Use of information from downstream user reports under Article 38 of REACH

1. Introduction

The REACH Regulation requires downstream users (DU) to report specified information to ECHA if any of the following applies:

- their use of a substance is not supported by the chemical safety assessment of the registrant as communicated in the exposure scenario(s) and
  - they choose to prepare their own chemical safety report (CSR)[1] *or*
  - they are exempted from preparing a CSR because they use the substance in low volumes or for product and process oriented research and development (PPORD)
- their classification of a substance is different from the classification provided by all their suppliers in the safety data sheets.

This document describes the downstream user reporting system and explains how the information in the downstream user reports has been used so far. It addresses Action 4.6 of the CSR/ES Roadmap, to increase the understanding of how authorities can use downstream user reports.

2. State-of-play of the downstream user reporting system

Unsupported uses

ECHA set up a submission procedure via REACH-IT in April 2011 to enable downstream users to report that they are preparing a downstream user chemical safety report (DU CSR) or that they are claiming exemptions to preparing a DU CSR[2]. This submission procedure required preparation of a IUCLID dossier and experience quickly showed that this was cumbersome for companies that did not normally use the IUCLID tool. To facilitate reporting, an additional submission mechanism via an on-line web form for these reports was made available in June 2012. Reporting via REACH-IT was also simplified in late 2015 by amending the system's business rules[3].

The downstream user report consists of the information prescribed in Article 38(2) of REACH: identification of the reporting company, relevant contact details, substance identification, and a description of the use(s) of the substance or on the new classification. The type of information gathered is explained in detail in Annex I. When the downstream user has the obligation to prepare a CSR, the

[1] "Not supported" can mean either "outside the conditions described in an exposure scenario" or "use advised against", as detailed in Article 37(4) of REACH.
[2] Reporting according to Article 38(1) of REACH.
[3] Business rules are a set of minimum conditions that a submitted dossier needs to fulfil to be able to enter the processing system of ECHA. Business rules are automatic checks that ensure that the dossier has the minimum information allowing meaningful outcome of the submission.

downstream user chemical safety report itself is not submitted to ECHA but should be made available if requested by the national authorities or ECHA.

It is anticipated that reporting via REACH-IT will be simplified following the introduction of IUCLID 6 and the webform submission mechanism will no longer be required.

Classification Differences
Implementation of the reporting obligation for a different downstream user classification of a substance (Article 38(4) of REACH) was clarified by the commission to be required when the downstream user has a different classification for the substance than all of his suppliers. The submission mechanism for a different classification was then introduced in December 2012.

Reporting of a different classification requires the preparation of a IUCLID dossier (section 2) to provide the classification and labelling information. Therefore the classification difference report can be submitted via REACH-IT only. As only one report has been received to end 2015, reporting of classification differences is not discussed in this document.

3. Reports received by the end of 2015

By 31 December 2015, ECHA had received in total 586 downstream user reports (see table 1). The main reason for submitting a downstream user report is the intention to prepare a DU CSR. Forty seven downstream users claimed exemption due to low tonnage and one reported new classification of a substance. The reports have been submitted by 244 legal entities and they concern 373 individual substances. The majority of companies that submitted a report are large companies, some of whom cover multiple entities across multiple countries.

When the downstream user prefers not to provide the information to suppliers, the reported reasons for preparing a DU CSR are presented in Table 2. For 13% of the DU reports, the downstream user has considered his own use as confidential business information and has deliberately opted to prepare a DU CSR. For 1% of reports, the uses were advised against by the supplier.

Table 1. Reasons for submitting DU report	
Downstream user to prepare chemical safety report	538
We use the substance in less than 1 tonne in total (Article 37(4) (c))	47
We use the substance for product and process oriented research (Article 37(4) (f))	0
We wish to report our own Classification & Labelling which is different to that of our supplier, according to REACH Regulation Article 38(4)	1
Total	586

Table 2. Reasons for not providing information to supplier*	
Confidential Business Information reasons (CBI reasons)	78
Burdens of supply chain communication mechanisms	94
Other reason(s):	26

*Multiple or no reasons can be reported

Reporting trends are also monitored and these shown in Figure 1. The average number of reports per 6 month period varied between approximately 40 and 90 and averaged 60 (or 10 per month).There has been a decline in the use of the IUCLID/REACH-IT option over time.

