and articles, and waste operations.

Note j – Check compliance with the conditions of the exposure scenarios

Go through each of the exposure scenarios, set by set, for the identified uses to ensure that the conditions of use in the exposure scenarios match those related to the identified uses of your preparation. Use the principles outlined for compliance checking in chapter 5 of this guidance. In chapter 5 you will also find an explanation of key terms used in exposure scenarios, such as “use”, “conditions of use”, “risk management measure” and “scaling”.

The compliance check will lead you to conclude whether or not your preparation is within the conditions set out in the exposure scenarios received.

After completing this step, you will also know where more in depth evaluation and communication with a supplier may be needed and if a certain use of your preparation is not covered by an exposure scenario. If this is the case you have different options as explained in chapter 6 of this guidance:

1. Make the use known to your supplier with the aim of having it identified and included in the chemical safety assessment (see chapter 8 of this guidance), or
2. Make a downstream user chemical safety report (see chapter 7 of this guidance), unless you use less than 1 tonne per year of the substance or preparation. In this case, you are exempted from this obligation, or
3. Adapt the use conditions of your preparation to the conditions in the exposure scenario, or
4. Change supplier or substitute the specific substance which does not have an appropriate exposure scenario with a substance or preparation with an exposure scenario covering the conditions of use of your preparation.

Note k – Make the final selection of operational conditions

Make the final selection of operational conditions for your preparation on the basis of the results of the compliance checking. Consolidate the information into one consistent set of operational conditions, e.g. with regard to application technique; use duration and frequency; critical amounts and critical local environmental conditions, with the aim of selecting appropriate risk management measures. If the same preparation can be used under different operational conditions leading to different risk management measures, more than one consolidated set of operational conditions may be needed.

Note l – List risk management measures related to the exposure routes

Compile the following information for each dangerous substance from the safety data sheet and the relevant exposure scenario(s) which you at this stage already have sorted into a set⁶⁶:

- Relevant exposure routes, e.g. human oral, human dermal, human inhalation etc., for the use of the preparation. The information in heading 6 and 8 of the exposure scenarios and sections 7, 8 and 9 of the safety data sheet enables decisions to be made on likely relevant exposures routes based on risk management measures and physicochemical properties of the

⁶⁶ Include also the information from your own downstream user chemical safety report of relevance for a use of your preparation, if you have made one.

substance.

- All risk management measures communicated in section 7 and 8 of the safety data sheet and in heading 6 of the relevant exposure scenarios related to the exposure routes. The risk management measures in an exposure scenario may be provided with a code which refers to the risk management measures library (Reference Technical Guidance Document on preparing the Chemical Safety Assessment under REACH, Part C)
- DNELs, DMELs and PNECs in section 8 of the safety data sheet and heading 8 of the exposure scenarios.
- Concentration range of the substance as determined (see note b).

Sort and list the risk management measures for each exposure route and link them to the other information, which could be compiled in a table as Table 24.

Table 24 List of data for each dangerous substance, for each use and life-cycle stage

Substance name:		Concentration range:	
Use: (e.g. Professional, Scientific And Technical Activities (NACE M-74), Washing and Cleaning Product, Air dispersive techniques)			
Life cycle stage: (e.g. Application of product)			
Possible exposure route ⁶⁷	Exposure route of relevance	DNELs, DMELs, PNECs,	Risk management measure
Human: Oral			
Human: Dermal			
Human: Eyes			
Human: Inhalation			
Environment: Water			
Environment: STP			
Environment: Sediment			
Environment: Air			
Environment: Soil			

This step results in defined data sets for the preparation to be used for consolidating the risk management measures for the preparation.

You may also have toxicological or other data for your formulated preparation. These data may be used as a supplement to support the assessment based on the data for the single substances.

Note m – Consolidate risk management measures for each exposure route

Identify the substances with hazards relevant to the same exposure route, e.g. inhalation, based on the data tables generated for each substance. Consider each use and life-cycle stage separately.

1. If only one substance is identified for each exposure route, select the risk management measures belonging to the exposure route and continue directly to the step explained in **note n** below.
2. If more than one substance is identified for an exposure route you have to consolidate the risk management measures. Compare all the risk management measures listed for a specific exposure route, including the precautionary measures provided by safety phrases (S-phrases) based on the classification of the preparation and any measures derived for occupational use and/or for the environment.

⁶⁷ To be divided in short and/or long term as needed.

For example, listed risk management measures or safety phrases related to “human inhalation” for five different substances could be the following:

- i) Half mask with a protection factor 10;
 - ii) Half mask with a protection factor 10;
 - iii) Appropriate half mask to be worn;
 - iv) Open windows, door, to allow sufficient ventilation. If this is not possible employ a fan to increase air exchange. (It is stated in the exposure scenario that this measure has to be combined with the operational conditions in the delivered exposure scenario, for example an air exchange of 3 times per hour).
 - v) Do not breathe vapour (S23; based on the classification of the preparation);
3. Remove duplicate risk management measures from your list, which in the above example will be one of the “Half mask with a protection factor 10”. After removal of duplicate measures, apply the ***critical component methodology*** outlined in Appendix 2 to identify the risk-determining substances for each route of exposure with the aim to select the most appropriate risk management measures.

Based on the ranking, it should be possible to identify one or more risk-determining substances per exposure route. These are the substances for which the exposure needs to be controlled in order to ensure safe use of your preparation. Select the risk management measures from your data list relevant to these risk-determining substances.

4. If there is more than one risk-determining substance per exposure route, you might need to add up their contributions to the risk, with the aim of selecting an appropriate risk management measure. Addition should be applied if the hazard effects of the substances were added when deriving the classification for your preparation (see note c). Furthermore, if you know that two or more of these substances will act additively on a target, you also need to apply the additivity rules to ensure the risks are adequately controlled.

When you need to add the risk of two or more substances, you shall use the risk characterisation ratios⁶⁸ or equivalent measures describing the risk of a substance, included under heading 8 of the relevant exposure scenario. You may use the following procedure:

- i) Collect the risk characterisation ratio under heading 8 of the relevant exposure scenarios for the risk-determining substances, or apply ratios you have derived during your compliance checking (see note j).
- ii) Compare the risk management measures belonging to the specific exposure route for each of the substances and check that they are in compliance. If one risk characterisation ratio is derived taking into account another risk management measure than the one you want to select, you need to assess the resulting effect of the risk characterisation ratio. Consult chapter 5 of this guidance on compliance checking.
- iii) Add the ratios belonging to the same exposure route.
- iv) Check whether the resulting sum of the ratios is below 1. If this is the case, the exposure of the risk-determining substances for the exposure route is sufficiently controlled. If the sum of ratios is 1 or more, you need to reconsider the operational conditions and the risk management measures (see chapter 5.4 Note j – Scaling of the conditions of use).

⁶⁸ Risk Characterisation ratio (RCR) is explained in Chapter 7 of this TGD.

Note n – Compile a set of consistent risk management measures

Compile consistent risk management measures to be included in section 8 of the safety data sheet. Be aware that the risk management measures in the safety data sheet and the exposure scenario(s) you are annexing have to be consistent.

When you compile the risk management measures for your preparation, you should also ensure that there are no conflicting risk management measures. Take care that the introduction of a risk management measure to reduce the emissions for one exposure route does not lead to an increase of the emissions for another exposure route.

One example is the risk management measure “ventilation”, which is a risk management measure for occupational inhalation exposure. The use of “ventilation” increases the emission rate to air, which could increase exposure of the general population living in the vicinity of the site. If this additional emission of the substance to air was not considered in the environmental safety assessment, this should be repeated, including the emission to air caused by the introduction of “ventilation”. Other examples are: use of gloves (occupational) and filtration (environment) which both increase emissions to waste. Also, the impact of handling the filtration equipment on occupational exposure should be considered⁶⁹.

Note o – Consolidate exposure scenario if appropriate

Before you continue with the following steps, you must decide which type of exposure scenario to deliver for your customer. You could either forward the relevant exposure scenario(s) for single substances, possibly after an adaptation, or you could make consolidated exposure scenario(s) for your preparation. You can apply the following recommendation if you are not sure what best fits your customer:

- If your customer is an SME end-user, it is likely that consolidated exposure scenarios are more convenient for them.
- If your customer is a formulator, forward the single exposure scenarios for the substances or preparations used in the formulation of your preparation. Also prepare a consolidated exposure scenario, if necessary.
- If your customer is a large end-user, you should choose the approach which is most convenient.

