

Explanatory note on the draft updated Guidance for downstream users¹

Background

In the framework of the further development of the Guidance for downstream users, ECHA has carried out a full revision of the original document (published in January 2008) in order to:

- Delete out-of-date information, information that is no longer relevant for downstream users, inaccuracies in the text and inconsistencies with the current practice.
- Reflect the experience and best practices developed by industry, ECHA and Competent Authorities over the past years with regard to helping downstream users (DUs) to fulfil their obligations. In particular, input from specific bodies (e.g. the ECHA-Stakeholder Exchange Network on Exposure Scenarios, ENES) has been considered and, where solid conclusions have been reached, implemented. In this respect, the main driver for this update was the need to provide more, and up-to-date, guidance on the application of scaling and the communication of information on the safe use of mixtures.
- Streamline the guidance: remove information that is now elaborated in newer and more appropriate practical guides and manuals, and render the structure clearer and more user-friendly for the reader.

Main changes

1. Changes to the structure and the presentation of information

- The structure of the guidance has been changed in order to present the main issues relevant for DUs in a clearer and more linear way. The original format consisting of flowcharts and explanatory notes has been largely dispensed with. The information is now presented in the following way.

0) In general, in each section the legal reference is given at the beginning, when relevant.

1) A general overview of the relevant REACH processes and how they affect the DUs, is given. Stress is put on the communication in the supply chain.

2) Then, the DU roles are described in order for a DU to identify their particular role(s) and the associated legal obligations.

3) Subsequently, the guidance explains how the use(s) of a substance by a DU should be described in a meaningful way and relevant information forwarded upstream in the supply chain in order to have them assessed as an identified use by the registrant.

4) The guidance then explains how a DU should react upon receipt of an exposure scenario (ES): how to check whether a use is covered in the ES received from a supplier and which options are foreseen by the REACH Regulation. The DU can conclude that i) the use is covered or ii) the use is not

¹ Status September 2013

covered. In the latter case different actions can be undertaken. These are described in the same section.

5) One of the options, when the use is not covered by the ES received or is advised against by the registrant, is the preparation of a DU CSR; guidance is provided for those who undertake this action.

6) Next, the obligation that the DU has to communicate upstream any new information (not included in the received extended SDS) on hazards, classification of the substance or the appropriateness of the risk management measures (RMMs) is addressed.

7) The original 2008 guidance on how to collect and forward appropriate information for the safe use of mixtures has been updated taking into account the experience gathered so far and the outcome of the discussion with the PEG and the consultation with the MSC and the Forum.

8) Finally, DU requirements related to authorisation, restriction and substances in articles are explained.

The original chapter addressing the main aspects relevant for distributors has been moved to an Appendix, as they are not downstream user under REACH but the information is considered relevant.

More detail on principles and methodology for scaling are provided in the new Appendix 2.

A list of principles to be applied for selecting information to communicate with mixtures has been developed and placed in a new appendix 3.

2. Changes to the content of specific sections

- How to collect and communicate information on the DUs uses (section 3). Focus has been placed on collective communication via sector organisations, which should be the preferred approach in cases where a sector organisation exists. The guidance nevertheless reflects the fact that direct communication of a description of use to the supplier by an individual downstream user is the only possible realistic way to communicate in some cases.

In the same section the supplier's response on receiving information on customer uses has been addressed, considering feedback in particular from the Forum and MSC. Guidance for the case when a use is not covered is given in subsequent sections.

