ECHA
EUROPEAN CHEMICALS AGENCY

How to prepare a downstream user chemical safety report

Practical guide 17

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The purpose and nature of practical guides

Practical guides aim to help stakeholders interact with the European Chemicals Agency (ECHA). They provide practical tips and advice and explain the Agency's processes and scientific approaches. Practical guides are produced by ECHA, under its sole responsibility. They do not replace the formal Guidance (which is established under the formal guidance consultation process involving stakeholders) that provides the principles and interpretations needed for a thorough understanding of the requirements of REACH.

This practical guide aims to assist downstream users to perform chemical safety assessments to fulfil their duties under Article 37(4) of the REACH regulation. It reflects current thinking in this area at the time of publication. The practical guide has been developed with input from the CSR/ES Roadmap task force on downstream users, under roadmap action 4.5, whose assistance is gratefully acknowledged.

See http://echa.europa.eu/csr-es-roadmap for more details on the Roadmap.

Table of Contents

1. Introduction

This chapter outlines the aims of this practical guide. It directs you to where you can find the information that will help you fulfil your duties relating to downstream user chemical safety reports, when required under Article 37(4) of the REACH Regulation.

A downstream user chemical safety report (DU CSR) is prepared by a downstream user (DU) to document the assessment of the conditions of safe use of a substance. It is undertaken for a use (including conditions of use) that is not covered in the exposure scenarios received from the supplier.

If you are a downstream user and intend to prepare a chemical safety report (CSR) for a substance, this practical guide describes the approaches you can take to assess the risks and document the assessment.

To benefit from this guide, you need to know some basics about REACH. You should already be familiar with the exposure scenarios (ESs) you receive from suppliers and how you can check that they cover your use. This information is not repeated here but TIP Box 1 directs you to where you can find useful background information and TIP Box 2 clarifies some terminology. ECHA guidance on DU CSR is provided in Section 5 in "Gui-dance for downstream users".

In this practical guide, we assume that:

- The substance is classified and registered under REACH, and you have received a safety data sheet with exposure scenarios.
- You know how to check the exposure scenarios for a substance that you have received from your supplier in order to meet your obligations under REACH.
- You have established that your specific use of the substance and/or conditions of use are not covered by the exposure scenarios received for that substance, or that the use is advised against.
- You are aware of the options available to you when your use/conditions of use are not covered, namely to:
    - ask your supplier to include your use within the identified uses and provide an ES for your use; or
    - implement conditions of use described in the ES from your supplier; or
    - replace the substance or process with a safer alternative; or
    - change supplier; or
    - prepare a DU CSR.
- You intend to prepare a DU CSR to cover your use of the substance, or are considering that as an option.
- You are aware of the exemptions that apply, such that a DU CSR is not required. These are summarised in TIP Box 3.

This practical guide does not specifically address how a downstream user should prepare a chemical safety report when applying for an authorisation for the use of a substance that is listed on Annex XIV of REACH (authorisation list). Nevertheless, many of the elements are relevant. Introduction

This chapter outlines the aims of this practical guide. It directs you to where you can find the information that will help you fulfil your duties under REACH.

Although this practical guide aims to give easy-to-follow advice to help you prepare a DU CSR, it is generally preferable that you contact your supplier and that your use is covered upstream. A DU CSR is likely to be the preferred option if:

- you want to maintain your use as confidential; or
- the use is advised against but you consider that the risk is controlled; or

- the suppliers are unwilling to include the use when you contact them.

Be aware that a DU CSR undertaken in compliance with the REACH Regulation does not fulfil obligations to undertake risk assessments under other national environmental and health and safety (EHS) legislation, which implement directives such as the Chemical Agents Directive (CAD) and Industrial Emissions Directive (IED). However, assessments undertaken under REACH can support those undertaken under EHS legislation and vice versa.

This practical guide does not address how a downstream user should prepare a chemical safety report when applying for an authorisation for the use of a substance that is listed in Annex XIV to REACH (Authorisation List). Nevertheless, some elements may be of interest.

Tip Box 1: Where to find background information

Downstream users and REACH

- ECHA website pages for downstrem users echa.europa.eu/downstream
- ECHA "Guidance for downstream users"

Safety data sheets (SDS) and exposure scenarios (ES), including checking exposure scenarios and your options

- eGuide 01 "SDS and ES - advice for recipients"
- Practical guide 13 "how downstream users can handle exposure scenarios"
- Section 4 in "Guidance for downstream users"
- Cefic/Concawe/FECC/DUCC - Messages to communicate in the supply chain on extended SDS for substances

Other sources of information on DU CSR

- Section 5 in "Guidance for downstream users"
- Downstream Users of Chemicals Co-ordination Group (DUCC) "Report on experience gained with performing a downstream user chemical safety assessment (DU CSA) and developing a downstream user chemical safety report (DU CSR)"

- Useful links to all references in this guide are given in Appendix 5

- For specific questions, contact your national helpdesk or the ECHA Helpdesk.

Tip Box 2: Understand the terminology

- An **exposure scenario** (ES) you receive typically covers a use, such as formulation, and may be composed of a number of **contributing scenarios** (CSs) within that exposure scenario. These CSs describe tasks or activities within the use (such as transfer, mixing, cleaning etc.) and may describe conditions relating to environmental, worker or consumer exposure and human health. The term "exposure scenario" in this practical guide refers to the exposure scenario itself, to contributing scenarios within the exposure scenario, or both.
- When the term "**use**" is referred to in this practical guide, it includes the **foreseeable use** by your customers of your products that contain the substance, unless stated otherwise.
- The term "your use/conditions of use are covered" includes the situation when you have used scaling to demonstrate that the actual conditions of use are covered.
- If some of the **acronyms and terms** used in this practical guide are new to you, have a look at the glossary in Appendix 4 or definitions in ECHA-term, http://echa-term.echa.europa.eu/

Tip Box 3: Check that a DU CSR is required by the legislation before you start

- When you establish that your use/conditions of use are not covered in the safety data sheet and exposure scenarios you receive from your suppliers, or that the use is advised against, REACH does not always require you to prepare a DU CSR. The main exemptions are:
    - **You use the substance in total quantities below one tonne per year.**
    - **You use the substance for Product and Process Orientated Research and Development (PPORD).**
    - **The substance is contained in a mixture in a concentration below the concentration limit that needs to be taken into account in classifying the mixture as hazardous (see Article 14(2) of REACH).**
    - **The substance is persistent, bioaccumulative and toxic (PBT)/very persistent, very bioaccumulative (vPvB) but is contained in a mixture in a concentration below 0.1% (weight by weight).**
- Check whether these exemptions apply before you start preparing a DU CSR. Consult ECHA Guidance for downstream users, section 4.4.2 for further details.
- You need to **report to ECHA** if you are claiming an exemption based on total quanities below one tonne per year or PPORD use. See Chapter 9 for details on reporting to ECHA.

Overview of the Practical Guide

Chapter 2 outlines various approaches to performing a chemical safety assessment (CSA) for a substance, and Chapter 3 describes aspects relating to gathering information, that are common to all approaches.

Chapters 4, 5 and 6 describe in detail the three main approaches to preparing a DU CSA. You can read about each approach to see what suits you best, or go directly to the approach you intend to use.

Go to Chapter 7 for advice on how to document your DU CSR and Appendix 1 for examples.If you are communicating the outcome of your DU CSR to customers, have a look at Chapter 8.

To find out about reporting unsupported uses to ECHA, see Chapter 9.

2. How to start

You can perform a downstream user chemical safety assessment in a number of ways. This chapter outlines the main approaches and describes when each approach is likely to be most suitable.

The main steps in a downstream user chemical safety report (DU CSR) for a substance are outlined in Figure 1, in accordance with Annex XII to REACH. The chemical safety assessment (CSA), that forms the core of the DU CSR can be performed in a number of ways and this practical guide describes three possible approaches. These are termed:

A. **Supplier exposure scenario:** modify the exposure/contributing scenario you receive from your supplier to show that the risk is controlled. This is usually done with the aid of easy-to-use recalculation tools (Chapter 4).
B. **Sector exposure scenario:** use an exposure scenario developed by industry or sector organisation. The sector exposure scenario is provided together with boundary conditions and an estimate of the exposure (Chapter 5)
C. **Own exposure scenario:** generate the exposure scenario yourself, estimate the exposure using modelled or measured data and characterise the risk (Chapter 6)

An overview of these three approaches is presented in Table 1, together with examples of when they may be useful to apply. A decision tree is shown in Figure 2, to help you select the appropriate approach for your situation. The approaches are detailed in Chapters 4 to 6.

A DU CSR does not have to be prepared according to one of these approaches, but should incorporate the main steps outlined in Figure 1. With all approaches, you also need to undertake the actions described in TIP Box 4.

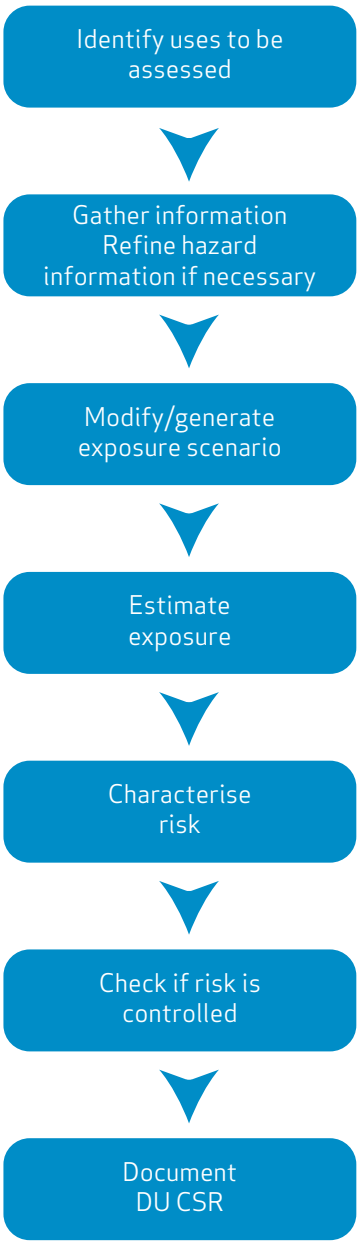
Next steps

See Question Box 1 at the end of this chapter if you have some questions about a DU CSR.

Go to Chapter 3 for advice on how to gather information on your substance.

Chapters 4, 5 and 6 describe the three main approaches to doing a DU CSA that were outlined here. You can read about each approach to see what suits you best, or go directly to the approach you intend to use.

Figure 1: Typical work process for a downstream user chemical safety report



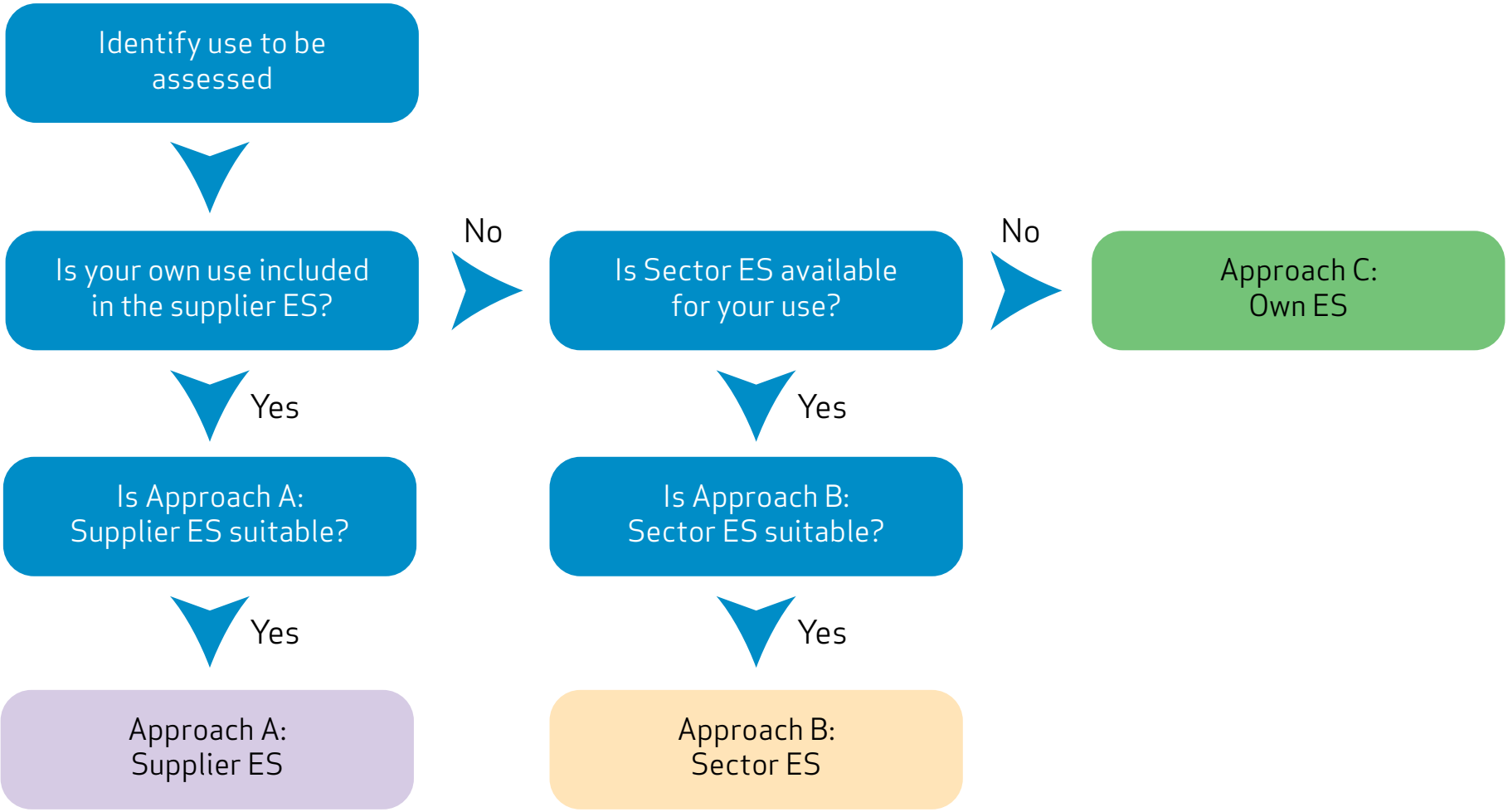
Tip Box 4: things to remember when you are preparing a DU CSR

