

10 years of REACH evaluation: Changes ahead

Information session on changes in
dossier evaluation

19 September 2018

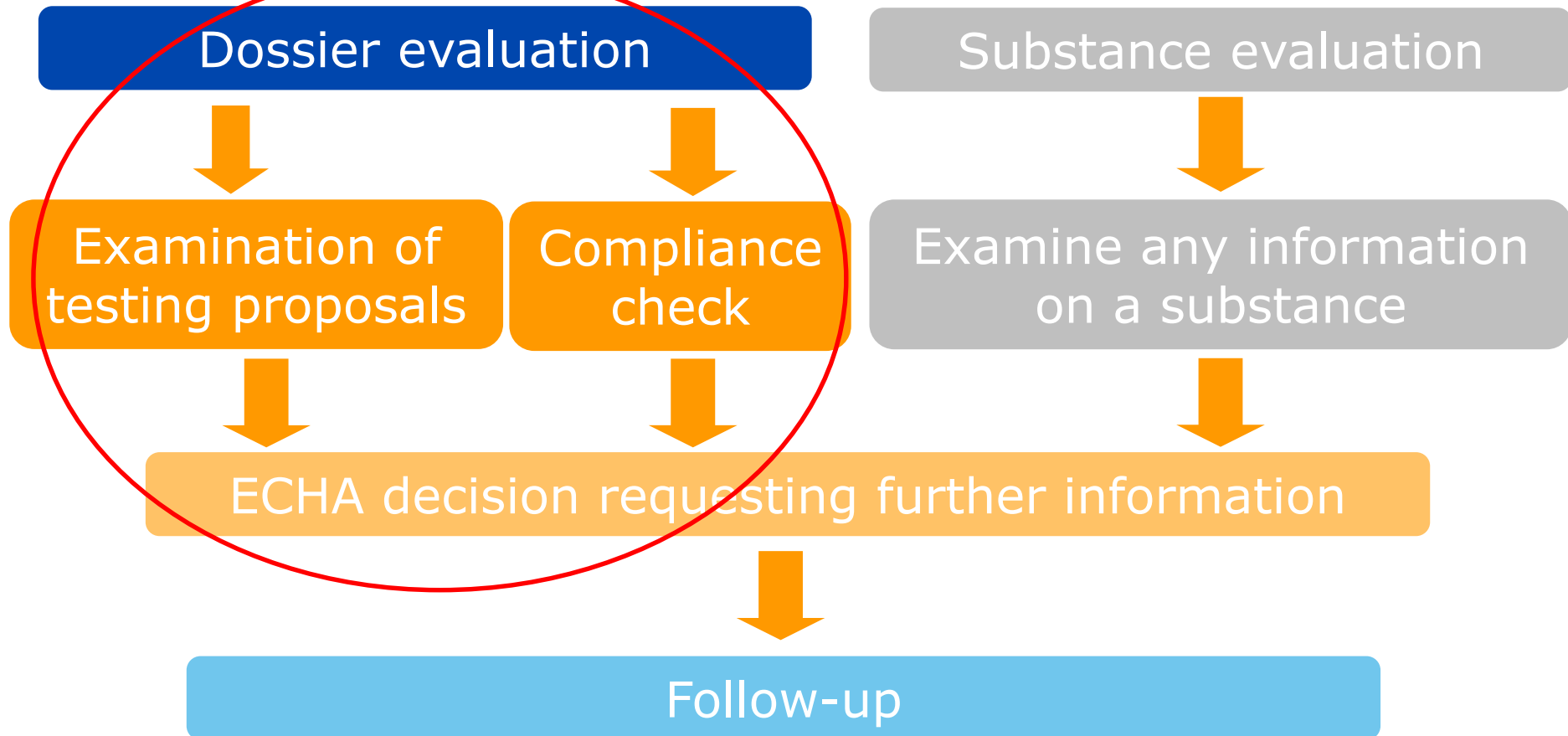
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Evaluation processes



