

## **Feedback from Dossier Evaluation**

***ECHA's Fourth Stakeholder Day***

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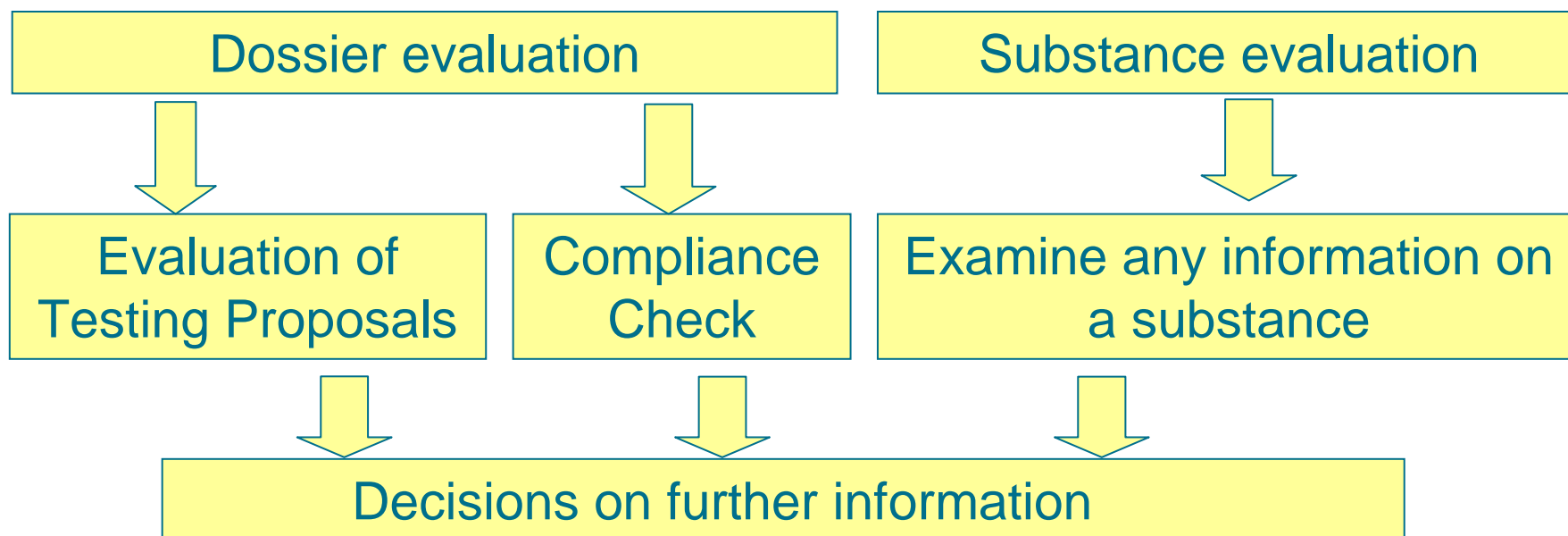
*ECHA – Evaluation Unit B1*