- Communicate all relevant information downstream, if supplying your substance/mixture down the supply chain (Chapter 8).
- Report to ECHA, to inform them that you are preparing a DU CSR (Chapter 9).
- Make sure that you implement the conditions of use you identify as adequate to control the risk in your DU CSR for your own use.
- Keep a record of what you have done for a period of at least 10 years.

Table 1: Overview of the main approaches for a downstream user chemical safety report

APPROACH	A: SUPPLIER EXPOSURE SCENARIO	B: SECTOR EXPOSURE SCENARIO	C: OWN EXPOSURE SCENARIO
SHORT DESCRIPTION OF APPROACH	Modify the exposure scenario received from your supplier.	Identify and use a suitable exposure scenario provided by a sector organisation for a generic DU CSR.	Demonstrate safe use based on a new exposure scenario including exposure estimation and risk characterisation.
WHEN THE APPROACH CAN BE APPLIED	Your use is described in the exposure scenarios you receive, but the conditions of use are different, and your use is not covered.	A suitable sector exposure scenario is available, exposure estimates are included and the substance properties and use are within the boundaries of that scenario.	This approach can be applied in all situations, in particular when a supplier exposure scenario or sector use scenario is not available or suitable or a more thorough assessment is warranted, including refinement of the hazard assessment.
COMMENT	This approach is similar to modifying the exposure scenario to check if your conditions of use are covered in the exposure scenarios you receive by using scaling, but is applied outside the defined boundaries of scaling.	This approach is applicable only when suitable exposure scenarios are available for this purpose, together with the exposure estimate and applicability domain. They are typically developed by sector associations.	This approach can often be based on the risk assessments you do on site, adapted to REACH requirements. The complexity of this approach varies, depending on the situation.
EXAMPLES, BASED ON A DU SITE WHERE THEY COAT ARTICLES BY DIPPING	You coat articles by dipping. The exposure scenarios you receive for that substance refer to coating by dipping using local exhaust ventilation. Your factory has good general ventilation, a less effective risk management measure, but you use it for a shorter duration than specified in the exposure scenario.	You coat articles by dipping. The exposure scenarios you receive refer only to spray coating or do not refer to coating at all. Your sector organisation has made an exposure scenario available that describes your use, and includes exposure estimates and information on boundaries.	You coat articles by dipping. The exposure scenarios you receive advise against this use. However, your system is an enclosed, remotely operated system and your on-site risk assessment has shown exposure to be low.
MORE INFORMATION	Chapter 4	Chapter 5	Chapter 6

Figure 2: Decision tree to select the appropriate approach for a downstream user chemical safety assessment



Question Box 1: General questions on DU CSR

Q1: I have undertaken a site-wide risk assessment under national environmental and health and safety regulations. From that, I conclude that all environmental and worker exposure risks are controlled. Do I still have to prepare a DU CSR?
A: Yes, you need to prepare a DU CSR for any uses not covered by the ESs received from your supplier. However, you should take account of any risk assessments taken out under other Community legislation and justify any deviations. Conversely, a DU CSR undertaken as part of the REACH Regulation can support assessments to be undertaken under other Community legislation but does not fulfil those requirements completely.

Q2: I have prepared a DU CSR but have now received an exposure scenario from another supplier, which is different to that from my original supplier. It again shows my use is not covered. Do I have to do another DU CSR?
A: There is no need to repeat it, as you have already demonstrated that your use or the use of your customer is safe. However, if the later supplier provides new information on risks and hazards which were not available when you prepared your DU CSR, you should communicate with your suppliers to investigate the reasons for such differences and assess the need to update your DU CSR and your on-site risk assessments under other environmental health and safety legislation.

Q3: We are formulators, and there are several substances in the mixture for which the use is not covered. Can I prepare the CSR for the mixture rather than for each of the individual substances?
A: The DU CSR under REACH is generally undertaken on a substance basis. A DU CSR can be prepared for a mixture although this is not addressed in this Practical Guide or in Guidance. Nevertheless, the advice provided for substance DU CSRs may be of use if undertaking DU CSRs for mixtures.

Q4: We are formulators, and a customer has asked us to cover their use. Are we obliged to prepare a DU CSR?
A: No. You can choose whether to forward the information to your own supplier, prepare a DU CSR or leave it to your customers to do their own DU CSR. See Chapter 3.5 of the Guidance for Downstream Users for more information.

3. Gather necessary information

Regardless of the approach you use, you need to identify the uses to be assessed and gather information on the substance. This chapter outlines some things to consider when you are gathering substance information. It also describes what to do if you receive different information from different suppliers and where you can find more information if needed.

3.1 COMPILE THE INFORMATION

The information you need on your substance and the complexity of the assessment depends on the approach chosen.

For Approach A (Supplier exposure scenario), the information needed can be as little as the physical form, vapour pressure and concentration of the substance. You are likely to need information on the physical and chemical properties if you intend to estimate the exposure by modelling and also to check you are within the boundaries of Approach B (Sector exposure scenario). Approach C (Own exposure scenario) generally requires the most comprehensive information, and this will depend on the complexity of the assessment.

In all cases, you may need to refer to substance classification to support conclusions when a quantitative assessment is not possible.

The primary source of information is the safety data sheet (SDS) provided by your supplier. The downstream user can accept the information provided. However, it is advisable to consult other sources if the safety data sheet does not follow the format of REACH Annex II, is inconsistent or is incomplete. The key sections to consult in the SDS, in particular for Approach C (Own exposure scenario), are as follows:

- Section 1 and 3 for the identification of the substance/mixture;
- Section 2 for the classification of the substance:
    - If you are preparing a DU CSR for a substance in a mixture, keep in mind that a DU CSR is not required below specified concentrations[1];
- Section 8 for control parameters (exposure limit values):
    - As you have been provided with exposure scenarios, you should also have been provided with DNEL/PNEC values (unless the substance is a non-threshold substances, such as an irritant or carcinogen. In such cases, DNEL/PNEC values are not provided);
    - DNEL values should be provided in the SDS for all relevant routes of exposure (inhalation, dermal and oral) and for all relevant populations exposed to the substance (workers and consumers);
    - The PNECs provided (aquatic, sediment, soil and air) indicate the environmental compartments that need to be considered in your assessment;

1 If the substance is contained in a mixture in a concentration below the concentration limit that needs to be taken into account in classifying the mixture as hazardous (see Box Tip 3 and Article 14(2) of REACH).

    - If relevant DNEL/PNEC values are not provided you can contact your supplier or consult alternative sources (see Chapter 3.3 and 3.4.).

- Section 9 for information on the physical and chemical properties:

    - This information may be relevant as part of the exposure scenario building and exposure estimation.

- Sections 11 and 12 for toxicological and ecotoxicological information respectively.

Internal consistency between these sections of the SDS can indicate whether the information is likely to be reliable. You should also check for consistency between the exposure scenarios and the main body of the SDS. Contact your supplier if the information you receive is incomplete or inconsistent, and see TIP Box 5 for advice when contacting your supplier.

Experience to date is that the required information is not always conveyed, or not conveyed precisely enough, in existing SDSs and exposure scenarios. Potential solutions to resolve these issues are currently being developed under the CSR/ES Roadmap[2].

Tip Box 5: Be aware of your responsibilities

- Be precise about the reasons for query/rejection.
- Where possible, give regulatory reference (e.g. REACH Annex II, ECHA SDS Guidance, etc.).
- Confirm any agreements or additional data in writing.
- Ask for a revised SDS/ES if appropriate.
- Follow up on agreed actions, agree a time limit and document your actions.

3.2 DIFFERENT INFORMATION FROM DIFFERENT SUPPLIERS

If you purchase a substance from different suppliers, you may receive different information from these different suppliers. If so, you should first verify that the safety data sheets you have received are for the same substance, with the same impurities/composition. If they are, but there are significant differences in information, contact your suppliers to inform them of the differences, asking them to align if possible.

If your suppliers do not provide aligned information, you need to consider carefully which information is appropriate for your assessment. It may be necessary to seek expert ad-vice or other sources of information when deciding.

Regarding classification, if there is a harmonised classification, you are required to use that classification. However, be aware that there may also be other hazard classes not covered by the harmonised classification, which should also be included. If your classification of a substance is different to all of your suppliers, you are required to report to ECHA[3].

2 http://echa.europa.eu/csr-es-roadmap

3 http://echa.europa.eu/support/dossier-submission-tools/reach-it/submitting-a-downstream-user-report-classification-differences

3.3 SOURCES OF INFORMATION

If the information available in the SDS is insufficient or inconsistent, you can use information from a range of other sources, such as those described below, when you prepare your DU CSR. The type of substance-related information you require could include the classification, exposure limits, and the physical and chemical properties. Some information, such as the molecular weight of UVCB substances, may be difficult to establish and you may need to seek advice on how to address such problems.

The ECHA website provides a substantial amount of information on substances[4] which has been gathered from the registration process and from notifications of substance classification.

The ECHA database on registered substances contains publicly available information from the registration dossiers submitted to ECHA, such as physical and chemical properties and hazard information and includes DNELs/PNECs.

The Classification and Labelling Inventory on the ECHA website contains all harmonised classifications as well as C&L information received from manufacturers and importers on notified and registered substances.

The information in these databases is provided by registrants and suppliers and has not been verified by ECHA.

Other public sources of information include the OECD eChemPortal[5] and Gestis[6].

If information is provided by your supplier but you use an alternative source for that information, this decision should be taken by a competent person. You need to justify the decision and assure yourself of the adequacy and appropriateness of any information you use. The information you use and the sources should be clearly indicated in the DU CSR.

3.4 EXPOSURE LIMIT VALUES

The exposure limit value you use is very important as it is the reference value for assessing whether the risk is controlled.

You are recommended to use the DNEL/PNEC provided in the SDS by the supplier. Alternatively, the DNEL/PNECs assigned by other registrants are provided in the sources referred to in Chapter 3.3 above and may be appropriate to use.

In accordance with ECHA guidance[7], when an EU indicative occupational exposure limit value (IOELV) exists you may use the IOELV in place of a DNEL for the same exposure route and duration, unless new scientific information is available which indicates that the IOELV does not provide the appropriate level of protection required by REACH.

ECHA guidance also states that you cannot use a national occupational exposure limit value (OELV) or binding OELV (BOELV) in place of a DNEL without an evaluation of the scientific background for setting the OELV/BOELV.

4 http://echa.europa.eu/information-on-chemicals

5 http://www.echemportal.org

6 http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Stoffdatenbank

7 See Appendix 13 in of Chapter R.8 of the IR&CSA Guidance

If a substance is restricted and an exposure limit value is referred to in the restriction conditions, this exposure limit value must be used in the DU CSR if applicable.

Certain substances, such as irritants and carcinogens, may not have a DNEL assigned for a given health effect because it has not been possible to establish a "threshold". In such cases, a qualitative approach must be taken. This may also apply to local effects. When there is no limit value, you need to justify why your conditions of use are adequate to control the risk. This is described in Chapter 6.6 on risk characterisation.

Note that there is no DNEL for exposure of eyes and the approach is always qualitative. Classification for hazards to eyes can be used together with the concentration to check whether certain eye protection is required.

