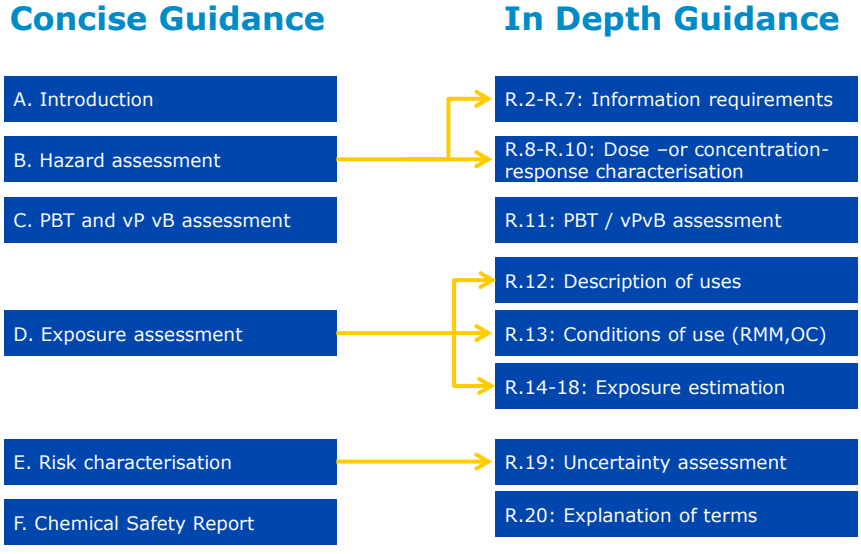
Review and revision of Guidance

ENES 7

19 November 2014

Celia Tanarro

European Chemicals Agency



CSA Guidance development

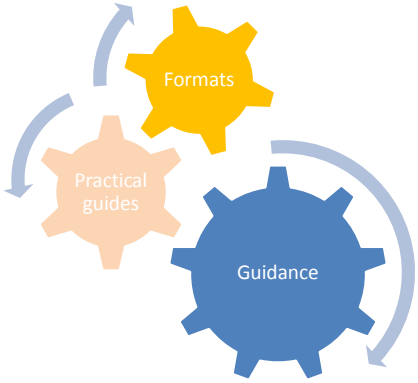
- Original guidance was develop before practical experience on top-down assessment was available
- Some guidance have been updated after 2008, but in isolation with the rest of the IR&CSA guidance
- Other documents completing the advice giving in the guidance (Examples, formats, practical guides) have been developed

Motivation of the project

Update the CSA guidance as a whole, making use of the experience/learning gained among industry and authorities since 2008:

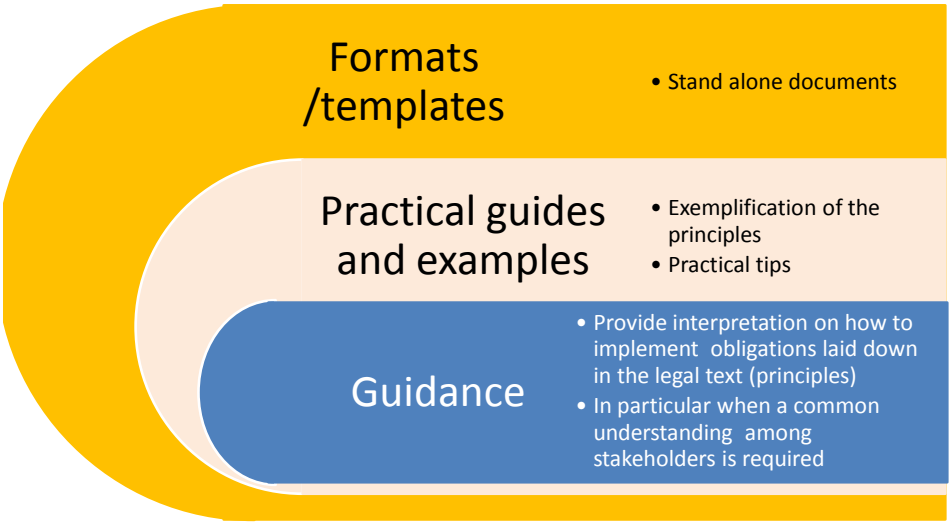
- Two registration deadlines, resulting in about 12.000 industry CSRs with exposure assessment for around 3,500 substances.
- Downstream users have received the first waves of exposure scenarios built on information from the CSAs.
- Chemical Safety Assessment and Reporting Tool (Chesar) aiming to transform 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
- Deliverables from the CSR/ES Roadmap

Streamlining of the information



- Removal of duplicate information
- Integration of relevant information in one place
- Better interrelation of the documents
- Clearer distinction on the type of information that should be presented in each type of document

Support package per topic



Description of support packages

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Use description

- 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.

