Update on the revision of the CSA – related ECHA guidance

ENES 9

5 November 2015

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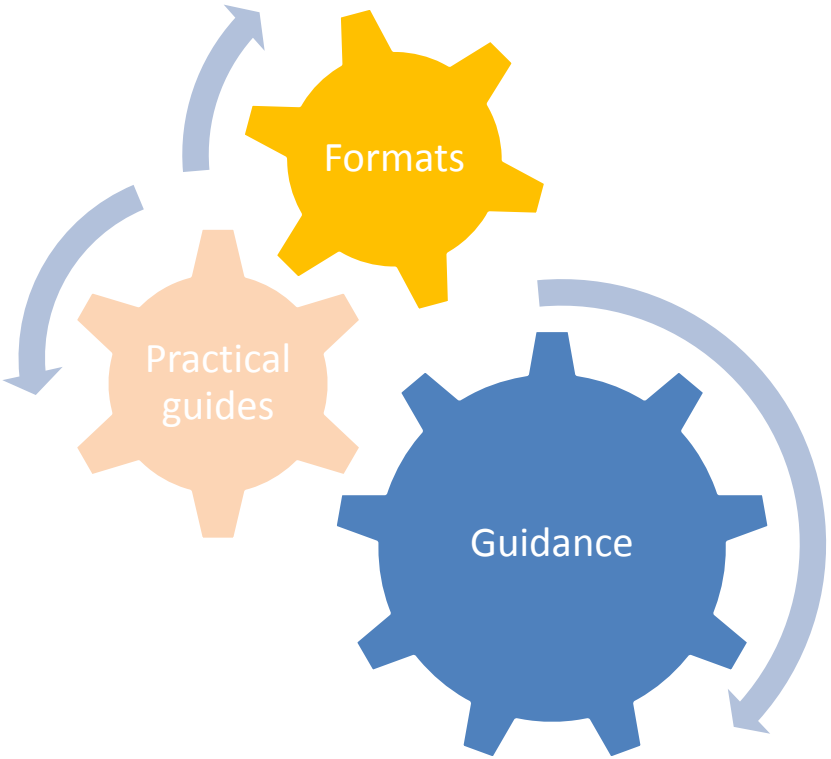
European Chemicals Agency

Streamlining of the information



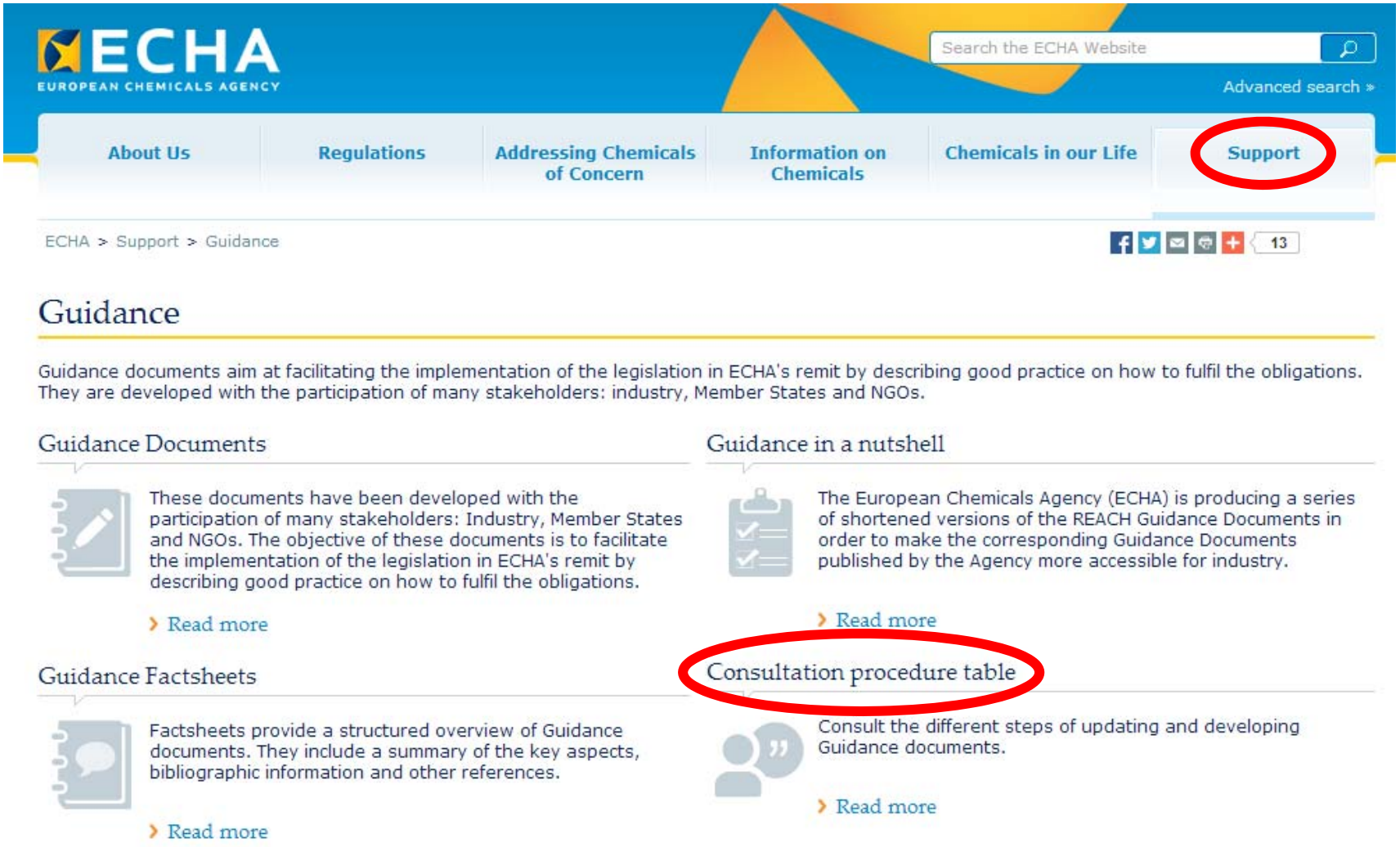
- Removal of duplicated information
- Integration of relevant information in one place
- Better interrelation between the documents
- Clearer distinction of the type of information that should be presented in each type of document