Tip Box 6: Be aware of your responsibilities

- You are responsible for the correctness of the CSA you undertake and its conclusions. You need to:
    - ensure the information you use is reliable and trustworthy; and
    - document the source of information in the DU CSR.
- If you have new information regarding the hazard properties of the substance, or other information that calls into question the appropriateness of the risk management measures identified in the safety data sheet, REACH requires that you communicate this information to your supplier.
- The hazard of the substance may change in your use, for example, if it is in a different physical form or it reacts on use. If so, you may need to refine your hazard assessment. See Chapter 6.3.

Next steps

Go to Chapter 6.3 if you think you may need to refine your hazard assessment.

Chapters 4, 5 and 6 describe the three main approaches for performing a DU CSA that were outlined here. You can read about each approach to see which suits you best, or go directly to the approach you intend to use.

4. APPROACH A: SUPPLIER EXPOSURE SCENARIO

The easiest way to prepare a DU CSR is to modify an exposure scenario provided by your supplier. This approach can be used when your use is described in an exposure scenario you receive but your conditions of use differ. It can be undertaken with the aid of easy-to-use recalculation tools.

4.1 STARTING POINT

- You receive exposure scenarios for the substance from your supplier.
- Your use is described in the exposure scenarios you receive but:
    - your conditions of use are different in one or more contributing scenarios;
    - you have established that your use is not covered, but the risk is still controlled.

4.2 OVERVIEW OF APPROACH BASED ON EXPOSURE SCENARIOS FROM YOUR SUPPLIER

The main steps of the supplier exposure scenario approach are presented in Figure 3. This is a very straight-forward approach, and the simplest described in this guide.

The initial steps shown in Figure 3 are that you identify the uses to be assessed, gather information and confirm that the information is appropriate. You then modify the exposure/contributing scenario provided by your supplier to reflect your actual conditions of use.

Next, you estimate the exposure for your conditions of use and/or the corresponding risk characterisation ratio (RCR = exposure/exposure limit value). This can be done using a recalculation tool. Alternatively, you can use an exposure estimation model that is the same as that used by the registrant, or follows the same algorithm.

The competency required is typically that of an environmental health and safety (EHS) practitioner, who can check exposure scenarios and undertake risk assessments as required by other EHS legislation, and who can recognise when greater expertise is needed to undertake the chemical safety assessment.

RECALCULATION TOOLS

Recalculation tools, also referred to as scaling tools, are used to show how changes in parameters such as the exposure duration, concentration or the effectiveness of risk management measures affect the exposure.

Recalculation tools can be used by a downstream user to check if the actual conditions of use are covered by the exposure scenario provided by the supplier, also termed "scaling". When you use recalculation tools to check your use is covered, you need to adhere to the boundaries specified by your supplier for a given exposure scenario. For example, your supplier may specify that you may not replace engineering controls with personal protective equipment. You also need to adhere to boundaries that are described in the Guidance for Downstream Users[8].

8 Scaling options, and how to apply them to checking your use is covered, are described in detail in Chapter 4 and appendix 2 of the Guidance for Downstream Users.

Recalculation tools can also be used to prepare a DU CSR, when the changes are outside the specified boundaries of scaling. Therefore, you can modify all parameters included in the supplier exposure scenario and the exposure can be increased beyond the specified boundaries. However, the exposure must be below the DNEL/PNEC, giving an RCR below 1. Depending on the tool, it might be possible to incorporate the input/output of recalculation tools directly in your DU CSR.

At the time of writing, a recalculation tool is under development by Cefic, termed ES Conformity Tool. The tool can be used to perform the ES check, and can also be used as a basis for a DU CSR if required. This tool is based on the Ecetoc TRA model and can only be used for exposure scenarios that were developed using this exposure estimation model, or tools based on it (such as EasyTRA).

Re-calculation tools generally require the exposure estimate and/or RCR as input information. If the tool requires such information but it is not provided, contact your supplier for this information. Alternatively, use the exposure estimation tool used by your supplier or consider Approach C: Own Exposure Scenario

An example of a DU CSR based on the supplier exposure scenario approach and using the Cefic ES Conformity Tool is given in Appendix 1.

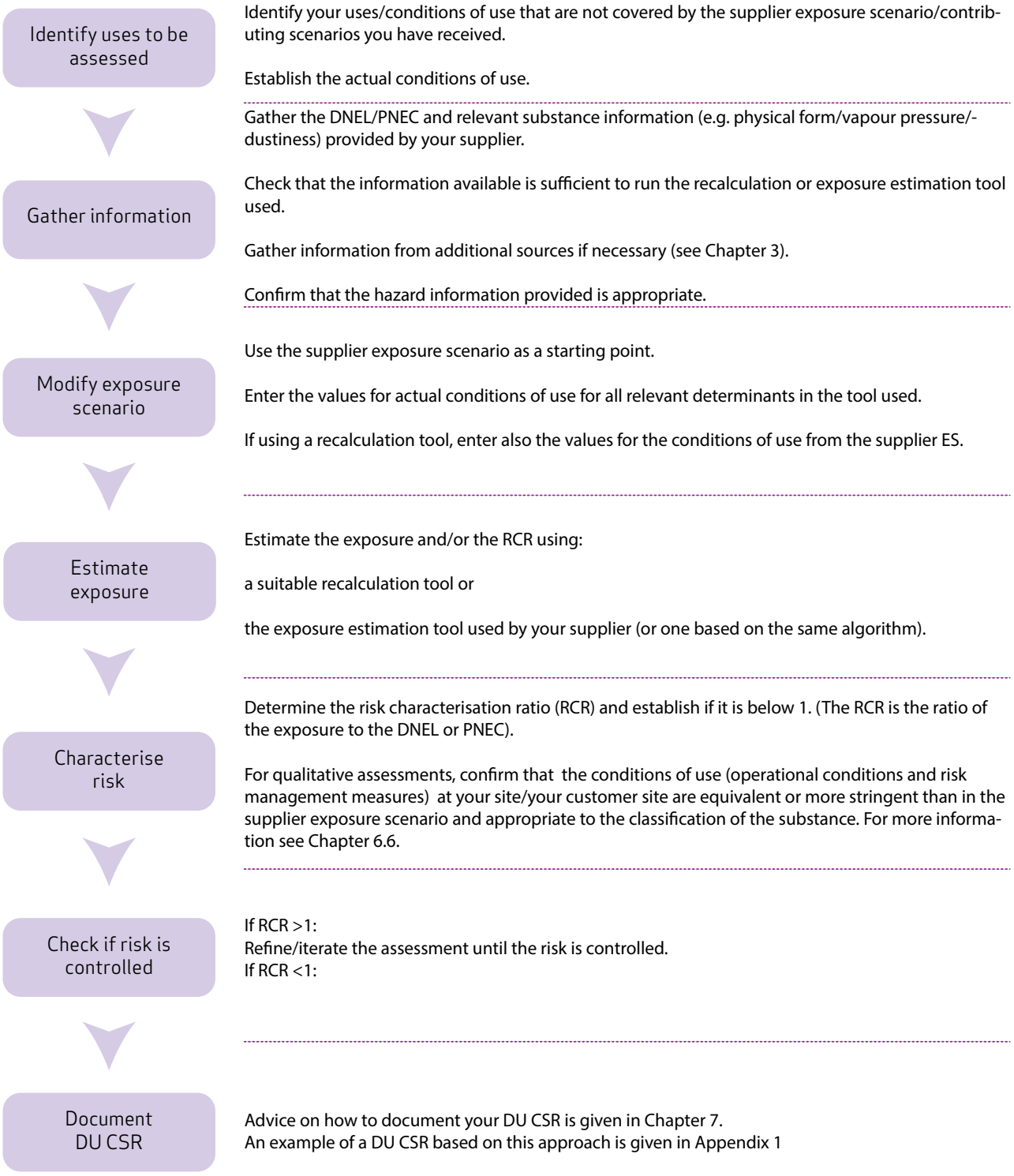
EXPOSURE ESTIMATION TOOLS

An alternative to a recalculation tool is to estimate the exposure using the same exposure estimation tool (model) as used by your supplier or a tool that follows the same algorithm.

Exposure estimation tools include ECETOC TRA, EMKG, Stoffenmanager, ART, EUSES etc. and are described further in Chapter 6.5 on exposure estimation in the "Downstream User Exposure Scenario" approach. These tools should be used according to generally agreed rules and/or specific advice and boundaries. Chesar and ES-modifier are software tools that incorporate and/or allow input from a number of exposure tools.

If you use a different exposure estimation tool than your supplier, use measured data, or substantially change the parameters in the exposure scenario, you are moving from Approach A towards Approach C (Own exposure scenario). This is described in Chapter 6. There is some overlap between these approaches, in particular when you use a supplier exposure scenario as a basis for generating your own exposure scenario in Approach C.

Figure 3: Main steps in Approach A: Supplier Exposure Scenario



! Remember to communicate downstream, report to ECHA and implement the conditions of use as necessary (TIP Box 4)

5. APPROACH B: SECTOR EXPOSURE SCENARIO

This approach is typically used when the supplier exposure scenario approach is not applicable and an appropriate generic assessment is available from a sector organisation.

5.1 STARTING POINT

- You receive exposure scenarios for the substance from your supplier.
- Your use and/or conditions of use are not covered in the exposure/contributing scenarios you receive.
- An exposure scenario/contributing scenario is available from a sector organisation that:
    - describes the conditions of use that ensure control of risk;
    - reflects your actual conditions of use;
    - includes exposure estimates and applicability domain.

5.2 OVERVIEW OF APPROACH BASED ON EXPOSURE SCENARIOS FROM A SECTOR ORGANISATION

Several industry sector organisations and companies have developed exposure scenarios for typical uses within their sector. These describe how certain mixtures and substances can be safely used in the applications considered to be relevant for that sector, by means of a standard set of conditions of use, i.e. operational conditions and risk management measures.

Such generic exposure scenarios have been developed to provide information on uses and use conditions to registrants and to communicate to downstream users in sector-specific terminology.

A similar approach can be used as a basis for a DU CSR and is under development. The sector organisation or company would provide the appropriate exposure scenario and define the boundaries that apply (such as vapour pressure, dustiness, limit values, classifi-cation, water solubility etc.). They also provide estimates of the exposure within this ap-plicability domain for the contribution scenarios within the exposure scenario and may also provide an outline report.

In some cases, such assessments would be based on sector-specific knowledge, such as when the potential risks of a substance reduce when in a typical mixture.

The main steps of the sector exposure scenario approach are presented in Figure 4, but these may vary depending on the information provided by the sector organisation. The initial steps are generally that you identify the uses to be assessed and gather all relevant information from your supplier (e.g. physical/chemical properties, DNEL/PNEC and other hazard information) and are satisfied it is appropriate.

You then select the sector exposure scenario (with relevant details) you need as the basis for your DU CSR. This exposure scenario includes the conditions of safe use that were determined at sector level. As these conditions reflect good practice for the majority of substances in use in your sector, it is likely that the properties of the substance to be as-sessed fall into the applicability domain of the relevant sector exposure scenario and the conditions of use reflect those that exist at the downstream user site. However, it is important that you check and demonstrate this.

