Evaluation

CEFIC REACH Implementation Workshop IX

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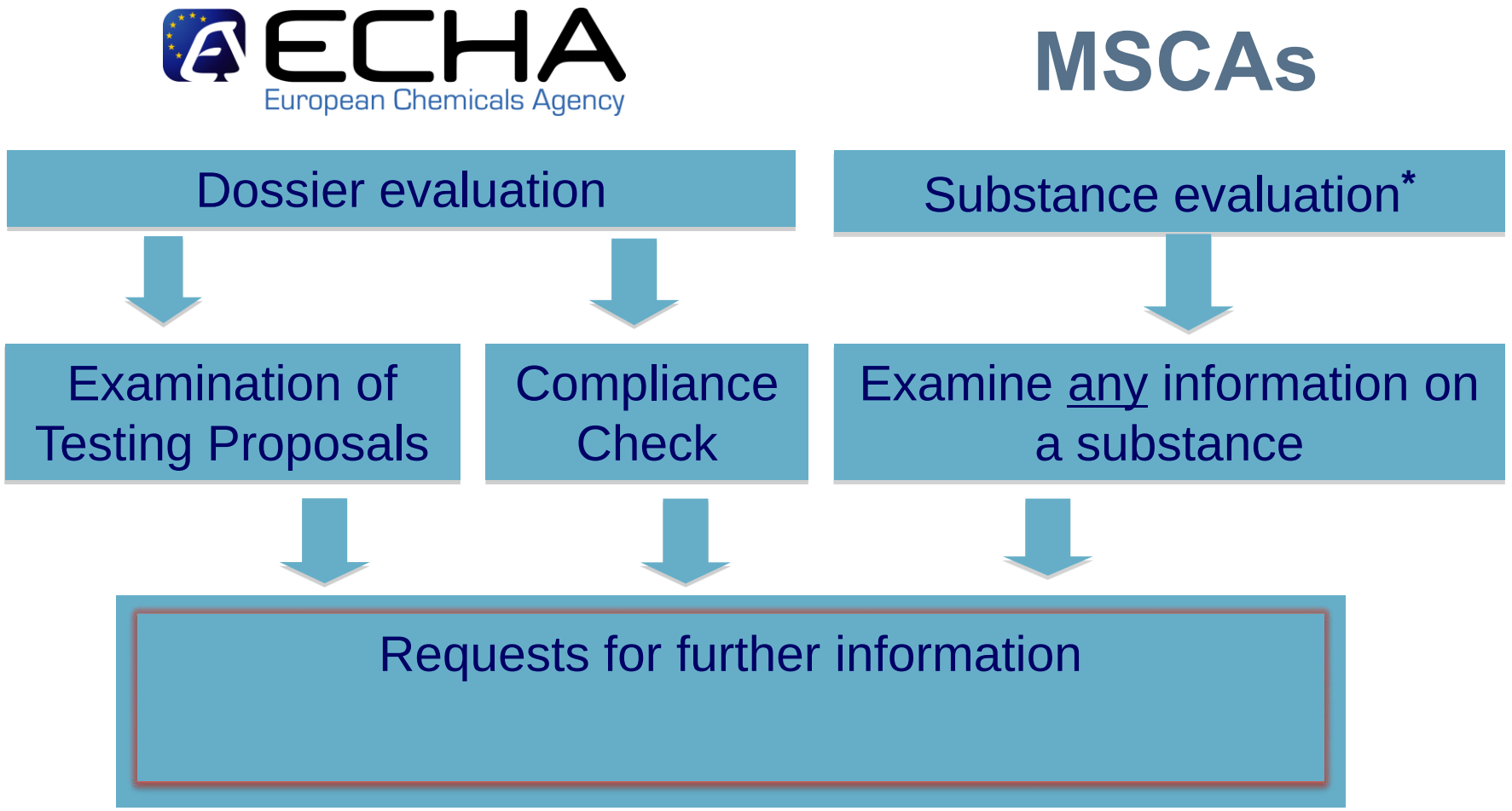
ECHA – Evaluation Unit II

Evaluation Overview



* Process in preparatory phase, evaluation to be started in 2012

MSCA = Member State Competent Authority;

Substance evaluation

- Start in 2012
- Preparations ongoing
- Draft Community Rolling Action Plan (CoRAP) under discussion
- Workshops organised with the Member States
  - Criteria for prioritising substances for the CoRAP
  - Timelines and processes leading to the first CoRAP
- Fact sheet available with more information
  - Factsheet Substance Evaluation (ECHA-11-FS-03-EN)

Scope, aim and outcome of dossier evaluation

Evaluation type	ECHA questions	ECHA examination conclusions	Numbers and timelines
Testing Proposal Examination (TPE)	Proposed test adequate and justified? Unnecessary animal testing avoided?	Article 40(3) draft decision: •Accept testing •Reject testing •Change test conditions •Request additional testing	All testing proposals •non phase-in: draft decision in 6 months •phase-in submitted by 1 Dec 2010: draft decision by 1 Dec 2012
Compliance Check (CCH)	Information requirements adequately fulfilled? Adaptations adequately justified?	Article 41(3) draft decision: •Request further information Other outcomes: •Quality Observation Letter – indicates elements to be improved •No further action	Select at least 5% of total received for each tonnage band •draft decision within 12 months of start CCH

