Background document for ENES 7

Session 4.2: Update of ECHA Guidance on Chemical Safety Assessment: Planning

The aim of this background document is to share ECHA's overall guidance update plan on chemical safety assessment and gather the first reactions from stakeholders.

1. Introduction

A registration under REACH contains the mandatory information on the substance properties (information requirements) and a description of the uses taking place during the life cycle of the substances. For substances above 10 tons an assessment report is required regarding the hazards resulting from the substance properties. If the substance is assessed to meet the criteria for being classified hazardous then in addition an exposure assessment and a risk characterization is required: This part of the Chemicals Safety Assessment is expected to i) describe the conditions under which the substance can be safely used (Exposure Scenarios), ii) estimate the extent of exposure under these conditions and iii) demonstrate in the risk characterisation that the exposure during all the uses is adequately limited or prevented.

Prior to REACH there was not much practical experience available with such kind of safety assessment, carried out top down from the perspective of the manufacturers and importers of substances. Extensive guidance documents related to Chemicals Safety Assessment (CSA) were developed by industry, discussed with authorities and published in 2008, as ECHA Guidance agreed by all stakeholders. The guidance package includes *Concise Guidance* (Part A to F) and supporting *Reference Guidance* (Chapters R.8 to R.20)[1]. Some parts of the guidance were slightly amended later on, but no comprehensive review across the package has taken place since their publication.

ECHA has decided to launch an update across the CSA package related to those documents addressing use description, exposure assessment and risk characterisation, in order to make use of the experience/learning gained among industry and authorities since 2008:

- Two registration deadlines have passed (2010 and 2013), resulting in about 12.000 industry CSRs with exposure assessment for around 3,500 substances.

- Downstream users have received the first waves of exposure scenarios built on information from the CSAs.

- ECHA in cooperation with industry and member states has developed a Chemical Safety Assessment and Reporting Tool (Chesar) aiming to transform the principles laid down in the guidance into a practical assessment workflow and related documentation functionalities.

- Member state authorities and ECHA have made use of CSA information for various ECHA processes, including dossier evaluation, selection and prioritisation for substance evaluation and authorisation candidates/recommendations

[1] http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment. The Reference Guidance R.2 to R.7 is mainly related to information requirements and testing strategies.

- The CSR/ES Roadmap was published in 2013 including a number of activities agreed by stakeholders, to improve the CSR in the registration dossiers as well as the ES communicated in the supply chain. Some of these activities have already started to be implemented and their deliverables are good practices to be included or referred to in updated Guidance documents.

It is also an objective to make the package of support documents more consistent in itself and more user-friendly. This includes removal of duplicate information, better integration of interrelated information in one place, and clearer differentiation between

- explanation of principles (guidance),
- exemplification and practical advice (practical guides),
- summary documentation of exposure tools (annexes to guidance or practical guides),
- standard formats (stand-alone outside guidance) and help-texts in the relevant tools themselves.

Eventually some of the existing chapters of the Guidance on IR&CSA will be made obsolete to avoid redundancy and improve readability. On the other hand certain aspects of the CSA may need additional Practical Guides and examples. Table 1 in Annex I, shows an overview on the structure of the support documents as they are now and on the anticipated new structure.

The guidance update project will cover:

- Identification of uses (use mapping), use description principles and use descriptors
- Exposure assessment (scope of exposure assessment, describing conditions of use, estimating exposure, characterizing the risk) for workers, consumers, environment, resulting in a
    - CSR for the authorities
    - exposure scenarios for communication to users

The guidance update packages are described in details in this background document below.

Timing

The aim is to have all the support material ready in 2016, parallel to the release of Version 6 of IUCLID and Version 3 of Chesar. This package of tools and guidance is meant to support registrant for the 2018 deadline and registrants who wish to update their dossiers.

In order to achieve this goal, the consultations will take place mostly in 2015 following the usual Guidance update process. The first package on use description is expected to be sent out for consultation in late 2014/early 2015. The other guidance document will sequentially follow during the first half of 2015.

