Data quality for evaluation

Lead Registrants Workshop, ECHA

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Evaluation Unit E3

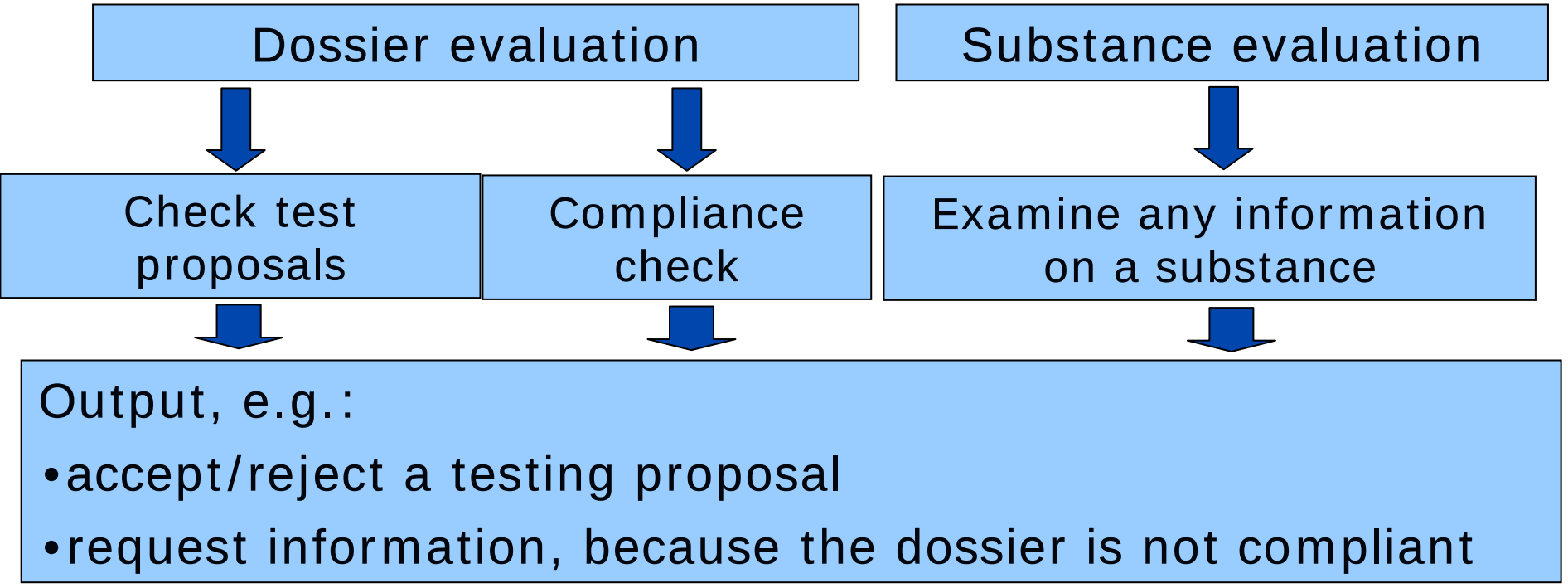
Outline

- Evaluation overview
- Dossier evaluation: compliance check
  - Feedback on data quality
- Dossier evaluation: testing proposal examination
  - Feedback on data quality
- Dossier evaluation: general recommendations
- Substance evaluation: initial recommendations
- Key messages for Registrants

Evaluation overview

ECHA

MSCAs



Dossier Evaluation: compliance check process

Evaluation type	ECHA questions	ECHA examination conclusions	Numbers and timelines
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

Dossier Evaluation: compliance check feedback (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 REACH Regulation;
  - sufficient justification for any adaptation should be provided;

- Robust study summaries: sufficient level of detail required to allow an independent assessment of information provided

- Classification and labelling: in line with the hazards identified or harmonized classification and labelling