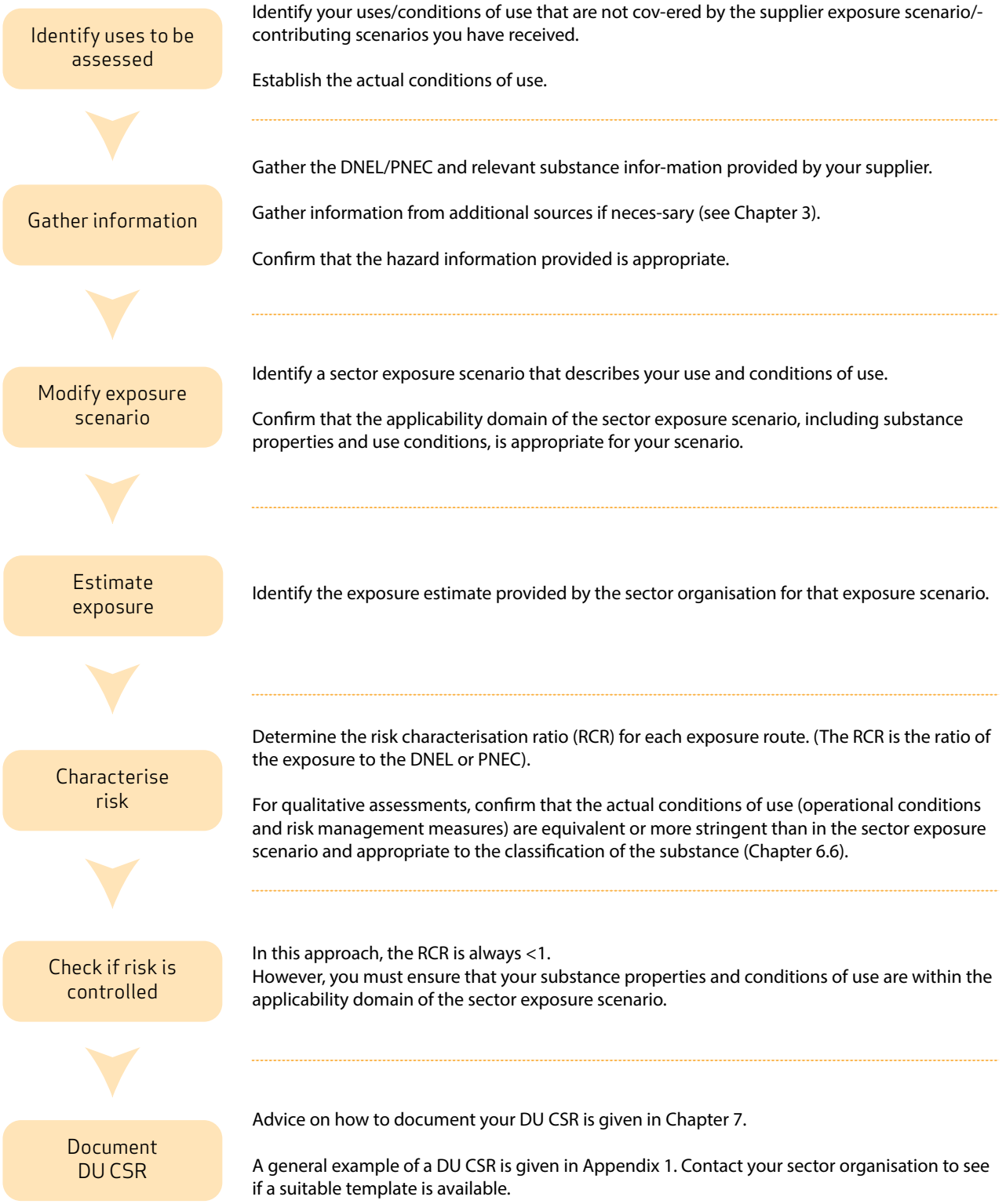
An advantage of this approach is that you do not need to perform the exposure estimation yourself, as this has been determined by the sector association. However, it is your responsibility to choose the appropriate exposure scenario and to check your substance and conditions of use meet the boundary conditions defined in the sector exposure scenario. Otherwise, the exposure estimate may not be applicable, and you should prepare your DU CSR using Approach C (Own exposure scenario). It is also your responsibility to report to ECHA, as described in Chapter 9.

At the time of writing this Practical Guide, several downstream user industry sector associations are in the process of developing this approach. Consult sector websites for fur-ther information[9].

The competencies required to apply this approach are typically those of environmental health and safety (EHS) practitioners, who can interpret and apply the information contained in the exposure scenarios to their workplace and undertake risk assessments as required by other EHS legislation, and recognise when greater expertise is needed.

9 http://www.ducc.eu is a useful central source of information relating to industry activity

Figure 4: Main steps in Approach B: Sector Exposure Scenario



! Remember to communicate downstream, report to ECHA and implement the conditions of use as necessary (TIP Box 4)

6. APPROACH C: DOWNSTREAM USER EXPOSURE SCENARIO

This approach is a more comprehensive chemical safety assessment than the other two approaches described in this Practical Guide. It is the most suitable option when your use is not described in the exposure scenarios you receive, when a sector use scenario is not available and/or when a more thorough assessment is warranted.

This chapter describes the various steps involved. An overview is given and then each element is described in detail.

6.1 STARTING POINT

- You receive exposure scenarios for the substance from your supplier.
- You establish that:
    - Your use and/or conditions of use are not covered in the exposure/contributing scenarios you receive.

and one or more of the following situations apply:

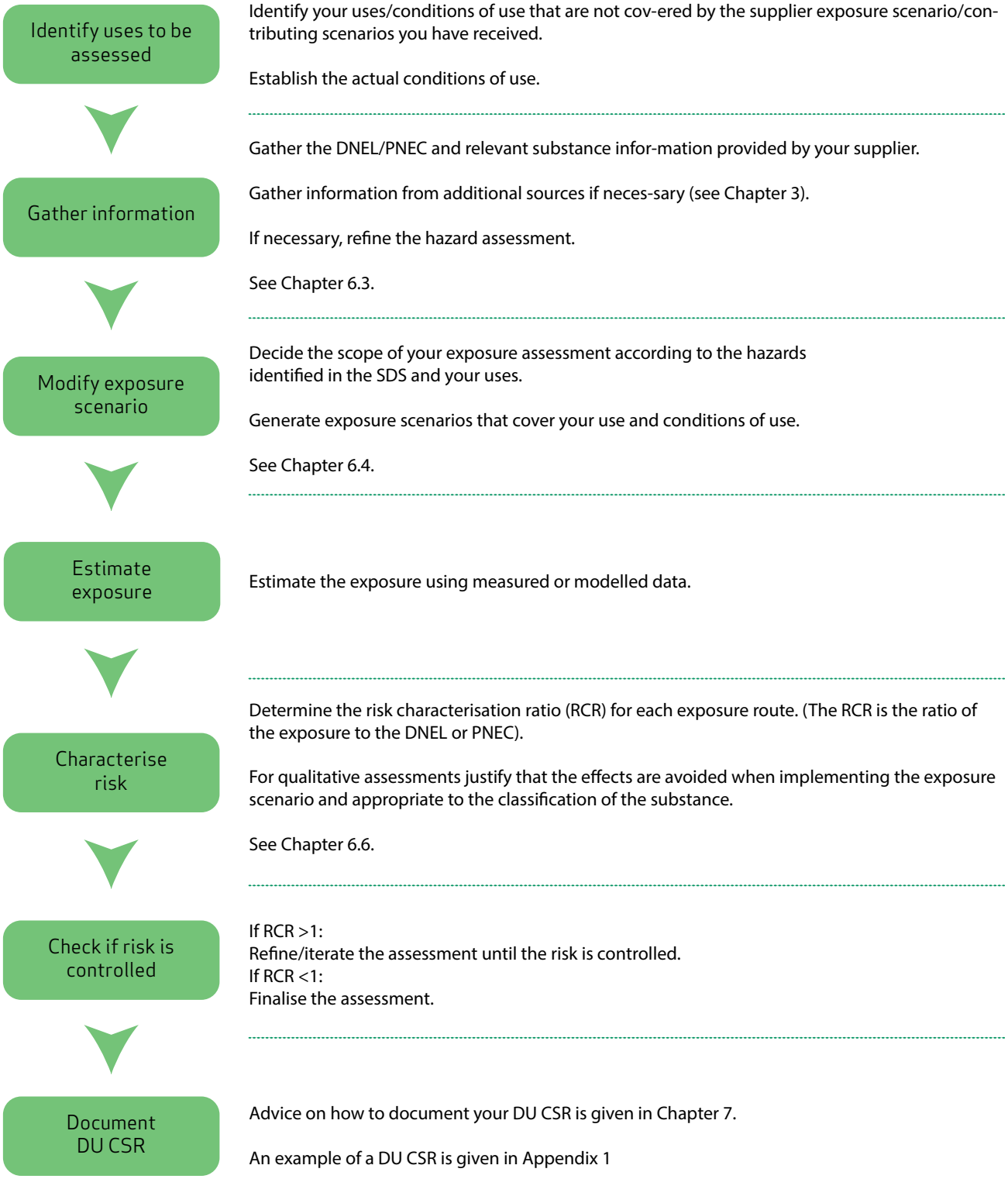
- A more thorough assessment is warranted, for example due to:
    - the hazardous properties of the substances;
    - the hazard information is insufficient or inappropriate.
- You want to estimate the exposure using measured data or a different exposure estimation tool than was used by your supplier.
- You want to keep your use confidential.
- Approaches A and B are not applicable.

6.2 OVERVIEW OF APPROACH BASED ON EXPOSURE SCENARIOS GENERATED BY THE DOWNSTREAM USER

The main steps for this approach are presented in Figure 5. They are discussed in more detail in the following sections.

The level of expertise required on the part of the person undertaking a DU chemical safety assessment based on this approach will depend on the complexity of the assessment. If you are competent to undertake risk assessments to comply with regulatory environmental, health and safety (EHS) requirements or have prepared CSRs for REACH registration purposes, this is normally sufficient. Greater expertise may be needed for more complex assessments, when a hazard refinement is needed and for uses which potentially pose a higher risk.

Figure 5: Main steps in Approach C: Own Exposure Scenario



Remember to communicate downstream, report to ECHA and implement the conditions of use as necessary (TIP Box 4). You may already be familiar with some of the steps above. Just go to those sections where you need more information.

6.3 REFINE HAZARD ASSESSMENT

Advice on how you can gather information on substance properties is provided in Chapter 3. If, for any reason, you do not agree with the hazard information available and have failed to reach agreement with your supplier, or the hazard of the substance changes in your use, you may need to refine your hazard assessment as described here.

If you consider that the hazard and PBT information reported in the safety data sheet supplied to you is appropriate, you can use the relevant information supplied. You don't have to undertake any further hazard assessment or PBT/vPvB assessment.

One reason that the hazard assessment from your supplier may not be appropriate is when the hazard of the substances changes in your use. Another reason may be that you do not agree with the hazard information available and you and your supplier do not align on the hazard assessment[10].

If either of these unusual situations arise, you may wish to refine the hazard assessment. You should carry out the relevant assessments in accordance with the requirements that apply to a registrant under REACH, according to Annex XII to REACH.

Some examples of when a refinement of the hazard assessment may be required include:

- If the substance is used in a different physical form or composition, such as nanoparticles or purified substance.
- If a substance reacts on use (bleaching agent, reactive dyes), or undergoes redox reaction, hydrolysis, microbiological transformation etc.
- If a DNEL/PNEC value is not provided for the target group that is relevant for your assessment. For example, you may want to derive a consumer DNEL from a worker DNEL.
- If a registrant did not undertake testing but it is relevant for the downstream user, as exposure could occur that was not envisaged by the registrant[11].

As these examples illustrate, the refinement may be relatively simple or complex. A competent person should be consulted as necessary. The guidance necessary to carry out a detailed hazard assessment is outside the scope of this practical guide[12].

6.4 SCOPE OF ASSESSMENT AND GENERATE EXPOSURE SCENARIOS

This section describes how you can generate an exposure scenario as part of a DU CSR for your use, or your customer's use, of the substance.

Before you generate exposure scenarios, you first need to consider the scope of your assessment.

10 Note that if you have new information on hazardous properties, you are legally obliged to communicate it up the supply chain (Article 34).

11 This is likely to be unusual but if you plan to undertake vertebrate testing, you need to provide a testing proposal to ECHA.

12 For further information see the Guidance on IR&CSA (in particular Part B and related Chapters R.2 to R.10), Practical Guide 14 on "How to prepare toxicological summaries in IUCLID and how to derive DNELs and Sections 1 to 4 of Annex I to REACH.

6.4.1 THE SCOPE OF THE EXPOSURE ASSESSMENT

You need to assess the risk for all the hazards that have been identified for the substance, and all the life cycle stages that are relevant for each of the uses in your DU CSR. ECHA guidance identifies three types of hazards that require exposure assessment:

1) hazards for which the substance is classified[13];

2) hazards for which there are classification criteria[14] and there is information showing that the substance does have these hazard properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified;

3) hazards for which currently no classification criteria exist, but there is information to show that the substance has such hazardous properties. For example, this could be for environmental hazards related to soil/sediment or air.

When deciding on the scope of your assessment, also consider if your site-based risk assessments conducted for other compliance purposes have identified any additional concerns which you should include in your assessment. It may also help to look at the scope of exposure scenarios from the supplier for other uses of that substance.

6.4.2 ENVIRONMENTAL ASSESSMENT

You need to assess the risk with respect to the environment if your use is not covered by the supplier and any of the following conditions apply:

- the substance is classified with respect to aquatic hazard or
- the substance is PBT/vPvB or

- the substance is classified with respect to hazards, other than environmental hazards, for which you have to undertake an assessment and PNECs have been derived from ecotoxicity data showing effects in aquatic organisms or in soil/sediment dwelling organisms, although they do not lead to classification.

6.4.3 HUMAN HEALTH ASSESSMENT

You need to assess the risk with respect to human health if your use is not covered by the supplier and any of the following conditions apply:

- the substance is classified with respect to human health hazards or

- the substance is classified with respect to hazards, other than human health hazards, for which you have to undertake an assessment and adverse effects have been observed in human health toxicity studies, although they do not lead to classification. (For example, DNELs may be assigned or information in Section 11 of the SDS or other sources would trigger concern).