Guidance document	Status
	UPDATES
R.12 (use description)	• 10 days cross check with the CARACAL • **Publication by the end of year**
Part D (ES building) Part F (CSR)	• Drafting phase • PEG consultation starting in November
R.14 (workers)	• Drafting phase • PEG consultation starting in November
Part E (Risk characterisation) (Focus on Physico-chemical hazards)	• PEG consultation closed – No PEG meeting foreseen
R.15 (consumers)	• PEG consultation and meeting finished • New draft on infrequent uses being consulted previous to formal cross-check
R.16 (environment)	• PEG cross-check just concluded

Guidance document	Status
OBSOLETE	
R.13 (OC and RMM)	Potentially to be withdrawn when the updated Part D, R.14, R.15 and R.16 are published
R.17	To be withdrawn when the updated R.15 and R.16 are published

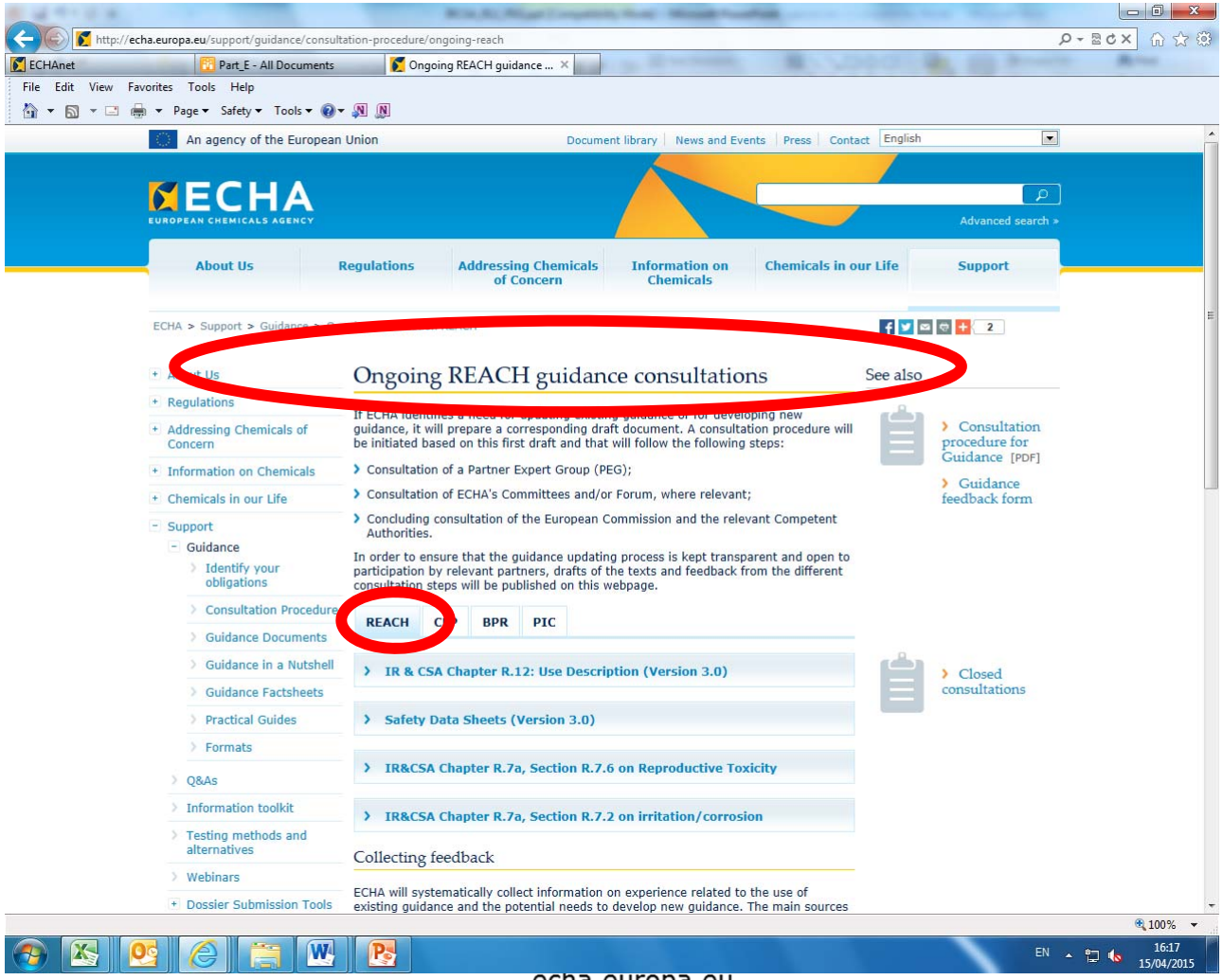
How to follow the process

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



R.12: Status

- ECHA further amended the guidance after the PEG meeting (+ comments during cross-check)
- Committees consultation (RAC & Forum) and CARACAL resulted in minor changes only
- Implemented agreed changes:
  - advice on changes implementation
  - new LCS use descriptor
  - revised scope of PROC1-3
  - examples and clarifications
- CARACAL cross-check on going (closing on 12 of November) and ECHA will proceed to publication unless objections are raised on the proposed final draft.

Part D