R12 Guidance update:

- 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
- Explain the life cycle stage approach in a clearer way and clarify the scope of each of the stages
- Clarify the concept of “use and contributing activity”
- Clarify the scope of use descriptor categories where needed; add/amend a few categories where experience shows gaps or misunderstanding.
- 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)

Use description

Updated R.12 guidance (**Use description**)

PG on use description including exemplification

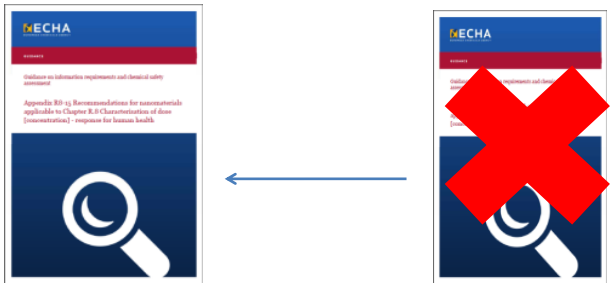
Exposure Scenario building

- A document needs to provide a general workflow for the ES building process, and provide a link to the specific principles and methodologies for exposure assessment in the Guidance chapters R.14 to R.16
- Practical approaches and tools to improve the ES by providing to registrants more specific and more realistic information on the conditions of use have been developed over the recent years , and can be described as good practice principles

Part D guidance update

- Better explain the exposure assessment process under REACH
- Focus on the general principles and the workflow regarding the ES building process; become less prescriptive regarding the specific steps
- Introduce the concept of contributing scenarios describing the use conditions at the level of a single activity or technique contributing to a use.
- Integrate the overview on exposure determinants and the concept of risk management libraries from Chapter R.13
- Introduce the concept of exposure assessment inputs as part of sector use maps
- Highlight the differences between an “own site assessment” and the assessment of uses further down the supply chain.
- Enhance the link between the exposure assessment and the exposure scenarios for communication
- Remove the (outdated) ES format from the Guidance
- 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)

Exposure scenario building



Updated Part D

Obsoleted Chapter R.13 **(OC and RMM)**

Occupational exposure assessment

- Occupational exposure assessment in CSRs often fail to generate realistic and relevant **risk management measures** for communication downstream
- Some of the advice on **exposure estimation** is no longer current
- CSRs prepared for applications for **Authorisation** have some special considerations that are currently not addressed at all in the guidance

Chapter R.14 Guidance Update

- Focus on **exposure assessment** instead of exposure estimation
- Risk management measures
  - Incorporate elements from R13 (OCs and RMMs)
  - Introduce worker exposure assessment approach
  - Strengthen link to existing OSH controls/hierarchy/banding etc.
  - Clarify aspects such as closed/open systems, industrial/professional settings etc.

- Exposure estimation
  - Reduce details on measurement data but if feasible, provide examples elsewhere
  - Reduce details on modelling tools
  - Modify rating criteria
  - Clarify acute exposure assessment
  - Expand advice on dermal exposure

- CSA in application for authorisation
  - Provide guidelines on elements to consider

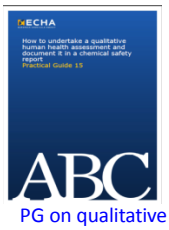
Occupational exposure assessment

Obsoleted R.13 **(OC and RMM)**

Updated R.14 guidance (**workers**)

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

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



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

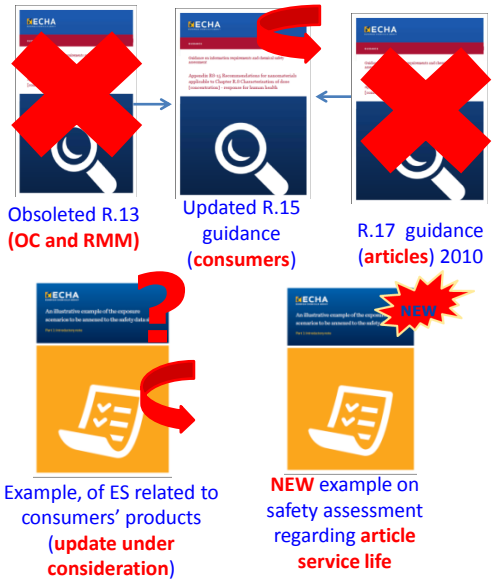
Consumers exposure assessment

- Industry has started to develop Specific Consumer Exposure Determinants (SCEDs) to link the Tier 1 exposure estimation tools
- Reduce details on modelling tools
- The information regarding exposure from articles is scattered in two guidance documents (Chapters R.15 and R.17)

