Update on the revision of the CSA – related ECHA guidance

ENES 8

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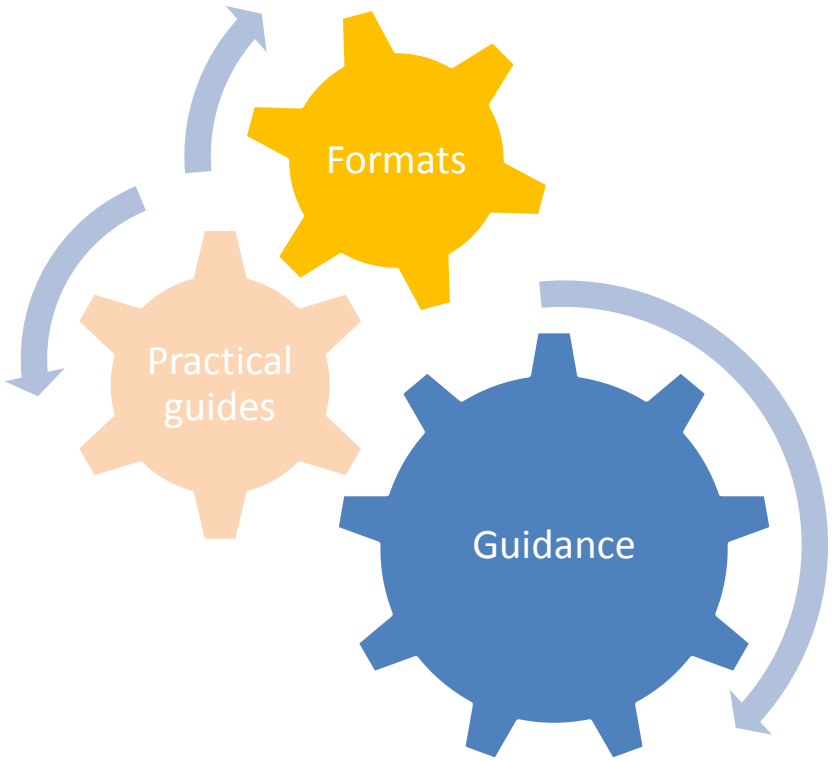
Streamlining of the information



- 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

Guidance: simplification of the information

- The information is gathered in **6 documents instead of 10**
- Separate section for formats
- **Only one format for CSR and ES for communication** will be available, to avoid confusion on what format to use.

Guidance document	Status
UPDATES	
R.12 (use description)	10 days cross check with the PEG (end of May) Committees consultation before the summer break
Part D (ES building) Part F (CSR)	Drafting phase PEG nominations closed
R.14 (workers)	Drafting phase PEG nominations closed
Part E (Risk characterisation) (The update only covers RC for Physico-chemical properties)	Drafting phase PEG nominations closed
R.15 (consumers)	Drafting phase PEG nominations closed
R.16 (environment)	Drafting phase PEG nominations closed

Guidance document	Status
OBSOLETE	
R.13 (OC and RMM)	To be withdrawn when the updated Part D, R.14, R.15 and R.16 are published
R.17	To be withdrawn when the updated, R.15 and R.16 are published
ES format	Obsoleting procedure to be launch in Q2/2015
Appendix to Part F	Obsoleting procedure to be launch in Q2/2015