- Objective: to provide a general workflow for the CSA and an umbrella for the specific principles and methodologies for exposure assessment in the Guidance chapters R.14 to R.16
- Proposed new title: Framework for Exposure Assessment
- Proposed Table of Content:

D.1. Introduction [including workflow and REACH exposure scenarios and other legislation]

D.2. Characterise the substance and its hazards [including considerations on the scope of exposure assessment]

D.3. Conditions of use [including key exposure determinant and link to use maps]

D.4. Exposure Estimation

D.5. Risk Characterisation

D.6. Building the Chemical Safety Report

D.7. Exposure Scenario for Communication

APPENDIX D-1 : Exposure scenario structure

Chapter R.14 Occupational exposure assessment

Objective

- Focus on **exposure assessment** instead of exposure estimation; more emphasis on control strategies and risk management measures
- Include reminders/advice corresponding to observations from dossier evaluation
- Reduce details on measurement data; instead provide examples outside the guidance document
- Reduce details on modelling tools
- Clarify expectation regarding exposure estimates
  - related to acute systemic hazards
  - to dermal exposure
- Include points to consider regarding exposure when applying for authorisation

Risk related to physicochemical hazards (in Part E)

- Experience from ECHA's compliance check shows that risk resulting from physicochemical hazards of a substance have not always been addressed to a level of 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.