Status of Dossier Evaluation

- Directorate Evaluation with three evaluation units
- Detailed process description on webpage
  (see http://www.echa.europa.eu/publications_en.asp)
- Objectives up to 2012 (see also ECHA's multi-annual plan)
  - 600 parallel dossier evaluations per year
  - About 570 testing proposals have to be examined by December 2012
  - Additionally 350 compliance checks will be concluded in 2011 and 2012
- By end of May: 210 CCh concluded, 61% draft and final decisions, 21 % quality observation letters
- By end of May: 572 TPEs to be conducted, 38 % started, 45 draft or final decisions submitted so far

Third party consultation of testing proposals

- 430 dossiers containing testing proposals concerning vertebrate testing
- Third party consultations already closed or ongoing: 223
- Relevant scientifically valid information related to the hazard properties of the substance is required
- Currently, hypothetical testing strategies are most often provided not meeting the characteristics of ‘relevant valid information’
- Therefore, testing needs are not changed due to the results of the third party consultations
- Increased transparency through publication of ECHA responses on third party feedback on our website
- This increased transparency could thus over time lead to improved contributions

Recommendations for registrants (i)*

- Identity of the registered substance – describe it clearly
- Adaptation to the standard information requirements
  - must meet the conditions set out in Annex XI or in column 2 of Annexes VII – X of the REACH Regulation;
  - sufficient justification for any adaptation should be provided;
- Experimental data for endpoints must meet the information requirements
- Robust study summaries - sufficient level of detail required to allow an independent assessment of the information provided
- Classification and labelling - in line with the hazards identified or harmonized classification and labelling
- Testing proposal

* See also Article 54 report on evaluation

Recommendations for registrants (ii)*

- Check consistency
  - Between CSR and IUCLID file
  - Between different parts of the CSR
- Always provide justifications for
  - Omission or modification of a standard CSR element (see REACH Annex I) (e.g. if it is not possible to derive a DNEL or PNEC)
  - Deviations from guidance documents (e.g. if non-standard assessment factors are used in PNEC or DNEL derivation)
- Qualitative assessment and justifications are not just statements
  - Detailed reasoning and supporting data are required
- Ensure transparency
  - Give details on model assumptions, versions, input parameters

* See also Article 54 report on evaluation

CSR = Chemical Safety Report; DNEL = Derived No-Effect Level; PNEC = Predicted No-Effect Concentration

Consultations of the registrant on the draft decision

Key steps during the decision-making process

- Step 1: After receiving a draft decision
  - Registrant may comment and provide dossier updates within 30 days
  - Also possibility of informal interaction (e.g. teleconference)
  - ECHA may amend draft decision or decide on no further action
- Step 2: After MSCAs provide proposals for amendments
  - Registrant may comment within 30 days on proposals for amendments (and update dossier)
- Step 3: During Member State Committee procedure
  - Case owner (registrant who received the draft decision) may participate in the MSC initial discussions on the draft decision
  - MSC result will be the final decision

MSCA = Member State Competent Authority; MSC = Member State Committee

Intermediates

- Isolated on-site and transported intermediates benefit from reduced information requirements when strictly controlled conditions are applied (Art. 17 & 18)
- After screening over 400 dossiers of substances registered as intermediates, in 86 % of the cases information was found to be inconsistent or missing in relation to:
  - Intermediate status
  - Specifications of strictly controlled conditions
  - Plausibility of risk management measures (RMMs)
- Missing information will be requested from the registrants
- ECHA may conclude that a registration dossier does not fulfill the conditions for reduced information requirements
- ECHA encourages registrants to proactively reassess and, where necessary, update their registration dossiers

New publications 2011

- Evaluation under REACH – Progress Report 2010
  - Yearly report according to Article 54
- Dedicated website section on evaluation
- Fact Sheet on Substance Evaluation, 2011 CoRAP Selection Criteria
- Practical Guide 12. How to communicate with ECHA in dossier Evaluation
- Updated guidance on Intermediates (Dec. 2010)
- Publications later this year 2011
  - Article 117(3) report on implementation and use of non-animal test methods under REACH
  - Guidance on scope of the exposure assessment

See http://www.echa.europa.eu/publications_en.asp

Key Messages

- Do not consider your registration dossier as a final product
  - Take a pro-active approach and update your dossiers when new information on hazards or uses becomes available
  - Take into account the recommendations in the Article 54 report
  - Do not await the outcome of potential compliance checks - improve the quality of the dossiers through updates on your own initiative
  - Further compliance checks will be conducted and reporting on the results will improve the quality of the dossiers
- Use the results of the evaluation processes for the dossiers to be submitted by the next deadline