ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

Downstream users

The document aims to explain in simple terms the obligations which downsteam users have to fulfil to comply with the REACH Regulation

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This document contains guidance on REACH and provides useful key elements to facilitate compliance with specific requirements under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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Table of Contents

1. Introduction

This Guidance in a Nutshell provides a concise and simple introduction to the obligations which the downstream users have to comply with according to the Regulation (EC) No 1907/2006 (the REACH Regulation). It explains in brief how to identify the downstream user's roles and illustrates the different circumstances that a downstream user may encounter. The different obligations and possible actions which a downstream user can choose to take according to the situation are also briefly presented. Furthermore, principles and requirements which suppliers of mixtures have to fulfil to comply with the obligation of providing relevant information to their customers are outlined.

This Guidance in a Nutshell is mainly aimed at managers and environmental health and safety (EHS) professionals of companies using chemical substances in the European Economic Area[1] (EEA). These companies are likely to be in a range of sectors and can be micro, small, medium (SME) or large. It will allow them to understand the downstream user's role and what is required by a downstream user under REACH. Eventually they will decide whether they need to read the full *Guidance for downstream users*.

This document will be useful also to manufacturers, importers and distributors. Although they are not downstream users, they will benefit from a correct understanding of the needs and obligations of their own customers and a consequent improvement in communication in the supply chain.

Companies located outside of the EEA whose products are exported to the EEA may use this Guidance in a Nutshell to understand the obligations the companies in the EEA have to fulfil.

[1] The European Economic Area is composed of Iceland, Liechtenstein, Norway and the 28 European union Member States.

2. Essential to understand

2.1 The downstream user's role

Downstream user is a specific role under REACH. Downstream users are companies or individuals who use a chemical substance, either on its own or in a mixture, in the course of their industrial or professional activities. The term "use" has a very broad meaning in REACH as it includes almost any activity carried out with a substance as such or in mixture (e.g. processing, formulation, storage, treatment).

Downstream users have a key role to play in advancing the safe use of chemicals by implementing safe use at their own site and by communicating relevant information on their use and their products both to their suppliers and customers.

The specific obligations of downstream users vary, depending on the type of activity carried out and the position in the supply chain. These activities include:

- formulators of mixtures
- industrial end-user of substances as such or in mixtures
- professional end-user of sbstances as such or in mixtures
- article producers
- re-fillers.

A company that has a downstream user role may also have other roles under REACH, such as a manufacturer, importer or distributor role. For example, manufacturers and importers have the obligation to register the substances they manufacture/import. Role and obligations depend on the exact activity carried out in relation to each specific substance used, either on its own, in a mixture or in an article.

If a company performs activities which are limited to storing and placing on the market a substance, on its own or in a mixture, for third parties, it has the role of a distributor. This is other than a downstream user role. A distributor's obligations are limited to forwarding information in the supply chain. These are described in Appendix 1 of the *Guidance for downstream users*.

The following actors are not downstream users according to the definition of REACH. However, subject to certain conditions, they have the rights and obligations of a downstream user:

- importers of substances where supplier has nominated an only representative
- re-importers of substances.

2.2 REACH processes and downstream users' activities

The REACH Regulation entered into force on 1 June 2007. It aims to ensure a high level of protection of human health and the environment, promote alternative methods for the assessment of the hazards of the substances and the free circulation of substances on the internal market while enhancing competitiveness and innovation. In order to reach its goals the regulation requires an active involvement, at different level, of all the actors in the supply chain.

Downstream users should be aware of the impact that each of the REACH processes may have on their activities and consider how they could collaborate for the best functioning of the whole system.

A. **Registration** is the main requirement of REACH and it means that for any substance manufactured or imported in quantities equal or above 1 t/y a defined set of information has to be provided to ECHA by the manufacturer or importer in the form of a registration dossier. If the quantity manufactured or imported reaches or exceeds 10 t/y also a chemical safety assessment is required to assess the hazards resulting from the intrinsic properties of the substance. If the substance fulfills certain hazard criteria the chemical safety assessment includes also an assessment of the exposure to demonstrate that the risk stemming from the exposure can be controlled with a set of operational conditions and risk management measures designed for the supported uses. The chemical safety assessment is documented in a Chemical Safety Report (CSR) by the registrant.

