REACH - Substance and Dossier Evaluation

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- 1. Types of evaluation - process
- 2. Procedural challenges – right to comment, right to update before adoption of final decision, participating to meetings, update during the deadline in the final decision, and consequences
- 3. What is “concern” in the context of substance evaluation?

- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

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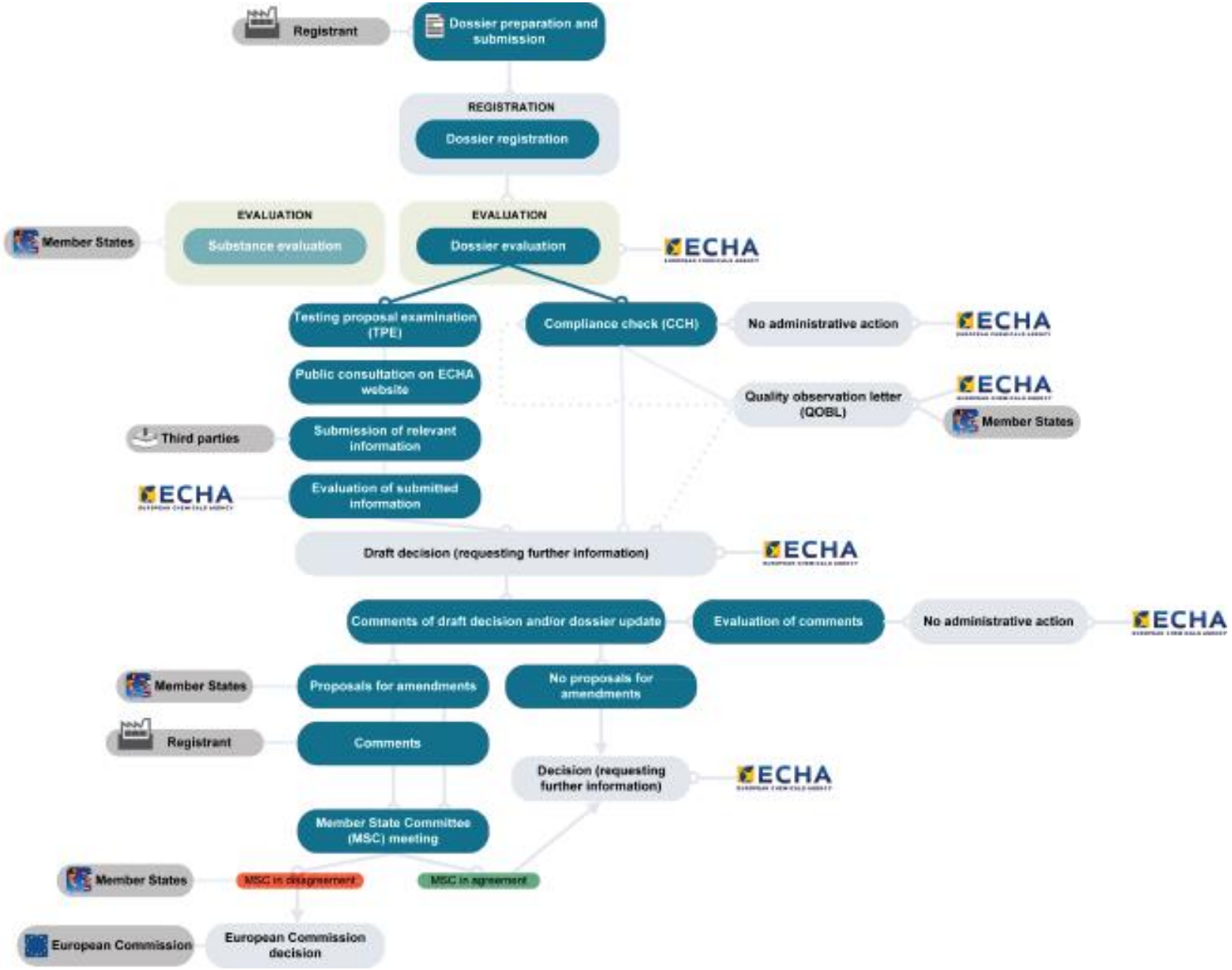
- Types of evaluation
  - Dossier
    - Compliance check (Article 41 REACH)
    - Testing proposals (Article 40 REACH)
  - Substance (Articles 44-48 REACH)
- Process
  - Leading to draft decision
  - Leading to final decision