Forwarding exposure scenario(s) is simple. However, you have to ensure that the information in the exposure scenario(s) you annex to the safety data sheet of your preparation is consistent with the content of the main body of the safety data sheet. You could also choose to use a generic exposure scenario if available from e.g. a library of scenarios relevant for the uses of your preparation. In this case you have to ensure that the generic exposure scenario is in compliance with the exposure scenario(s) delivered by your suppliers.

Having performed the actions of the workflow so far you have collected all the necessary information for compiling the consolidated exposure scenario(s) such as:

- Short title of exposure scenario(s) and descriptions of activities/processes cf. note h
- Operational conditions cf. note k
- Risk management measures corresponding to the operational conditions cf. note n

⁶⁹ Concise TGD for Preparing the Chemical Safety Assessment – Chapter D

- Risk characterisation ratios, DNELs, PNECs etc. cf. note m
- Possible scaling algorithms cf. note m (and chapter 5.4)

Use the template for the exposure scenario(s) of your preparation shown in the examples included in Appendixes 3 to 5. Include all the necessary information for your preparation under the relevant heading of the exposure scenario(s).

Note p – Preparations intended for consumer use

Where dangerous substances or preparations are sold to consumers, a safety data sheet need not be supplied if sufficient information is provided to enable safe use, unless requested by a downstream user or distributor.

Provide your customer with trade name, your name and address, name of substance responsible for classification, hazard symbols, risk and safety phrases as derived from classification and labelling of your preparation etc. in accordance with Directives 67/548/EEC (article 6) and 1999/45/EC (articles 4 & 10). Furthermore, reflect the risk management measures you have compiled in your consumer information.

Be aware that use by consumers may be advised against in heading 16 of a safety data sheet delivered by your supplier. This means that the supplier has assessed consumer use as not being safe and you do not comply with REACH if you provide the substance to the general public. It is, however, possible for you to carry out your own chemical safety assessment and to prepare a downstream user chemical safety report (see chapter 7 of this guidance).

Note q – Compile safety data sheet

Both article 14 (safety data sheet) of Directive 1999/45/EC and the safety data sheet Directive 1991/155/EEC were repealed with effect from 1 June 2007. The requirement for how to compile a safety data sheet lies from that date under article 31 and Annex II of the REACH Regulation.

Finish compiling the safety data sheet and annex the relevant exposure scenario(s) as derived in the former steps of the work flow. If no exposure scenario is to be annexed you still have to provide suitable and adequate information on risk management measures in order to control exposure to human and environment according to Annex II of the REACH Regulation.

The general procedure for compiling a safety data sheet for a preparation has not been changed, but additional information is required under several of the headings (see Table 25).

When compiling the safety data sheet you shall also consider information received according to article 32 of REACH.

Guidance on how to include information from an exposure scenario into the main body of a safety data sheet is given in the Guidance on the Chemical Safety Report, Part G. The following table shows which information to transfer from the supplier safety data sheets received to the safety data sheet for your own preparation.

Table 25 New information in a safety data sheet (also see Annex II of REACH for more details)

Task for preparing your safety data sheet	Information to take from the safety data sheets of suppliers, Art. 32 information or your own downstream user chemical safety report	Information to be included in the safety data sheet for your own preparation
Heading 1.1: Registration number of a substance is placed here.	Collect the registration numbers of already registered substances for inclusion under heading 3 in the safety data sheet for your preparation	
Heading 1.2: List identified use(s) under this heading. All identified used relevant to the recipient of the safety data sheet shall be listed for substances with Chemical Safety Assessment.	The most important use(s) of a substance or preparation are listed under heading 1.2. For registered substance(s) (in preparations), the description is likely to be according to the use descriptor system in the guidance on the Chemical Safety Assessment. If one or more exposure scenarios are attached to the safety data sheet, their short titles correspond to the identified uses.	List the use(s) of relevance for your own preparation in your safety data sheet. If you cannot find the uses of your preparations here, contact your supplier and ask whether your use is identified.
Heading 3: List required information. New information is PBT/vPvB substances and registration numbers	For a preparation, you will find the substance name, classification and registration number, if already registered, as well as the concentration ranges	Check if dangerous substances in you preparation are diluted below the threshold limits in Annex II §3 of REACH. Include those which are above the limits into heading 3 of your safety data sheet. Copy registration number and classification.
Heading 7.1: Addresses various engineering controls.	Advice on technical measures will be included	Include the relevant technical measures for the use(s) of your preparation.
Heading 7.3: Make reference to sector specific guidance.	If available, you could find reference to industry or sector specific approved guidance	Include the references in your safety data sheet.
Heading 8: List available Derived No Effect Levels (DNELs), Occupational Exposure Limits (OELs), Predicted No Effect Levels (PNECs) and environmental quality standards (EQSs).	The DNELs for human health hazards and the PNECs for hazards to the environment are new data which you should find under heading 8. However, they will be available mainly for registered substances which have been subjected to a Chemical Safety Assessment.	Include the DNELs, DMEL and PNECs of relevance for the use(s) of your preparation under heading 8 of the safety data sheet. You should include these values for all substances above the concentration limits given in article 14(2) of REACH and for the exposure routes assessed to be of relevance for your use as a minimum. OEL and EQS also have to be included under heading 8 of the safety data sheet.
Heading 8.2: List all risk management measures and summaries of risk management measures for identified use(s)	You will find here risk management measures for control of occupational and environmental exposure for the use of the substance/preparation. If a Chemical Safety Report has been prepared, summaries of risk management measures in annexed exposure scenario will also be stated here.	Include a compiled set of consistent risk management measures and the corresponding summaries which are taking from the relevant exposure scenario. The risk management measures in the main body of

Task for preparing your safety data sheet	Information to take from the safety data sheets of suppliers, Art. 32 information or your own downstream user chemical safety report	Information to be included in the safety data sheet for your own preparation
		the safety data sheet and an annexed exposure scenario shall be consistent.
Heading 12: Include results of PBT/vPvB assessments (only for substances ≥ 0.1 %)	The result of a PBT/vPvB assessment for a substance will be given under heading 12 of the safety data sheet. It will only be available when a Chemical Safety Report has been required.	Compile the available results from the substances in your preparation and include them under heading 12 of the safety data sheet when compiling your own safety data sheet.
Heading 13: Include information on waste management measures	Waste management measures shall still be given under heading 13 of the safety data sheet. Where an exposure assessment is required the waste management measures shall be consistent with the exposure scenario annexed to the safety data sheet.	Include the waste management measures of relevance for the use(s) of your preparation in the safety data sheet under heading 13 of the safety data sheet. Ensure that it is consistent with the exposure scenario your annex to your safety data sheet.
Heading 15: Include information on authorizations and restrictions	Substances subject to authorisation and details about any authorisation granted or denied shall be given under heading 15 of the safety data sheet. Also substances subject to restrictions shall be stated under this heading.	Include the information delivered to you in your own safety data sheet for your preparation ⁷⁰ .
Heading 16: Include any use advised against.	Any use advised against shall be included under heading 16 of the safety data sheet. This could e.g. be a statement that the preparation is not to be used by children or that certain exposure routes shall be avoided.	Include the delivered information in your own safety data sheet.

Note r – Information to be communicated for preparations when no safety data sheet is required

You may need to communicate information on certain substances in your preparation, although no safety data sheet for the preparation is required according to articles 31 (1), 31 (3) or 31(4) of REACH. It could also be necessary to provide information to your customers on how to use your preparation safely.

When no safety data sheet is required for your preparation, you still have to deliver the following information to the recipient of your preparation, according to article 32(1) of REACH:

- Registration number of the substances contained, if:
 - i. The substances are subject to authorisation. Details about any granted or denied authorisation and the authorisation number shall be delivered. The authorisation number also has to be stated on the label of a product containing a substance subject to authorisation.
 - ii. Substances subject to restrictions including details of any restrictions.
 - iii. Information necessary to enable appropriate risk management measures.

⁷⁰ Furthermore, you have to include specific national requirements.