Downstream users should communicate their uses to the registrants and, in return, for hazardous substances will typically receive information on the safe use of the substance via the safety data sheet which may include exposure scenario information (see chapter 2.3 of this Guidance in a Nutshell).

B. **Evaluation** is undertaken by the authorities on a certain number of substances and dossiers. Even if downstream users are not directly affected by these processes, a dossier evaluation may result in a change of the registrant's assessment and consequently in the uses supported or in the reccomendations received from the supplier.

Furthermore a substance may be eventually identified as Substance of Very High Concern (SVHC) and placed on the Candidate List, triggering obligations for downstream users, in particular communcation obligations. This is briefly mentioned in chapter 3 of this guidance and explained in detail in the parent *Guidance for downstream users*.

C. When a SVHC included in the Candidate List is subsequently placed in Annex XIV of REACH, it will be subject to **authorisation**. A downstream user may use such a substance only if he complies with the conditions specified in the authorisation granted to an actor up his supply chain or if he applies for an authorisation himself (an application can also be submitted by different actors together). To be noted that the REACH Regulation provides for exemptions from the authorisation requirements for uses of substances placed in Annex XIV under certain conditions (more information is provided in chapter 8 of the parent *Guidance for downstream users*).

D. Finally, **restrictions** may limit or ban the manufacture, placing on the market or use of a substance in order to protect human health and environment from unacceptable risks. This substance can be used by a downstream user only if the use is not one of the restricted uses. Chapter 8 of the parent *Guidance for downstream users* provides the details which are relevant for downstream users.

2.3 Exposure scenario and identified uses

Once the registrants have concluded their chemical safety assessment, they use the CSR as a basis for the generation of **exposure scenarios**. Exposure scenarios are annexed to the safety data sheet of substances that have been registered and assessed.

Exposure scenarios are one of the main innovations of the REACH Regulation, and aim to support the safe use of the substances. They describe how people and the environment may be exposed to a substance during manufacture, industrial, professional and consumer use and during the article service life. Most importantly, the exposure scenario describes how the manufacturer or importer recommends that the exposure of humans and the environment to

the substance is controlled in order to ensure its safe use. These are referred to as the **conditions of use.**

The conditions of use include **operational conditions** and **risk management measures**. Operational conditions describe the conditions under which workers and consumers use a substance (e.g. process conditions, characteristics of the surroundings). Risk management measures are measures that limit or prevent exposure of humans and environmental compartments during manufacture or use of a substance (e.g. exhaust ventilation, waste gas incinerator). When properly implemented, operational conditions and risk management measures ensure that the risks from the uses of the substance are controlled.

The exposure scenarios received by a downstream user should cover all his uses and the uses of his customer downstream. These are **"identified uses"** under REACH. Each downstream user has the right to make his uses known to the supplier with the aim to have them assessed and covered by an exposure scenario, if one is required. An exposure scenario can cover one single use or a group of identified uses.

Many of the downstream user obligations are related to exposure scenarios. These are summarised in chapter 5 of this guidance and described in more detail in chapters 4 and 5 of the full *Guidance for downstream users*.

3. Main obligations of downstream users

Depending on the circumstances and sometimes also on the personal choice, the downstream user may need to fulfil one or more obligations or carry out voluntarily one or more actions. This chapter provides a summary of the main activities and timelines relevant for downstream users.

Inform the supplier of a use when the substance is not yet registered

The downstream user needs to make a request twelve months before the registration deadline, and the supplier needs to assess the risk of that use. Downstream users need to provide the supplier with enough information to allow him to include the use(s) in his assessment.

The deadline for the last 2018 registration (for quantities at or above one tonne per year) is 31 May 2017.

This is a voluntary action, based on business considerations.