2. Use description

Motivation and scope of the update

Chapter R.12 of the IR&CSA guidance explains the principles for describing the uses of a substance in the registration dossier. This includes a system of use descriptor categories. The description of uses is based on information communicated up the supply chain, potentially in the framework of sector use maps. The description of use is essential to properly assess the uses and to develop corresponding exposure scenarios. The uses identified and assessed in a registration dossier are then to be communicated down the supply chain. Downstream users should be able to identify which exposure scenarios in the extended safety data sheet are potentially relevant to them.

Experience in industry shows that registrants and downstream users need to develop a common understanding on which aspects of the uses matter, in terms of safety assessment, and in terms of communication on risk management. Experience by Member States and ECHA in the context of dossier evaluation and screening of substances also indicate some need for improvement, in particular the need for uses to be described in a more systematic and concrete way.

The current update of the guidance intends to:

- Explain the life cycle stage approach in a clearer way and clarify the scope of each of the stages
- Extend the scope of the guidance from the focus on "use descriptors" to a broader concept of "use description", and give more detailed information on the different elements of use description; clarify the concept of "use and contributing activity"
- Explain how to describe a use appropriately, including a break down in contributing activities and the assignment of the use descriptors.
- Clarify the scope of use descriptor categories where needed; add/amend a few categories where experience shows gaps or misunderstanding.
- Update the use descriptor system article service life (regarding the relationship between material-based categories and article types)
- Clarify that there are very few exemptions from the requirement to describe the uses of a registered substance.
- Stress the role of the use description in the overall communication process between all REACH actors (DU, registrants, authorities and general public)

Final Package

- Updated Chapter R.12 of the IR&CSA guidance
- Practical guide on use description including examples

Links with tools and other developments

- The list of use descriptors and the various other elements of use description are included in IUCLID and Chesar.
- ESCOM is meant to support the communication of the relevant use description elements
- The refinement in the definition of various use descriptor categories aims to support compatibility with those exposure estimation tools that work on the basis of use categories (like for example the ECETOC TRA).

3. Exposure scenario building

Motivation and scope of update

Part D of the IR&CSA guidance on Exposure Scenario Building is meant to explain the overall workflow for the exposure assessment process: Based on the conclusions from the hazard assessment, derive the scope of exposure assessment. Identify all the uses, preferably with the help of use maps generated by downstream user sector organisations. Describe the conditions of use for the contributing activities (contributing scenarios), potentially using exposure assessment inputs generated by downstream user sector organizations. Carry out exposure estimates for each contributing scenario, using suitable modelling tools or measured data sets. Compare the identified risk management measures and the exposure estimates with the hazard profile of the substance to be assessed. Demonstrate in the CSR that risks are adequately controlled, and derive the exposure scenarios for communication.

Experience in industry shows, that the ES building process can be improved by making available to registrants more specific and more realistic information on the conditions of use. Practical approaches and tools to achieve this in an efficient manner have been developed over the recent years, and can be described as good practice principles in Guidance Part D. Experience by Member States and ECHA in the context of dossier evaluation also indicate that the content of the exposure scenarios is often not sufficiently concrete to understand whether or not exposure and risk are adequately controlled. Finally, there is some need to better focus the Guidance Part D on the workflow aspects of ES building, while the specific principles and methodologies for exposure assessment would be concentrated in the Guidance chapter R.14 to R.16.

The current guidance update intends to:

- Better explain the exposure assessment process under REACH
- Focus on the general principles regarding the ES building process and become less prescriptive regarding the specific steps
- Highlight the differences between an "own site assessment" and the assessment of uses further down the supply chain.
- Introduce the concept of contributing scenarios describing the use conditions at the level of a single activity or technique contributing to a use. For each single contributing scenario control of risk is then to be demonstrated in a qualitative or qualitative way.
- Integrate the overview on exposure determinants and the concept of risk management libraries from Chapter R.13 into Part D.
- Introduce the concept of exposure assessment inputs as part of sector use maps
- Introduce the concept of short titles for exposure scenarios for communication
- Remove detailed information on exposure estimation and specific tools and refer to the three in depth guidance chapters on exposure estimation (Chapters R.14, R.15 and R.16 of the IR&CSA guidance).
- Remove the (outdated) ES format from the Guidance [2]