Aspects you need to consider include:

13 According to Article 14(4) of REACH

14 See Guidance on IR&CSA Part B, Section B.8

- Who is likely to be exposed, workers and/or consumers?
- What are the routes of exposure, (inhalation, dermal and, for consumers only, the oral route)?

6.4.4 GENERATING EXPOSURE SCENARIOS

Exposure scenarios describe the conditions under which a hazardous substance can be used for the given scenario such that the risk is considered adequately controlled. When you prepare a DU CSR, you need to generate exposure/contributing scenarios for the uses of the substance you are assessing.

When you are preparing the chemical safety assessment for your own use, the conditions of use are usually exactly those conditions that occur on your site. When you are preparing the chemical safety assessment for your customer use, the conditions of use should reflect those conditions that actually occur on their site, or are feasible to implement. See Appendix 3 for more information on selecting risk management measures.

A number of sources may help you generate your exposure scenario. These include exposure scenarios you receive from your suppliers for similar uses, use maps or generic exposure scenarios provided by your sector organisation and the scenarios embedded in exposure estimation tools.

If you are assessing worker or consumer uses, contact your sector organisation to establish if SWEDs or SCEDs are available respectively. SWEDs are sector-specific worker exposure descriptions, and are under development at the time of writing. It is intended that they will document typical conditions of use for workers. SCEDs are specific consumer exposure determinants and document typical conditions of use of consumer products. SWEDs and SCEDs are intended to represent realistic assumptions and the determinants are expressed in a form that can be easily input into the commonly applied exposure assessment tools.

If you are assessing environmental exposure and using modelling tools, be aware that the environmental release categories (ERCs) incorporated in some modelling tools may overestimate the release from industrial sources. If so, refine the releases to environment using literature sources, relevant sector-specific ERCs (termed SPERCs) or site-based information, as appropriate.

If you are providing the exposure scenario to customers, you are strongly recommended to use the format for the exposure scenario agreed by industry and the authorities[15]. You should always communicate relevant conditions of use to your customer in a way that is readily understood. See Chapter 8 for further information.

6.5 ESTIMATE THE EXPOSURE

You can estimate the exposure using measured data or exposure modelling. The method and the modelling tool you use to estimate the exposure will depend on aspects such as the information available to you, limitations imposed by the use or by the substance, and your current practices. This section describes the main considerations.

Aspects to consider when you use measured data and modelling tools to estimate exposure are presented in Tables 2 and 3 respectively. In general, it is recommended that you use the method you are familiar with, such as one you currently use for site-based risk assessments, if it is applicable.

15 http://echa.europa.eu/support/practical-examples-of-exposure-scenarios

Table 2: Exposure estimation using measured data

EXPOSURE ESTIMATION USING MEASURED DATA	
Possible sources	You may have measured releases/exposures to demonstrate compliance with the Chemicals Agents Directive, Industrial Emissions Directive or other relevant EU-EHS or local legislation, or for other corporate requirements. Or you may have access to suitable databases.
Suitability	Measured data is suitable when you have sufficient and adequate measured data for the substance and use of interest that is reliable, representative and relevant. It is likely to be personal exposure data, possibly including supporting information obtained by biological monitoring. Static workplace measurements may be suitable, if they are likely to represent worker exposure.
Limitation	Measured data is not suitable when you do not have sufficient and adequate data that reflect the conditions of the exposure scenario. The data is not suitable if the conditions of use during measurement provide less control of risk than the conditions you specify in your ES.
Ease of use	Straightforward when the measured data is considered of high relevance and directly applicable. More challenging when selecting relevant data, using databases or when extrapolating data from analogous/surrogate measurements
Expertise required	Moderate to high. Expertise is required to select appropriate data, to determine what is sufficient, to interpret the data and to extrapolate from the data if necessary, and appropriate experience in measurement and/or interpreting measured data is necessary. Detailed advice on how to interpret measured data is beyond the scope of this practical guide. If you undertake this task you will need to have competence in this area.
Tip	If your measured data is not sufficient to base your assessment on, perhaps it can still be used to support the output of exposure modelling.
Word of caution	A measurement or risk assessment report conducted for environmental or health and safety compliance purposes can often form the basis of a DU CSR. However, because a CSR under REACH must characterise the risk by comparison of the exposure with the DNEL/PNEC (or qualitatively if appropriate), it is not normally possible to use such reports directly as a DU CSR. There are also specific requirements on documentation of a DU CSR, as described in Chapter 7.
Further info	Guidance on evaluating the quality and suitability of measured data is provided in ECHA Guidance R.14 "Occupational Exposure Estimation" and ECHA Guidance R.16 "Environmental Exposure Estimation" (both of which are under review at the time of writing).

Table 3: Exposure estimation using modelling tools

EXPOSURE ESTIMATION USING MODELLING TOOLS	
Possible sources	Tools which are publically available are presented in Table 4.
Suitability	Modelling tools are suitable for many situations, including when you have no adequate measured data; when you are assessing uses further downstream; when you are experienced in using exposure models.
Limitation	Modelling tools are not suitable when the use is outside the stated domain of applicability of the exposure model.
Ease of use	Depends on the model and existing knowledge/experience in using them.
Expertise required	Moderate to high, depending on model and scenario. Instruction on how to use the various exposure estimation tools is outside the scope of this practical guide.
Tip	A suitable tool is one that is fit for the task from a scientific perspective and which you find convenient to use. If you are already competent in using a particular tool, use that tool if it is appropriate. If you have limited experience in exposure modelling, it may be more practicable to use external expertise. However, developing the capacity in-house may support site risk assessment for other safety and compliance purposes, and allow you to compare model outputs with your own experience.
Another Tip	It may be appropriate to adjust the modelled estimate based on knowledge of the actual release rates. For example, when a substance is used as a reactive diluent, a significant proportion of the diluent may be incorporated in the matrix, resulting in release of less substance than initially estimated. Consequently, there is less exposure than might normally be expected and the exposure estimate can be amended accordingly, if this can be justified.
Word of caution	The user is responsible for the correct and appropriate use of any tool. The use and the conditions of use must be within the domain of reliable applicability of the exposure tool being used.
Further info	Information is provided on the websites of the tool providers (see Table 4). Guidance on modelling tools is provided in ECHA Guidance R.14 "Occupational Exposure Estimation", ECHA Guidance R.15 "Consumer Exposure Estimation" and ECHA Guidance R.16 "Environmental Exposure Estimation" (all of which are under review at the time of writing).

Table 4: Exposure estimation modelling tools

MODEL NAME	OWNER	DESCRIPTION	CATEGORY	LINK TO WEBSITE
ART	TNP	Advanced worker inhalation exposure assessment	worker	http://ww.advanced-reachtool.com
ConsExpo	RIVM	Exposure assessment of compounds in non-food consumer products	consumer	http://www.consexpo.nl
EMKG-EXPTOOL	BAUA	Quantitative tier 1 assessment of occupational exposure (inhalation) to hazardous substances.	worker	http://www.reach-clphelpdesk.de/en/Exposure/Exposure.htm
ES modifier	DHI group	Model developed mainly for Downstream users needing to check and modify the REACH Exposure Scenario received from their suppliers.	worker consumer environment	http://esmodifier.dhigroup.com/Indhold.htm
EUSES	EC-JRC	EUSES is a decision support instrument to carry out assessments of the general risks of industrial chemicals and biocides posed by substances to man and the environment.	environmenr, man via environment	http://ihcp.jrc.ec.europa.eu/our_activities/publichealth/risk_assessment_of_Biocides/euses
MEASE*	Eurometaux	1st tier screening tool for the estimation of occupational inhalation and dermal exposure to metals and inorganic substances, based in TRA/EASE(Herag).	worker	http://www.ebrc.de/tools/mease.php
RiskOfDerm	TNO	Worker potential dermal exposure assessment	worker	http://www.tno.nl
Stoffenmanager	TNO	Control banding for worker dermal and inhalation exposure and quantitative exposure assessment for worker inhalation exposure	worker	http://www.stoffenmanager.nl
TRA*	Ecetoc	Model developed mainly for chemical safety assessment for REACH registration	worker consumer environment	http://www.ecetoc.org/tra
WPEM	US-EPA	E stimates the potential exposure of consumers and workers to the chemicals emitted from wall paint	consumer, worker	http://www.epa.gov/opptintr/exposure/pubs/wpem.htm

Source: Extract from Table 1 of OECD report ENV/JM/MONO(2012)37, with amendments. Models indicated by * were added for completeness. A more comprehensive overview of consumer exposure tools in included in ECHA Guidance IR & CSR R.15.

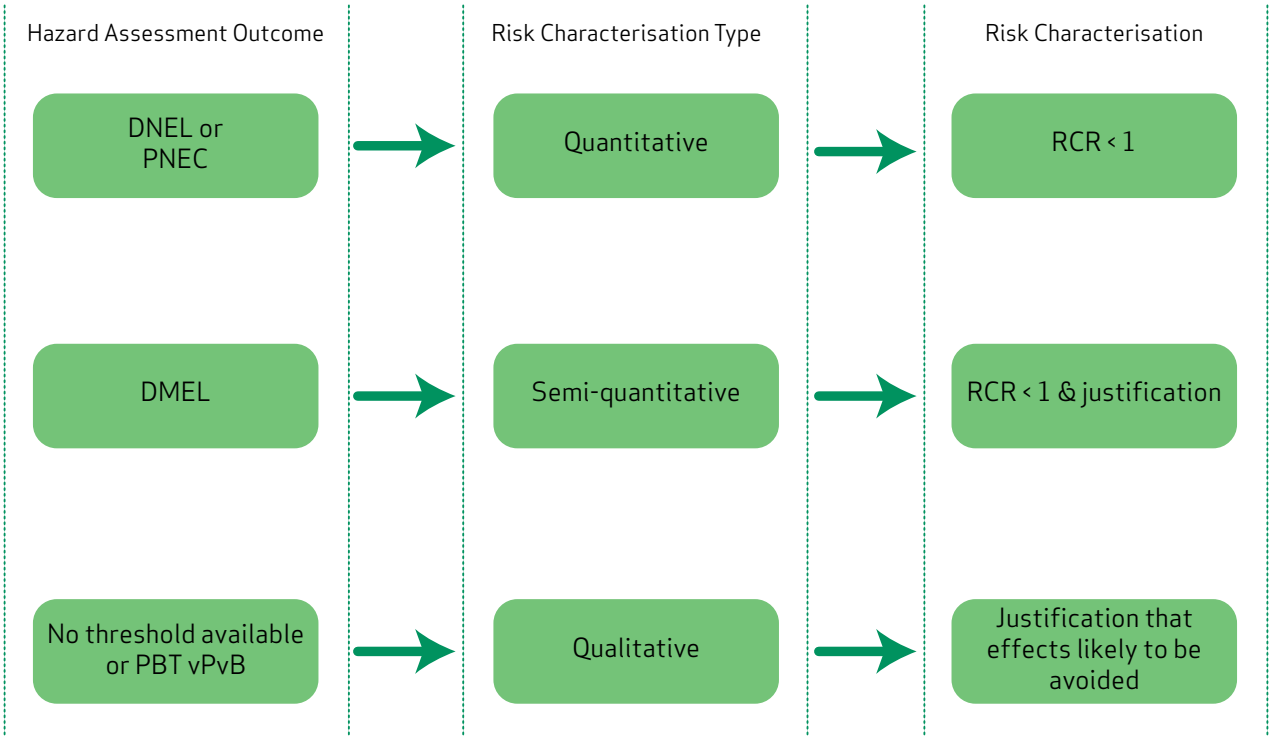
Note: ECHA has developed a software tool to assist registrants in preparing a chemical safety report (CSR), called Chesar. The current version, Chesar version 2, does not support the preparation of downstream user chemical safety reports. Nevertheless, it can be used by downstream users who are familiar with IUCLID and Chesar and who have access to the IUCLID dossier of the substance of interest. (The export file that can be generated from IUCLID includes the information necessary for exposure assessment using the main modelling tools used).

6.6 CHARACTERISE THE RISK

This section describes the ways in which you can characterise the risk, to make sure the risk is controlled.

When you have estimated the exposure, you need to characterise the risk to demonstrate control. The type of risk characterisation can be quantitative, semi-quantitative or qualitative. The type of risk characterisation you use is determined by the outcome of the hazard assessment, namely whether or not you have a threshold value at which an effect is observed. This is illustrated in Figure 6 and the different types of risk characterisations are described further here.

Figure 6: Overview of principle types of risk characterisation



6.6.1 QUANTITATIVE RISK CHARACTERISATION

A quantitative risk characterisation is undertaken if derived no effect levels (DNELs) or predicted no effect concentrations (PNECs) are available. Divide the exposure estimate by the corresponding DNEL or PNEC to get the risk characterisation ratio (RCR).