Inform the supplier of a use not covered in the safety data sheet of registered substance

The suppliers need to comply with their obligations before the next supply. However, if the next supply is within one month of receiving the downstream user request, suppliers have one month to comply. Downstream users need to provide the supplier with enough information to allow him to include the use(s) in his assessment.

This is an optional action, based on the downstream user review of the safety data sheet.

Take appropriate actions when a safety data sheet is received

When downstream users receive a safety data sheet, they need to identify and apply appropriate measures to adequately control the risks at their site.

When downstream users receive a safety data sheet with information on operational conditions and risk management measures from exposure scenarios, they must check whether these

cover the use of the substance and the conditions of use.

If the conditions on-site correspond with the exposure scenario information received, then no further action is required, except to document the compliance. If this is not the case, downstream users have to take actions, as described in chapter 5 of this Guidance in a Nutshell.

These actions should be completed within twelve months of receipt of the safety data sheet for a registered substance.

Downstream users have also to comply with the conditions of any restriction or authorisation which may apply to that substance and which are normally indicated in the safety data sheet.

Communicate information to suppliers

Downstream users need to inform suppliers if the suggested risk management measures are inappropriate and whenever new information on hazards becomes available. This should be undertaken without delay.

Downstream users are advised to communicate with their supplier if they are using a substance included in the Authorisation List. A downstream user may apply for an authorisation or have their use included in an authorisation applied for by a supplier or manufacturer.

Communicate information regarding safe use to own customers

Downstream users who supply hazardous substances or mixtures to other downstream users or distributors have to provide a safety data sheet. However, this does not apply if the substances or mixtures are sold to the general public and sufficient information on necessary measures is provided, unless a safety data sheet is requested by a downstream user or distributor.

A safety data sheet should be provided if requested by downstream users or distributors for certain mixtures which are not classified as hazardous but which contain hazardous substances above specified concentrations.

Downstream users need to update the safety data sheet if new information on risk management measures or hazards becomes available, an authorisation has been granted or refused, or a restriction has been imposed. This has to be done without delay.

Downstream users who supply articles to downstream users or distributors have to provide sufficient information to allow safe use of the article if the article contains a substance that is on the candidate list and is present in a concentration ≥ 0.1% (w/w) in the article. This information should be provided to consumers on request.

Preparing a downstream user chemical safety report

A downstream user may need to prepare a downstream user chemical safety report. This is one of the possible actions to undertake when a downstream user's use is not covered by the exposure scenario (more information in chapter 5 of this Guidance in a Nutshell). This action has to be undertaken within twelve months of receipt of the safety data sheet for a registered substance.

Downstream user report to ECHA

Downstream users are required to submit certain information to ECHA in the form of a report in specific cases.

This requirement applies when:

- they need to prepare a DU CSR because their use is not supported;
- their use is not supported and they are exempted from preparing a DU CSR under certain circumstances;
- they have a different classification of a substance to that of all of their suppliers.

4. Communication along the supply chain

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

When the registrant has to conduct a chemical safety assessment for the substances he intends to register, he first needs to compile information on hazardous properties and uses of the substance. This compilation covers all the uses of the substance through its life cycle, (both as such and in a mixture), including the use of articles containing the substance and the waste stage.

This means that the registrant needs to understand how the substance is used further down the supply chain. The information he receives on uses from downstream users is crucial, as the registrant himself may have limited knowledge on the use of the substance.

4.1 Making a downstream user's use known to the supplier

There are specific mechanisms foreseen under REACH to bring together the knowledge on the substance properties from registrants with knowledge on the substance uses from downstream users [2]. Downstream users have the right to make their uses known to the supplier in order to have them identified, assessed and covered in the registration dossier for a substance. This is particularly relevant for substances for which a chemical safety assessment is required. The downstream user will have to comply with the conditions identified in the chemical safety report and communicated via the safety data sheet. It is therefore in the downstream user's interest to communcate in a timely and effective manner with the supplier. This communication may occur before the substance is registered or after the registration has been made in case a particular use is not covered by the exposure scenarios received.