There is no specific format for article 32 information, but it may be delivered in the format of a safety data sheet (see also [chapter 4](#) of this guidance, note h “Other information”). Whatever the format in which such information is presented, it would be useful to include a statement that the information is provided in accordance with article 32 of REACH.

15 COMPLIANCE WITH REACH FOR DISTRIBUTORS

This section sets out the main aspects of the REACH regulation which are relevant to distributors including retailers.

15.1 Introduction to the section for distributors

Before reading this chapter, you should consult chapter 2 of this guidance and identify whether you are a **distributor** or a **retailer** under REACH.

A **distributor** under REACH is an actor who only stores and places on the market (e.g. sells) substances and preparations⁷¹ exclusively inside the EU, without any kind of modifications or re-packaging (see article 3(14) of REACH). A **retailer** under REACH is an actor who sells substances and preparations to private consumers and/or professional users in retail stores. Retailers are a sub-group of distributors. **Storage providers**, who only store substances or preparations, are a sub-group of distributors. As long as they don't perform any operations or activities with them, they only have to forward information in the supply chain.

By checking your roles, you may have identified that you also have roles other than distributor/retailer under REACH. The most common additional roles of a distributor are:

- **Importer** of substances, preparations or articles. In this case you may have obligations to register and other obligations related to the import of substances/preparations or of articles. Consult the guidance on registration⁷² and on articles⁷³ for further details. General guidance can be found on the Chemicals Agency website⁷⁴.
- **Re-filler**, who transfers substances or preparations from one container to another, is a downstream user and as such has the obligation of a downstream user under REACH.

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 (http://reach.jrc.it/navigator_en.htm) or the introductory information on REACH on the website of the Chemicals Agency (http://reach.jrc.it/about_reach_en.htm).

15.2 Short Overview of REACH for distributors

As a distributor, it is your obligation to pass on information on the goods you distribute from one actor in the supply chain to another. This includes safety data sheets for substances and preparations. Furthermore, it requires certain information to be provided for substances, preparations or articles when a safety data sheet is not required. You are not a downstream user of substances/preparations according to REACH, but have a key position regarding information flow within the supply chain. In principle, your role is similar to that before REACH. Therefore, your

⁷¹ A person who solely stores and places articles on the market (i.e. neither substances on their own nor in a preparation), for third parties is not a distributor according to the definition in the REACH Regulation.

⁷² http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.1_REGISTRATION_GUIDANCE/RIP_3.1_registration_en.pdf

⁷³ http://ecb.jrc.it/documents/REACH/RIP_FINAL_REPORTS/RIP_3.8_ARTICLES/RIP_3.8_Final_report_Draft_TGD_May_2006.pdf

⁷⁴ http://ec.europa.eu/echa/home_en.html

previous experiences and methods for delivering information in the supply chain could also be used under REACH.

You may encourage preparatory actions during the phase in period of REACH⁷⁵. This could be done by initiating communication between a manufacturer or an importer of substances and your customers, who will often be downstream users. The downstream users could be formulators of preparations as well as end users of substances and preparations.

A formulator or end-user of substances or preparations, i.e. the downstream user, has the right to make a use known in writing to his supplier with the aim of making this an identified use. He should also provide a description of his use(s) in writing to the supplier. 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 preparation. This could be of relevance, for example, if he wants to keep a use confidential or the supplier does not want to support a specific use. The downstream user may not be able to make the 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 e.g. the hazardous properties of a substance or on exposure assessment; that means assumptions on the conditions of use and exposure assessment tools used. This additional information will mainly be related to the exposure assessment; that means assumptions on the conditions of use and exposure assessment tools used. If this is the case, it is your role as distributor to pass the request for further information to your supplier and to deliver the response of the supplier to the downstream user.

15.3 Obligations of Distributors

15.3.1 Obligation to pass information

Passing information through the supply chain is your only obligation under REACH. You may have direct contact with the manufacturer/importer and the end-user of a substance/preparation, but the supply chain may also consist of several actors, where you as distributor are placed between two downstream users in the chain (Figure 15.1). The type of information you have to pass could include:

- 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
- Specific requests for information from a downstream user who wants to make a downstream user chemical safety report
- Safety data sheet with and without exposure scenario⁷⁶
- Information on, for example, authorisation of a substance
- Information about substances of very high concern in articles.

⁷⁵see chapter 3 of this guidance - Preparing for REACH

⁷⁶ 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 26 Information flow in the supply chain

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. 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.

You should note that a distributor shall keep information on a substance/preparation for at least 10 years after his last supply (article 36 of REACH).

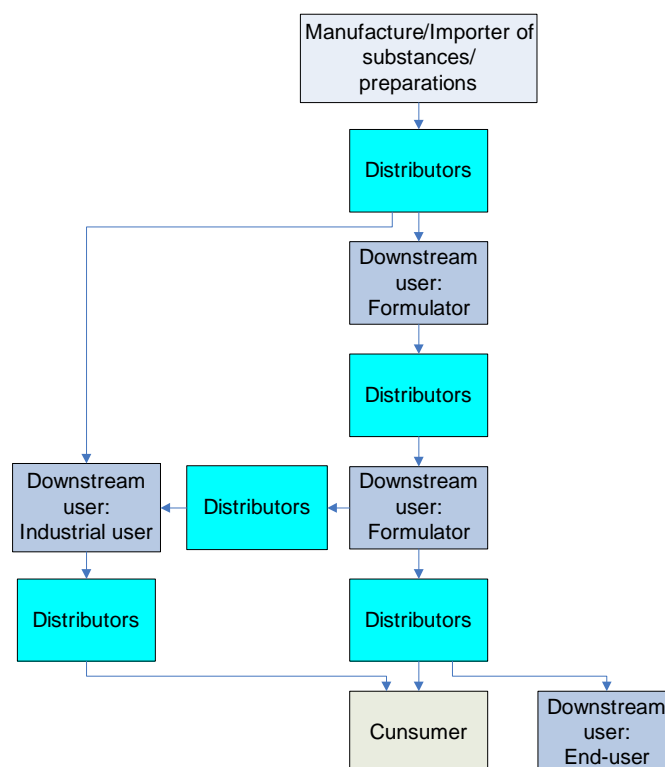


Figure 15-1 The distributor and the supply chain

An overview of the type of information you are obliged to pass up and down the supply chain is given in Table 26 Information flow in the supply chain

15.3.2 What happens if a substance is not registered for the use(s) of one of your customer?

When your customer is a downstream user, he has to compare his own conditions of uses with the information in the safety data sheet and relevant exposure scenario (if provided). If he uses the substance or the preparation differently than described in the exposure scenario, and the total amount he uses is one tonne/year or more, he has to notify the Chemicals Agency of the difference and implement measures to ensure safe use. However, if the amount he uses is 1 tonne/year or more, he has the following options:

- To contact the supplier with the aim of getting an exposure scenario that covers his use
- To make his own downstream user chemical safety report
- To implement the conditions of use in the exposure scenario

- To substitute the substance/preparation

Table 26 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/preparations 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.
Downstream user preparatory activities and requesting that a use becomes an identified use ⁷⁷	Responses to questions from suppliers and additional questions for clarification of use conditions.	Information on the uses of a substance as such, in preparations and in articles, possibly accompanied by a request to make a use identified for inclusion in the registration of the manufacturer/importer.	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.
Safety data sheet and other information on substances and preparations			
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. ⁷⁸	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 preparations and downstream user chemical safety report ⁷⁹	Delivery of information for making a safety data sheet and /or a chemical safety report for a preparation, 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 preparation is above a threshold value for	If a customer makes a downstream user chemical safety report for a substance or preparation, he may request information on substance hazards. You may receive requests from customers for safety data sheets for non-classified preparations. If hazardous substances are contained above the

⁷⁷ See chapter 3 and chapter 8 of this guidance

⁷⁸ See chapter 10, chapter 11 and chapter 4 of this guidance

⁷⁹ See chapter 14 and chapter 7 of this guidance

Subject	Type of information received	Type of information to be forwarded	Remarks
		providing of safety data sheet ⁸⁰ .	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.		Even if no safety data sheet is required, you may receive information from the supplier according to article 32 of REACH. A non-classified preparation may, e.g. contain 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 preparation safely.
Information to consumers	Information on: - the classification, as a minimum. - Recommendation on safe conditions of use should also be included.		Classified substances or preparations for the general public do not require a safety data sheet if sufficient documentation to enable safe use is provided.
Authorisation/restriction ⁸¹			
	Questions from suppliers on the use(s) of a 'substance of very high concern', on its own or in preparations.	Answers to questions from suppliers on the use(s) but also questions from the downstream user on the substance concentration in preparations (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 ⁸² (Article 33 – see Appendix 1)			
Information in the supply chain for articles	For articles with a substance on the candidate list for authorisation present in a concentration > 0.1 % (weight/weight): - Available information on safe use of the articles. Name of the substance as a minimum	Downstream user may request information on the content of 'substances of very high concern' in articles.	You have to pass the information from your supplier of an article to your customers (downstream users and distributors/retailers). Furthermore, you should pass any requests upstream.
Information to consumers	For articles with a substance on	Requests from a consumer	If you receive a request

⁸⁰ Article 31(3) in: REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 13. December 2006.

