Pre-reading document

Working session B.4.3

Exemplification of use description

9th Meeting of the Exchange Network on Exposure Scenarios (ENES9)

5-6 November 2015

Background

One of the action areas of the CSR/ES Roadmap is the Action 2.2: Develop and illustrate good practice for description of use. This action is meant to produce a series of illustrative good practice examples on description of uses.

Different projects were undertaken in 2014 and 2015 with the aim to improve the quality of use information communicated in the supply chain and in registration dossiers. Among those are the update of *Chapter R.12* of ECHA's *guidance on information requirements and chemical safety assessment* (on use description) and the development of an updated/improved sector use maps template. These projects are about to be finalised with the deliverables published by the end of the year. During the development phases of these projects, the need for illustrative examples on use description was identified. It is therefore proposed to start working on the preparation of these examples.

The aim of the working session at ENES9 is to agree among stakeholders on a process to prepare these examples as well as what are the main aspects that should be exemplified.

What is expected from the participants and how will the working session be organised

The CSR/ES Roadmap coordination group would like to take the opportunity at ENES9 to explore what additional support downstream users and registrants will find beneficial to ensure that the uses are described in an adequate and consistent manner and how this support could be best provided.

Two aspects will be considered during the session.

1. Content

The updated R.12 guidance addresses a number of points where shortcomings or inconsistencies have been observed. In recent discussions e.g. at the Partner Expert Group (PEG) consultation, it appeared that for some topics further advice or illustrations are needed. ECHA has collected these topics (see Annex I).

Participants to the working session are invited to reflect on the list provided to (i) confirm that it reflects the points that need clarification and (ii) share any other additional need identified by them.

The first part of the session will be dedicated to collecting and discussing the participant's views on this collection of cases in Annex I, including whether real life cases can support one/various topics.

Note that it is fully acknowledged that further needs may arise e.g. when sector associations will develop their improved use maps. The idea of the session is not to define a 'closed' list of issues but to get confirmation on the most common needs at this stage.

2. Format

The question that will be addressed and on which **participants are invited to reflect is 'How could this additional support be best organised'?**

- Which format would best fit the needs? Reproduction of a filled-in IUCLID section 3 (many fields), or would it be better to limit the information presented to what is strictly needed to illustrate the issue? A first idea was tried out for one of the topics listed in Annex I. This example is presented in Annex II. Is the format fit for purpose? How could it be improved?

- Should the deliverable from this work be a practical guide or illustrative examples (addressing the most common needs) or would there be a need for more flexible solutions (e.g. Questions & Answers regularly updated?)

- Is publication on ECHA website the proper way to distribute the deliverable or do you have any other idea?

- The support provided should help the majority of companies/sectors (it cannot therefore be too specific, or focus on individual cases). What other support would be needed, in particular for the sector use maps developers?

Annex I

The main area where the need for further support has been identified is the assignment of PROCs and the Life Cycle Stage (LCS) assignments. At the same time, it was identified that further examples on use names and contributing activity names would be welcome. Support on how to use the IUCLID fields that will be newly introduced in the next release of IUCLID (IUCLID 6.1 foreseen by mid-2016) has also been identified as a need.

The following topics are proposed for the exemplification:

Assignment of uses to the relevant life cycle stage

The use description should cover the whole life-cycle of the substance. Each use described should be assigned to one life-cycle stage (LCS). Experience shows that it is not always easy to decide on the appropriate life -cycle stage. The scope of each life-cycle stage is further described in the updated R.12 guidance[1] but the need for more specific advice/illustration has been identified in the following cases:

- Formulation at manufacturing sites (-> Under which LCS(s) should formulation or end-uses happening at the manufacturing sites be reported?)
- Mixing during end-use (-> Under which LCS should mixing happening at end-use stage be reported? Why is the Formulation LCS not relevant in that case?)
- 'Consumer use' of articles (-> What is the scope of the LCS 'Consumer use' and why should the use of articles by consumers not be reported there in? How should it be reported then?)
- Further processing of articles at industrial sites (-> Under which LCS should the further processing of articles at industrial site be reported, and to which extent is it relevant?)
- Border line cases: 'industrial' versus 'professional' uses, when should uses be reported under the LCS 'use at industrial site' and then under the LCS 'widespread use by professional workers'?