MEMBER STATES

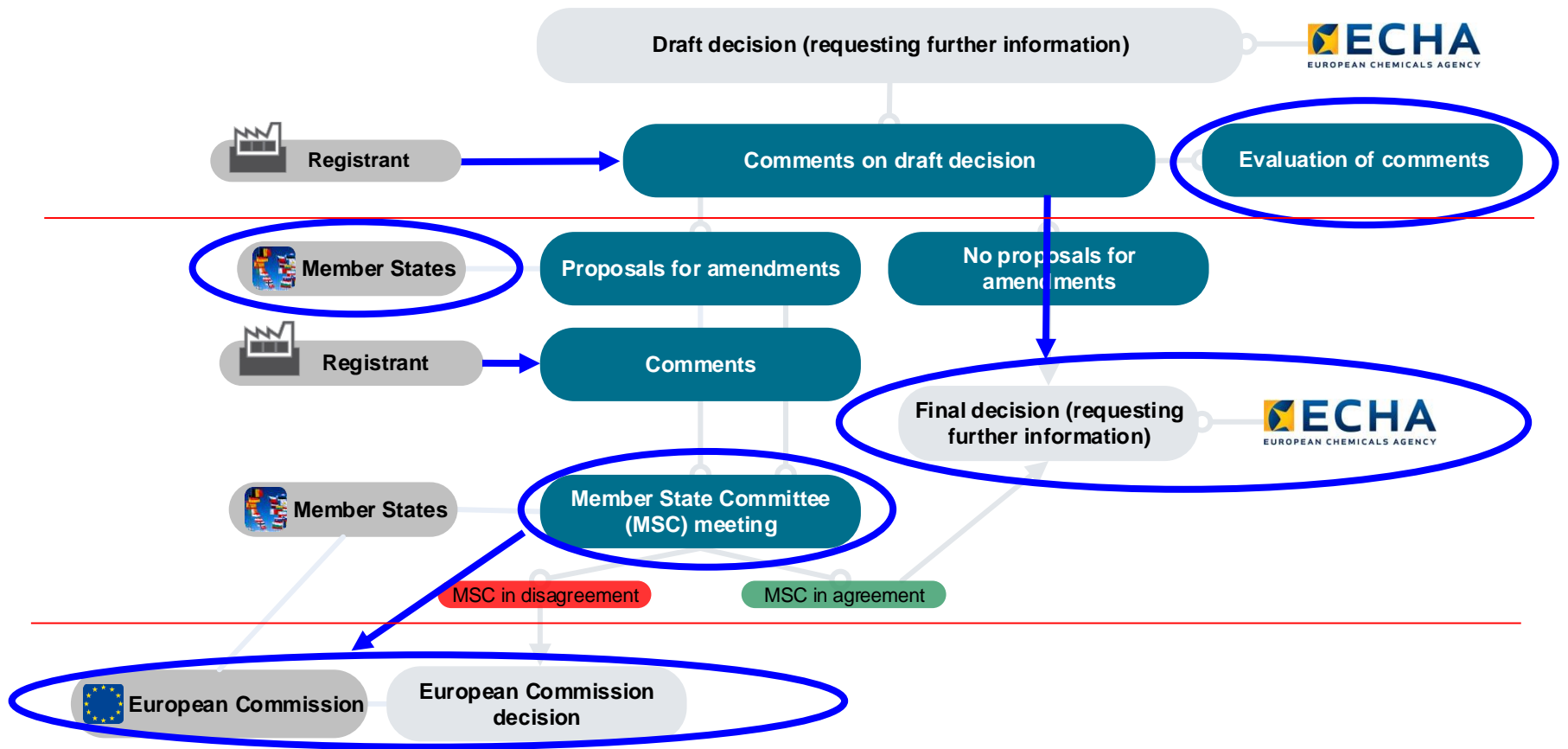




Dossier evaluation

- Ensures compliance with REACH information requirements
 - If your dossier is selected for compliance check and found non-compliant, we issue a decision requesting you to bring the dossier into compliance
 - We examine every testing proposal submitted in the dossiers and issue a decision on them
- Since 2015, compliance checks focus on high volume dossiers, higher tier endpoints and substances of potential concern
 - Substances with potential exposure, data gaps in high tier information, hazardous properties
 - Serving identification of substances requiring EU level risk management

Decision-making process



10 years of dossier evaluation: Lessons learnt

- Ca. 1800 dossiers checked for compliance
 - Majority of cases, non-compliance(s) found, leading to (draft) decision
 - **Compliance checks on substances in >100 tn registrations needs to continue**
- Decision making procedure working. Small proportion of cases not unanimously agreed
- Low proportion of decisions appealed
- Over 1400 cases with our decision concluded:
 - **High rate (> 85%) of compliance with our decisions**





Other learnings

- Lack of incentives to update dossier spontaneously
 - Many registrants only update after receiving a draft decision – or otherwise prompted by us
- Most >100 tn dossier lead registrants already familiar with dossier evaluation process
- Many joint submissions and member registrants not prepared to receive dossier evaluation decisions
 - Communication within a joint submission
 - Discussing and reacting jointly to a decision
 - Tackling data and cost sharing issues resulting from dossier evaluation decisions

The journey continues ...

Improving efficiency and effectiveness of dossier evaluation



Review of REACH operations

Commission Communication (March 2018) – selected key messages:

- REACH is fully operational and delivering results
- Further opportunities to improve and simplify have been identified
- The issues requiring most urgent action include non-compliance of registration dossiers
- The efficiency and effectiveness of the evaluation procedures need to be improved

REACH review

Action 2

“ [...] Significantly increase the efficiency of the evaluation procedures by:

(1) identifying the main reasons for non-compliance of registration dossier and developing remedies;

(2) where appropriate, applying evaluation procedures in parallel;

(3) systematically implementing a grouping approach, where this is possible;

(4) improving work-sharing across evaluation activities with Member States; and

(5) improving decision-making procedures.”



Changes to dossier evaluation process

1. Extending dossier evaluation to all joint submission members
 - Applied for **both** compliance check and testing proposal evaluation
2. Increased efficiency and renewed ways of working
 - Pre-alerts
 - Informal interaction
 - Grouping
 - Dossier updates





What stays the same?

- Our priorities and focus on:
 - Substances that matter
 - Endpoints critical for identification substances of concern (i.a. CMRs and PBTs)
- Efforts to induce dossier updates before evaluation starts, i.a.
 - Enhanced completeness checks
 - Sector collaboration
 - Early interaction especially when addressing groups & categories
- Commitment to transparency
 - Improving dissemination of both substance and process information
- Safeguarding your procedural and legal rights