⁸¹ See chapter 12 of this guidance - Compliance with the authorisation and chapter 13 - Compliance with restrictions

⁸² Guidance document on articles

DISTRIBUTORS

Subject	Type of information received	Type of information to be forwarded	Remarks
for articles	the candidate list for authorisation present in a concentration of 0.1 % or more (weight/weight): - Available information on safe use of the article. Name of the substance as a minimum.	about an article containing a 'substance of very high concern'.	from a consumer, you have to provide him with the information, free of charge, within 45 days after you have received the request.

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APPENDIX 1: REFERENCE INFORMATION ABOUT EXPOSURE SCENARIOS**1.1 What is an exposure scenario?**

An exposure scenario tells you how to use a dangerous substance as such, in a preparation or an article so that it does not cause any harm. It describes the ‘conditions of safe use’ or how to ‘adequately control the risks’ of a dangerous substance in a specific use. The exposure scenario can relate to a substance or a preparation.

4. An exposure scenario covers the entire life-cycle of a dangerous substance (see below)
5. A dangerous substance or a preparation can have different uses and can therefore have several, different exposure scenarios.
6. An exposure describes the safe use of a substance, taking account of the various types of risks for humans and the environment
7. An exposure scenario consists of a name (short title) and information on the operational conditions of use and the risk management measures that ensure adequate control of risks.

1.2 Who is required to develop exposure scenarios under REACH?

It is primarily the task of the manufacturers and importers of substances to develop exposure scenarios as part of their chemical safety report and the registration dossier. Only in special cases does a downstream user have to develop an exposure scenario. Exposure scenarios are only required for dangerous substances and PBT/vPvB substances which are produced or imported in amounts exceeding 10 tonnes per year per manufacturer/importer.

Registrants frequently do not know for what purpose and how a substance is used in the supply chain. They can therefore either make assumptions or collect information from their downstream users on the conditions of use. The latter approach ensures that the actual situation is better reflected in the chemical safety assessment and thus the exposure scenarios are likely to cover the majority of conditions of use at downstream user level.

1.3 What does it mean that an exposure scenario covers a substance’s life-cycle?

In the chemical safety assessment, all life-cycle stages are to be considered, to identify potential risks and derive relevant risk management measures to adequately control these. The life-cycle of a substance means the time span from its manufacture to its disposal (cradle to grave). The following table gives examples of life-cycles of substances.

Table A- 1 Examples of life-cycles of substances

Name of life-cycle step	Example Pigment	Example flame retardant	Example Chromium
Manufacture Production of substance	Synthesis	Synthesis	Extraction and refining
Formulation ⁸³ Mixing of substance with other substances or preparations	Mixing of paste Mixing of paint	Mixing of additive package	--
Industrial use Use of substance or preparation in industrial activity	Painting of furniture or construction elements at industrial premises	Conversion and production of flame retarded computer	Electroplating of steel for car bumpers
Professional use Use of substance or preparation in professional activity	Painting with decorative paint	--	Welding and grinding of bumpers at a garage during bumper repair
Consumer use Use of substance or preparation by consumers	Painting with decorative paint	--	--
Service life Use of articles	Wall inside house	Use of computer	Use of car bumper
Disposal Disposal of substance, preparation or article	Disposal of residues of paint, disposal of old painted wallpaper	Disposal of computer and recovery/recycling	Dismantling of car and recovery / recycling

1.4 What is an exposure scenario used for?

Under REACH, exposure scenarios have two functions:

1. Based on the exposure scenario, exposure levels of humans and the environment are estimated and risks characterised in the chemical safety assessment carried out by the manufacturer / importer. Downstream users may also decide to prepare a downstream user chemical safety report.
An initial exposure scenario based on available information is used for a first assessment. If a risk is identified using the initial exposure scenario, the assessor can refine the assumptions on the use conditions, or collect further hazard information, until he can show adequate control of risks.
2. Exposure scenarios that describe the conditions of use under which the risks are adequately controlled are called 'final exposure scenarios'. Relevant information to control risk is communicated in the form of an exposure scenario as attachment to the safety data sheet.

1.5 What is communicated in the exposure scenario along the supply chain?

Currently, it is expected that exposure scenarios can have different formats and be different in their level of detail and content. However, a standard format is proposed and a core set of information, called determinants of exposures is defined in the guidance on the chemical safety report, which will most likely be used. Examples of exposure scenarios can be found in the guidance on the

⁸³ There can be several formulators in one supply chain

chemical safety report.

1.6 Do exposure scenarios always relate to a specific substance?

No, exposure scenarios can apply to groups of substances that have similar properties or to different substances which are contained in a preparation, for example (exposure scenario for a preparation).

Most exposure scenarios will be delivered as annexes to safety data sheets of preparations. Safety data sheets of preparations could have:

1. an exposure scenario relating to the preparation
2. several exposure scenarios, each relating to one of the dangerous substances requiring one and being contained in the preparation or
3. both an exposure scenario for the preparation and several for the individual dangerous substances.

Exposure scenarios for preparations may be developed by formulators who merge the exposure scenarios they receive with the substances and preparations they use (see Section 13 of this guidance).

1.7 What does exposure mean exactly?

The word ‘exposure’ is the scientific term for ‘coming into contact with something’: any type of contact between a person or the environment and a substance is an exposure. The exposure can take different routes, as humans take up and the environment receives substances through various channels, which are called exposure routes or exposure pathways.

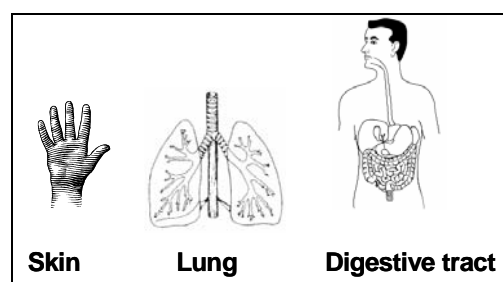
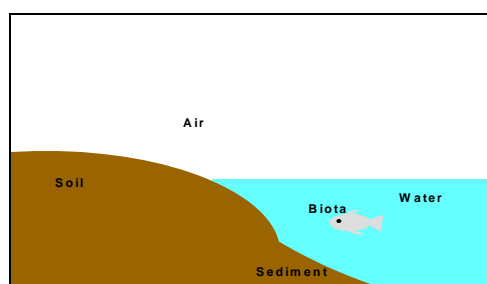


Figure A- 1 Environmental compartments and human exposure routes and

The exposure level of humans or the environment – the concentration or dose they are exposed to – is a numeric value that relates to the specific exposure route through which the substance is taken up. The (severity of the) effect will depend, in addition to the exposure level, on the duration and frequency with which the exposure occurs.

The exposure level can, together with its duration and frequency, be determined by estimation or measurement. This may already be done for some substances, in order to check compliance with occupational exposure limit values at workplaces or to control air emissions and water discharges. Under REACH, exposure estimations – or measurements of exposure levels- are performed in the frame of a chemical safety assessment.

1.8 How is the exposure scenario structured?

The exposure scenario describes the ‘conditions of use’, which determine the exposure level. The conditions of use are divided into two types of parameters: the operational conditions of use and the

risk management measures.