RCR = exposure estimate/DNEL (or PNEC)

Ensure that the RCR is below 1. If not, repeat the assessment with more stringent conditions of use until the RCR is below 1.

6.6.2 SEMI-QUANTITATIVE RISK CHARACTERISATION

Semi-quantitative risk characterisations are usually undertaken when it is not possible to establish a "no effect" level but it is possible to establish a level at which there is minimal effect. In such cases, the conclusion of the hazard assessment is a derived minimal effect level (DMEL) rather than a DNEL. Examples of substances where this applies are some carcinogens and mutagens, and it applies only to human health effects.

A semi-quantitative risk assessment is a combination of a quantitative and qualitative assessment approach. Divide the exposure estimate by the DMEL to get the risk characterisation ratio (RCR). Control of risk is demonstrated if the risk characterisation ratio (RCR) is below 1 and additional justification is provided to demonstrate that the proposed control measures described in the exposure scenarios minimise the exposure.

In some cases, it may be possible to establish dose-response relationships for some non-threshold CMR substances. These are quantitative relationships that calculate "excess risk" associated with a given level of exposure. Risk characterisation can be based on such a relationship, usually together with justification that the excess risk is acceptable.

6.6.3 QUALITATIVE RISK CHARACTERISATION

Qualitative risk assessments are undertaken when a DNEL/DMEL or PNEC cannot be established. This arises when it is not possible to identify a threshold below which adverse effects are not observed. It often applies to sensitisers, irritants/corrosives, non-threshold CMR substances and PBT/vPvB substances and always applies to the potential for damage to eyes.

A qualitative assessment differs from a quantitative or semi-quantitative assessment in that you cannot quantify the risk in the form of an RCR. Therefore, you must provide robust justification to support the conclusion that the operational conditions and risk management measures described in the exposure scenario are sufficient to avoid adverse health or environmental effects. You should propose steps to avoid the exposure when the substances are of high hazard, such as CMRs, sensitisers or PBT/vPvB substances.

It is sometimes appropriate to support a quantitative risk assessment with a qualitative risk assessment. One situation where this often applies is for dermal exposure. Quantitative assessment of dermal exposure is required when a systemic DNEL is available, yet the limitations of dermal exposure estimation are recognised. Consequently, it is recommended to also evaluate the outcome from a qualitative standpoint, to ensure the risk management measures are appropriate. Generally, the workplace risk management measures implemented to control dermal exposure aim to prevent exposure as far as possible.

Qualitative assessments for workplace exposure are sometimes undertaken using control banding. Control banding tools include COSHH Essentials[16] and EMKG[17]. For further information, see Practical Guide 15 "How to undertake a qualitative human health assessment and document in a CSR" and Part E of the Guidance on IR&CSA.

16 http://www.coshh-essentials.org.uk

17 BAuA, the German Federal Institute for Occupational Safety and Health http://www.baua.de/EMKG

6.6.4 COMBINED RISK

You also need to consider the combined risk, if appropriate. For example, a worker handling a substance with a systemic health effect may be exposed both by the inhalation and the dermal route. If so, the RCR for both routes should be summed. (Note that you consider acute and chronic effects separately.)

You must repeat the assessment with more stringent conditions of use if the summed RCR is above 1 or a qualitative assessment indicates that the risk may be not controlled.

7. DOCUMENT THE DU CSR

This chapter outlines the information that should be documented in a DU CSR, and the format that should be followed.

According to Annex XII to REACH, a chemical safety report prepared by a downstream user should consist of Part A and Part B, as outlined below. Part B uses the format set out in Annex I to REACH (for registrant CSR). The downstream user should include exposure assessment and risk characterisation (sections 9 and 10) and the other sections if appropriate:

Part A

A. Declaration that the downstream users implement the risk management measures outlined in the relevant exposure scenarios for their own uses

B. Declaration that the downstream users communicate the risk management measures outlined in the relevant exposure scenarios for the identified uses further down the supply chain.

Part B

i. Appropriate information and/or reference to sources of information relating to:

A. The identity of the substance and physical/chemical properties.

B. The use(s) being covered by the DU CSR.

C. Classification and labelling.

D. Environmental and human health hazard assessments.

ii. Exposure assessment and risk characterisation

The extent of the documentation will depend on the complexity of the DU CSR, as indicated in TIP Box 7. The main section headings of the CSR format that are set out in Annex I to REACH are presented in Table 5. Those sections that are likely to be included in a DU CSR, and under which circumstances, are also indicated in Table 5.

Examples of different DU CSRs are provided in Appendix 1 and possible questions are addressed in Question Box 2.

Tip Box 7: Keep the report proportionate

- Keep the report simple , especially when your assessment is straightforward. When it is complex, make sure the report clearly describes all the issues.
- Approach A/Supplier Exposure Scenario: the re-calculation tool may provide all relevant aspects of documentation.
- Approach B/Sector Exposure Scenario: the sector may provide a report template with the other information.
- Approach C/Own Exposure Scenario: the documentation is likely to be more comprehensive and should be sufficient to present the chemical safety assessment clearly.

Table 5: Main section headings of Part B of the CSR format (adapted from Annex I to REACH) and their relevance for inclusion in a DU CSR.

CSR REPORT FORMAT / SECTION HEADING	INCLUSION IN DU CSR
1. Identity of the substance and physical and chemical properties	Usually included. May refer to SDS
2. Manufacture and uses	USES usually included. Manufacture applicable only to registrants (note that formulation is a use, not manufacture)
3. Classification and labelling	Usually included. May refer to SDS. Labelling not normally relevant to include
4. Environmental fate properties	Included as appropriate to indicate information sourced from SDS, from alternative sources or if new hazard assessment was undertaken (Approach C).
5. Human health hazard assessment	
6. Human health hazard assessment of physico-chemical properties	
7. Environment hazard assessment	
8. PBT and vPvB assessment	
9. Exposure assessment 9.1. (Title of exposure scenario 1) 9.1.1. Exposure scenario 9.1.2. Exposure estimation 9.2. (Title of exposure scenario 2) 9.2.1. Exposure scenario 9.2.2. Exposure estimation (etc.)	Always included, with sub-headings as appropriate. The risk characterisation for each exposure scenario/contributing scenario is also provided here.
10. Risk characterisation 10.1. (Title of exposure scenario 1) 10.1.1. Human health 10.1.1.1. Workers 10.1.1.2. Consumers 10.1.1.3. Indirect exposure to humans via the environment 10.1.2. Environment 10.1.2.1. Aquatic compartment (including sediment) 10.1.2.2. Terrestrial compartment 10.1.2.3. Atmospheric compartment 10.1.2.4. Microbiological activity in sewage treatment systems (etc.)	Included when it is appropriate to characterise the risk for combined/aggregated uses across different uses assess.

Note: the documentation will vary with the approach used, and be most detailed with Approach C.

8. COMMUNICATING TO CUSTOMERS

This chapter applies to you only if:

- **You are supplying the substance onwards, and**
- **You are required to provide a safety data sheet and**
- **you have undertaken a DU CSR for your customer use.**

When you have prepared a DU CSR for a customer use, and you are required to provide an SDS for the substance (as such or in a mixture), you also need to provide your customers with any relevant exposure scenarios/contributing scenarios for their use, for which you prepared a DU CSR. You should place the relevant exposure scenarios for the substances assessed in an annex to the safety data sheet.

When supplying a mixture, you may also choose to provide consolidated safe use information for the mixture, in addition to the substance ES you are required to provide. Your sector organisation may have developed generic safe use of mixtures information (SUMI) sheets which you can use or adapt. Make sure that the information contained in the SDS and SUMI (if provided) is consistent with the exposure scenario.

The exposure scenario should be provided in an official language of the Member State of the recipient, in the same way as a safety data sheet. It is recommended that you use ESCom Phrases[18] where available and the format for the exposure scenario that has been agreed by industry and the authorities[19]. This is based on four sections, namely:

1. Title

The title section gives an overview of all the tasks/activities covered by the ES. It typically gives a short description of the scope of the ES, and lists the tasks/activities (or "contributing scenarios") covered by the ES. This listing is most often based on the Use Descriptor System (PROCs, PCs, ERCs etc.)[20].

2. Conditions of use affecting exposure

This essential section is the core of the ES as it describes the conditions of use (operational conditions (OCs) and risk management measures (RMMs)) for each task/contributing scenario you are assessing. This should be clearly described, with all the necessary information for safe use by your customer.

3. Exposure estimate and reference to its source

This section of the exposure scenario documents the estimation method used in the assessment. It presents the exposure estimate and the risk characterisation. If your customers are end users, include this information only if it is relevant for them.

4. Guidance for Downstream Users

This section can be used to provide information to customers that may be helpful to them when comparing their actual conditions of use with those in the ES. For example, it could refer to information on scaling. Include this section if you supply to downstream users who also supply further downstream. Otherwise, it is not normally relevant.

18 http://www.cefic.org/Industry-support/Implementing-reach/escom/

19 http://echa.europa.eu/regulations/reach/downstream-users/exposure-scenarios

20 http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Question Box 2: Questions on Documentation

Q: Do I have to write my DU CSR in English?
A: No. You can write it in any official EU language of choice. If you are required to send exposure scenarios to customers, they must be provided in an official language of the Member State of the recipient (see Chapter 8).

Q: Do I have to submit my DU CSR to ECHA?
A: No. You do not submit the actual DU CSR, but make it available to enforcement authorities on request. However, in most cases, you have to inform ECHA that you have undertaken a DU CSR. See Chapter 9 for details.

Q : Do I have to keep a copy of the supplier's SDS together with my DU CSR?
A: It is advisable to do so. The DU CSR should also include a clear reference to the version and date of any SDS used, as well as to the name of supplier. The sources of any other information used should also be given.

Q : How long do I have to keep records?
A: You are obliged to keep the information required to carry out your DU CSR for at least 10 years after you last supply or use the substance or mixture (Article 36).

9. REPORTING TO ECHA

The REACH Regulation requires that you report to ECHA when you intend to prepare a DU CSR, or if you are exempt from preparing a DU CSR. The reporting required is explained in this chapter.

You are obliged to report to ECHA if you are preparing a DU CSR, unless your particular use is less than one tonne per year.

You also have to report to ECHA if you are exempt from preparing a DU CSR because:

- You use the substance in total quantities below 1 tonne per year or
- You use the substance for Product and Process Orientated Research and Development (PPORD).

The reporting requirements are specified in Article 38 of REACH and summarised in Table 6. The information to be reported includes aspects such as identification details of the downstream user and the supplier (for the use not covered), the substance and a brief general description of the use and conditions of use. This information is used to support decision making at various stages in regulatory risk management processes. You do not have to send the DU CSR itself to ECHA.

A downstream user can report to ECHA by using a user-friendly webform or, for users familiar with IUCLID, through REACH-IT. Detailed information on how to provide a downstream user report is available on the ECHA website[21].

21 http://echa.europa.eu/regulations/reach/downstream-users/downstream-user-reports

In the unusual event that you intend to perform additional testing on vertebrate animals as part of a DU CSR hazard refinement, you must submit a proposal to ECHA. Testing cannot proceed before agreement is received from ECHA.

Table 6: Overview of reporting requirement

TOTAL USE (TONNES PER YEAR)	PARTICULAR USE (TONNES PER YEAR)	IS IT USED FOR PPORD?	A DU CSR IS REQUIRED BY ARTICLE 37(4)	NEED TO REPORT TO ECHA?
>1	>1	no	yes	yes
>1	<1	no	yes	no (particular use <1 tonne/year)
<1	<1	no	exempt (<1 tonne/year)	yes
>1	>1	yes	exempt (PPORD)	yes

Tip Box 8: Know how much time you have

- Make sure you complete the necessary actions within the regulatory timeframe.
- You have six months to inform ECHA from the moment you receive a safety data sheet of the substance containing a registration number for which there is no ES that covers your use.
- You have 12 months in which to complete the necessary action, such as preparing the DU CSR.
- Implement appropriate provisional risk management measures if necessary.

Appendix 1: Examples of a DU CSR

Examples of a DU CSR are presented in the following pages. The examples are based on an imaginary substance, called ECHA Substance, which has been used in other examples produced by ECHA. The safety data sheet can be seen in the ECHA e-Guide on SDSs[22].

The examples are all for the same scenario, which is worker exposure for a dipping process on the downstream user's own site. The activity takes place with good general ventilation, without personal protective equipment, and for a duration of up to four hours per shift. Environmental or consumer assessments are not illustrated but would be prepared in a similar way.

In the examples, the necessary substance information was provided by the supplier and a refinement of the hazard was not required. The relevant supplier contributing scenario is given in Appendix 2.