R.12: Status

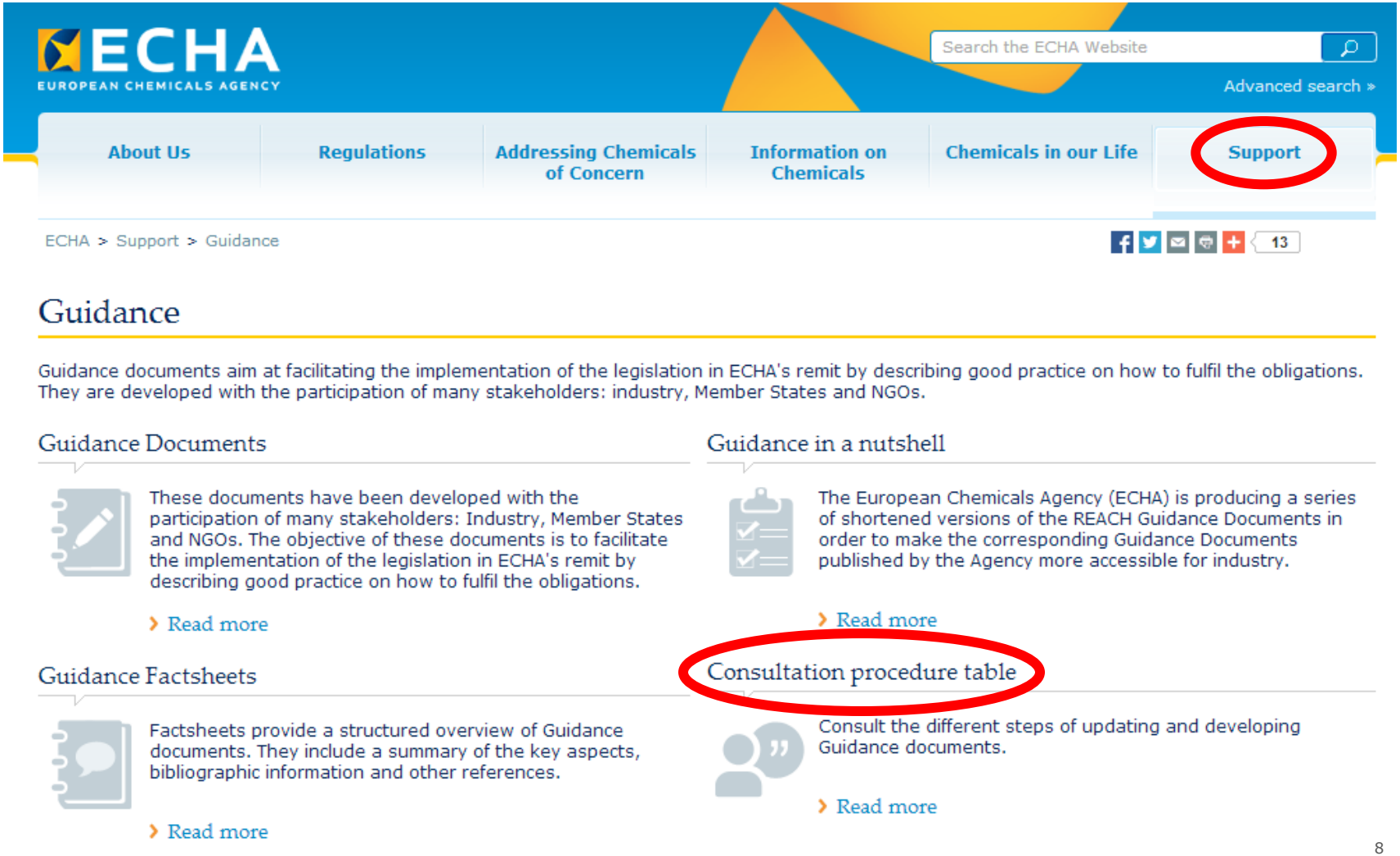
- PEG written consultation: 367 PEG comments received
- PEG meeting held on 21 of April:
  - An agreed solution could be reached for all issues raised
- ECHA is implementing the agreements in the guidance that will move to the next step of the consultation

Some of the agreements….

- Advice on how to manage the changes implemented in the guidance, including “adaptation period” and ECHA’s expectation on receiving updated information
- New LCS use descriptor: to support adaptation of industry (IT) systems to this new Use descriptor, temporary “work arounds” will be explained
- PROCs 1-3: scope revised to include uses outside the chemical/ refinery industry, but with similar containment conditions
- Further examples and clarifications included