The operational conditions describe how a process or activity is carried out. Examples of such information are the amount, duration and frequency with which a substance or preparation is used. Other parameters could relate to the operating temperature, pressures, or pH as well as the degree of containment of technical equipment (e.g. is the substance handled in a closed vessel or applied outside). In principle, the operational conditions of use determine the emission of a substance from a process.

The risk management measures include all measures and devices that are applied in order to prevent substance which is emitted from a certain process from reaching humans or the environment. Examples of risk management measures are local exhaust ventilation, air filters, sewage treatment plants or personal protective equipment such as gloves, respirators and goggles.

Information about the surroundings of the place where the chemical is used can also be part of the exposure scenario. Information may be needed, for example, on the dilution of the substance in surface water or the air volume of the workplace to which a substance is emitted.

1.9 Why is exposure estimation needed?

It is necessary to know the level of exposure of humans and the environment to a substance in order to determine whether or not there is a risk. The definition of a risk under REACH is that the exposure level exceeds the threshold below which no adverse effects are expected. The comparison of exposure and safe level is numeric and, therefore, it is necessary to quantify the exposure. The two values to be compared in the risk characterization are:

1. The highest doses / concentrations at which no effect on humans is likely to occur, taking into account all relevant endpoints and durations of exposure (short term, long term, repeated). Similarly, the highest concentration levels at which no effect is likely to occur in the environment can be estimated. These values are specific for a substance and an exposure pathway and are called Derived No Effect Levels (DNEL⁸⁴) for humans and Predicted No Effect Concentrations (PNEC) for the environment. They are based on toxicological and eco-toxicological data on the substance, which shall be generated and provided by the manufacturer/importer.
2. The actual exposure level of humans or the environment to the substance as such, in preparations or in articles expressed for each of the lifecycle steps separately. This value can be estimated based on the information in the exposure scenario or it can be a measured value. In the later case, the exposure scenario describes the conditions of use during the measurements.

The ratio of these two values is determined for all potential areas of risk. It gives an indication of the level of risk of the subject of protection in relation to a specific use of a substance under the conditions described in the exposure scenario.

⁸⁴ For some substances, in particular carcinogens, mutagens and reprotoxicants, it is not possible to determine an exposure level below which no effects could occur. In order to provide a value similar to the DNEL for the risk characterisation under REACH, the value of a DMEL (derived minimum effect level) has been proposed to be used. For more details c.f. Guidance Document for the preparation of the Chemical Safety Report.

$$\text{Risk ratio} = \frac{\text{actual level}}{\text{level of no concern}} = \frac{PEC}{PNEC} \text{ or } \frac{\text{dose / concentration}}{DNEL} \quad \text{Equation 1}$$

If the risk ratio(s) exceed(s) the value of '1', the risks from the use of the substance are not adequately controlled. This means that the conditions of use in the (tentative) exposure scenario are not safe. This triggers a requirement to refine the exposure scenario. Refining an exposure scenario can mean adding further risk management measures to the scenario, modifying the operational conditions of use or refining the DNEL/PNEC derived from (eco)toxicological data. If the ratio(s) remain under the value of '1', the risks can be regarded as adequately controlled.

In summary, exposure estimation is needed in order to know whether or not an exposure could occur that may pose risks to humans or the environment. Since this is usually not possible to determine by 'common sense', the quantification of exposure is an essential step of the safety assessment.

APPENDIX 2: FORMAT OF THE EXPOSURE SCENARIO AND EXPLANATION

Table A- 2 Exposure scenario format and explanation for uses in processes

Title of section	Explanation and potential information sources
1. Short title of Exposure Scenario	The short title may also include an indication which life cycle stages are covered in the ES. Information on the descriptor system is given in Section 7.
2. Description of activities/process(es) covered in the Exposure Scenario	Describe with your own words, which activities or work steps are carried out with the substance
3. Operational conditions	
3.1 Duration and frequency of use	Identify how long the substance is applied per day. List how often the substance is applied per day and how many times per year This information should be available from the HSE management or technical staff, risk assessments of workplaces or applications for IPPC permits
3.2 Maximum amount used per time or per activity	Identify the amount of the substance used per day and per year. This information should be available from the HSE management or technical staff, risk assessments of workplaces or applications for IPPC permits
3.3 Other operational conditions determining exposure, e.g. <ul style="list-style-type: none"> temperature other 	List the operational temperature under which you apply the substance or any other special processing conditions (e.g. very low pH values or clean-room conditions). This information should be available from the HSE management or technical staff, workers instructions, internal process descriptions or other technical documentation.
<ul style="list-style-type: none"> capacity of receiving environment (water flow; room size x ventilation rate) 	The surroundings into which the substance is emitted to should be described. Information on the set-up of the workplace should be available from the HSE management or workers instructions. In case of changing work-place settings for service providers, a worst case assumption should be made first and refined if necessary (e.g. smallest room size and no ventilation). Information on the receiving environment will mainly relate to whether or not waste water is discharged to a municipal sewage treatment plant and the water volume of the receiving surface water (rivers). This information could be obtained from the municipality.
<ul style="list-style-type: none"> emission or release factors to the relevant compartments; 	This information relates to a factor that describes the percentage to which a substance is released from your process. <i>(for such factors it must be always defined, to which extent risk management measures described under 6 already contribute to the value of the factor)</i> These factors could relate to whole preparations (e.g. if an aerosol is formed by the application of a spray piston or dust particles are emitted) or to substances contained in a preparation (e.g. solvents evaporating during a coating process) or to substances applied as such (pure solvent evaporates from drying oven).
4. Physical form of product	Is the substance contained in a preparation that is a liquid, gas or solid
5. Product specification	This should correspond to Section 2 of the SDS.
6. Risk Management Measures ⁸⁵ <ul style="list-style-type: none"> Occupational measures Environment related measures; 	Describe which risk management measures are applied at the workplace and to protect the environment. Use your workplace instructions, documented risk assessments at the workplace and ask HSE or technical staff. Information on environmental measures are included e.g. in permits, emission reports or other installation related documentation.

⁸⁵ Target groups are the humans workers and/or the environment (air, water, soil) potentially being exposed

Title of section	Explanation and potential information sources
	For both types of measures, document their efficiency related to the substance
7. Waste related measures	Describe how the processing waste of the substance is disposed of.
8a. Prediction of exposure resulting from the conditions described above	Here, you document how you assessed the exposure and what is the result. You may give several values if you have specified variations of the conditions of use or suggest scaling. Indicate which exposure assessment tool has been used
9. Set of variables which together indicate safe use	<p>The set of variables (and a suitable algorithm) which together indicate safe use, but which have some flexibility in the respective values for each variable (through e.g. rule of proportion, either linear or with a known function). Note: This will mostly be specific conditions for certain types of product; this section may also include a link to a suitable (e.g. easy-to-use) calculation tool.</p> <p>Where relevant; Other methods to check compliance at DU level may be included here as well</p> <p>This section is not relevant to end-users, as they do not forward the exposure scenario to customers who have to check their compliance.</p>

Table A- 3 Main determinants of exposure

Main determinants of exposure; Determinant	Examples (not exhaustive)	Remarks
<i>Substance characteristics</i>		
Molecular properties	Molecular weight Molecular size	Gives an indication of bioavailability
Physicochemical properties	Physical state, dustiness Vapour pressure (for liquids) Octanol-water partitioning coefficient Water solubility	Determines exposure at workplace and partitioning in the environment The exact property and degree of detail is highly variable and depends on protection target and input requirements for the exposure models or tools
Biological properties	Degradation (half-life in water, soil, air)	Determines degradation in environmental compartments incl. STP
<i>ES characteristics</i>		
Life cycle of substance or product to which the ES refers	Manufacture or import, synthesis, compounding, formulation, use, service life, waste phase	Identify relevant exposures for all target groups, supports selection of suitable broad ES
Operational conditions	Type of activity/use Duration of activity/use Frequency of activity/use Temperature, pH, etc. Containment of process [open/closed]	Determines type of exposure (short term vs. long term) and choice of PNEC or DNEL
Preparation characteristics	Weight fraction of substance Migration rate	Determines exposure of humans and environment for preparations or products
Used quantity	Use rate [tonnes/year] Amount handled [kg/day, etc]	Determines the exposure potential per time
Risk Management Measures (within control)	Local exhaust ventilation ⁸⁶ On-site waste (water) treatment Personal Protective Equipment	RMMs as part of process or under direct control by DU
<i>Surroundings</i>		
Dimensions	Volumes of receiving compartment, rates, areas	Room, hall, application rate, surface area treated, receiving water body flow rate
Risk Management Measures (outside control)	Sewage treatment plant, waste treatment	RMMs outside direct control by DU, e.g. STP type, flow rate
Exposure factors	Inhalation volume Intake of dust, soil	Determines the human exposure potential
Other characteristics	Market penetration, amount of product used	Determines likelihood of other emissions in area

⁸⁶ These are only given as examples.