- Dossier Evaluation
- Key Recommendations
- Intermediates
- Summary

# Dossier Evaluation Overview



**MSCAs**



# Compliance Check



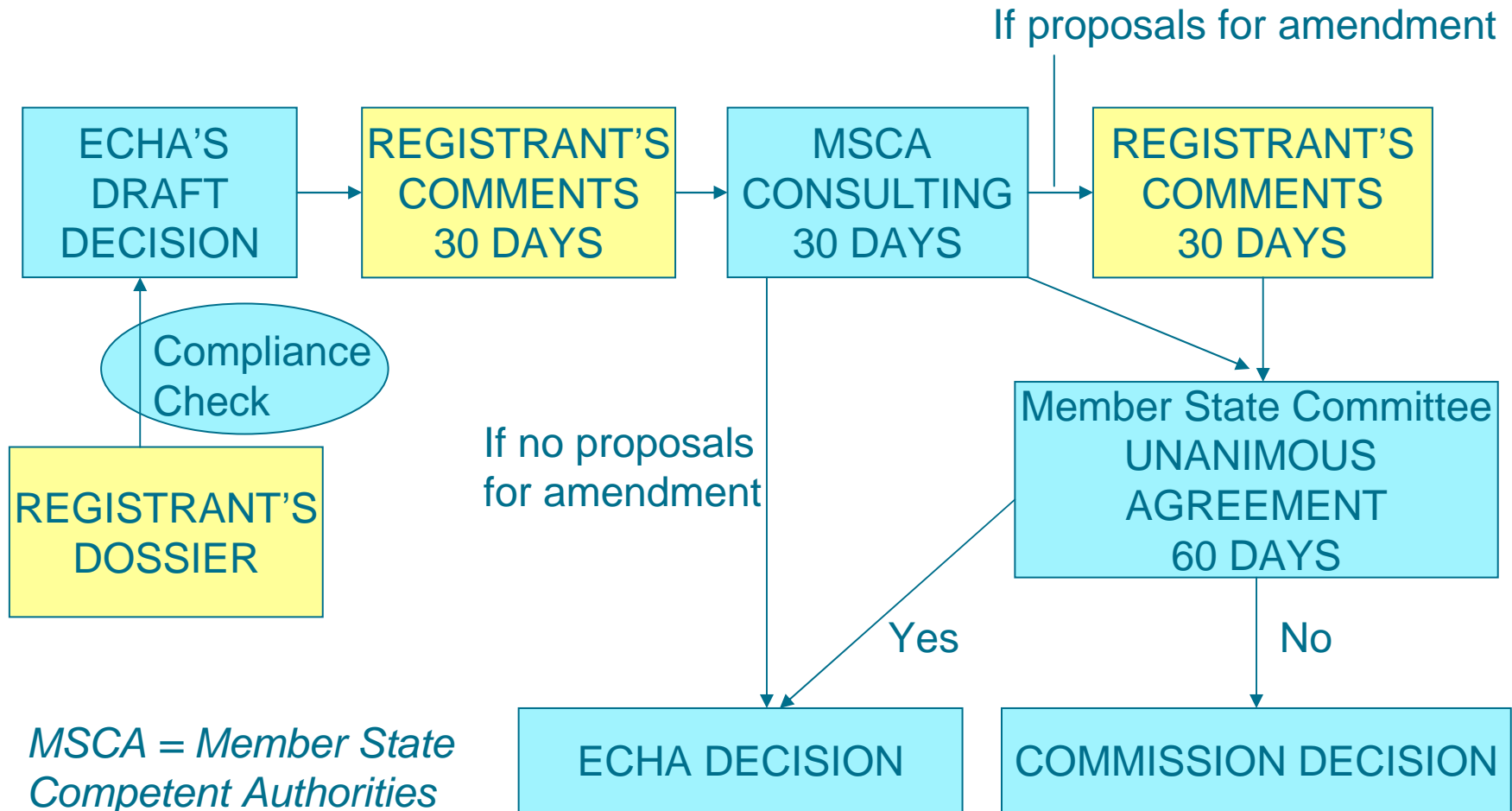
- Aim
  - Verify compliance with information requirements
  - Check adequate justifications for adaptations
- Which dossiers?
  - Only selected dossiers (Article 41)
  - At least 5% of dossiers from each tonnage band
- Outcome
  - Formal Decision, Article 41(3): request for further information
  - Quality observation letter: Indicate shortcomings & request update

# Testing proposal evaluation



- Aim
  - Examine proposals for tests specified in Annexes IX and X
  - Decide whether a proposed test is justified or adequate
  - Avoid unnecessary (animal) testing
- Which dossiers?
  - All dossiers containing a testing proposal
- Outcome
  - Formal Decision, Article 40(3):
    - Request or reject performance of test
    - change conditions
    - request additional testing

# Decision making process: Involvement of the Registrant



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# Key recommendations

Based on current experiences 2 major types of recommendations related to:

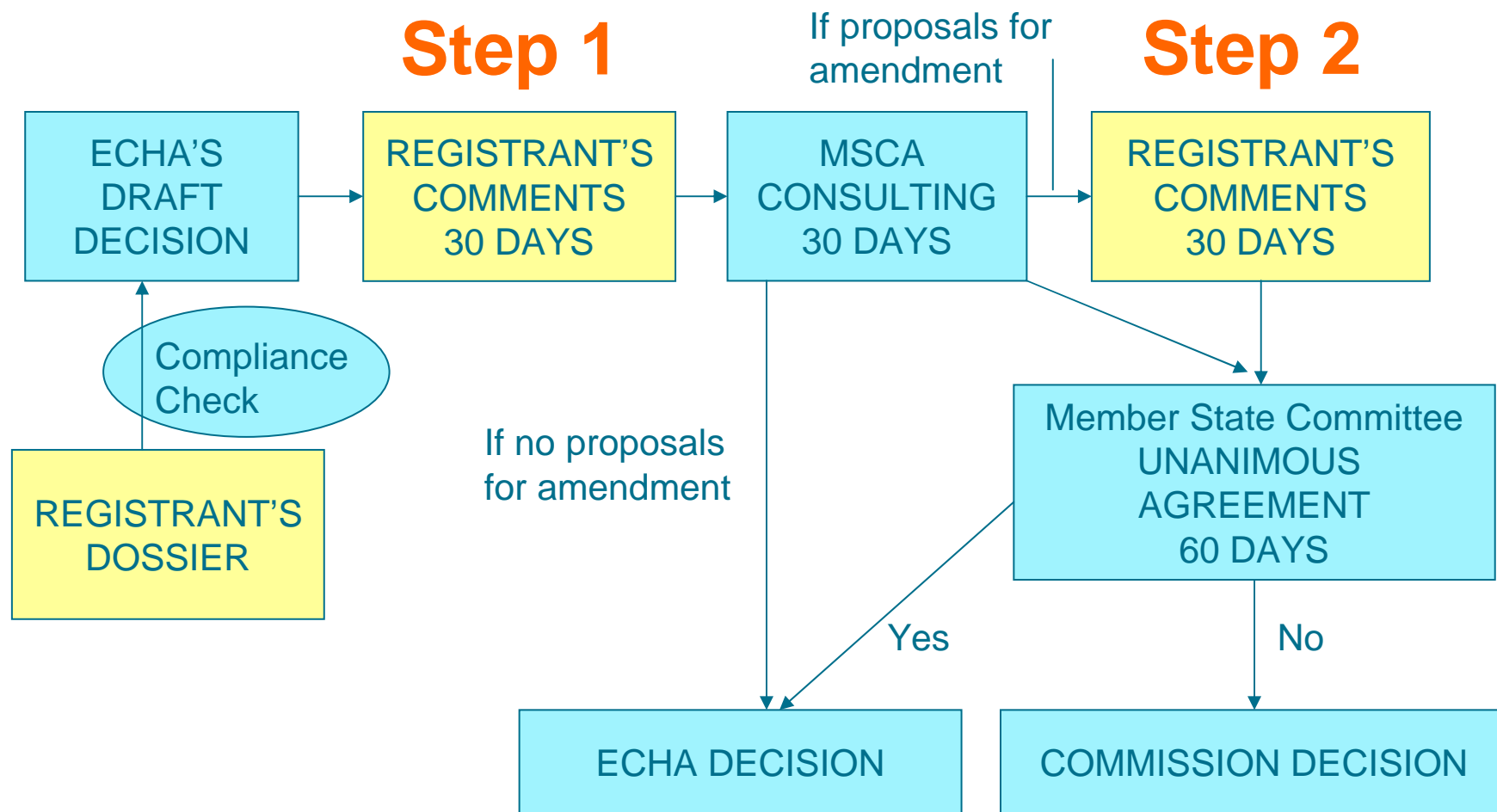
- Commenting role of registrants during decision making process (compliance check & testing proposal)
- Quality aspect of registration dossiers submitted

# Key recommendations: Commenting role of registrants-1



- During decision making process there are 2 key steps where registrant can provide requested information and bring dossier in compliance
- Step 1:
  - 30 days for commenting on ECHA's draft decision by registrant
  - ECHA could adapt draft decision
- Step 2:
  - If MSCA provides proposal for amendments to ECHA
  - 30 days for commenting by registrant
  - ECHA and MS could adapt draft decision (Member State Committee)