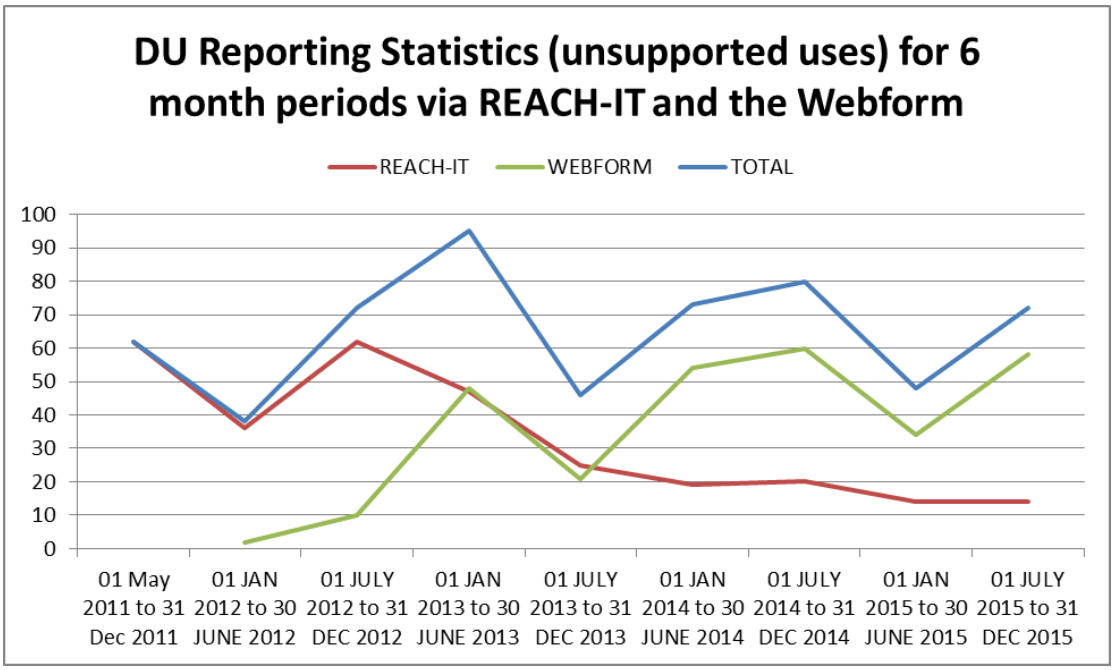

Figure 1. Trends in the usage of the two reporting possibilities for downstream user reporting.

4. Communication of reported information received by ECHA

Published information

Downstream user reports are analysed every six months (first and second half of the year) and an overview is posted on the ECHA website[4]. This biannual report includes the number and country of origin of the reports as well as the main reasons for downstream user reporting for the preceding six months. In addition, the aggregated data from the start of the reporting system, May 2011, is displayed. The more detailed information contained in downstream user reports is not disseminated.

Communication within ECHA

In addition to the public report, an internal memo is prepared that elaborates on items of interest for different REACH and CLP processes. This memo typically includes information on downstream user reports that are related to SVHC, authorised or restricted substances. In addition, if noteworthy usage patterns are observed in the incoming downstream reports, these are described.

Communication with the regulatory stakeholders

The reports submitted via REACH-IT are available to the authorities. MSCA can see the reports submitted by legal entities in their countries, and enforcement

[4] http://echa.europa.eu/regulations/reach/downstream-users/downstream-user-reports/overview-on-downstream-user-reports.

authorities can see an extract of the reported information via RIPE. However, information submitted via the web form cannot be automatically retrieved via REACH-IT or RIPE. Hence web form data is not automatically available to authorities outside ECHA but can be requested.

5. Use of data on unsupported uses by authorities

REACH foresees that the information contained in a downstream user report would be used for enforcement and evaluation purposes.[5]

Information received in downstream user reports complements information on uses and classification that is reported by the registrant in their registration dossier, giving authorities more information on uses and on the supply chain. However, REACH does not include specific provisions on the use of the information gathered via the process. Nevertheless, a number of regulatory purposes have been identified which benefit from the information in downstream user reports and/or DU CSRs.