It is important to underline that to communicate the uses upstream is not an obligation. Downstream users may have their reasons for not making their uses known to others (e.g. business or confidentiality reasons). However, in case he decides not to make his use known upstream, further actions need to be undertaken, e.g. the downstream user needs to stop using the sustance or carry out a downstream user chemical safety assessment.

Effective communication on the safe use of the substance relies on an unambiguous

[2] Downstream users can even request to become a member of the Substance Exchange Information Forum (SIEF) for a specific substance with the intention to share relevant data which they may own. Companies that intend to register the same phase-in substance will join a Substance Information Exchange Forum (SIEF) to share data on the intrinsic properties of the substance, avoid the duplication of studies (in particular, they have the obligation to share all test data on vertebrate animals) and eventually come to the preparation of one joint submission for each substance. For more information on the data sharing processes and possible involvement of downstream users, please consult the *Guidance on data sharing* available at echa.europa.eu/guidance-documents/guidance-on-reach.

description of the use and the conditions of use. Collective communication via sector organisations has been found to be an efficient way of handling the flow of communication on uses, where such sectors exist. Harmonised approaches with generic, sector-specific descriptions have been developed within many sectors. Registrants typically base their chemical safety assessments on these sector specific descriptions of use.

Downstream users are advised to contact their sector organisation to check if such standard descriptions of use exist and to confirm that they cover their uses.

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

A downstream user who is communicating directly with his supplier or his customers on uses, is advised to use the publicly available templates or supplier questionnaires developed for this purpose.

Chapter 3 of the full *Guidance for downstream users* provides more support for companies who need to communicate information on uses to the supplier.

4.2 Supplier's response to information on a customer's uses

A supplier who deals with communication from a downstream user may also be a downstream user, a distributor or a manufacturer/importer who has registered the substance. If the supplier is a downstream user, (such as a formulator who supplies mixtures further downstream), he can choose whether to forward the information to his own supplier or deal with it directly himself. If the supplier is a distributor, he should forward the information to his own supplier without delay.

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

- The supplier can assess the use and update or prepare a chemical safety assessment as applicable. If appropriate, the supplier then provides the resulting exposure scenario to the customer.
- The supplier can conclude that he is unable to include the use as an identified use because it is not safe for human health or the environment. In this case, this becomes a use he advises against. The supplier must provide the user and ECHA with the reason(s) for that decision in writing without delay.

If the use remains unsupported by the supplier's asessment, the downstream user has to decide which action to take if he wants to continue his use(s).

5. Downstream users and information received from the supplier

A downstream user is required to identify and apply the appropriate measures to control risks. These measures are normally communicated via the safety data sheet. It is to be noted that downstream users can expect different types of communication from their suppliers depending on the hazardousness of the substance and on the quantity manufactured/imported by the registrant up in their supply chain.

When a downstream user receives information from exposure scenarios, he should check if the

use and foreseeable uses of their products and conditions of use are covered in it. In order to verify this, the downstream user has to gather and assess information on how the substance is used in his own company and, if necessary, how it is used by his customers. This needs to be compared with the information included in the exposure sceanarios. This process is explained in more details in chapter 4 of the full *Guidance for downstream users*. Additional useful information is provided in the Practical Guide "How downstream users can handle exposure scenarios"[3].

The outcome of such a check may result in the following situations:

1. Use, operational conditions and risk management measures correspond to those specified in the exposure scenario. If so, no further action under REACH is needed.
2. Use, operational conditions and risk management measures do not exactly correspond to the exposure scenario, but adjustments may be applied to balance the differences and maintain, as a minimum, an equivalent level of exposure (also referred to as scaling). If so, no further action under REACH is needed.
3. Use and/or conditions of use are not covered by the exposure scenario. In this case, the downstream user has multiple options and needs to decide what action to take.

The downstream user needs to document his conclusions and keep them available for enforcement authorities

5.1 Conditions of use are not covered by the exposure scenario

If the downstream user concludes that his use is not covered by the exposure scenario received, he has to decide what action to take. He has several options to choose from..