PEG comments overview (127 comments)

- Which properties trigger hazard assessment? Objective of HA is classification, so which classifications trigger exposure assessment and risk characterisation?

- BAuA have asked for their assessment method to be included in the Guidance

- How to to report the RMM, in the ES or main body of the SDS. Where to report in Chesar/ IUCLID? Phrase catalogue available or to be developed?

Chapter R.15 Consumer exposure estimation

Objective

- Update the information regarding modelling tools.
- Integration of the relevant sections from Chapters R13 and R17
- Develop new sections on Specific Consumer Exposure Determinants (SCEDs), specific children exposure and infrequent use

Overview of the issues discussed at PEG

- Aggregated exposure from different sources
- Accidental exposure & foreseeable uses
- Applicability of models (exposure via house-dust; Tier 1 approach to exposure from articles)
- Revised approach regarding assessment of low frequency of use and short duration of exposure:
  - The revised approach was presented at the meeting and it was agreed to give an extra time [3 weeks] for written consultation before proceeding to the cross-check period.
  - The draft is available as a “second draft to PEG” in the guidance consultation site. Key points:
    - Adjust the RCR that had been determined based on the long-term systemic DNEL
    - Default adjustment factor of 10; increase up to 100 based toxicological characteristic

Chapter R16: environmental exposure assessment

- Objective: Provide user friendly description of the various steps of environmental assessment in one document (improved accessibility for less expert users)
  - All equations (e.g. related to fate modelling) and technical details moved to appendix
  - Not updated with regard to “recent” science development

- Key elements:
  - More focus on the various types of conditions of use driving the releases, for example:
    - Tonnage: clarification on site tonnage and use tonnage
    - Design of technical process
    - On site risk management measures
  - More focus on release estimation methods: SPERCS, site specific cases, considerations for Article service life

Some issues discussed at the PEG (i)

- Scope of exposure assessment: new visual description
- Clarification on different options for registrants to define use tonnage (used in the assessment):
  - EU tonnage for the use (for all registrants)
  - Registrant' s own share of EU tonnage for the use
  - Joint submission highest share of EU tonnage for the use
  - Worst case based on registration tonnage
- Clarification on combined exposure (across uses or across activities at the same site)

Some issues discussed at the PEG (ii)

- Waste life stage. Advice to make reference to existing standards when applicable. Specific advice on how to carry out the assessment is kept in guidance Chapter R.18.

- ERC factors changes:
  - Release factor for water for ERC 8C has been modified:
    - To a default 30% (substance is dissolved/dispersed in a surplus of water and applied to an article via dipping/immersion/spreading).
    - A release factor of 5% is applicable for other widespread uses
  - The release factor for ERC 8F has been adjusted accordingly (relevant only regarding non-water-based activity). The values for 8C and 8F are fully based on TGD Table A.4.1 and A4.5

Exposure to Substances in Articles

ENES 9

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An example of consumer exposure to Substances in Articles

- Example aims to give **registrants support in addressing the exposure assessment** for SiA
- Hypothetical (semi volatile) substance in a synthetic resin used in buildings material (e.g. for walls)
- Focus on release from the article to indoor air
- Example covers “passive” use by consumers (dermal and inhalation exposure); not DIY processing of the material (cutting, machining).
- Example published on ECHA website
  - http://echa.europa.eu/web/guest/support/practical-examples-of-exposure-scenarios

What you can find in the example

- General framework explains assessment steps for exposure to substances in articles
- How to build the exposure scenario from the assessment case (collection of conditions of use, definition of the activities covered and not covered)
- Tier I as well as Tier II exposure assessment (only for inhalation) based on a refined modelling tool.
  - Tier I exemplified via ECETOC TRA, Tier II (inhalation) via RIVM emission model (main assessment) and Consexpo (supportive assessment)
- Exemplification of an uncertainty analysis
- General advice to registrant based on the example
- Exposure scenario provided in “Chesar format”

Follow up activities: under consideration

- Identify via examples when the registrant can consider the exposure assessment to substance in an article is not relevant (or negligible) and what kind of evidence is expected to justify his decision
- Filling the specific gaps identified in the exposure assessment for substances in articles:
  - Extrapolation of releases or exposure from different sources, routes or similar substances
  - How to generate ad hoc measured data
- Examples of environmental exposure, with particular reference to the waste stage

Thank you!

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