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ENES 7

Breakout sessions 4.2

Summary of main points discussed and concluded

This document summarises the outputs of the four breakout sessions held at ENES 7 under the Programme session 4.2 *Review and revision of Guidance*.

The session explained the CSA-related Guidance affected, the scope of the changes and the timeline(s) in order to inform stakeholders on the items that are planned to be reviewed / added / made obsolete and gather feedback on the scope of the projects before they are officially launched.

This document covers the following four subject areas:

1. Description of use
2. Environment
3. Consumer
4. Workers

The supporting background document and the PowerPoint presentations can be found at the ENES 7 web page under Session 4.2: http://www.echa.europa.eu/web/guest/view-article/-/journal_content/title/seventh-meeting-of-the-echa-stakeholder-exchange-network-on-exposure-scenarios-enes-7-

1. Breakout group on Use description (Guidance R12 update)

A short overview of the intended changes in the R12 update was presented, both on the main part of the Guidance as well as the Annexes. It included the foreseen changes in the use descriptors (*see presentation link under point 4.2. on the ENES7 website).*

http://echa.europa.eu/documents/10162/21771098/4_2_breakout_discussions_use_description_en.pdf

The main points raised by different industry representatives during the discussion were:

- The proposed changes are considered major changes as they have significant impact in all the well-established systems in the supply chain: communication with customers, training of employees, etc. Industry is concerned, that this update may trigger a lot of re-doing of work within companies.
- Stability is needed for the Use descriptor system as it is used in many processes across companies and throughout the supply chain.
- It was requested to analyse the impact in companies of 'structural' changes i.e. those having an impact in existing systems such as new fields in IT tools or deletion of existing categories. This could be done via a testing phase and examples.
- Some of the clarifications are welcome e.g. scope of the different Life cycle stages (industrial vs professional), legal clarifications.
- The proposed structure (which links use descriptors and contributing activities) is welcome.
- A system for updating the lists of use descriptors outside of Guidance update should be found as there may be more changes coming up from the implementation.
- Advice for the transition period should be given to avoid confusion in the supply chain with two sets of descriptors co-existing.
- A mapping of the existing and the new Use descriptors should be done, in particular where the list changes (Technical functions) and new Use descriptors are replacing existing ones (New Use descriptor Life cycle stage replacing main sector of use). The mapping may show the actual extent of the changes and their impact.
- The proposed new names for ERCs are welcome as they facilitate the understanding of the applicability of each ERC.
- The alignment with other activities is appreciated.
- The preparation for 2018 registrations needs to be taken into account in the timing. Some registrants will rely on the work done by the lead Registrant in previous registration deadlines. New registrants may be given information based on different fields than the ones in the new system (already adapted to new lists).
- These changes may also have an impact on the implementation of other initiatives discussed at ENES e.g. development of use maps by industry, ES short titles (For "selling" purpose, it is good to "freeze" the product).
- The removal of the PC19 for intermediate use will have an impact on companies that have used it for short titles.

- The limitation of PROC1[1] for chemical industry and refinery sectors will have a big impact as this means re-doing many assessments that have used this PROC.
- Coordination with ECETOC is crucial to ensure consistency with the assumptions behind the PROCs.
- Further investigation is needed on the best way to reflect different conditions of uses for one same activity (decouple activity description from description of uses *versus* creation of sub-PROCs).
- The new Use descriptor for a Life cycle stage means a new 'field' in companies' systems which has big impact.

In summary, the main impact seems to be caused by:

- The clarification of the applicability domain of PROCs 1-3 (applicable only to closed processes in chemical industry and oil refinery) as this will trigger the need to re-assess the exposure from process types like dipping or spraying where the registrant had claimed closed system conditions by simply PROC 1 to 3.
- New use descriptor Life cycle stage

According to the participants, the proposal of new names for use descriptor categories does not seem to have a significant impact in companies' systems.

The main demands were the call for an analysis of the impact in industry of the proposed structural changes, to carefully assess the timing of the update, and to think on solutions to facilitate smooth transition period with two systems co-existing.