Final Package

- Updated Part D of the IR&CSA guidance as umbrella for the three guidance chapters on exposure assessment (R.14 to R.16)
- Obsoleted Guidance Chapter R.13

[2] Please note that, as explained in the introduction, "formats" (such as the ES format currently available in Part D) will be removed from guidance documents and provided in other type of documents. Please check the package "Format of CSR and ES for communication" below for further information about formats

4. Occupational exposure assessment

Motivation and scope of update

Exposure assessment under REACH aims to identify and describe, in enough detail for subsequent interpretation, the operational conditions and risk management measures required to protect workers' health. The current *Chapter R.14 of the IR&CSA guidance* describes the generation of exposure estimates at the different assessment levels (Tiers) based on modelled predictions or measured data sets.

Due to the structure of the IR&CSA guidance package, the focus of the current Chapter R.14 is on exposure estimation and it is somewhat isolated from the safety assessment process it is a part of. Also experience shows that many of the REACH exposure assessments carried out so far have not sufficiently integrated the exposure estimation with the identification of appropriate and suitable RMMs for the substance. Consequently, the update intends to change the scope of the guidance from exposure estimation to exposure assessment. In order to achieve this, information regarding RMMs from *Chapter R.13 of the IR&CSA* will be integrated into Chapter R.14[3], and a workflow explaining the assessment framework including a link to control banding and qualitative assessment will be introduced.

Changes will be made to improve clarity and remove unnecessary duplication. Material that is not related to guidance principals (such as details on modelling tools) will be removed.

Finally, at the time of the writing of the guidance, the authorisation process had not started, and the guidance gave no concrete advice for it. A separate chapter explaining the main issues regarding exposure assessment specifically for the authorisation process will therefore be added.

The current guidance update intends to:

- Integrate relevant information on RMMs and OCs from Chapter R.13
- Make the guidance content more accessible to assessors under REACH
- Include a new section describing the principles to convert the conclusions from the hazard assessment (classification and DNELs/DMELs) into appropriate risk management strategies.
- Extend the advice on dermal assessment regarding i) identification of suitable risk management measures and ii) the (less prominent) role of exposure quantification in this.
- Clarify the interpretation of the general rating criteria for exposure data quality used in the context of workplace assessment (see section 14.4.2)
- Focus on principles regarding the suitability of measured data, rather than prescribing the number of data points needed to support the registrant's safety assessment under REACH. Differentiate approaches for measured data between own site assessment and exposure estimation for downstream uses (significant difference in knowledge of conditions under which a dataset was generated). Consider providing more detailed advice in another publication on use of measurement data via development of examples.
- Clarify the principles for the assessment of the different types of high exposure events during the shift of a worker (e.g. variability of exposure during a full shift

[3] Other sections of *Chapter R.13 of the IR&CSA guidance* will be integrated in the Part D (above) and Chapters R.15 and R.16 (see description of the packages below), once all the updated guidance have been published the *Chapter R.13 of the IR&CSA guidance* will be obsoleted.

task versus single event peak exposure during a shift); include clarification on the applicability domain of ECETOC worker in this respect.
- Update the information regarding applicability domain for the modelling tools. Limit the description of the tools to characterisation of inputs and outputs. Include approaches to overcome the limitations regarding the identification of risk management advice, including development of sector or process specific exposure assessment input data sets (analogues to SpERCs and SCEDs).
- Add a new section on exposure assessment for applications for authorisation

Final Package

- Updated Chapter R.14 of the IR&CSA guidance
- Practical Guide 15 on How to undertake a qualitative human health assessment and document it in a chemical safety report (existing)
- Examples for using measured data to support an exposure assessment under REACH (under consideration)
- Updated example for exposure scenarios related to worker uses: exploring the possibility of updating the current example.
- Obsoleted Guidance Chapter R.13

5. Consumers exposure estimation

Motivation and scope of update

Chapter R.15 of the IR&CSA guidance on Consumer exposure estimation details how to assess consumer exposure to chemicals. The aim of the chapter is to describe a step-wise and iterative procedure for the estimation of consumer exposure to substances on their own, in mixtures or in articles.