Evaluation Process



Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

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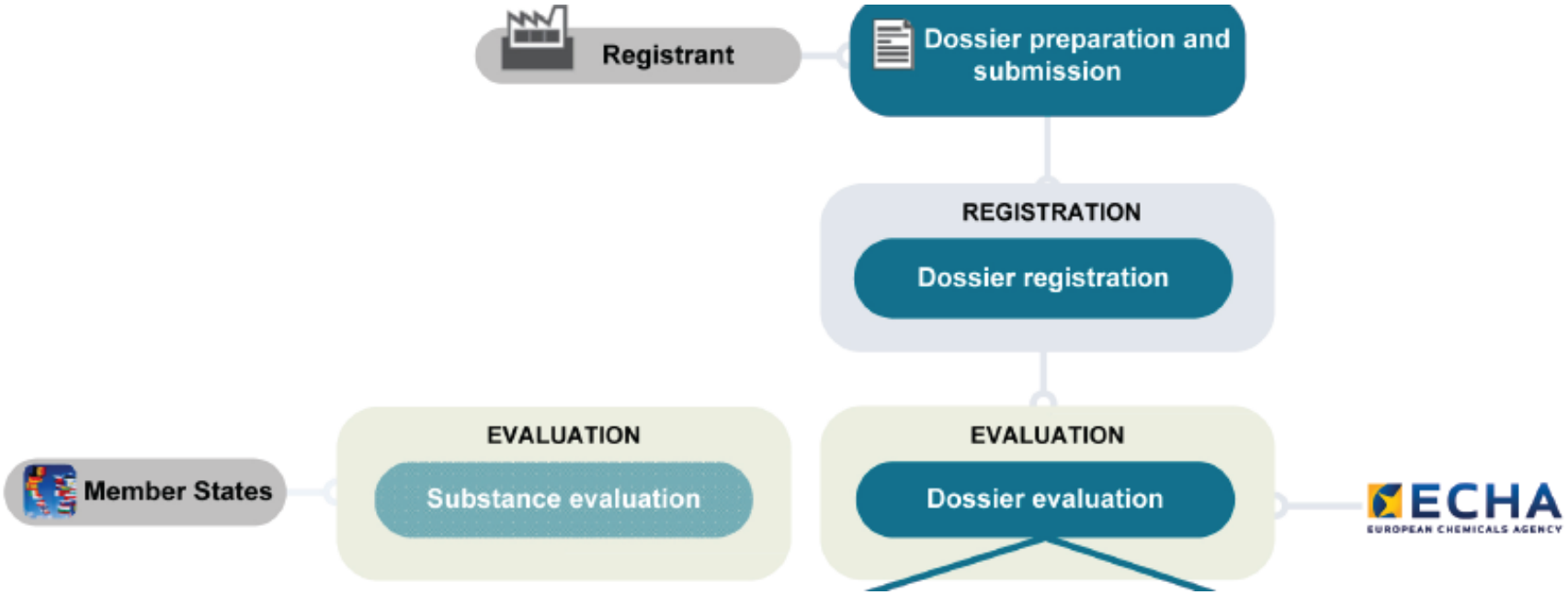
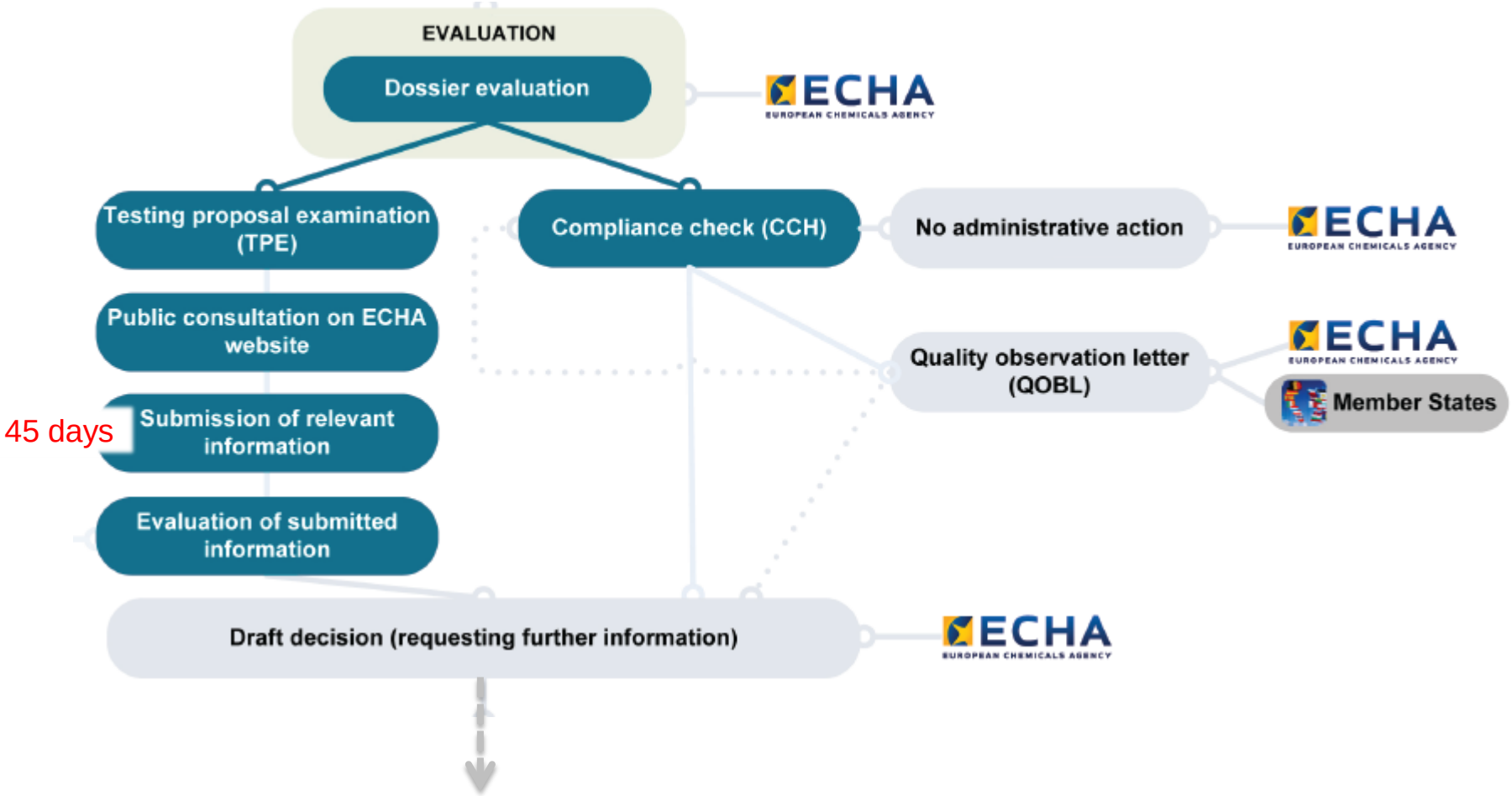
Dossier Evaluation / Substance Evaluation: Actors Involved