- DU and ES (section 4). The possible actions that the DU can undertake in terms of checking if his use and/or conditions of use are covered upon the receipt of an ES have been collected within the same section and clearly presented, taking into account practical experience. The application of scaling has been reviewed on the basis of the discussions and experience gathered by industry, ECHA, and Competent Authorities and now combines information from other existing guidance (Part G of Guidance on IR&CSA). The current draft reflects the common conclusions reached so far (such as the definition of scaling, who communicates the scaling options, the responsibility of the supplier in identifying the limits of the scaling parameters and reporting the scaling options). For other aspects where a common understanding has not been reached, ECHA's view has been presented. The major difference in views between ECHA and industry stakeholders apparent from the PEG discussions is related to the possibility for a DU to use scaling to justify conditions of use that differ substantially from those in the exposure scenario supplied to him (e.g. different RMM), and where scaling leads to a higher level of exposure compared to the exposure estimate of the registrant without carrying out a DU CSR.

Details on the methodology have been placed in an appendix to the updated guidance while practical examples have been left out as they will be developed as part of a future update to the ECHA Practical Guide 13 *How downstream users can handle exposure scenarios*.

- DU CSR (section 5). The description of the process for a chemical safety assessment carried out by a DU has been simplified by clearly identifying the key steps and main technical details relevant for DUs. The reader is referred to the relevant chapters of the Guidance on IR&CSA for further details on how to carry out the assessment. Up-to-date information on how the downstream users should report their intention to prepare a DU CSR to ECHA has been included. The text referring to the preparation of DU CSR for a mixture (preparation) has been deleted due to lack of agreement on practical methodology.

- Information requirements for mixtures (section 7). First, a detailed description of the legal requirements is presented. The guidance then describes the main actions to be undertaken by the formulator: receipt and collation of information from the suppliers, identification of the information on the mixture to be communicated downstream, and selection of the best way to communicate such information. The guidance describes two possible approaches for the identification of the information to be communicated downstream which have been discussed and agreed with the PEG ("Exposure scenario approach" and "existing controls approach"). The texts then identify the three options for communicating the information foreseen by the Regulation: integrating ES information into the main body of the SDS for the mixture, appending safe use information for the mixture and annexing relevant ESs for the substances in the mixture. A set of core principles underpinning methodologies that can be used for carrying out an assessment of a mixture has been identified, discussed with PEG and presented in a specific new appendix.

The relationship between this Guidance update and other activities on supply chain communication

This guidance update is taking place at a time when there are parallel activities (on-going or being planned) to develop further and improve the processes related to the communication of information in the supply chain. These include, in particular, the Roadmap towards good quality information on the safe use of chemicals in the REACH chemical safety report and the extended safety data sheet (the CSR/ES Roadmap)² and the activities of the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES)³. The impact of these two activities with regard to the Guidance update process is briefly explained below.

CSR/ES Roadmap

The CSR/ES Roadmap was initiated by ECHA in autumn 2012 as a response to the need to improve the clarity and accuracy of information both in the CSR and the resulting exposure scenarios for communication via the extended SDS. Industry and Member State authorities have been consulted on the drivers for a Roadmap at various forums – e.g. CARACAL, ENES, the Forum – and broad support gained. The Roadmap was drafted by a cross-stakeholder group of Member State authorities, industry organisations and ECHA, and underwent consultation with CARACAL and the Forum. It was published in July 2013.

The Roadmap brings together on-going initiatives by industry sectors and ECHA as well as new ideas to improve the generation and communication of exposure scenario information in the supply chain. Downstream users will be direct beneficiaries of the outputs of the proposed activities and outputs described in the Roadmap mainly in the form of good practice guidelines and IT tools. Such practical tools and advice will complement many of the principles set out in the revised Guidance for downstream users and can be communicated via other vehicles (Practical Guides, illustrative examples, ECHA web site).

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

³ echa.europa.eu/enes

ENES

ENES is an informal cross-stakeholder network that shares good practices and identifies solutions for the smooth implementation of supply chain communication. ENES can act as a “testing ground” for proposals to improve supply chain communications, some of which will be developed via the CSR/ES Roadmap. These outcomes are not considered to contradict the text of the guidance but rather to complement it. The results are expected to lead to the publication of examples in future ECHA Practical Guides, or sector specific instructions from industry organisations.