The following list summarises the key options that are available to a downstream user. More details are provided in chapters 4 and 5 of the full *Guidance for downstream users*.

A. Contact the supplier to make the use known to him with the aim of making it an "identified use" and included in the supplier's chemical safety assessment. Effective ways to communicate with a supplier are described in chapter 4.1 above.

B. Implement the conditions of use described in the exposure scenario received; this may entail changes in the process or the introduction of new risk management measures.

C. Substitute the substance with a different substance for which an exposure scenario is not required or for which an exposure scenario is available which covers DU's conditions of use. Alternatively, substitute the process with a process not requiring the substance.

D. Find another supplier who provides an SDS for the substance or mixture with an exposure scenario attached that covers your use.

E. Prepare a downstream user chemical safety report (DU CSR). A DU CSR documents the conditions of use under which a substance can be used safely for the use(s) not covered in the exposure scenario of the supplier. It should be clear that this downstream user chemical safety assessment is an easier and smaller undertaking than the one performed by the registrant. Chapter 5 of the full *Guidance for downstream users* describes the key steps which should be followed.

Please note that REACH grants some exemptions from the need to prepare a DU CSR even if the use is not covered by the supplier's exposure scenario. Cases where the exemptions apply

include:

- the substance does not require a safety data sheet
- the supplier himself does not need to prepare a chemical safety report
- the total use of the substance or mixture is less than 1 tonne/year
- the substance is diluted below concentrations specified in Article 14(2) of REACH
- the substance is used for product and process orientated research and development (PPORD).

Chapter 4 of the full *Guidance for downstream users* provides the full list of exemptions and relevant explanations.

6. Communication in the supply chain related to mixtures

REACH and CLP contain legal obligations that are relevant to formulators when they are communicating information on mixtures. An overview of when a safety data sheet or other information on a mixture must be forwarded to downstream users and distributors is provided in Figure 1.

When compiling his own safety data sheet, a formulator is obliged to include relevant exposure scenarios, and use other relevant information, from the safety data sheet(s) supplied to him. The objective is to convey information that helps to protect human health and the environment in a way the recipient can easily understand. The main steps are to:

• **Collate the information** received by the formulator from his suppliers

- The formulator may also need to align information received for different substances and from different suppliers so that it is readily accessible for further processing.

• **Identify the information** that is relevant to communicate downstream

- The main objective is to communicate the appropriate conditions of use. This is an evolving area, and the appropriate methodology will depend on the situation. These methodologies are not detailed in the full *Guidance for downstream users* but the main approaches and key considerations are outlined.

• **Communicate the information** effectively

- If the formulator has prepared a chemical safety report for the mixture or its component substances, the relevant exposure scenarios must be annexed to the safety data sheet. Otherwise, the formulator can choose the most appropriate means to include the information. The following options are available:

a. integrate the information into the main body of the SDS; or

b. append safe use information for the mixture; or

c. attach relevant exposure scenarios for the substances in the mixture as an annex.

The process should be as efficient as possible, proportionate to the risk, and relevant and understandable to the recipients.

Further details on the legal obligations and on how information can be communicated are provided in chapter 7 of the full *Guidance for downstream users.*

