Dossier evaluation

CHÉMIA 2012
Safe Management of Chemicals

3-5 October 2012, Liptovský Ján, Slovakia

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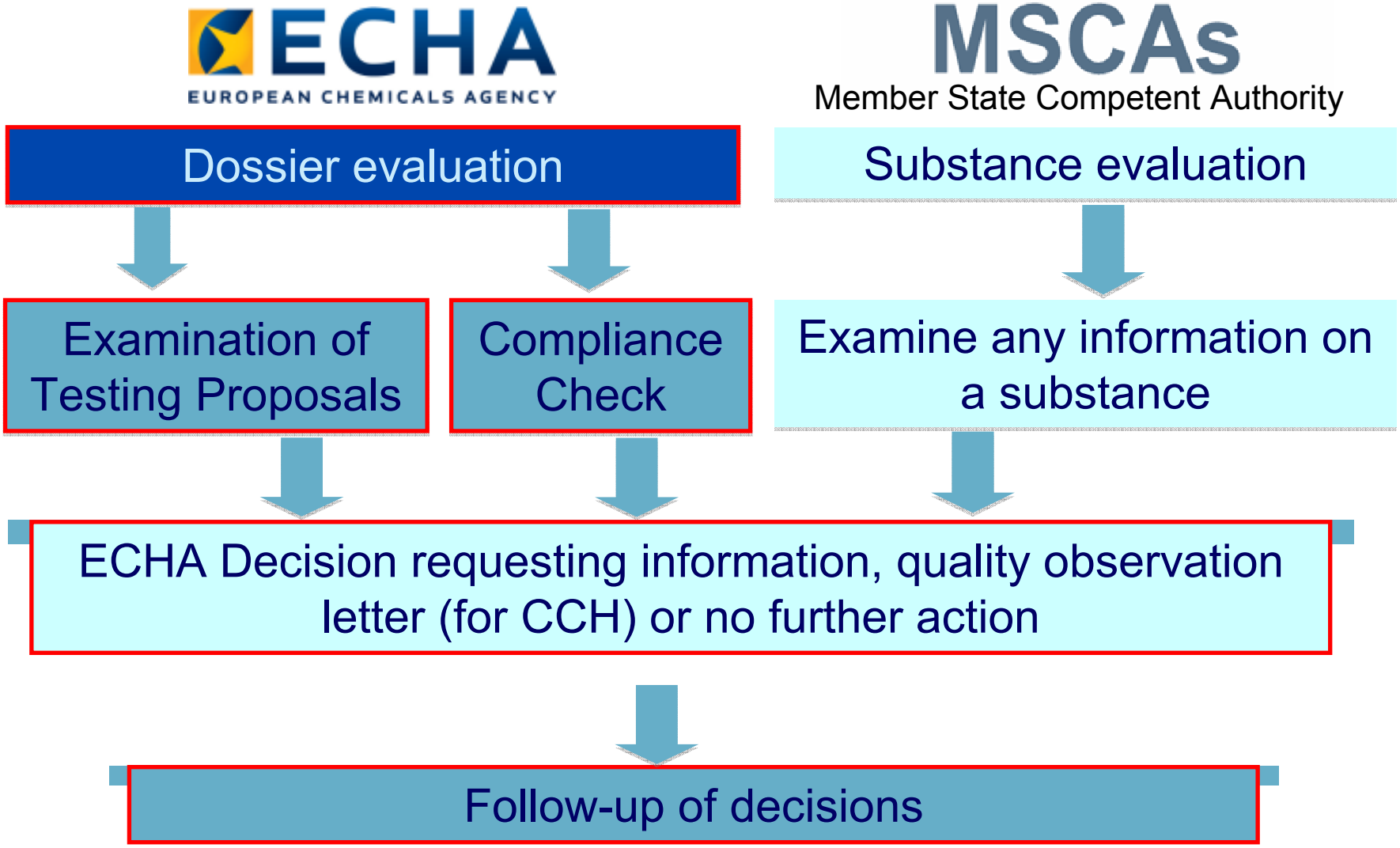
Evaluation - Overview