Experience from previous registration shows that consumer's exposure prediction via existing tier 1 tools (in particular the TRA) is often very conservative, and it is difficult to demonstrate control of risk based on the default settings for the various product groups. To overcome this limitation, industry has started to develop Specific Consumer Exposure Determinants (SCEDs) to link the Tier 1 exposure estimation tools with more realistic conditions of use described within the exposure scenario. This may also include data sets specifically addressing i) children exposure and ii) products with occasional/rare use.

As in the case of the exposure estimation for workers, it seems more logical that the information regarding RMM relevant for consumer products (currently in Chapter R.13) is integrated into Chapter R.15 to improve consistency and readability. Additionally, the modelling tools have evolved from the time of the original writing of the document, and other parts of the guidance present minor shortcomings or require clarification.

Finally, the information regarding consumers' exposure from articles is scattered between *Chapter R.15* and *Chapter R.17 exposure from articles*[4]. The information should be gathered together, for consistency and user friendliness. At present ECHA is developing an example for assessing the article service life stage of a substance. This example is meant to provide practical guidance complementary to the principles explained in the Guidance.

The current guidance update intends to:

- Update the information regarding modelling tools, including the latest versions of the tools, their applicability domain and the inputs and outputs
- Clarify how to assess exposure from occasional/rare uses when only a chronic DNEL is available
- Integrate in Chapter R.15 the relevant sections from Chapters R13 and R17
- Develop a new chapter on Specific Consumer Exposure Determinants (SCEDs), including considerations for specific children exposure and occasional/rare uses

Final Package

- Updated Chapter R.15 of the IR&CSA guidance
- Example for a safety assessment regarding article service life
- Updated example for exposure scenario related to consumer products: exploring the possibility of updating the current example.
- Obsoleted Guidance Chapter R.13 and Chapter R.17

[4] Other sections of Chapter R.17 regarding article service life will be integrated into Chapter R.16. Once both the updated Chapter R.15 and R.16 have been published *Chapter R.17 of the IR&CSA guidance* will be obsoleted

6. Environment exposure assessment

Motivation and scope of update

Exposure assessment under REACH aims to identify and describe the operational conditions and required environmental risk management measures for protecting the environment. The current *Chapter R.16 of the IR&CSA guidance* describes how to estimate releases and how to calculate the subsequent environmental exposure.

Experience shows that many of the REACH exposure assessments carried out so far focused on obtaining "figures" for exposure estimation and risk quantification rather than identifying adequate and concrete RMMs for the substance to be applied to ensure safe use. This is obvious in the Specific Environmental Release Categories (SpERCs) industry has published so far in order to provide realistic and well documented release factors to be fed into the tier 1 exposure estimation tools. Two projects run by Member States and by ECHA to reflect the content/format of available SpERCs point into the same direction: The documentation of the conditions leading to a specific release factor needs improvement.

Similar to the other exposure assessment chapters, the clarity of the document will be improved by presenting the exposure estimate integrated into the safety assessment process. This includes information regarding OC and RMM for the environment (currently in Chapter R.13). Also, the technical summary information on the standard environmental exposure estimation with the EUSES tool will be moved into an annex to the guidance.