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, preparations 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 5 of this guidance, on compliance checking). If any of the deviations are of qualitative nature, you should turn to Section 6 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, you should assess which factor the exposure level is affected by in relation to the exposure scenario. A comparison of all deviations and their influence on the exposure level, by applying rules of proportion and common sense, will then lead you to a conclusion on 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 A- 4 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 A- 5 Operational conditions

Item ⁸⁷	Operational conditions in the exposure scenario	Present operational conditions	Consequence for exposure level⁶	Action need⁶
(Maximum) duration of use event				
(Maximum) frequency of use event				
(Maximum) amount used per time				
(Maximum) processing temperature				
Concentration of the substance in the preparation / 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 <ul style="list-style-type: none"> • Water flow • Soil area • ... 				
Capacity of receiving workplace <ul style="list-style-type: none"> • Air volume/room size • Ventilation rate • ... 				
Capacity of consumer environment <ul style="list-style-type: none"> • Room size • 				
Emission or release factors specified				
Specific conditions related to wear and tear of articles, e.g. abrasive conditions				
Containment of process				
...				

⁸⁷ 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!

⁶In 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 A- 6 Risk management measures

Item ⁷	Risk management measures (and efficiencies) in the exposure scenario	Risk management measures (and efficiencies)	Consequence for exposure level⁸	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 A- 7 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	
Consumers	

⁷ 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!

⁸In 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 A- 8 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: EXAMPLES OF EXPOSURE SCENARIOS FOR PREPARATIONS – CLEANING PRODUCTS

Preliminary example for an exposure scenario related to a preparation for professional hard surface cleaning	
1. Short title	Public domain (SU22) Washing and Cleaning Products (PC35) Spraying outside industrial settings and/or applications - professional (PROC11)
2. Activities or processes	<ul style="list-style-type: none"> Delivered product is a concentrated solution, which is diluted with water by the user Diluted product is sprayed on surfaces to be cleaned. A suitable trigger spray is used for this Product is wiped off surface with a cloth When the cloth becomes wet, the cloth is cleaned in water and wringed carefully out The rinsing water is changed at least every 1 hour Cleaning of the equipment
Operational Conditions	
3. Duration and frequency	Workers (professional) 8 hrs/day, 5 workdays/week Consumers Product is not intended for consumer use Environment Up to 365 days per year
4.1 Physical form	The product is a liquid. On application, aerosols may be formed.
4.2 Concentration of substances in preparation	Concentrations of classified substances in supplied concentrate are: A (surfactant): 6% B (solvent): 2% C (fragrance): 0.3%
4.3 Amount per time or per activity	Workers (professional) 2 kg/d Consumers Product is not intended for consumer use Environment -
5. Other operational conditions determining exposure	Worker (professional) Product concentration in cleaning solution : 1% (relevant both for inhalation and dermal uptake) Temperature: room temperature, i.e. 20°C (relevant for inhalation). May however vary between 15 and 30°C Repeated short time skin contact: 12 times per hour, duration 30 seconds (relevant for dermal uptake), i.e. total contact time = 0.8 hours/day Environment All product is assumed to be discharged to waste water. If waste water is not discharged via public sewer system, then the capacity of the receiving water environment should be at least 1,000 m ³ /d.

Risk Management Measures	
6.1.1 Occupational measures	<p>Inhalative exposure No measures required</p> <p>Dermal exposure Wear gloves, e.g. latex gloves ore similar, when diluting the product</p> <p>Oral exposure Oral exposure is not expected to occur</p>
6.1.2 Consumer related measures	Product is not intended for consumer use
6.2.3 Environment related measures	Preferably discharge cleaning water into sewer. Do not discharge cleaning water into small waters
7. Waste related measures	No measures required
References related to exposure prediction and guidance on how the downstream user can evaluate whether he works within or outside the conditions set in this exposure scenario	
8. Prediction of exposure	<p>Worker exposure</p> <p>Inhalation Predicted inhalation exposure based on ECETOC TRA⁸⁸ Risk determining compounds: A+C: A: 75 mg/m³; C: 2 mg/m³. ECETOC results corrected for actual concentration in cleaning solution.</p> <p>Dermal uptake Predicted systemic, dermal exposure based on the “HERA approach”: Risk determining compounds: A+C: A: 15.2 mg/kg bodyweight/day, C: 1.8 mg/kg bodyweight/day</p> <p>Local dermal exposure During dilution; the concentration of “A” (6%) is above the DNEL (1%) for local effects.</p> <p>Environmental exposure Not relevant to inform upon</p>
9. Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario	<p>Worker</p> <p>Inhalation: Safe use with respect to inhalation is ensured independently of the dilution of the product</p> <p>Dermal: Ensure that you have diluted the product at least 10 times before using it for cleaning. Use a bucket with water with a capacity of at least 10 L for frequent cleaning of the cloth Change the water in the bucket at least every 1 hour Do not use more than 2 kg product per day Use a trigger spray for applying the product</p> <p>Environment: Preferably discharge cleaning water into sewer system. Do not discharge cleaning water directly into small waters.</p>

⁸⁸ ECETOC use scenario: “Wide dispersive – spraying of the substance or preparation“

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Table A -9 Substance data for the examples

Comp	Classification	Mw	S	Vapor pressure	logKow	BP	Penetration through skin	DNEL (inhal.)	DNEL (dermal, systemic)	DNEL (dermal, local)*	PNEC (water)	PNEC (sediment)	PNEC (soil)
		(g/mol)	(mg/L)	(Pa)	(-)	°C	%	mg/m3	Mg/kg bw/d	%	µg/L	Mg/kg	Mg/kg
A	Xn; R22 Xi;R38-41	302	160	2·10 ⁻¹¹	2.18	600		210	60	1	40	1.1	1
B	F; R11 Xi;R36 R67	60	1,000,000	6,100	0.05	82		1400	400	10-100	300	0.24	0.043
C	Xn; 21/22 Xi; R36/38 R43	164	170	1.6	3.04	266		245	70	0.025	4.8	0.024	0.024
D	Xn; R22 Xi;R38-41	302	160	2·10 ⁻¹¹	2.18	600		210	60	10	40	1.1	1
E	F;R11 Xi;R36 R66 R67	88.1	8,300	9720	0.73		30	250	100		96.5		
F	Xi; R36/R38	132.2	85,000	163	0.98	171.5	30	90.8	8.8		560	0.57	0.2
G	Xi; R36	162.2	1,000,000	2.7	0.56	231	30	16.8	20		1000	0.57	0.2