This could be done by a mapping of the changes, a testing phase and the generation of examples. The clarification of concepts and scope of applicability of some use descriptors was generally accepted and even welcome.

ECHA agreed to reflect all the comments expressed in a short meeting report. The comments will be taken into account in the proposal for an update of the R12 Guidance. They can also be further discussed during the PEG discussions. Stakeholders are encouraged to send their comments once the consultation is launched, via the corresponding PEG representatives.

[1] PROC1 was presented as an example. Limitation of the scope of other PROCs will have the same impact

2. Breakout group on the update of guidance for the environment

The breakout group had been set up to get feedback on the initial considerations from ECHA for updating the guidance on environmental assessment (*see presentation link under point 4.2. on the ENES7 website).*

http://echa.europa.eu/documents/10162/21771098/4_2_breakout_discussions_environment_en.pdf

The work has not started yet and will take into account this feedback. The time target is to be able to release the updated guidance in 2016.

Points raised by different industry representatives during the discussion follow.

Generic concerns:

- With all the guidance update foreseen this will require a substantial amount of resources to be able to feed back on the drafts.
- How much will the change in the guidance impact on the need to redo an assessment?

Answer: the proposal for the update of the guidance on environmental assessment largely intends to move information from various existing guidance (Part E, Part D, R13, R17) with as little modification as possible. Regarding the new text foreseen, or modification of the existing text, no changes in how the environmental assessment is carried out are expected. It is mainly about clarification and largely targeted to “new assessors”.

Generic remarks:

It was seen as useful to regroup all information related to environmental assessment into one document as it is at the moment quite cumbersome to find the relevant pieces. In particular it is expected that for new or less experienced assessors this would be helpful. For experienced assessor such a change was considered as only “nice to have”. It was nevertheless suggested to have a version of the updated guidance where it would be possible to track back the source of the information using for example colour codes (e.g. if it is transferred from other guidance to R16 or whether it is a new piece of text), as this would be useful for those who are already familiar with the guidance.

It was mentioned that the various equations related to the fate of the substance are useful to keep. There was no objection that they go into an annex; nevertheless a high level overview of the key steps for exposure estimation would be useful to have.

It was mentioned that the impact on the registrant’s strategy for describing his uses may be driven by the outcome of the discussion on scaling. At the moment the DU guidance suggests that scaling is to be done within the boundaries of the registrant’s release rate (i.e. increase of volumes to be compensated by risk management, lack of risk management to be compensated by decrease of volume) but does not allow scaling on the basis of the dilution in the receiving system. It will have to be considered how such considerations should be included into the update of R16.

Specific remarks regarding clarifications on the release:

It was asked whether any change in the ERC system is foreseen. With regard to the use descriptor (update of R12) there is no changes foreseen on the ERCs, but only clarification. The proposal for R12 is to get more systematic names for the ERCs. A workflow for the selection of the ERC is also proposed. This has no impact on existing registrations (unless registrants realise they had selected a wrong ERC based on misunderstanding).

Regarding the clarification on industrial/agricultural soil, it was mentioned that it would be useful to provide explanations on the tool developed by ECPA related to the assessment of PPP (intended direct release to agricultural soil). ECHA mentioned that any input on other tools used for the environment assessment would be very welcome. Some clarification on the applicability of EUSES may be included.

It was clarified that the release to underground or agricultural sols will only have to be taken into consideration when relevant.

Regarding SpERCs, the level of details to be included in the guidance will have to be considered. The detailed format may better be presented outside the ECHA guidance: e.g. a practical guide or industry guidance on SpERCs.

3. Breakout group on the update of guidance for consumers

The session started with ECHA presenting the motivation for the R15 Guidance update, and outlining the issues that the update would concern. ECHA also clarified the timing of the process, explaining that the aim is to have an updated Guidance published in 2016. The update drafting and consultation will follow the normal ECHA procedure with ECHA producing the first draft document which subsequently goes through the consultation with stakeholders and REACH bodies (*see presentation link under point 4.2. on the ENES7 website).*

http://echa.europa.eu/documents/10162/21771098/4_2_breakout_discussions_consumers_en.pdf

On the proposed updates, the intention to include the SCEDs concept into the revised Guidance as best practice was agreed in principle. However it was highlighted that some clarification is needed regarding the assessment approach to infrequent uses.