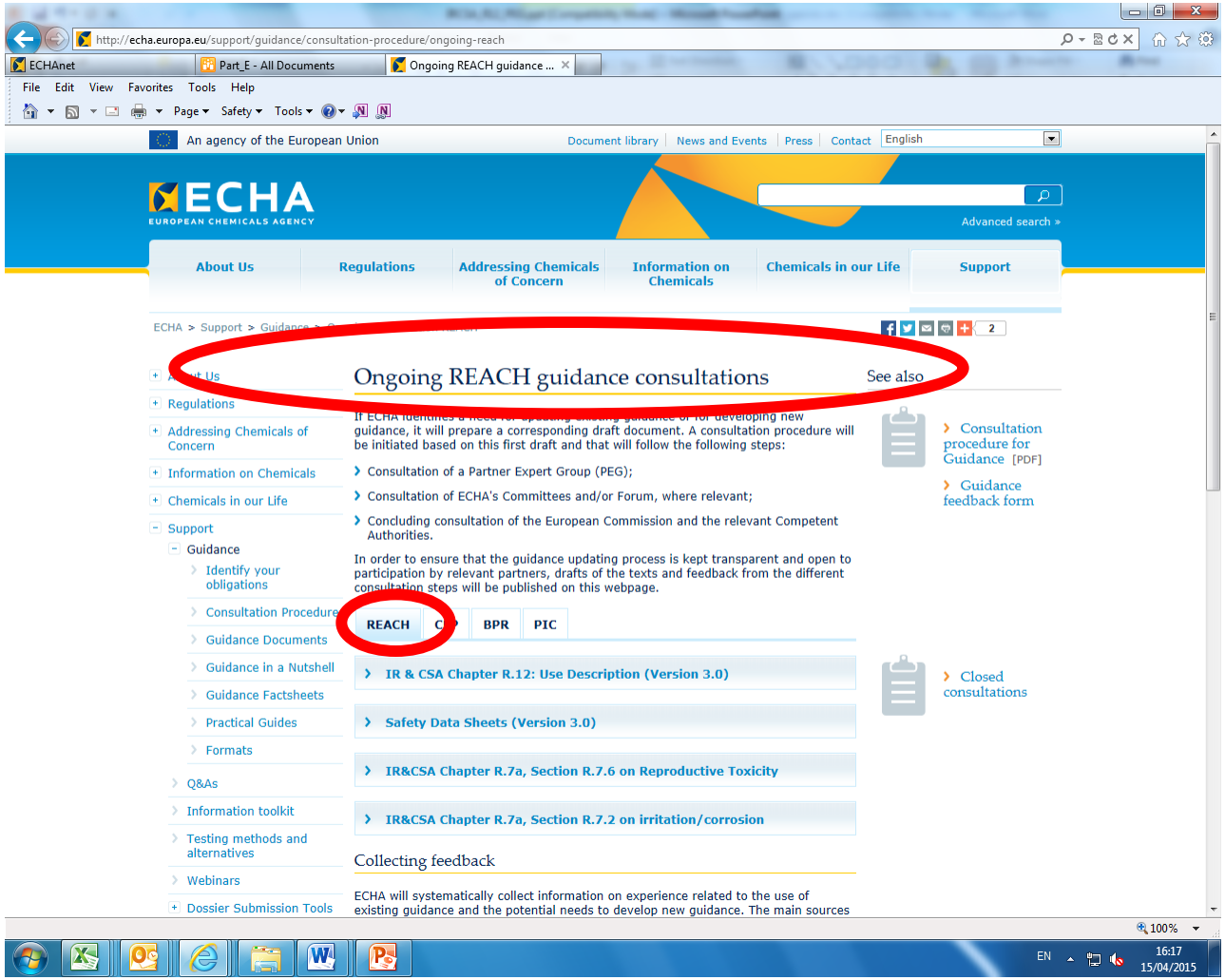
How to follow the process

You can track this process: http://echa.europa.eu/support/guidance



How to follow the process

… and see its output when finalized: http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach



Part E: Risk characterisation

- Experience from ECHA's compliance check shows that the risk characterisation for physicochemical properties on Registration dossiers has not always been reported to the level detail and quality required.

- The aim of the update is to further clarify the legal obligations and the expectations from Authorities on this point, and to provide support on how to fulfil them.

Part D: Exposure Scenario building

- A document needs to provide a general workflow for the ES building process, and provide a central point to 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

Chapter R.14 Occupational exposure estimation

- 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

Chapter R.15 Consumer exposure estimation

- 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

Chapter R16 environmental exposure estimation

- **Integrate** the various parts related to environmental assessment in one document:
  - Overall scope of envi assessment from Part E
  - extend explanations on SPERC concept
  - - include article relevant information

  -> guidance on environmental **exposure assessment** instead of exposure estimation
- **More focus** on the conditions of use and release.

Thank you!

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