Identification of the need for further regulatory risk management measures

Downstream user reports indicate that registrants' identified uses and CSR do not reflect all uses and all use conditions of a substance. This information can be used by authorities when identifying substances for further information gathering or when evaluating substances for regulatory risk management. It can complement information received from other sources, such as information in the registration dossier of that substance (IUCLID section 3 and CSR).

Currently the biannual internal memo is shared with ECHA Directorate D (Risk Management) who decides on further actions. Data from DU reports is routinely included in the risk management option analysis (RMOA) of a given substance by Member States.

Identifying issues where further support is needed in the supply chain communication

The biannual report and internal memo of the reasons for and the content of downstream user reports is used to monitor trends in the reports which might trigger further support needs.

When a larger database is available, the information could be used to identify problems in the functioning of the REACH process of communication in the supply chain. This would help to target the support to specific sectors (e.g. tools, examples, practical guides) which ECHA and industry provide in the context of the CSA/ES Roadmap with regard to supply chain communication and updating of the registration dossiers.

Input for report on REACH operations

ECHA produces a report on the operation of REACH every five years according to Article 117(2). Downstream user reports provide an input to this report on the functioning of REACH mechanisms, specifically in relation to supply chain

[5] Recital 60: "For enforcement and evaluation purposes, downstream users of substances should be required to report to the Agency certain basic information if their use is outside the conditions of the exposure scenario detailed in the safety data sheet communicated by the original manufacturer or importer and to keep such reported information up-to-date."

communication.

Identifying potential enforcement actions based on DU reporting

Identifying potential enforcement actions from the number and sources of downstream user reports is challenging, particularly while the number of reports is relatively low. The possible conclusions are not clear-cut. A large number of reports to ECHA can indicate widespread compliance with REACH requirements or conversely, serious shortcomings in supply chain communication. The absence of reports can indicate effective communication in the supply chain or conversely, that downstream users are not aware of their obligations.

Consequently, downstream user reports alone are not routinely used as a reason for compliance inspection by national enforcement authorities at present. The focus is mainly on substances of concern. ECHA forwards information in DU reports for substances on the candidate list/authorisation list/restrictions to the relevant parties for follow-up as appropriate.

Annex I. Detailed description of information gathered via downstream user reports

When a downstream user is obliged to report to ECHA according to Article 38(1), the following information on the unsupported uses is required, according to Article 38(2):

- Identity and contact details of the downstream user
- Registration number(s) of the substance
- Identity of the substance
- Identity of the supplier
- Brief general description of the use(s)
- Brief general description of the conditions of use(s)
- Testing proposal, if considered necessary by the downstream user to complete his CSR

Downstream users have the obligation to update the DU report if any of the above changes (Article 38(3)).

When reporting, downstream users are asked if they intend preparing a DU CSR or rely on the exemptions from preparing a downstream user chemical safety report because of low tonnage, i.e. use of less than 1 tonne/year in total; or because they use it in process and product oriented research and development. They are also asked for background information on the reasons for reporting unsupported uses for the purposes of evaluation and possible resolution of the causes. These are:

1. Particular use(s) are not covered in the exposure scenarios received from the supplier due to:
   - Exposure scenario title(s) is/are inconsistent with downstream user's actual use(s);
   - Downstream user's conditions of use are outside the conditions described in the exposure scenario;
   - Downstream user's use is advised against by the supplier;
   - Other reasons (to be specified in a free-text field).

2. DU prefers not to provide the information on the uses to supplier due to:
   - CBI (confidential business information) reasons;
   - Burdens of supply chain communication mechanisms;
   - Other reasons (to be specified in a free-text field).

The brief general description of the uses and conditions of use is currently provided directly in the web form when using that method or using a template[6], when reporting via REACH-IT. The webform can be seen in a short tutorial available on the ECHA website[7]. It is anticipated that reporting via REACH-IT will be simplified following the introduction of IUCLID 6 and the webform submission mechanism will no longer be required.

[6] Template for describing conditions of use.

[7] Webform tutorial