

Survey on Downstream User Chemical Safety Assessment/Report

Action 4.5. of the CSR/ES Roadmap aims to collect experience and to identify the needs for further support on carrying out a downstream user chemical safety assessment (DU CSA), which will be documented in a downstream user chemical safety report (DU CSR). Ultimately, practical examples of DU CSR will be published.

A working group has been established, consisting of representatives from DUCC, Cefic and ECHA. In the beginning of 2014 the group developed a survey which went on from early February until early March. The main objective of the survey was to collect experience on carrying out a DU CSR and to identify issues where clarity and/or further support is needed. The survey has been addressed to two different audiences: companies who have already performed a DU CSA and companies who have not yet performed a DU CSA. For promoting the survey within the first group, ECHA has used the contacts from companies who have notified to them the intention to perform a DU CSA. For the rest of the companies, industry has done internal communication.

The main findings of the survey are summarised herewith:

General

There was a total of 128 respondents, from which half represented large companies (more than 250 employees). Most respondents have multiple roles under REACH but the majority are formulators.

The survey was addressed to both companies who have performed a DU CSA and companies who have not. Around 25% of the respondents have performed an assessment, mostly in a large company. From those, 39% has prepared a single report; 33% prepared between 2 and 5 reports; 21% prepared between 5 and 10 reports; and, 6% has prepared more than 10 downstream user chemical safety reports.

Extended Safety Data Sheets

Larger companies have received more extended Safety Data Sheets – 30% of respondents have received more than 100 ext-SDS; 30% between 50 and 100; 26% between 20 and 50; and, 2% between 5 and 20 ext-SDS.

When questioned whether it was easy to establish if own or customer use was covered by the exposure scenario received, around half of the respondents does not find it straightforward to evaluate if the use is covered. From the answers and comments received, it can be concluded that the easiness of assessing if the use is covered or not depends on the quality of the exposure scenario, including how it is structured.

Reasons for preparing a DU CSR

The DU CSR was prepared to cover both own use and customer use. In the latter, the companies were mostly formulators and had existing knowledge about the customer use so did not seem to need asking them any information.

The main reasons indicated for the use (own use or customer use) not being covered are due to missing use or missing use descriptor (e.g. PROC, ERC), followed by operational conditions or risk managements measures not covered or not appropriate.

The most frequent situations that lead to a DU CSR are the fact that the supplier is not willing or not able to cover that use and also because the DU is not able or not willing to change the substance or process.

Preparing the DU chemical safety report

In terms of preparation of the DU CSR, small companies seem to rely on consultants whilst the larger companies have a mixed in-house/consultant situation.

About half of respondents have a set procedure in place to prepare DU CSRs but smaller companies usually don't.

The main source of information that has been consulted for instructions on how to prepare a DU CSR is ECHA website. For obtaining substance data, SDS were the main source but ECHA dissemination website has also been checked.

The DU CSR can report one or more kinds of assessment (workers, environment and consumer exposure). From the replies received, the majority of DU CSR has addressed the worker part (79%), although environmental and consumer parts also show high numbers (56% and 48%, respectively).

Estimations of exposure are mainly based on ECETOC TRA but other (higher) tier tools and measured data are also mentioned. In most cases both quantitative and qualitative risk characterisation have been performed.

The report has been generated according to "ECHA CSR style". Company standard format or own (free) format have also been used.

For the format of the exposure scenario, it was typically based on company knowledge of the processes.

Preparing a DU CSR requires a high level of expertise and is associated with technical issues, such as substance data or, if needed, the hazard assessment. Other issues mentioned are the lack of resources/expertise and lack of guidance documents.

The time needed to prepare the DU CSR depends on the complexity. An average of 3 days was needed for low complexity situations and about 8 days were spent for high complexity situations. For moderate complexity situations 5.5 days in average were needed to prepare the DU CSR.

When looking at the different levels of complexity, it can be concluded that around 42% of the reports have been prepared within 5 days.

When looking at difficulty level of the various technical steps of the DU CSR, the main difficult to handle topic was refining the hazard assessment made by the supplier, in cases where needed. All other topics have been considered of equivalent difficulty (understanding the overall process, collecting information on the substance, collecting information on the use, performing the exposure estimation, performing the risk characterisation, creating the exposure scenario and generating the DU CSR). The notification to ECHA did not show any difficulties for the majority of companies.

Companies that have not prepared a DU chemical safety report

For the companies who have not prepared a DU CSR, the main reasons stated were that the uses were covered by supplier and that the supplier agreed to cover the use.

The lack of resources/expertise has also been an issue which was mentioned.

Around 27% of the companies who have replied to the survey intend to prepare a DU CSR in the foreseeable future. The main reasons for that to possibly happen are that the supplier will not be able to/willing to cover the use and the company will not be able/willing to substitute the substance or process. The sources of information that these companies intend to consult are ECHA.

Support for the preparation of a DU chemical safety report

All respondents expressed a need for support/guidance, regardless of company size, REACH role or experience level. The respondents are of the opinion that standard template(s), a practical guide and worked examples would help in preparing a DU CSR.

Concluding remarks

Concerning the **outcome of the survey**, the working group thinks that:

- The answers have confirmed the perception, there were no real surprises
- The feedback from the companies who have performed a DU CSA was satisfactory and their comments very helpful
- The survey showed that issues are wide-ranging and a number of concerns need to be addressed.

The working group wishes to thank the respondents for their time and input.

Next steps

Based on the outcome of the survey, identified issues and needs, a Practical Guide is being prepared by ECHA. The document will be initially discussed within the working group and later a wider consultation will take place. The document shall be published on Q3/2014.

For the identified issues that will not be addressed in the Practical Guide, the working group will draft a plan in Q2-Q3/2014. It is expected that most of the outstanding issues can be resolved by Q2/2015.

Communication activities for disseminating the Practical Guide and related documents are also under scrutiny.

*Document prepared by the Working Group on Action 4.5
28 April 2014*