***Max. concentration of substance in solution, at which contact with skin is not expected to damage the skin**

Preliminary example of exposure scenario to annex to the SDS of CleanYourHouse	
1. Short title of Exposure Scenario	Consumers, general public (SU21) Washing and Cleaning Products (PC35)
2. Description of activities/process(es) covered in the Exposure Scenario	<ul style="list-style-type: none"> Product is sprayed on surfaces to be cleaned. Product is wiped off surface with a cloth. Washing of the cloth (after handling)
Operational Conditions	
3. Duration and frequency of use for which the ES ensures control of risk	<p>Workers (professional)</p> <p>-</p> <p>Consumers</p> <p>1 task per day. Spray duration: 1 minute per task. Exposure duration 60 minutes per day.</p> <p>Environment</p> <p>Up to 365 days per year</p>
4.1 Physical form of substance or preparation (gas, liquid, powder, granules, massive solids); surface area per amount of article containing the substance (if applicable);	The product is a liquid. Product is delivered in formulated cleaning product trigger spray. On application, the product forms aerosols.
4.2 Concentration of substance in preparation or article	Concentrations of classified substances in supplied formulation are: D (surfactant): 8% B (solvent): 8% C (fragrance): 0.7%
4.3 Amount used per time or per activity for which the RMMs, in combination with other operational conditions of use ensure control of risk	<p>Workers (professional)</p> <p>-</p> <p>Consumers</p> <p>Max. 500 g product/day - realistic amount 20 g/day</p> <p>Environment</p> <p>-</p>
5. Other Operational Conditions determining exposure	<p>Worker (professional)</p> <p>-</p> <p>Consumer</p> <p>Temperature: room temperature, i.e. 20°C (relevant for inhalation). May however vary between 10 and 30°C</p> <p>Environment</p> <p>All product is assumed to be discharged to waste water. If waste water is not discharged via public sewer system, then the capacity of the receiving environment should at least be 1,000 m³/d.</p>
Risk Management Measures that, in combination with the Operational Conditions of use, ensure adequate control of risk related to the different target groups	
6.1.1 Occupational measures	Product is not intended for professional use
6.1.2 Consumer related measures	No measures required
6.2.3 Environment related measures	Preferably discharge cleaning water into sewer. Do not discharge cleaning water into small waters

Preliminary example of exposure scenario to annex to the SDS of CleanYourHouse	
7. Waste related measures	No measures required
References related to exposure prediction and guidance on how the downstream user can evaluate whether he works within or outside the conditions set in this exposure scenario	
8. Prediction of exposure resulting from the conditions described above (entries 3-6)	<p>Worker exposure</p> <p>-</p> <p>Consumer exposure</p> <p>Inhalation</p> <p>Predicted consumer inhalation exposure based on ConsExpo⁸⁹:</p> <p>Risk determining compounds: D+C: daily average air concentration: D: $5 \cdot 10^{-4}$ mg/m³; C: $4 \cdot 10^{-5}$ mg/m³</p> <p>Dermal</p> <p>Predicted systemic, dermal exposure based on the “HERA approach”.</p> <p>Risk determining compounds: D+C: D: 0.4 mg/kg bodyweight/day, C: 0.1 mg/kg bodyweight/day</p> <p>Environmental exposure</p> <p>Not relevant to inform upon</p>
9. Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario	<p>Worker</p> <p>-</p> <p>Consumer</p> <p>Do not use more than 500 g or ½ L of the product per day</p> <p>Environment:</p> <p>Preferably discharge cleaning water into sewer system. Do not discharge cleaning water directly into small waters.</p>

⁸⁹ ConsExpos scenario used:

“Cleaning and washing” - “All purpose cleaners” – “Spray cleaner –spraying” (inhalation)”

APPENDIX 5: EXAMPLE OF EXPOSURE SCENARIO FOR PREPARATION - DECOPAINTING

Preliminary example of exposure scenario to annex to the SDS NicePaint (a decorative paint)	
1. Short title of Exposure Scenario	General public domain (SU22) Coatings and Paints, Fillers, Putties, Thinners (PC9) Roller application or brushing of adhesive and other coating professional (PROC10)
2. Description of activities/process(es) covered in the Exposure Scenario	<ul style="list-style-type: none"> Preparation of paint: stirring of the paint, possibly addition of water Manual application of paint in-door with brush or roller Cleaning of the equipment by rinsing water
Operational Conditions	
3. Duration and frequency of use for which the ES ensures control of risk	Workers (professional) 8 hrs/day, 5 workdays/week Consumers Product is not intended for consumer use Environment Up to 365 days per year
4.1 Physical form of substance or preparation	The product is a liquid. It does not form aerosols on application.
4.2 Concentration of substance in preparation or article	Concentrations of classified substances in supplied formulation are: E (solvent): 10% F (solvent): 2% G (solvent): 5%
4.3 Amount used per time or per activity for which the RMMs, in combination with other operational conditions of use ensure control of risk	Workers (professional) 8 kg/day Consumers Product is not intended for consumer use Environment -
5. Other Operational Conditions determining exposure	Worker (professional) Temperature: room temperature, i.e. 20°C (relevant for inhalation). May however vary between 10 and 30°C Consumer Product is not intended for consumer use Environment Emission factor to waste water: 10% If waste water is not discharged via public sewer system, then the capacity of the receiving environment should be at least 12 m ³ /d.

Risk Management Measures that, in combination with the Operational Conditions of use, ensure adequate control of risk related to the different target groups	
6.1.1 Occupational measures	No measures required
6.1.2 Consumer related measures	Product is not intended for consumer use
6.2.3 Environment related measures	Preferably discharge waste water into sewer. Do not discharge waste water into small waters
7. Waste related measures	Residual paints and empty cans should be disposed off via municipal collection system. No waste related measures required.
References related to exposure prediction and guidance on how the downstream user can evaluate whether he works within or outside the conditions set in this exposure scenario	
8. Prediction of exposure resulting from the conditions described above (entries 3-6)	<p>Worker exposure</p> <p><i>Inhalation – calculated by StoffenManager⁹⁰</i></p> <p>Concentration in air: 154 mg/m³ of substance “E”. The concentration of “F” and “G”: 2.3 respectively 0.1 mg/m³. Total RCR (E+F+G): 0.6.</p> <p><i>Dermal – calculated by BPD⁹¹</i></p> <p>4.4 mg/kg bw/day of substance “F” (critical component). Total RCR (E+F+G):0.8</p> <p>Consumer exposure</p> <p>-</p> <p>Environmental exposure</p> <p>Not relevant to inform upon</p>
9. Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario	<p>Worker</p> <p>-</p> <p>Consumer</p> <p>-</p> <p>Environment:</p> <p>Preferably discharge cleaning water into sewer system. Do not discharge cleaning water directly into small waters.</p>

⁹⁰ Stoffenmanager: accessible from: <http://www.stoffenmanager.nl/>. Scenario settings in calculations Indoor application, manual, ventilation: mechanical/natural, room volume <100m³, area: medium, duration 8 hrs

⁹¹ Brush painting, Biocidal Products Directive, TNsG part 2, p. 200).

APPENDIX 6: EU LEGISLATION WITH REQUIREMENTS RELEVANT TO REACH

Table A- 10 EU legislation with requirements relevant to REACH

EU Directive ¹	Requirement	Potential difficulties you may experience	How REACH could help ²
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)	<p>Requires employers to identify risks arising from chemical agents through risk assessment. Risks should be reduced by substitution, prevention, protection and control.</p> <p>Where a national occupational exposure limit value (OEL) is exceeded, the employer must remedy the situation through preventative and protective measures.</p> <p>The production, manufacture or use at work of certain chemical agents and activities set out in Annex III is prohibited.</p>	<p>The provisions for risk assessment may be difficult to implement, especially if you use many different chemical agents.</p> <p>OELs are important risk reduction tools in specific work scenarios.</p> <p>Prohibitions specified in Annex III may be difficult to implement and control, especially if you are a small company.</p>	<p>Information in the extended SDS (eSDS) may assist you to identify the risks associated with substances and the risk management measures required to address them.</p> <p>eSDS should provide clear advice on measures that can be used to meet OELs.</p> <p>eSDS may help you to identify the presence of such substances in preparations (and articles, where the substances are intended for release) that they use.</p>
Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens 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.	eSDS can assist you by giving clear recommendations on the most appropriate risk management measures necessary to control exposure to carcinogenic substances.
Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding	The employer is required to assess the nature, degree and duration of exposure, in the undertaking and/or establishment concerned, in order to assess any risks to the safety or health and any possible effect on the pregnancy or breastfeeding and decide what measures should be taken.	The provisions are important risk reduction tools in specific work scenarios but may be difficult to implement at small and medium-sized enterprises. Resources for control are required.	Information in eSDS may assist SMEs to identify the risks associated with substances and give clear guidance on the RMM required to address them
Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the	Employers must provide PPE free of charge and give information to workers on the risks which the wearing of the PPE protects them against.	The directive does not give detailed information to the employer how to select the proper PPE.	Information in eSDS may assist you to identify the risks associated with substances and give clear guidance on

