

“ECHA’s first experiences with evaluation”

ECHA’s Second Stakeholders Day

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Evaluation

European Chemicals Agency



Topics

- Introduction
- Compliance Check
- Key Messages
- Decision Making Process
- Summary

ECHA: Dossier evaluation

**Member States:
Substance
Evaluation**

**Testing
Proposal**

**Compliance
Check**

1st list of
substances by
1.12.2011

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Compliance check: What is Checked?

- Art 41(1): ECHA **may** examine **any** registration in order to verify **any** of the following:

Information requirements in compliance with REACH

Articles 10, 12 and 13, Annex III and Annexes VI-X

Justifications for adaptations of standard information requirements

Annexes VII-X, column 2 and Annex XI

Compliance of CSR with Annex I, Adequacy of RMM

Objective basis for opt-out from joint submission

Compliance check:

What are the possible outcomes?

1) Formal Decision (Article 41(3))

When

- Provided information is not in compliance with REACH

Content

- Specifies additional information needed for compliance
- Includes a statement of reasons
- Sets a deadline for an update of the registration dossier

Note

- Subject to appeal

Compliance check:

What are the possible outcomes?

2) Communication Letter

When

- Further information is requested which should already be available to the registrant, e.g. a full study report
- Shortcomings in the dossier which do not justify to the opening of the formal decision-making procedure
- Deviations from the guidance which lack adequate justification

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Experience 1: Unclear substance identity

Clear and unambiguous identity is a prerequisite for evaluation

- Registered substance
 - Chemical identity
 - Composition (e.g. impurities)
- Test material used for the studies

Experience 2: Missing or inadequate justifications

- Adaptations from the standard requirements must be based on the provisions of the legal text
 - Annex XI and
 - Annexes VII – X, column 2.
- An adequate justification must be provided each time.

Experience 2: Justifications

How to improve - Examples

- Grouping of substances/read-across:
 - describe substance ID (including impurities) of the analogues/similar substances
 - provide hypothesis for why the category is formed/read-across can be applied (criteria on similarities)
 - compare the available phys-chem, toxicological (including toxicokinetics), ecotoxicological and environmental fate data
- (Q)SARs:
 - provide information on the model, in particular on its scientific validity (QSAR Model Reporting Format (QMRF))
 - explain the applicability of the model to the query substance (applicability domain) and provide information about the prediction (QSAR Prediction Reporting Format (QPRF))

Experience 3: Poor Quality of documentation

- Detailed Robust Study Summaries for key studies are needed.
- Robust Study Summaries must allow an independent assessment of the study!
- In most cases: MORE = BETTER

Exposure based waiving (Annex XI. 3)

- New provision since 20 February 2009:
Commission Regulation 134/2009
- Applies to:
 - Repeated dose and reproductive toxicity studies (Annex VIII)
 - All testing requirements \geq 100 t/a (Annex IX and X)

Exposure based waiving

→ How to apply Annex XI.3?