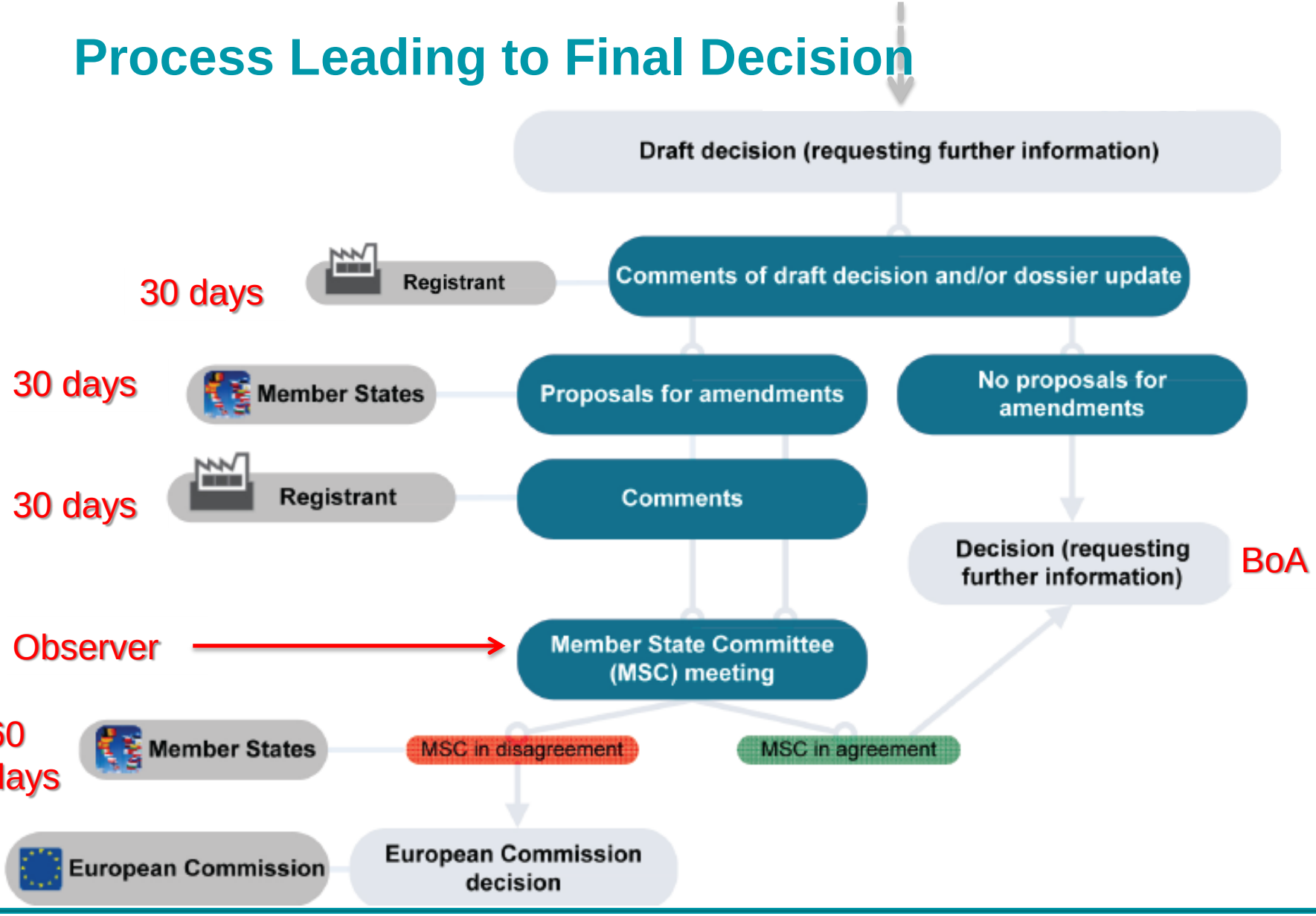
Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

TPE/CCh: Process Leading to Draft Decision



Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure and Steptoe & Johnson LLP