The rest of the breakout group discussion concentrated on assessing exposure resulting from infrequent consumer uses. ECHA explained that the basic principle is to first assess the exposure during a single daily event (”event exposure”) against the chronic DNEL. If adequate control of risk cannot be demonstrated, the next step would be to refine the event exposure, which can be done e.g. by assuming a more realistic amount of substance available for exposure per event. Finally, if it is not possible to demonstrate control of risk for the daily event and the use takes place only infrequently, it can be considered to refine the exposure estimate or risk characterisation accordingly.

A discussion followed on how to define infrequent use. Mostly the conclusion on infrequent is based on common sense or market behaviour arguments. For example, there are certain consumer products that are meant to be used from time to time only (e.g. carpet cleaners) or products that logically used on a seasonal basis. Also sales information can be used to demonstrate that consumers in general use a product occasionally only.

From a more toxicological perspective, the Federal Institute for Risk Assessment (BfR) highlighted that a use can be considered infrequent only when it can be shown (e.g. based on toxicokinetics) that the time between two exposures is long enough so that the exposure from two consecutive exposures does not accumulate. This time is substance specific. From industry perspective it was however highlighted that such specific information does not exist for many chemicals at present. It was discussed whether it would be possible for Tier 1 assessments to set a simple rule, e.g. that if a use takes place less than once a week (or once a month), recovery is assumed to have happened and thus the use can be considered infrequent.

It was also discussed what would be an adequate level of certainty that would be needed on consumer behaviour: Is it adequate to demonstrate that on average the use of a product by consumers is infrequent (common sense), or would one need to demonstrate e.g. that at least 95% of consumers behave in the expected way. Current SCEDs are based on collecting information from the major companies in the sectors and taking the worst case assumptions into account. In other words, they are (still) pretty conservative. It was concluded that regardless of the definition of infrequent use, concrete examples

should be developed to illustrate the arguments based on which a registrant could assume “infrequent uses only”.

Finally, the connection to the assessment tools, specifically ECETOC TRA, was discussed. Current version of ECETOC TRA implements a banding approach where the exposure estimate is corrected by exposure reduction factors, depending on the frequency of use 0.2 for uses < once/week; 0.04 for uses < once/month; 0.01 for uses < once/six months). ECHA highlighted the general need (also for other tools) to explain the rationale behind such factors if meant to be accepted as general convention.

The following points were noted for further discussion ahead of the Guidance update procedure:

1. **Need to clarify** what is understood as infrequent use. Should it be based on generic considerations regarding toxicokinetics?
2. **How to document/demonstrate** that a use really is infrequent? What kind of evidence is expected?
3. How to assess the **exposure level based on the chronic DNEL**? Extrapolate? Use dilution factors – which are based on what?

As for next steps, ECHA will contact the participants of the breakout group via e-mail and ask for their interest in contributing to these discussions.

4. Breakout group on the update of guidance for workers

The breakout group had been set up to get feedback on initial considerations from ECHA for updating the guidance on workers' exposure assessment. The aim of breakout group is to communicate ECHA's preliminary ideas and receive feedback from stakeholders (that will be taken into account at the time of the drafting). The main changes proposed by ECHA were discussed within the group. The discussions and agreements the issues raised are summarized below. (*See presentation link under point 4.2. on the ENES7 website).*

http://echa.europa.eu/documents/10162/21771098/4_2_breakout_discussions_occupational_exposure_en.pdf

1. Obsoleting of Chapter R.13

This includes the re-structuring of information related to workers or general exposure considerations in Chapter R.14 (occupational exposure estimation) and Part D (Exposure scenario building) of the IR&CSA Guidance.