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EU Directive¹	Requirement	Potential difficulties you may experience	How REACH could help²
use by workers of personal protective equipment at the workplace	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 provisions for risk assessment may be difficult to implement, especially if your are a small company.	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 toxic 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 eSDS may assist you to identify the presence of any toxic substances, the risks associated with such substances and give clear guidance on the risk management measures required to address them
Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the member States concerning equipment and protective systems intended for use in potentially explosive atmospheres	Applies to equipment that has its own source of ignition, is intended for use in potentially explosive atmospheres and is under normal atmospheric conditions. It covers components essential for safe use and safety devices contributing to the safe use of such equipment	N/a	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			
Council Directive 92/59/EEC of 11 August 1992 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.	Satisfactory assessment of the risks posed by chemicals within products may be difficult, in the absence of reliable information from suppliers.	Information in eSDS may assist manufacturers to identify the risks associated with substances and preparations 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 Directive 88/378/EEC on 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 dangerous substances or preparations 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).	There is no restriction on the use of specified substances; the use is dependent on the actual risk. 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.	Information in eSDS may help manufacturers to identify the presence of dangerous substances in preparations (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.
Council Directive 89/106/EEC on	Buildings must be designed and built in such a	Standards may be developed where	eSDS may help construction companies

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EU Directive ¹	Requirement	Potential difficulties you may experience	How REACH could help ²
Construction Products	way that it will not be a threat to the hygiene or health of residents or neighbours.	demands on technical performance are in conflict with the need to reduce risks relating to harmful substances.	to identify safe uses of preparations and necessary risk management measures
Environmental Protection			
Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (IPPC)	An application for a permit must include descriptions of raw and auxiliary materials, nature and quantities of foreseeable emissions, proposed technology or other techniques for preventing or reducing emissions, and measures planned to monitor emissions.	If no need to reduce emissions of the chemical is mentioned in the relevant BREFs, expert knowledge is needed on where the chemical is likely to be emitted in significant quantities. In addition, applicants have to identify and assess emission reduction possibilities, which may require a lot of work.	eSDS may provide useful information on the nature and concentration of substances contained within raw and auxiliary materials, which will help in 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	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 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 Directive
Council Directive 91/689/EEC of 12 December 1991 on hazardous waste	The directive requires development of a list of "hazardous waste". 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.	eSDS 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	Establishes emission limit values for VOCs in waste gases and maximum levels for fugitive emissions. Gives industrial operators a possibility to be exempted from limit values provided that they achieve by other means the same reduction as would be made by applying them. This could be achieved by substituting products with a high solvent content for low solvent or solvent free products and changing to solvent free production processes	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 than implementation of end-of-pipe techniques.
1. REACH can also help you to comply with national legislation on occupational health, product safety and environmental protection.			

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EU Directive ¹	Requirement	Potential difficulties you may experience	How REACH could help ²
	2. 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 7: 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.

Table 1: List of communication needs						
	(A) Subject	(B) Sender	(C) Recipient	(D) Date	(E) TGD section	(F) Available tools and formats
<i>Preparing for REACH</i>						
1.	(Voluntary) request for information to assist with registration	Supplier (M/I; distributors; DU)	Any DU	Any time before registration	TGD3	Guidance from RIP 3.2-2
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	TGD3	Guidance from RIP 3.2-2
3.	(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	TGD3	List of pre-registered substances
4.	(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	TGD3	
5.	(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	TGD3	Part of REACH IT?
<i>Actions triggered by information – substances on their own or in preparations</i>						
6.	(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	TGD4	
7.	(Voluntary) Request for Article 32 information (for non-dangerous substance) if not received by due date	Any DU	Supplier (M/I, distributor, other DU)	First supply after registration	TGD4	

Table 1: List of communication needs

	(A) Subject	(B) Sender	(C) Recipient	(D) Date	(E) TGD section	(F) Available tools and formats
8.	[Format for Article 32 information]	Supplier (M/I, distributor, other DU)	Any DU	First supply after registration	TGD4	Annex II, SDS guidance from sector organisations
<i>Actions triggered by information – substances in articles</i>						
9.	(Voluntary) Request for information on whether substances subject to restriction are contained in an article	DU recipients of articles	Supplier (producer/importer) of articles	Once restrictions process begins	TGD4	
10.	(Voluntary) Request for information on whether SVHC are contained in an article at concentrations > 0.1%	DU recipients of articles	Supplier (producer/importer) of articles	Once candidate list is published	TGD4	
11.	Information on SVHC in articles under article (32(2))	Supplier (producer/importer) of articles	Recipients of articles	Within 45 days of request being received	TGD4	
12.	[Format for notifying SVHC in articles under article 7(2)]	Supplier (producer/importer) of articles	Agency	[Not specified]	TGD4	Agency will implement this in the REACH IT
<i>Checking compliance with the exposure scenario</i>						
13.	Reporting use of a dangerous substance outside the supplier's ES (article 38(1)) (needs to cover the different exemptions and may therefore have different information	DU	Agency	Before commencing use after the substance has been registered	TGD5	Agency will implement this in the REACH IT

Table 1: List of communication needs

	(A) Subject	(B) Sender	(C) Recipient	(D) Date	(E) TGD section	(F) Available tools and formats
	needs)					
14.	(Voluntary) Documenting compliance with the ES, in particular if conditions are not exactly the same.	Any DU	Local regulatory authorities	Once supplier SDS/ES is received	TGD5	Annex 1 of this TGD
<i>Making a downstream user chemical safety report</i>						
15.	(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	TGD 7	Guidance from RIP 3.2-2; standard codes for broad descriptions of use, industry associations
16.	(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	TGD 7	Based on format for use descriptions/ES developed in RIP 3.2-2, Section 9 of this TGD
17.	(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	TGD 7	SIEF to be checked if possible, may be IT-based.
18.	(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	TGD9	Based on exemplification work of RIP 3.2-2, questionnaires
<i>Requesting that a use becomes an identified use</i>						

Table 1: List of communication needs

	(A) Subject	(B) Sender	(C) Recipient	(D) Date	(E) TGD section	(F) Available tools and formats
19.	Requesting that a use becomes an identified use (article 37(2))	Any DU	Supplier (M/I, distributor, other DU)	At least 12 months before the deadline for registration	TGD8	RIP 3.2-2 TGD part A and section 8 of this guidance
20.	(Voluntary) Checking whether a generic ES has been prepared (by an industry association)	DU wishing to maintain confidentiality about own use	Industry association or other	At least 12 months before the deadline for registration	TGD 8	Guidance from RIP 3.2-2; standard codes for broad descriptions of use
21.	Informing that a use cannot be included as an identified use for reasons of protection of human health or the environment	Supplier (M/I, distributor, other DU)	DU requesting that a use becomes identified	‘without delay’	TGD 8	
<i>Collecting information on uses</i>						
22.	(Voluntary) Obtaining information on own use of a substance	Any DU, but primarily IU	[other departments/entities within own company]	Any time before registration or before preparing DU CSA	TGD9	RIP 3.2-2 TGD part A
23.	(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	TGD9	Based on exemplification work of RIP 3.2-2,
<i>Informing suppliers about new information on hazards</i>						
24.	Communicating any new information on the hazardous properties (article	Any DU	Supplier (M/I, distributor,	Any time (not	TGD10	No standard format

Table 1: List of communication needs						
	(A) Subject	(B) Sender	(C) Recipient	(D) Date	(E) TGD section	(F) Available tools and formats
	34)		other DU)	specified)		useful
25.	Informing if a classification of a substance is different to that of the supplier (article 38(4))	Any DU	Agency	Any time (not specified)	TGD10	Agency will implement this in the REACH IT
<i>Informing suppliers about information calling into question the appropriateness of risk management measures</i>						
26.	Passing on information that may call into question the appropriateness of risk management measures (article 34)	Any DU	Supplier (M/I, distributor, other DU)	Any time (not specified)	TGD11	No standard format, exposure scenario including exposure assessment if appropriate
<i>Compliance with requirements related to authorisation</i>						
27.	Notifying use of a substance subject to authorisation (article 66(1))	DU	Agency	Within 3 months of first supply of the substance	TGD12	Agency will implement this in the REACH IT
28.	(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	TGD12	
29.	(Voluntary) Contacting potential partners about the possibility of making a joint application for authorisation of use of a substance	Any DU	Supplier (M/I, distributor, other DU); customers; competitors	Once a substance has been included in Annex XIV	TGD12	Potential guidance from RIP 3.7??