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

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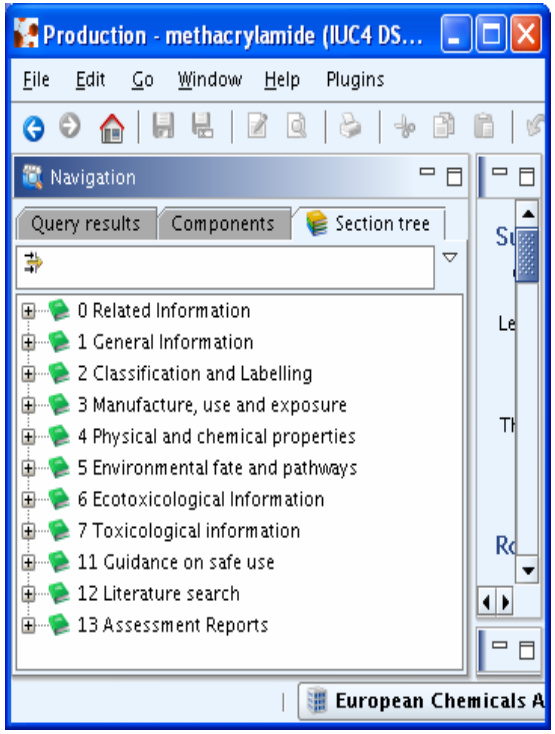
Dossier Evaluation

Compliance check

Dossier quality and compliance

- Good quality information in registration dossiers is needed to ensure the safe use of chemicals
- REACH places the responsibility on companies to ensure safe use of their substances and compliance
- Evaluation (the “E” in REACH) is there to support registrants in their obligation to provide adequate information on registered substances
- The main findings of the evaluation processes are reported each year in Evaluation reports (since 2008)

Aims of the Compliance Check



- To check whether the information requirements are fulfilled in the registration dossiers
- To promote the quality of registrations
- ! Main instrument to request missing information, if information requirements are not addressed (=non-compliance)

When will ECHA perform a Compliance Check?

- The Agency may perform a compliance check of any registration dossier.
- Currently concern drive selection is applied (e.g. certain toxic/ecotoxic properties, wide use/exposure, many waivers, read-across/categories)
- Some priority setting is suggested in the legislation:
  - Dossiers where information is submitted separately (opting-out of joint submission)
  - Dossiers [1, 10t] , not full Annex VII (not fulfilling the criteria of Annex III)
  - Substance is on Community Rolling Action Plan (Substance Evaluation)
- Random selection (currently about 25 % of cases)

What is checked for compliance?

1. **Information in the technical dossier(s)** complies with the requirements of Art. 10, 12 and 13 and with Annexes III, VI to X;
2. **Adaptations** of the standard information requirements in the technical dossier(s) comply with Annexes VII to XI;
3. **Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR)** comply with Annex I and that the proposed **Risk Management Measures (RMM)** are adequate;
4. **Explanations** for separate submission from other registrants have an objective basis.

ECHA's strategic approach for Compliance Checks (CCH)

- ECHA's observations on the quality of registration dossiers: significant part have important quality deficiencies
- ECHA's strategic aim: "*improve the quality of data submitted by industry and disseminated by ECHA to enable the safe manufacture and use of chemicals*"
- Improved IT tools for Evaluation are crucial for Dossier Evaluation throughput
  - Supporting consistency and efficiency
  - IT-supported selection and pre-assessment essential

Types of Compliance Check

Full Compliance Check (mostly random)

1. Substance ID CCH
2. Technical dossier
3. Chemical Safety Report - CSR

Targeted Compliance Check (concern based)

- General concern ("Very poor content")

- **Area of Concern (AoC)**
  - **1. Selected (combination of) endpoints**

  - **<u>2. Including "Special AoCs"</u>**
    - **SID CCH** (Testing proposals, Categories, Read Across)
    - **Substance Evaluation** (Concern for CoRAP)
    - **Individual submission** (Violation of "joint submission principle")

Improving dossier quality by targeted Compliance Checks

- Complements current compliance check activities
- Aimed at having maximum impact on safe use of chemicals
- More efficient use of limited ECHA Evaluation resources
- ECHA will target compliance checks to specific dossier issues (e.g. endpoints) that have immediate impact on safety
- Poor information on these endpoints affects safety and reliability of the chemical safety assessment

And how will it work?