Section R.13.4 regarding RMMs library will not be included in Part D as such, the updated Part D will explain possible sources of information regarding RMM efficiency, such as RMM libraries and Sector use maps.

There were no objections raised to this proposal.

2. Risk management measures

Section R.13.2.2 on OC and RMMs for workers will be moved (and re-drafted) into the Chapter R.14. ECHA wants to improve the guidance (R.14) on how to provide realistic and relevant risk management advice.

Some points were raised during the discussion:

- give guidance on validation of efficiency data (or where to find this information)

- provide hints on how to justify reduction factors and make clear in the guidance that they need to be justified

- guidance on which type of protection factor to use for RPE (APF or NPF)

- put emphasis on RMMs and hierarchy of controls, including principles and borderline examples.

3. Use of measured data

ECHA is considering deleting the table R.14-2 (Indicative number of measurements needed to determine confidently that the true RCR is below 1) and substituting it with more general principles. Also, adding text making the distinction (for use of measured data) between own site assessment and top down. This proposal was well received, but it was mentioned that the concept and key elements should be retained. Including guidance on sources of measured data was suggested.

ECHA asked the participants whether developing an example on use of measured data will be a good idea, and whether they could provide ideas for such example. (Ideas or proposals for the example can be sent to ECHA-guidance.update@echa.europa.eu)

4. Exposure models

ECHA's proposal was to reduce the information on the models to input data and scope of applicability.

In addition participants proposed to include in the guidance a check list of things to be looked at when using/choosing a model (for instance, latest date of revision, type of revision performed etc)

It was agreed that including current information in the checklist is not necessary as this type of information evolves fast and, if included in the guidance, it will make the document obsolete soon. Thus, it was proposed to explore the possibility of getting this information (in cooperation with tool developers) and provide it in place easier to be updated such a webpage.

5. Rating criteria

ECHA identified the need to increase the current rating of modelled data from medium to low in some situations. During the breakout session, it was proposed to rework table R.14-2 to explain clearly the confidence in data for different situations, for both measured and modelled data.

6. Acute toxicity

The proposed clarifications on the guidance regarding acute exposure were well received:

1. The table R.14-3 of the guidance will be re-visited to consider if it is necessary to provide 8 different extrapolation factors as at present and the values of these factors. (This refers to extrapolation from 8 hours exposure to short term).
2. The above mentioned extrapolation is not applicable to address short term exposure resulting from a specific activity that creates a exposure peak (i.e. opening a vessel), this type of exposures arising from identified short-term activities with higher exposure levels need to be addressed separately.
3. To clarify that the option of ECETOC of <15 min, is not meant to address short term exposure, but an activity that is performed less than 15 min per day

7. Dermal exposure

Regarding dermal exposure, ECHA proposed to strengthen the role of qualitative assessment in identifying risk management measures for dermal exposure (for instance to avoid overly precautionary risk management measures due to tools limitations or to consider if closed conditions can lead to zero exposure).

There were mixed reactions and it was stated that quantitative assessment needs to be part of the picture.

Regarding the use of closed systems, it was argued that zero exposure cannot always be assumed. For instance after painting in a closed system, the object may still need to be moved or touched-up, there will be maintenance operations etc.

It was agreed to expand the dermal exposure sections with these considerations and explain the difficulties of the dermal assessment.

It was also discussed whether new PROCS for maintenance could be created, however, the difficulty will be to assign an exposure estimate to them.

New chapter on applications for authorisation (AfA)

ECHA proposed including a section outlining elements to consider for a CSA in AfA, such as more emphasis on measured data, actual OC/RMMs etc. There was some discussion as to whether CSA for authorisation was really different to that for registration.

Additionally, it was said that the principles in these respect need to come from the RAC practice on AfA and some participants offered to gather some feedback from colleagues involved on RAC activities.

Other issues

Regarding other clarifications needed such as professional and industrial use and certain PROCs and their meaning in terms of level of containment / closed systems, these issues will be covered by the update of Chapter R.12 on Use Description.