The current guidance update intends to:

- Add information from other documents and re-structuring the content to follow the logic workflow of an exposure assessment:
  - Make reference to the concept of i) industrial site uses and ii) widespread uses (chapter R.12) and introduce the corresponding environmental assessment approach (industrial point source, municipal point source). Explain regional and local assessment (as already described in R16).
  - Describe from the environmental perspective the conditions under which the identified uses of the substance take place, including the used tonnages and existing risk management. General information on types of RMMs and OCs relevant for the environment, currently in chapter 13 and part D, should be updated and moved to R.16.
  - Based on the conditions of use and the substance properties release factors or release rates can be derived. Registrants are expected to provide sufficient explanation how they have derived the release rates and which conditions of use these release rates reflect. Existing tools/methods to make the assessment realistic and efficient, like sector use maps and SpERCs, will also be introduced here.
  - Predict the distribution and fate of the released substance and the resulting concentrations in the different compartments based on the EUSES model. The current R.16 guidance includes a short version of the EUSES documentation which is not needed for the "normal assessor" who would simply rely on the

EUSES tool. It is therefore suggested to briefly explain the principles encoded in EUSES, but to move the model description into annex of the guidance.
    - Based on predicted environmental concentration (PECs) and PNECs (derived in the hazard assessment) characterise the risk. It is proposed to use the corresponding guidance parts from chapter E in chapter R.16 to generate one coherent document on environmental exposure assessment.
    - Determine the information that needs to be communicated down the supply chain in order to inform downstream users what they need to do to ensure safe use (exposure scenario for communication).
- In addition to the re-structure as outlined above some other particular elements in the guidance are planned to be updated:
    - Information regarding release from articles relevant for the environment, currently in Chapter R.17, should be updated and moved to R.16.
    - Some clarifications on release to soil (agricultural soil, industrial soil, underground) may be needed
    - Explanations on the possibility for site specific STP (providing a higher removal efficiency compared to the (municipal) standard STP) should be included.
    - Include information specifically relevant for applicants for authorisation regarding exposure assessment for men via environment for non threshold substances.

Final Package

- Updated Chapter R.16 of the IR&CSA guidance (main body text)
- Appendix to Chapter R.16 with the summary documentation of EUSES
- Updated example for exposure scenario related to environment: exploring the possibility of updating the current example.
- Obsoleted Chapter R.13 and Chapter R.17 of the IR&CSA guidance

7. Format of CSR and ES for communication

Motivation and scope of update

Part F of the IR&CSA guidance aims to explain the principles and the structure of the Chemicals Safety Report, as laid down in Annex I of the REACH regulation.

At present Part F includes also an Appendix with a CSR template (including explanation on the information expected), which is however outdated. Part D of the IR&CSA Guidance also includes a format for presenting exposure scenario information, however this format is also outdated. An interim update of the exposure scenario format had been published in 2010.

A simplified exposure scenario format better aligned with industry tools such as ESCom, and a more easy to read CSR structure have been developed in the context of ECHA's Chemical Safety Assessment and Reporting Tool (Chesar). The CSR template had been published on ECHA website in 2012.

Subsequently an illustrative CSR example with explanatory note has been published in summer 2013. An annotated template (format) for the exposure scenario for communication with examples is available since summer 2014.

Experience with processing the existing CSRs from the first two registration deadlines indicates that a diversity of formats for CSR has been used, some of them clearly outside the boundaries of Annex 1 or presented in a way that reading is very challenging. Also, for the more complex assessment cases (diverse and variable composition/forms/constituents of a substance, relevant transformation products), authorities have some difficulties to understand the scope and the logic of the presented information.

The current guidance update intends to:

- amend the guidance Part F reflecting experience with CSRs from the first registrations deadlines
    - include principles regarding the description of the assessment approach in the CSR in particular regarding the assessment approach in case of substances with a more complex "chemistry" (Chapter 1) and the scope of the exposure assessment (chapter 9.0)
    - include some principles regarding the format of section 9 and 10 of the CSR in order to ensure that CSR can be efficiently processed by authorities (including a more integrated way in presenting the conditions of use, the exposure estimates and the corresponding risk characterization for a use).
- remove the formats for CSR and exposure scenario for communication from the guidance documents (Part D and part F)
- to obsolete and remove all outdated formats from the ECHA website
- to enable easy access to the recommended format for CSR and ES for communication

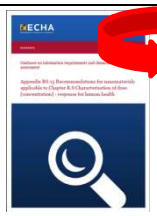
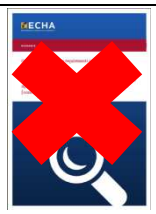
Final Package