Note that the irritancy effect cannot be addressed in a quantitative approach and is addressed qualitatively based on the concentration of the substance in the mixture, and with reference to the substance and mixture classification.

The examples are provided in the following order:

Example 1: Cover page
Example 2: Part A
Example 3: Part B - Approach A: Supplier exposure scenario
Example 4: Part B - Approach C: Own exposure scenario (measured data)
Example 5: Part B - Approach C: Own exposure scenario (modelled data)

Notes

These examples are intended to illustrate the content of a DU CSR, to assist downstream users. DUs must make sure that the DU CSR is appropriate to the assessment.

A DU CSR undertaken in compliance with the REACH Regulation does not replace or fulfil the obligations to undertake risk assessments under other national environmental and health and safety legislation.

In this worked example, an employer would be required under the Chemical Agent Directive to undertake a risk assessment of the worker that includes the combined exposure from different tasks and chemicals.

22 e-Guide 01 "SDS and ES - advice for recipients": http://view.pagetiger.com/ECHAeGuide1-1/Issue1

Example 1: Cover page

The cover page can be adjusted to match in-house reporting styles. An example is presented below.

Downstream User Chemical Safety Report

[DUCompany_Name]

Report

Report title	*Dipping process in Plant 3&4*
Reference	*F1234*
Version	*1.0*
Prepared by	*Alice Bruno, EHS Dept*
Date prepared	*29/12/2015*

Substance

Name	*ECHA substance*
EC number	*####*
CAS number	*####*
REACH registration no.	*####*

Report to ECHA

REACH-IT submission no.	*####*
Notification date	*01/01/2015*

*******End of Example 1*******

Example 2: Part A

Declaration that risk management measures are implemented
DUCompany_Name declares that the risk management measures (RMMs) outlined in this chemical safety report are implemented by our company for our own uses.

Declaration that risk management measures are communicated
DUCompany_Name declares that the risk management measures outlined in the relevant exposure scenarios for the identified uses in this chemical safety report are communicated further down the supply chain

! This paragraph is required only if you are communicating further downstream.

Statement on the hazard and PBT/vPvB assessments reported in the safety data sheet supplied and/or gathered from other sources of information
DUCompany_Name assumes the hazard and PBT/vPvB assessment conclusions reported in the safety data sheet of [supplier], version [number] date [date] and/or the information on the hazard and PBT/vPvB assessments gathered from other sources, as documented in the CSR, to be appropriate. For this reason, company [x] has used the relevant information reported by the supplier and/or gathered from other sources for the risk characterisation for further risk assessment

! This paragraph is not mandatory but it is recommended to include an appropriate statement either here or in part B. Identify any ad-ditional sources used.

*******End of Example 2*******

Example 3: Part B - Approach A with Cefic ES conformity tool

Approach A: Supplier exposure scenario.
Exposure estimation: Cefic ES conformity tool.
Situation: You coat articles by dipping. Your use (dipping) is described in the supplier contributing scenario but the conditions of use differ from those on site. The received contributing scenario specifies LEV over a full shift. In your case, LEV is not used on site but good general ventilation is provided with an air change rate of 3.5ach^{-1} and exposure time is reduced.

In this example, it is assumed that you attach/link the safety data sheet to the DU CSR. It may also help to attach the relevant exposure/contributing scenarios.

A copy of relevant sections of any recalculation tool or exposure modelling tool may be sufficient to document the DU CSR, together with the safety data sheet for the substance. The report should be expanded where necessary, to include qualitative assessment, as illustrated here with respect to irritancy.

Note: this extract is for **Part B** only.

PART B

CS for a Simplified Downstream User Chemical Safety Report			
eSDS for:	Product X	**Main User Group:**	3
Supplier: **Substance name:**	Supplier Y ECHA substance	**SU** **other information 1:**	16 xxxx
Substance CAS#: **ES#:**	1234-56-7 3	**other information 2:** **ES name:**	yyyy Coatings & Inks
Worker CS#:	5	**Done by:**	AB
		Date:	01-Sept-15

Operational Conditions and Risk Management Measures TRA version	Supplier 3	DU actual 3
Scenario name Process category (PROC)	Dipping PROC 13	Dipping PROC 13
Type of setting Is substance a solid?	industrial No	industrial No
VP (Pa) at ambient or process temperature	10	10
Duration of activity [hours/day]	> 4 hours (default)	1 - 4 hours
Use of ventilation?	Indoors with LEV	Indoors with good general ventilation
Use of respiratory protection?	No	No
Substance in preparation?	1 - 5%	1 - 5%
Dermal PPE/Gloves Consider LEV for dermal exposure?	No No	No No

Exposure estimation		
Long-term Inhalation Exposure	2.5 mg/m^3	10.5 mg/m^3
Long -term Dermal Exposure	2.7 mg/kgbw/day	2.7 mg/kgbw/day
Risk Characterisation		
Risk Characterisation Ratio - Long-term Inhalation	0.1	0.42
Risk Characterisation Ratio - Long-term Dermal	0.39	0.39
Risk Characterisation Ratio - Long-term Total Exposure	0.49	0.81

Adverse irritancy effects are controlled by substance concentration (< 10 %) in the product. The mixture is not classified for skin or eye irritation and no local effects are expected. Furthermore, the potential for dermal and eye contact is minimal due to automated transfer between dipping baths and forced air drying of parts before contact (enclosed system with LEV). Personal protective equipment is available for non routine intervention. All other ingredients in the mixture are non hazardous and so the combined risk to the mixture is also considered to be controlled.

*******End of Example 3 (supplier exposure scenario approach)*******

! Note: this table is taken from the draft Cefic ES Conformity Tool and amended to aid clarity. Cells where the actual conditions of use differ from the supplier's are highlighted in yellow. The exposure and the RCR in the green highlighted cells are calculated values.

Example 4: Part B - Approach C with measured data

Approach C: Own exposure scenario.
Exposure estimation: Measured data.
Situation: You coat articles by a dipping process. The exposure scenarios you receive do not refer to coating at all. You have measured data available from personal exposure monitoring over the previous three years.

This example also illustrates a more narrative approach in the documentation, in particular with respect to the exposure scenario. The key substance information is included but the safety data sheet would normally be also attached to the DU CSR. Note that this DU CSR is for the DU own site and is not being communicated onwards, and hence standard phrasing or format is not a consideration.

This extract is for **Part B** only.

PART B

DUCompany_Name assumes the hazard and PBT/vPvB assessments reported in the safety data sheet of [supplier], version 1.0, September 2014 and/or the information on the hazard and PBT/vPvB assessments gathered from other sources to be appropriate. For this reason, DUCompany_Name has used the relevant information reported by the supplier and/or gathered from other sources for the risk characterisation for further risk assessment.

All information is sourced from that safety data sheet unless otherwise specified.

1. Substance information and hazardous properties

The identity of the substance and physical/chemical properties

2. Uses being covered by DU CSR

CAS number	11111-11-1
CAS name	ECHA Substance
IUPAC name	ECHA Substance
Molecular formula	CxHyOz
Molecular weight range	ca. 300
Vapour pressure	10 Pa
Description	Monoconstituent substnace
Physical state at 20o C and 1013 hPa	Liquid

Worker exposure during dipping process in Plants 3 & 4.

This use was described in the supplied exposure scenario ES2: General industrial use of coatings and inks, Contributing Scenario 9: "control of worker exposure: dipping, immersion and pouring" [PROC 13][23].

! See Appendix 2 for the supplier ES for this example. This would normally be attached to the DU CSR.

23 ECHA Publication "An illustrative example of the exposure scenarios to be annexed to the safety data sheet".

The conditions of use differ from those on our site. The received contributing scenario specifies local exhaust ventilation (LEV). We do not use LEV but we have good general ventilation with an air change rate of 3ach-1, as verified by weekly monitoring of ventilation system in accordance with our Standard Operating Procedure 1234, and ventilation of the drying oven. Also the work duration per shift never exceeds 4 hours.

3. Classification

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H412: Harmful to aquatic life with long lasting effects.

4. Human health hazard assessment

Control parameters/DNEL values (workers)

Inhalation, long-term systemic: 25 mg/m^3
Dermal, long-term systemic: 7 mg/kg bw/day

5. Exposure assessment

5.1 Plants 3 & 4 / Worker exposure scenario – dipping line

5.1.1 Exposure scenario

See example 5 of this DU CSR, for DU CSR based on modelled data, and an exposure scenario based on the modelling tool.

Table A2 - exposure scenario ***(for example, based on measured data. Note that this is for DU's own use and will not be communicated downstream and is described in DU's own words, rather than standard phrases).***

Plants 3 & 4 Worker exposure scenario - dipping line
Product characteristics
The dipping solution in Tank 3 contains ECHA substance at a concentration of 3 - 4%
Frequency and duration of exposure
The shift duration is 8 hours and workers may perform this task throughout half the shift
Technical and organisational conditions and measures
The dipping is undertaken on Lines 1 and 3 in accordance with Standard Operating Procedure 12345. The work pieces to be dipped are loaded onto racks by hand and lifted into the surface treatment line (at room temperature) using an overhead crane. The rack is lowered and raised remotely into the tank. The rack is moved automatically into a ventilated drying oven and then left to stand overnight. The work pieces are unloaded when fully dry. There is no dermal contact with the substance in solution under normal operating conditions. There is no LEV on the dipping line but the air change rate in the production area is about 3 ach^{-1}
Conditions and measures related to personal protection, hygiene and health evaluation
The operators wear Tyvek suits. Nitrile gloves and eye protection are available if any unintended contact is likely. Good housekeeping practices are implemented. There is regular inspection of workers' skin as part of a site-wide health monitoring programme.

5.1.2 Exposure estimation

The measured data is summarised in Table A.3. The measured data is considered to be sufficient and reliable. The data is from the dipping lines being assessed and the conditions of use have not changed since measurements were taken. The measurement duration ranged from 150 to 220 minutes and represents the concentration in the worker breathing zone during routine operating conditions. The exposure was determined as an 8 hour time weighted average (TWA) based on a shift exposure duration of 240 minutes.

Table A3- example of measurement data

Year	Report ref.	No. of personal samples	Mean 8 hour TWA mg/m^3	Geometric standard deviation	90th percentile 8 hour TWA mg/m^3
2012	A-12345	9	0.27	2.0	0.56
2013	B-12345	7	0.20	1.9	0.41
2014	C-12345	9	0.18	2.7	0.45
	Overall	**25**	**0.22**	**2.3**	**0.49**

6. Risk characterisation

The mean 90th percentile 8 hour TWA is 0.49 mg/m3, giving an RCR of 0.02 (0.49/25) [24]. This is well below 1 and the risk is considered to be controlled with respect to long-term inhalation exposure to ECHA substance.

Adverse irritancy effects are controlled by substance concentration (< 10 %) in the product. The mixture is not classified for skin or eye irritation and no local effects are expected. Furthermore, the potential for dermal and eye contact is minimal due to automated transfer between dipping baths and forced air drying of parts before contact (enclosed system with LEV). All other ingredients in the mixture are non hazardous and so the combined risk to the mixture is also considered to be controlled. Personal protective equipment is provided for non routine intervention.

******END of Example 4 (own exposure scenario approach with measured data)*******

24 The 90th percentile is recommended in Guidance R.14, for most situations. The RCR is the ratio of the exposure estimate to the DNEL(or PNEC)

Example 5: Part B - Approach C with modelled data

Approach C:	Own exposure scenario
Exposure estimation:	Modelled data, using Ecetoc TRA v3.
Situation:	You coat articles by a dipping process. The exposure scenarios you receive do not refer to coating at all. You do not have measured data available, and use modelled data.

You coat articles by a dipping process. The exposure scenarios you receive do not refer to coating at all. You do not have measured data available, and use modelled data.

PART B

Sections 1 to 4: These are the same as shown in Example 4

5. Exposure assessment

5.1 General industrial use of coatings and inks: "control of worker exposure: dipping, immersion and pouring" [PROC 13]

5.1.1 Exposure scenario and exposure estimation

This DU CSR is based on exposure estimation for PROC 13 using Ecetoc TRA v.3. The contributing scenario information is shown in table A.4. The exposure estimate is shown in table A.5.

6. Risk characterisation

The risk characterisation is shown in Table A.5. The quantitative assessment shows that the combined RCR for systemic effects is below 1. Adverse irritancy effects are controlled by substance concentration (< 10 %) in the product, and no local effects are expected. Nevertheless, personal protective equipment is available for non routine intervention when there is potential for direct contact (Tyvek suit, nitrile gloves and chemically resistant face shield).

All other ingredients in the mixture are non hazardous and so the combined risk to the mixture is also considered to be controlled.