PROCs assignment

- ✓ Differences among PROCs for transfer operations (PROC 8a, 8b or 9): when to use each of these PROCs?
- ✓ Sampling: how to tackle the sampling operations? When to consider them included in the various PROCs? If not included, which PROC to use?
- ✓ PROC 1-3: illustration of cases where equivalence to the closed containment conditions in the chemical industry allows the use of these PROCs

[1] See latest version here: http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach?panel=r12-30

- ✓ PROC 28 maintenance: examples of cases where this needs to be reported/assessed separately and cases where it is not.

ERCs assignment

- ✓ How to deal with mixtures in which substances have different environmental fate (e.g. solvent versus pigment in paints), how to assign the ERCs for the mixture in use maps.
- ✓ Mixing at non-industrial sites (e.g. mixing of fertilisers before application): what is the most appropriate ERC?

Uses with specific regulatory status

- ✓ Illustration of the concept of precursor use: which uses are relevant and how to report them in IUCLID.

Market description for cross-sector uses

- ✓ How to describe uses that take place across many different sectors/markets?

Intermediate use

- ✓ How to report intermediate uses? What level of information is expected to describe an intermediate use? Situations when strictly controlled conditions apply and not apply?

Annex II

Question:

Under which life-cycle stage(s) (LCS) should formulation or end-uses happening at the manufacturing site be reported?

Answer:

The activities by which the registered substance is manufactured from raw materials are to be reported under the LCS ‘manufacture’. Activities which are solely and strictly necessary for the handling of the substance on its own during the manufacturing are considered to be part of the manufacturing stage (e.g. filling into appropriate containers, storage, addition of a stabiliser, dilution to a safer concentration for the purpose of transport).

Where a manufacturer mixes at his own site the manufactured substance with other substances in order to put the mixture obtained on the market, the corresponding activities (mixing, transfer) should be reported under the LCS ‘formulation or re-packing’.

In a similar way, where the manufacturer further process the substance manufactured for end-use (e.g. production of an article), the corresponding activities should be reported under the LCS ‘uses at industrial sites’ even if they happen at the manufacturer’s site.

Where an exposure assessment is needed, one exposure assessment should be created for each use, leading to different Exposure Scenarios.

Example:

The registrant is a solvent manufacturing company that directly mixes the substance manufactured with other substances at the manufacturing plant in order to produce mixtures for vapour degreasing and surface cleaning.

The registrant has measured data from his site (covering all the uses) and wants to make use of these data for his exposure assessment.

The table below shows how the uses should be reported in this case. A simplified format compared to a screenshot of IUCLID section 3, has been used for illustration purposes.

LCS	Use name	Further description of use	Market description (SU / PC / AC)	CA name	CA descriptor	Other information
M	**Manufacture of substance**	Closed process - batch operations (7 t/batch-~ 10 batches/week) - Partly at elevated temperature	n/a	Manufacture of substance - Dry process - closed system - Indoor	ERC1	**Manufacturing site:** *link to the site defined in IUCLID* **Tonnage of substance manufactured (tonnes/year):** 2,500 **Details on tonnage reported:** Registrant own tonnage. Average tonnage per year over the last 3 years (2011-2014). Tonnage produced has been stable over these years. No significant change expected for the next 3 years based on current business previsions. **Total EU tonnage for this use:** no **Related assessment:** use assessed in an own CSR
				General manufacturing process (closed equipment - automated process) including sample collection	PROC3	
				Bulk transfer	PROC8b	
				Clean down and maintenance	PROC28	
				Laboratory activities (quality control)	PROC15	
F	**Formulation &(re)packing of substances or mixtures (vapour degreasing and surface cleaning products)**	Closed process - Batch operations (~5 t/batch, ~15 batches/week) - Ambient temperature – Remote control room - Occasional potential for exposure limited to visual checks of equipment, occasional sampling and to oversee the drumming process.	PC35 - Washing and cleaning products	Formulation and (re)packing - Solvent-based process – closed system - Indoor	ERC2	**Site for this use:** *link to the site defined in IUCLID* **Technical function of the substance during formulation:** No technical function **Substance supplied to that use in form of:** As such **Tonnage of substance for this use(tonnes/year):** 2,500 **Details on tonnage reported:** Registrant own tonnage. Average tonnage over the last 3 years (2011-2014). **Total EU tonnage for this use:** No **Limited number of sites for this use:** Yes **Details on limited number of sites:** The total tonnage manufactured is formulated at the registrant own plant. **Related assessment:** use assessed in an own CSR
				General formulation process (closed equipment - automated process) including sample collection	PROC3	
				Bulk transfer	PROC8b	
				Drum and small package filling	PROC9	
				Clean down and maintenance	PROC28	
				Laboratory activities (quality control)	PROC15	