- Updated Part F of the IR&CSA guidance (without Appendix)
- One single annotated CSR format

- Illustrative CSR example: document already existing, but currently exploring the possibility of developing an additional example with a more hazardous substance
- ES example: documents already existing, but currently exploring the possibility of developing an additional example with a more hazardous substance

Annex I

Table 1: Overview of the changes on CSA related documentation

<table>
<tr><th>CURRENT (QUASI) GUIDANCE</th><th>SUPPORT DOCUMENTATION IN 2016</th></tr>
<tr><td colspan="2">USE DESCRIPTION</td></tr>
<tr><td> 
R.12 guidance (Use descriptor system)</td><td> 
Updated R.12 Guidance on use description
 
PG on use description including exemplification</td></tr>
<tr><td colspan="2">CSR /ES Format</td></tr>
<tr><td> 
Part F Guidance (CSR)
 
Appendix to Part F Guidance (CSR template with explanation)
 
ES format Guidance
Format
vPvB Format
 
CSR example
 
ES example</td><td> 
Updated Part F
 
Obsolete Appendix to Part F
 
Obsolete ES format
INFO
 
Annotated CSR
 
CSR example
(Exploring to develop an additional example for a more hazardous substance)
 
ES example (Exploring to develop an additional example for a more hazardous substance)
INFO
 
Format
 
vPvB Format</td></tr>
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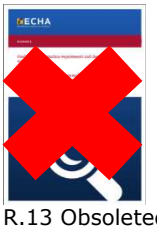
ES Building

Part D Guidance (**ES building**)

R.13 guidance (**RMM/OC**)

Updated Part D

INFO



R.13 Obsoleted (also transfers info in other SP, see below)

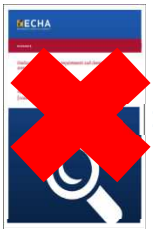
Workers exposure

R.13 guidance (**RMM/OC**)

R.14 guidance (**workers**)

Example, of ES related to workers' uses

PG on qualitative assessment **(remains the same)**



R.13 Obsoleted (also transfers info in other SP, see below)

INFO

R.14 updated

Possible NEW on example, worker's exposure estimation (measured data)

Example, of ES related to workers' uses **(update under consideration)**

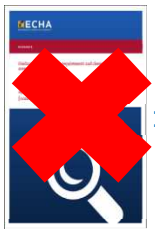
PG on qualitative assessment **(remains the same)**

Consumers exposure

R.13 guidance (**RMM/OC**)

R.15 guidance (**consumers**)

R.17 guidance (**articles**)



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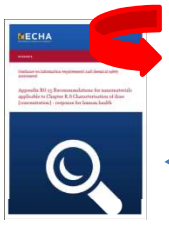
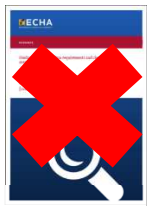


R.15 Updated

INFO



R.17 Obsoleted (also transfers info into other SP, see below)

R.13 Obsoleted (also transfers info in other SP, see above and below)

Example of ES related to consumers' products

Example of ES related to consumers' products **(update under consideration)**

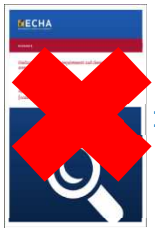
NEW example on safety assessment **regarding article service life**

Environmental exposure

R.13 guidance (**RMM/OC**)

R.16 guidance (**environment**)

R.17 guidance (**articles**)



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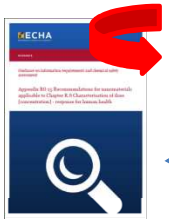
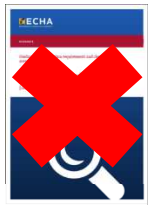


R.16 Updated

INFO



R.17 Obsoleted (also transfers info into other SP, see above)

R.13 Obsoleted (also transfers info in other SP, see above)

Example of ES related to the environment

Example of ES related to the environment **(update under consideration)**