Table A.4: Contributing scenario/Conditions of use

Scenario name	Process Category (PROC)	Type of setting	Is substance a solid?	VP or volatiles (Pa) at process temperature	Duration of activity [hours/day]	Use of ventilation?	Use of respiratory protection?	Substance in preparation?	Dermal PPE/Gloves
dipping	PROC 13	industrial	No	10	1 - 4 hours	Indoors with good general ventilation	No	1 - 5%	No

Table A.5: Exposure estimates and risk characterisation ratios

Scenario name	Long-term inhalative Exposure Estimate (ppm)	Long-term inhalative Exposure Estimate (mg/m^3)	Long-term Dermal Exposure Estimate (mg/kg/day))	Short-term Inhalative Exposure Estimate (mg/m^3)	Local Dermal Exposure Estimate ($\mu g/cm^2$)	Risk Characterisation Ratio - Long-term Inhalation	Risk Characterisation Ratio - Long-term Dermal	Risk Characterisation Ratio - Long-term Total Exposure
dipping	0.84	10.5	2.4	70	400	0.42	0.39	0.81

******END of Example 5 (own exposure scenario approach with modelled data)*******

These tables are copied from Ecetoc TRA v3 with minor amendments for clarity.

Appendix 2: Contributing scenario example

The contributing scenario that provides the basis for example 3 in Appendix 1 is presented here, together with the corresponding exposure estimate and risk characterisation[25]. The contributing scenario received from the supplier describes the use (dipping, PROC 13) and specifies LEV, for full shift operation.

2.2.9 Control of worker exposure: Dipping, immersion and pouring (PROC 13)

Product (article) characteristics
Limit the substance content in the product to 5%.
Amount used (or containted in articles), frequency and duration of use/exposure
Covers daily exposures up to 8 hours.
Technical and organisation conditions and measures
Provide a basic standard of general ventilation (1 to 3 air changes per hour).
Local exhaust ventilation - efficiency of at least 90.0%
Other conditions affecting workers exposure
Indoor use
Assumes process temperature up to 40.0 °C
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply.
Use suitable eye protection. Personal measures have to be applied in case of potential exposure only.
Wear suitable gloves tested to EN374. Personal measures have to be applied in case of potential exposure only.

2.3.9 Worker exposure: Dipping, immersion and pouring (PROC 13)

Route of exposure and type of effects	**Exposure estimate**	**RCR**
Inhalation, systemic, long-term	2.5 mg/m^3 (TRA Worker 3.0)	0.101
Dermal, systemic, long-term	2.742 mg/kg bw/day (TRA Worker 3.0)	0.392
Combined routes, systemic, long-term		0.493

25 Taken from ES2; contributing scenario 9 in "illustrative example of exposure scenarios"

Appendix 3: Specifying risk management measures

A crucial aspect of a DU CSR is to establish the risk management measures (RMMs) to ensure that the risk is controlled. When the DU CSR is prepared for a customer site, clear communication of appropriate RMMs is vital. Some pointers on describing the risk management measures are provided here:

- Specify the release estimation/efficiency that the assessment is based on, or details of the conditions on site.

- When using SPERCs or literature sources such as an OECD Emission Scenario Document, include all the relevant supporting information.

- When an RMM is required in the workplace, engineering controls such as process design measures to prevent or reduce personal exposure, including containment and LEV, should be considered before personal protective measures, in accordance with European health and safety legislation and good occupational hygiene practice.

- When PPE is required, be as detailed as possible on what is adequate and suitable. For example, where possible, specify the filter type necessary in respiratory protective equipment (RPE), the material for gloves and the relevant protective clothing, with reference to European Standards. Also indicate the degree of management and training required to make sure the implemented PPE provides the required level of effectiveness.

- Typical conditions of use are available on industry sector websites and are implemented in some software (e.g. ECETOC TRA version 3.1) and further development is continuing. These are described in documents termed SWEDs, SCEDs and SPERCs (for workers, consumers and the environment respectively). See the glossary for definitions.

Appendix 4: Glossary

Binding occupational exposure limit value (BOELV)
BOELVs, which are binding values established at EU level, take account of socio-economic and technical feasibility factors as well as the factors considered when establishing IOELVs.

Competent person
A competent person is described in REACH Annex I as someone who has "appropriate experience and received appropriate training, including refresher training". What is "appropriate" will depend on the complexity of the situation but should enable them to identify the hazards, evaluate the risks and recommend appropriate control measures. The term "competent person" may also be defined in national legislation or guidance.

Conditions of use
Conditions of use include the operational conditions (OCs) and risk management measures (RMMs)

Contributing scenario
A contributing scenario is the set of conditions of use (OCs and RMMs) for a particular task or activity within a "use", that relates to the exposure of a specific risk receptor (environment or human).

Chemical safety assessment (CSA)
A chemical safety assessment has to be performed by registrants for substances manufactured or imported in quantities starting at 10 tonnes per year. A downstream user may choose to perform a downstream user CSA if their uses are not addressed by their supplier.

The CSA is the process that identifies and describes the conditions under which the manufacturing and use of a substance is considered to be safe. It has three major steps: hazard assessment, exposure assessment and risk characterisation. The process needs to be documented adequately and the results have to be documented in a chemical safety report (CSR), which is to be submitted to the European Chemicals Agency as part of the respective registration dossier. The purpose is to make sure that the risks related to the substance are controlled.

Chemical safety report (CSR)
The chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process, and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction.

Derived minimal effect level (DMEL)
A reference risk level which should be used to better target risk management measures for substances for which no DNEL can be derived, such as nonthreshold mutagens/carcinogens.

Derived no effect level (DNEL)
Levels of exposure to a substance above which humans should not be exposed. Manufacturers and importers of chemical substances are required to calculate DNELs as part of their chemical safety assessment (CSA) for any substance used in quantities of 10 tonnes or more per year. The DNEL is communicated to recipients in an extended safety data sheet.

Downstream user (DU)
Any natural or legal person within the EU (other than manufacturers or importers) who uses a substance,

either on its own or in a mixture, in their industrial or professional activities. Examples include processors, formulators and packagers. Distributors and con-sumers are not considered downstream users

Downstream user chemical safety assessment (DU CSA)
A downstream user chemical safety assessment establishes the conditions of safe use for a substance, for the downstream users' own use or the use(s) of their customers, when this information is not provided by the supplier. Downstream users can apply the hazard conclusions provided by the suppliers when performing the DU CSA for their own uses.

Downstream user chemical safety report (DU CSR)
The downstream user chemical safety report documents the chemical safety assessment undertaken by the downstream user.

ECHA
The European Chemicals Agency is an agency of the European Union which manages the technical, scientific and administrative aspects of REACH, CLP, the Biocidal Products Regulation and PIC.

Exposure scenario (ES)
An exposure scenario is a set of information describing the conditions during manufacturing or use of a substance that may give rise to exposure to humans and/or to the environment. A final ES describes the conditions under which the risk is considered adequately controlled.

Identified use
A use of a substance on its own or in a mixture, or a use of a mixture that is intended by actors in the supply chain, including their own use, or that is made known to them in writing by an immediate downstream user. Where an exposure assessment and a risk characterisation is required, the identified use is a use that had been assessed by the registrant or downstream user and which is covered in the exposure scenarios attached to the SDS.

Indicative occupational exposure limit value (IOELV)
These community IOELVs are health-based, non-binding values, derived from the most recent scientific data available at the moment of their adoption. They set threshold levels of exposure below which, in general, no detrimental effects are expected for any given substance after short term or daily exposure over a working life time.

Operational conditions (OC)
The operational conditions are the set of information on the conditions under which a substance is used. They describe the types of activities 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.

Persistent, bio-accumulative and toxic (PBT)
Persistent, bio-accumulative and toxic substances (PBTs) are chemicals that do not easily degrade in the environment. PBTs typically accumulate in fatty tissues and are metabolised slowly, often increasing in concentration within the food chain. Certain PBTs have been linked to adverse health effects in both humans and animals.

Predicted no effect concentration (PNEC)
Concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur.

REACH
REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorisation and Restriction of chemical substances. The law entered into force on 1 June 2007.

The purpose of REACH is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances. At the same time, REACH aims to promote the free circulation of substances on the internal market while enhancing competitiveness and innovation.

Risk characterisation ratio (RCR)
The risk characterisation ratio is the ratio of the predicted or calculated exposure to the predicted no-effect concentrations (PNECs) or derived no-effect levels (DNELs), for environmental and human exposure respectively. When the RCR is less than 1, the risk is considered to be controlled for the conditions of use for which the exposure was determined.

Risk management measures (RMMs)
The term risk management measure (RMM) means an activity or device that reduces or avoids the direct and indirect exposure of humans (including workers and consumers) and the different environment compartments to a substance during its use. Risk management measures applied in industrial uses include local exhaust ventilation (LEV), waste gas incinerators or on-site and municipal waste water treatment and personal protective equipment (PPE).

Safe use of mixtures information (SUMI)
Downstream user sector organisations are developing generic safe use of mixtures information (SUMI) sheets. SUMIs describe the conditions of safe use for a given use of a mixture in a readily understandable way that is sector specific.

Sector specific worker exposure description (SWED)
SWEDs document typical conditions of use for a given activity/process in a given sector. The content of the SWED can be communicated to the end-user using the associated SUMI (a harmonised form for safe use of mixtures information in a language easily understandable by the end-user and which is attached to the SDS).

Specific consumer exposure determinant (SCED)
SCEDs document the typical conditions of use (such as habits and practices of consumers and assumptions on the product design) related to substances in consumer products.

Specific environmental release category (SPERC)
SPERCs document the typical conditions of use and emission factors for a given activity/process from the environmental perspective.

Use
Use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, and production of an article or any other utilisation. In general, a use is any activity carried out with a substance as such or in a mixture.

Use descriptor system
Set of five descriptors which can be used to briefly describe identified uses in a standardised way and to build the short title of an exposure scenario. The descriptors are designed to harmonise and facilitate how uses are described in the supply chain. The five descriptors are:

- Sectors of use (SU);
- Chemical product category (PC);
- Process category (PROC);
- Environmental release category (ERC); and
- Article category (AC).

UVCB
Substance of unknown or variable composition, complex reaction products or biological materials.

Very persistent very bio-accumulative (vPvB)
These are substances which are very persistent (very difficult to break down) and very bioaccumulative in living organisms. As a result they can build up in the food chain to levels which are harmful to humans and the environment.

Appendix 5: Useful references and links

DOCUMENTS

- ECHA "Guidance for downstream users"
  http://echa.europa.eu/documents/10162/13634/du_en.pdf
- e-Guide 01 "SDS and ES - advice for recipients"
  http://view.pagetiger.com/ECHAeGuide1-1/Issue1
- Practical guide 13 "how downstream users can handle exposure scenarios"
  http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf
- Practical Guide 14: How to prepare toxicological summaries in IUCLID and how to derive DNELs
  http://www.echa.europa.eu/documents/10162/13655/pg_14_on_hazard_endpoint_en.pdf
- Practical Guide 15: How to undertake a qualitative human health assessment and document it in a chemical safety report
  http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf
- ECHA Guidance on information requirements and chemical safety assessment (IR&CSA)
  http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
- DUCC "Report on experience gained with performing a Downstream User Chemical Safety Assessment (DU CSA) and developing a Downstream User Chemical Safety Report (DU CSR)"
  http://ducc.eu/documents/DUCC Orientation DU CSA v1 June 2012.pdf

ECHA WEBSITE

- Downstream user pages:
  http://echa.europa.eu/regulations/reach/downstream-users
- ECHA-term:
  http://echa-term.echa.europa.eu/
- Reporting to ECHA:
  http://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-report
- Guidance documents:
  http://echa.europa.eu/support/guidance
- REACH legislation:
  http://echa.europa.eu/regulations/reach/legislation
- National and ECHA Helpdesks;
  http://echa.europa.eu/support/helpdesks

- ECHA's accredited stakeholder organisations:
  http://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations

Websites of other organisations:

- Downstream Users of Chemicals Coordination Groups
  http://www.ducc.eu

- European Agency for Safety and Health at Work:
  https://osha.europa.eu/en

- Exposure Estimation Tool owners: See Table 4

- OECD eChemPortal:
  http://www.echemportal.org

- Gestis database:
  http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Stoffdatenbank

- Cefic:
  http://www.cefic.org/Industry-support/Implementing-reach/

- Cefic/Concawe/DUCC/FECC Guidance on how to check ES - Messages to communicate in the supply chain on extended SDS for substances II:
  http://www.cefic.org/Documents/IndustrySupport/CeficcommunicationonextSDS_130711.pdf

- BAuA, the German Federal Institute for Occupational Safety and Health:
  http://www.baua.de/EMKG

- HSE Health and Safety Executive:
  http://www.coshh-essentials.org.uk

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