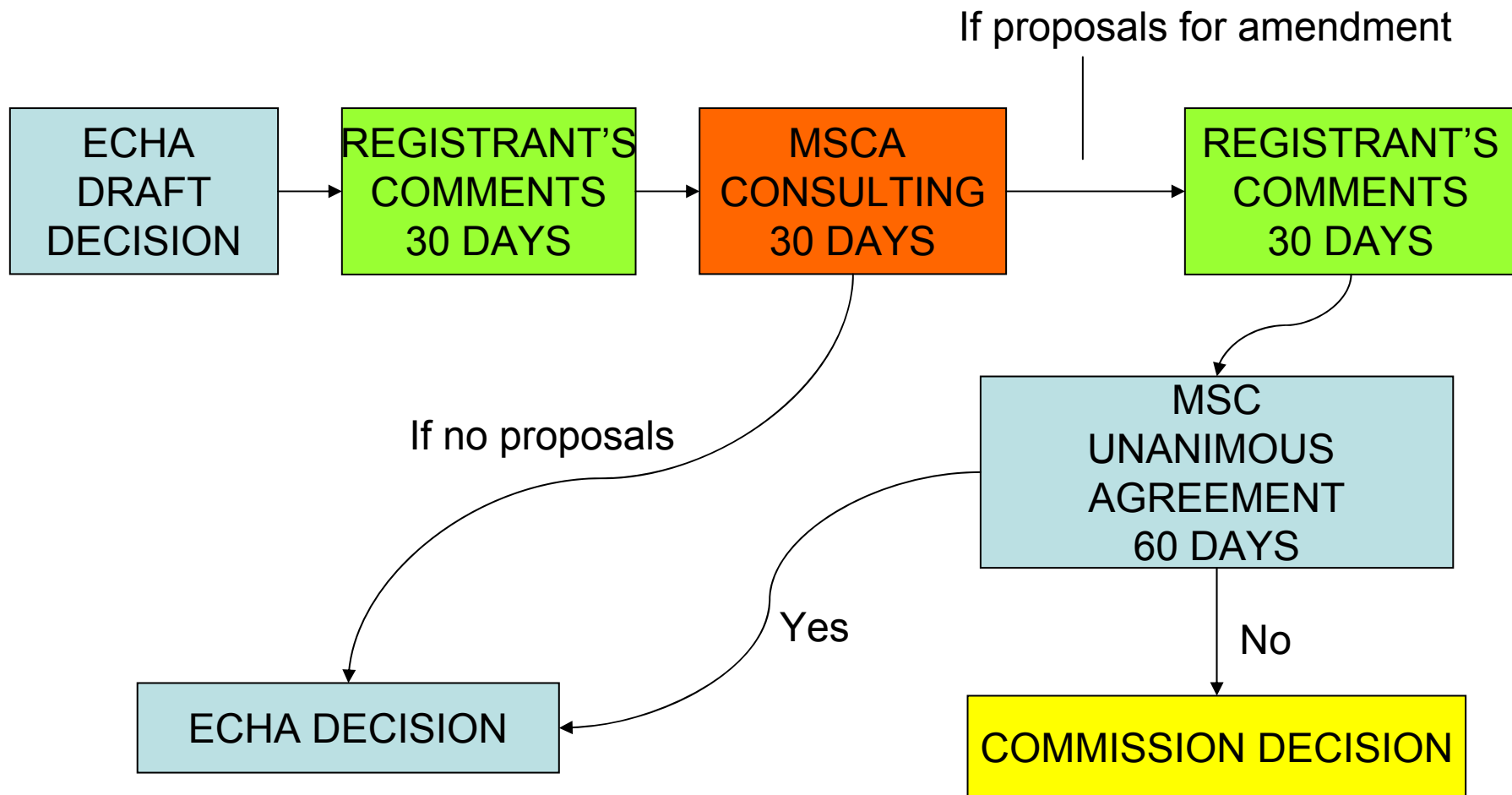
- All relevant exposures throughout the life cycle must be covered.
- Adequate justification and documentation must be provided in the Chemical Safety Report.
- The specific conditions of use must be communicated through the supply chain.

Good Laboratory Practice

- Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with GLP (or equivalent)
- GLP-status is required for mandatory studies after 1.6.2008.
- The GLP status will be checked
 - in case of doubts or
 - through spot-checks.
- ECHA will co-operate with GLP Monitoring Authorities to request study audits.

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Decision making process: Involvement of the Registrant



MSCA = Member State
Competent Authorities

<http://echa.europa.eu>

MSC = Member State
Committee

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- Provide sufficient information on substance identity.
- Provide adequate and reliable documentation and justification for QSAR, Read across, grouping and exposure based waiving.
- Ecotoxicological and toxicological tests and analyses must be carried out in compliance with GLP.
- Ensure good quality and content of the documentation.
- Read annual ECHA reports on evaluation (published on internet by 28 February each year).

Thank You
for your attention