Dossier Evaluation: compliance check feedback (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)
  - Deviations from guidance documents
- Qualitative assessment and justifications are <u>not just statements</u>
  - Detailed reasoning and supporting data are required
- Ensure transparency
  - Give details on model assumptions, versions, input parameters
- Use of Chesar and QSAR toolbox is recommended

Dossier Evaluation: testing proposal evaluation process

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

Dossier Evaluation: testing proposal evaluation feedback (i)

- Submit proposals for tests required under Annex IX and X before undertaking them
  - Performing testing without an approving ECHA decision may lead to enforcement actions
- Provide adequate Substance identity information
  - Registered substance
  - Test material
- Check consistency between IUCLID file and CSR
  - Make sure the testing proposal is present in IUCLID
  - Do NOT propose testing only in CSR
- Be clear that you are proposing a new test
  - choose correct study type in IUCLID: “Experimental study planned”

Dossier Evaluation: testing proposal evaluation feedback (ii)

- In case of using category/read across approach:
  - Provide justification on why you think this is appropriate
    - Consider legal text Annex XI 1.5 of REACH
    - Strengthen your rationale for read-across
    - Not “wishful” thinking but “more information is better”
  - Value generated by prediction must be adequate for the purpose of risk assessment and/or classification and labelling
    - Information must be equivalent or better quality
- IUCLID
  - Include robust study summaries on the read across substance (including read-across test material data) in your IUCLID file
  - Ensure the category justification is clearly presented in IUCLID
    - Do NOT propose category approach only in CSR

Dossier Evaluation: recommendations (i)

- Continuous development of new test methods
  - Follow the latest developments on current status of methods and their applicability
    - *in vitro* methods: Tracking System for Alternative test methods review, Validation and Approval in the Context of EU Regulation on Chemicals (TSAR);
    - http://tsar.jrc.ec.europa.eu
  - Extended One-Generation Reproductive Toxicity Test (OECD TG 443)
    - ECHA considers the test guideline can be used
    - The modular nature of the guideline requires further specification of the study design to meet information requirements for Annex IX and X, 8.7.3 of the REACH Regulation
    - This is still under discussion between the Member States and European Commission
  - Transgenic Rodent Somatic and Germ Cell Assays (OECD TG 488; Annex IX, 8.4 of the REACH Regulation)
  - Chronic Toxicity to Higher Plants (ISO 22030; Annex X 9.4.6 of the REACH Regulation)

Dossier Evaluation: recommendations (ii)

- Chemical safety assessment
  - "*To assess and document that the risks arising from the substance…[]…are adequately controlled*" (Annex I Section 0.1)
- Hazard assessment
  - Follow advice of ECHA Guidance on use of assessment factors (AF) and derivation of no-effect levels (DNELs)
  - Justify and document your choice and any deviations in approach
- PBT assessment
  - Take into account and address all available information on your substance (e.g. substance is on candidate list of SVHC)
  - Minimisation of emissions for PBT substances needs to be demonstrated
- Exposure assessment, risk assessment and risk characterisation
  - Adapt generic exposure scenarios to the identified uses
  - Describe sufficiently and concretely operational conditions and risk management measures
  - Demonstrate safe use of your substance

http://echa.europa.eu

Substance evaluation: Recommendations

- CoRAP (to be published end February 2012)
  - Is your substance on the CoRAP?
  - Get prepared within your consortium!

- Substance evaluation draft decisions will be prepared within one year
  - Could result in further requests for information. Such as:
    - Testing requirements that go beyond the REACH standard information requirements
    - Exposure related information

- Be prepared to handle the incoming draft decisions

- Organise your commenting (same timelines as under Dossier Evaluation)

Key Messages for Registrants

- **Do not consider your registration dossier as a final product once submitted**
  - 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 yearly Article 54 report
  - Do not await the outcome of potential compliance checks - improve the quality of the dossiers through updates on your own initiative
  - Make use of the informal communication offered by ECHA
  - Further compliance checks will be conducted and reporting on the results will improve the quality of the dossiers

Thank You!

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