- ECHA and Member State Competent Authorities identify dossier issues, e.g. endpoints, of highest concern
- IT tools screen **all** submitted registration dossiers to identify suspicious dossiers with respect to the specific concern
- The specific endpoints in selected dossiers are then evaluated manually under a REACH compliance check
- Criteria for automatic selection for checking will include, *inter alia*:
  i) Dossiers submitted individually outside an existing joint submission;
  ii) Dossiers with incomplete essential elements of Chemical Safety Report
- If incompliant, the registrant receives a compliance check decision from ECHA

Effects of the targeted CCH strategy 1(2)

- REACH does not limit the number of compliance checks so registrants with a number of incompliances in a dossier may get multiple CCH decisions
- Registrant has an opportunity to make formal comments
- ECHA does not foresee an opportunity for informal communication with ECHA during the 30-day commenting period due to the reduced complexity of the cases and the high numbers of such targeted CCH draft decisions
  - The series of Webinars is provided instead
- When receiving a draft decision requesting testing, registrants have the opportunity to check if the adaptations used could be improved in order to avoid testing

Therefore:

- Registrants are encouraged to proactively update their dossiers to avoid multiple decisions
- Doing a good job from the start is worth the effort and will help you avoid getting one or more draft decisions

Effects of the targeted CCH strategy 2(2)

- Rewards companies that do a good job by addressing poorly performing companies effectively
- The chances of poor quality dossiers being picked up for compliance check are even higher with the new approach
- Companies have the last chance to update their dossiers before they are picked up for evaluation – **improve your dossier quality now**!
- Joint registration is not an option, it is a legal obligation
- To be able to follow the legally bound Evaluation decision-making procedure ECHA will not take into account dossier updates received after when ECHA has sent the draft decision to Member State Competent Authorities
  - ECHA will notify the Member State Competent Authorities without undue delay after the Registrant's 30-day commenting period
- Monitoring and follow-up of compliance with the ECHA decisions is an integral part of Evaluation

Evaluation of testing proposals

Aim of testing proposal evaluation (TPE)

- To stimulate and support industry towards efficient testing
- To conduct testing **only as a last resort**, in particular for vertebrate animal testing

When testing proposals are submitted?

Required by REACH Annexes IX and X:

- Registrants identify a data gap and cannot otherwise fulfil the REACH information requirements;
- Additional testing is triggered by risk, e.g.:
  - available information of the substance is inconclusive;
  - further investigation is needed

Art. 40: the Agency shall evaluate any testing proposal in a registration or DU report

Deadlines:

- for non phase-in substances: 180 days after receipt

- for phase-in substances:
  - by 1 Dec 2012 (if received by 1 Dec 2010; >1000 tpa, CMR…)
  - by 1 Jun 2016 (if received by 1 Jun 2013; 100-1000 tpa)
  - by 1 Jun 2022 (if received by 1 Jun 2018; 1-100 tpa)

How we evaluate testing proposals?

- Is the testing proposal justified?
  - Is the test requested by Annexes IX-X?
  - Is all available information considered?
  - What impact on risk characterization, C&L or PBT/vPvB?
  - Information received from the 3rd parties during public consultation should be considered

- Is the testing proposal adequate?
  - Is the proposed test method reliable and relevant?
  - Is there a need to modify/adapt the test protocol?
  - Is further testing needed?

Third party consultation of testing proposals

- Launched for all testing proposals – 481 up to now
- 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

Commenting on draft decisions (DD)

- **Registrant has two possibilities to comment:**
  - 1st: on the DD, that he received from ECHA; he also has the possibility for informal interaction at this stage (phone conference) for clarification
  - 2nd: he can comment on the Member States (MS) proposals for amendments
- MS can propose amendments on the DD2, in which ECHA has considered the registrants comment on the DD1
- When drafting DD3 for the member states committee (MSC) , ECHA thereby takes into account:
  - DD2
  - Member States Comments on DD2, and
  - Registrants comments on MSs comments
- The Registrant is invited to the MSC meeting discussing his case, if there are no confidentiality reasons to prevent this, also stakeholders will be present.

Follow-up of Final Decision

- Registrant submits an updated dossier prior to the deadline set:
  - a) Examination by ECHA
    - The update of the dossier is in line with the requests for further information
    - The update of the dossier is found to be not in line with the request or the results are not taken into account in risk assessment: follow up action has to be decided (e.g. enforcement by MS, recommendation for national risk management measures)
    - Informing Commission and MSCAs of the conclusions
  - b) Possible further EU-wide follow up
    - MSCAs/ECHA: Inclusion in CoRAP
    - MSCA: Annex XV dossier for authorisation
    - MSCA: Annex XV dossier for restriction
    - MSCA: C&L proposal

If no update submission by the registrant → MS enforcement matter

Recommendations for registrants *

- 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; Detailed reasoning and supporting data are required
- Robust study summaries - sufficient level of detail required to allow an independent assessment of the information provided
- C&L - in line with the hazards identified or harmonized classification and labelling

* ***See also Article 54 report on evaluation***

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Recommendations for registrants *

- 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)
- Ensure transparency
  - Give details on model assumptions, versions, input parameters
- Art. 117(3) report on use of non-animal test methods in REACH submitted to the Commission 30 June 2011 (every three years)

* ***See also Article 54 report on evaluation***

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CoRAP list –
Community Rolling Action Plan

What is a CoRAP?