# Key recommendations: Commenting role of registrants-2



# Key recommendations: Commenting role of registrants-3

## Experience from Step 1 & 2:

- Hardly used to provide the requested information
- Rather used as a way to contend ECHA's decision without solid argumentation
- Very seldom new or additional scientific or experimental information is provided

### Example:

- Draft decision: based on missing QSAR documentation/justification, performance of test was requested.
- Commenting phase (Step 1) was opportunity for registrant to provide this missing information → unfortunately no new documentation provided
- No proposals for amendment from MSCA
- Therefore Final decision: request performance of test

# Key recommendations: Commenting role of registrants-4

## Reminder:

- If draft decision reaches MSC: In total about 5-6 months time could be available to provide new information before final decision is made
- Missed opportunities for registrants:
  - to update the dossier with missing information during decision making process
  - to avoid performing additional testing
    - E.g. by providing transparent and scientifically sound detailed justifications
- Right to comment = another chance to provide information

# Key recommendations: quality of dossiers - 1

## Clear and unambiguous substance identity is a prerequisite for evaluation

- Information on substance identity:
  - consistent and should allow unambiguous identification
- Naming convention according to guidance
  - ‘Guidance for identification and naming of substances under REACH’.
- Analytical information provided must confirm composition of substance
- Data requirements (Annex VI, 2) need to be fulfilled
  - provide scientific justifications if it is not possible to derive the required information.
- One substance = one registration

# Key recommendations: quality of dossiers - 2

## Missing or Inadequate Justifications

- Animal testing used as last resort, but...
- Adaptations from the standard requirements must be based on the provisions of the legal text
  - Annex XI and Annexes VII – X, column 2
- Adequate justification must be provided
  - Sufficient level of detail required
  - Need for scientific sound case building

# Key recommendations: quality of dossiers - 3

## Missing or Inadequate Justifications

- Animal testing used as last resort, but...
- Registrant's responsibility to provide adequate and well-documented justifications
- ECHA and MS assess remaining uncertainty if non-animal testing or alternative tests are proposed
- Make convincing cases = minimize testing

# Key recommendations: quality of dossiers - 4

## Improve justifications

- Grouping of substances/read-across
  - Substance ID of the analogues/similar substances
  - Hypothesis for the category formed/read-across
  - Compare the available data for support
- (Quantitative) Structure-Activity Relationship (QSAR)
  - Information on the model, on its scientific validity
  - Applicability of the model to the substance
- Weight of Evidence (WoE)
  - Build a scientifically valid case

# Key recommendations: quality of dossiers - 5



## 6 Practical guides available

1. How to report in vitro data
2. How to report Robust Study Summaries
3. How to report Weight of Evidence
4. How to report waiving
5. How to report (Q)SARs
6. How to report read-across and categories



*Practical guide 3:*  
**How to report  
robust study summaries**

*See: [http://www.echa.europa.eu/publications\\_en.asp](http://www.echa.europa.eu/publications_en.asp)*

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# Special attention: Intermediates

- Isolated on-site and transported intermediates (Art. 17&18) can benefit from reduced information requirements
- After screening of intermediate dossiers several doubtful cases were detected related to:
  - intermediate status
  - missing information
  - specifications of strictly controlled conditions
  - plausibility of risk management measures (RMMs)
- Several quality observation letters have been sent to the registrant:
  - requesting clarifications on status as intermediate
  - data on RMMs and/or on strictly controlled conditions
- Evaluation work on intermediates will be continued

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# Key Messages

1. Use the opportunities given during decision making to bring dossier in compliance
  - “commenting” = provide requested or missing information
  - “commenting” ≠ arguing, battle, contend...
2. Provide sufficient information on substance identity
3. Provide adequate justification for QSAR, Read across, grouping and weight of evidence cases
  - In order to avoid unnecessary animal testing, build scientifically sound cases
  - Transparent and well-documented justifications

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