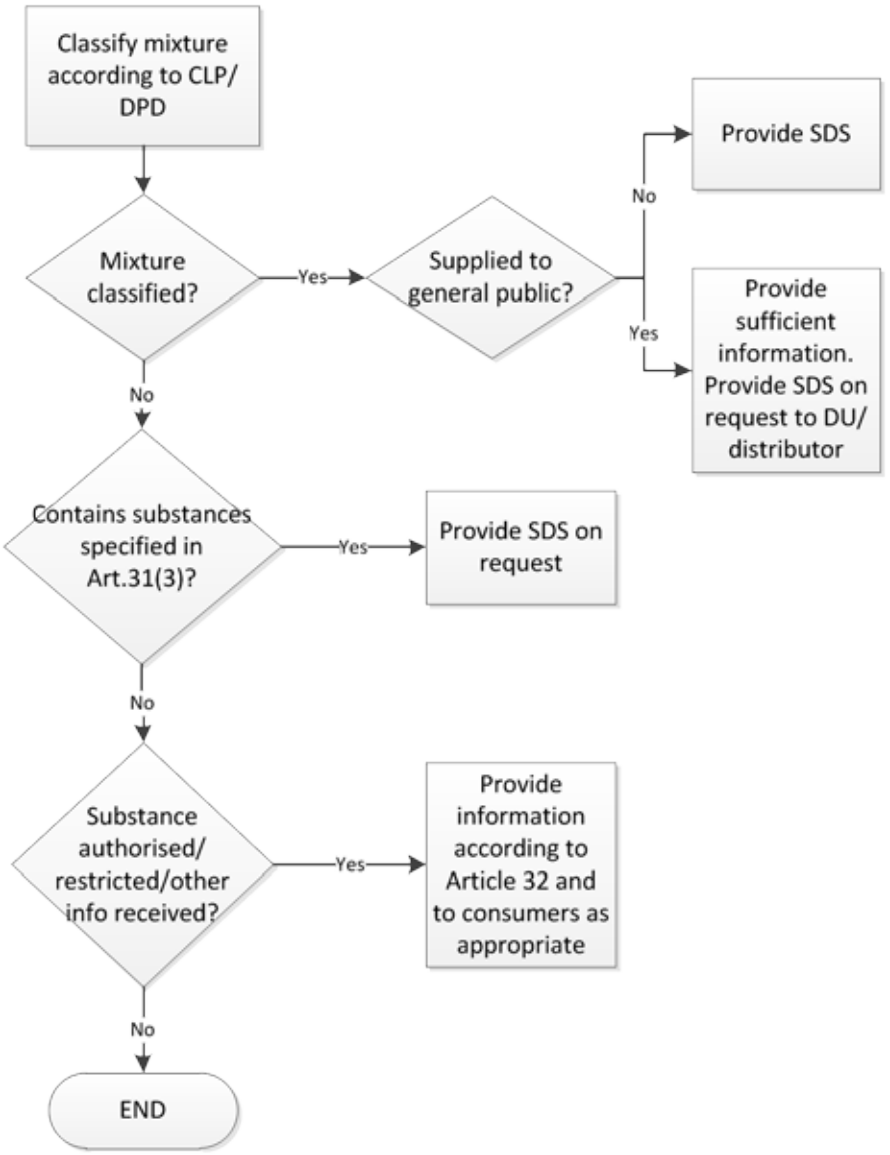

Figure 1 Workflow summarising when a safety data sheet or other information on a mixture must be forwarded to downstream users and distributors. Note that a supplier is not obliged to provide a safety data sheet to consumers.

7. Where to find further guidance and other relevant information

This Guidance in a Nutshell aims to provide a summary and short explanation of the main obligations which the REACH Regulation lays down for downstream users. However it is recommended to consider whether you need to consult the full *Guidance for downstream users* to meet your requirements and possible obligations. Companies which conclude on reading this document that they have a downstream user's role are recommended to consult the full guidance document. This is available at echa.europa.eu/guidance-documents/guidance-on-reach.

The full *Guidance for downstream users* provides more detailed information on the different obligations and options which the downstream user has according to the situation and the information received from the supplier. Additional insight and relevant information may also be gained by consulting in particular the following documents and web pages:

- The "Downstream users" web page on the ECHA website: http://www.echa.europa.eu/regulations/reach/downstream-users;
- Practical Guide 13 *"How downstream users can handle exposure scenarios"*: http://www.echa.europa.eu/practical-guides;
- Questions and answers on DU reports echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/Downstream+users+reports;
- The *Guidance on the compilation of safety data sheets*: echa.europa.eu/guidance-documents/guidance-on-reach;
- The Navigator tool which helps to identify industry's obligations: http://www.echa.europa.eu/support/guidance-on-reach-and-clp-implementation/identify-your-obligations;

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