- The Community Rolling Action Plan (CoRAP) specifies the substances that are to be evaluated by MS.
- Covers 3 years period – substances on the first CoRAP for 2013-2014 may be dropped or new ones introduced.
- When published on ECHA website, it triggers the start of substance evaluation process
- Published on ECHA website - 29 February 2012
- Rolling character
  - Annual updates
  - Selection criteria shall be refined in the coming years

- **2012 CoRAP list contains 36 substances**
- **Deadline 28.2.2013**
- **Q&A available**
  http://echa.europa.eu/web/guest/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

What happens after publication of CoRAP?

- Evaluation: from publication of CoRAP, evaluating MSCA has **12 months** for considering the need for further information and preparing request (draft decision).
- After adoption of decision, registrant(s) shall within timelines specified in the decision submit requested information to ECHA by updating the registration dossier(s) with new data.
- Follow up evaluation: Following this, MSCA must examine any information received and, if needed, draft any further appropriate decision within another 12 months of the information being submitted (Article 46(3)).

CoRAP
selection criteria development

- **Draft criteria** developed in collaboration of ECHA and the MSCAs / MSC meetings in 2010/11
- ECHA used the draft criteria to the extent possible in selecting substances for the first CoRAP
  - Items that can be searched via IT-applications
- For the purpose of establishing the 2012 CoRAP no further substantial amendments to the criteria

Selection Criteria

HAZARD related

- Suspected/Known PBT, vPvB, PBT-like
- Suspected endocrine disrupters
- Suspected/Known CMRs
- Suspected/Known sensitizers

RISK related

- RCR (characterisation criteria) not well below 1
- Cumulative exposure from structurally related substances with critical hazardous properties

Selection Criteria

EXPOSURE related

- Wide dispersive use
  - The number of sites of use
  - Pattern and amount of releases/ exposure
  - The number and type of uses and exposure scenarios from different registrants
  - The substance is incorporated into mixtures or articles used by the public
  - The potential size of the exposed population
- Consumer use and exposure of sensitive subpopulations such as children
- Aggregated tonnage

Substance evaluation: decision making

- Substance evaluation (draft) decisions are adopted in accordance with Articles 50 and 52 ➔ similar to CCH and TPE.
- Evaluation of substance, drafting and reviewing of decisions, checking of information received based on decision and follow-up, is the task of the Member States and/or MSC.
- Final decision is taken by ECHA.
- In case unanimous draft decision cannot be reached, decision making is referred to Commission ➔ Comitology procedure.
- Final ECHA decisions will be subject to possible appeals by registrants to ECHA's Board of Appeal, Article 51(8).

Follow up evaluation

- Registrant submits the further information to ECHA in updated dossier
- ECHA informs responsible MSCA of information received
- MSCA evaluates information within 12 months
- If no further information is needed to clarify the risk, the process is finalised (outcome document).
- If still further information is needed to clarify **new concern**, substance evaluation process could be repeated

Intermediate substances

Intermediates

- Isolated on-site and transported intermediates benefit from reduced information requirements when strictly controlled conditions are applied (Art. 17 & 18)
- ECHA has undertaken a more systematic IT-screening of intermediate dossiers.
- After screening of about 5500 dossiers of substances registered as intermediates, in 2388 of the dossiers information was found to be inconsistent or missing in relation to:
  - Intermediate status
  - Specifications of strictly controlled conditions
  - Plausibility of risk management measures (RMMs)
- Requests for clarifications are sent to 574 registrants
- ECHA encourages companies to carefully review the reported uses within intermediate dossiers

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Intermediates

- The possible options for registrants:
  - ✓ to better report intermediate uses in IUCLID 5.4
  - ✓ to update registration to a full Article 10 registration
- After three months period ECHA will undertake new screening
- ECHA may conclude that a registration dossier does not fulfill the conditions for reduced information requirements that may require regulatory actions
- http://echa.europa.eu/view-article/-/journal_content/0d1a14fe-9c63-4807-a3de-380c0dbffdf5

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Evaluation Progress Report 2011

- Annual Report
- On ECHA website, available in 22 languages
  - Progress in our activities
  - Information on common pitfalls
  - Recommendations
- All (existing and future) registrants are strongly advised to read this report
- Progress Report 2012 – will be published in February 2013
- http://echa.europa.eu/regulations/reach/evaluation

Thank You.

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