Chapter R.15 Guidance update

- 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

Consumers exposure assessment



R16 environmental exposure assessment

- Environmental exposure assessment in CSRs often lacking documentation on
  - the conditions of use (incl. risk management) driving the release
  - explanations on how release was estimated
- Streamline the guidance and make it easier to read

R16 update: main purpose

- **Integrate** the various parts related to environmental assessment in one document:
  - Overall scope of envi assessment from Part E
  - Conditions of use leading to releases from R13, part D (+ expansion needed based on SPERC development experience)
  - For articles, move relevant information from R17
  - Exposure estimation from R16
  - Risk characterisation from part E
  - Adding a section on information for communication

  -> guidance on environmental **exposure assessment** instead of exposure estimation
- **More focus** on the conditions of use and release. Move to annex the EUSES algorithms related to distribution in the environment.

Environmental exposure assessment

Obsoleted R.13 **(OC and RMM)**

Updated R.16 guidance (**environment**)

R.17 guidance (**articles**) 2010

Example, of ES for the environment(**update under consideration**)

Guidance on CSR

- 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 I or presented in a way that reading is very challenging.
- 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 registrants CSRs
- Part F includes also an Appendix with a CSR template, which is outdated. Other documents (ES CSR format guidance, CSR template, etc) present also (partial) CSR formats.

Guidance update

- 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
    - to introduce the "chemistry of the substance" from the assessment perspective for substances with more complex "chemistry" (in Chapter 1) and
    - to provide an overview of the exposure assessment approaches, including its scope (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 characterisation for a use).
- to enable easy access to the recommended format for CSR and ES for communication

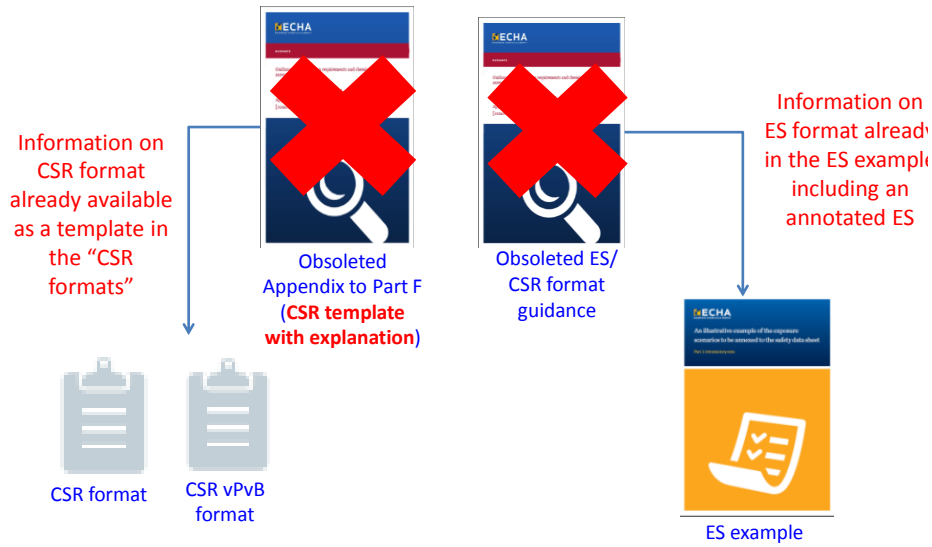
Part F CSR format: Step 1

- At the beginning 2015, ECHA intends to obsolete the outdated IR & CSA guidance on ES and CSR formats :
  - Appendix to Part F
  - ES format in part D and CSR format in part F

- Advice on ES and CSR format is still provided to registrants via the CSR templates published in 2012 and the ES example published in 2014 that includes and an annotated ES.

ECHA would like to ask at ENES7 whether this view is shared by stakeholders prior to launch the obsoleting of the documents

CSR Format: step 1



Part F CSR format: Step 2

- Update of Part F
- Publication of an annotated CSR
- Obsoleting of the CSR templates, as the annotated CSR could be used instead

CSR Format: phase 2

Updated Part F (**CSR**)

ES example

CSR example

(Exploring to develop an additional example for a more hazardous substance)

CSR format

CSR vPvB format

Annotated CSR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