Process Leading to Final Decision



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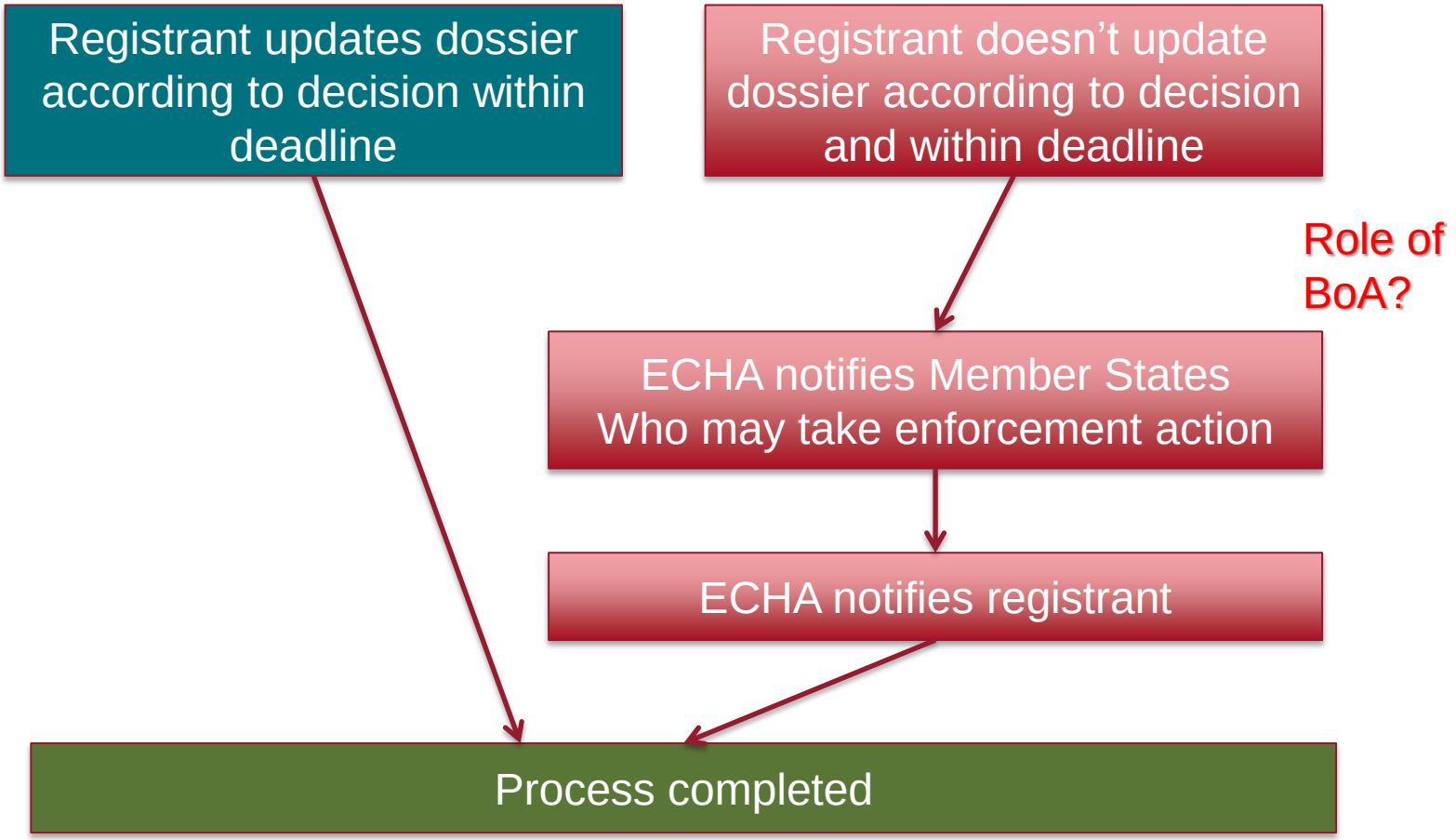
Outcome of Dossier Evaluation



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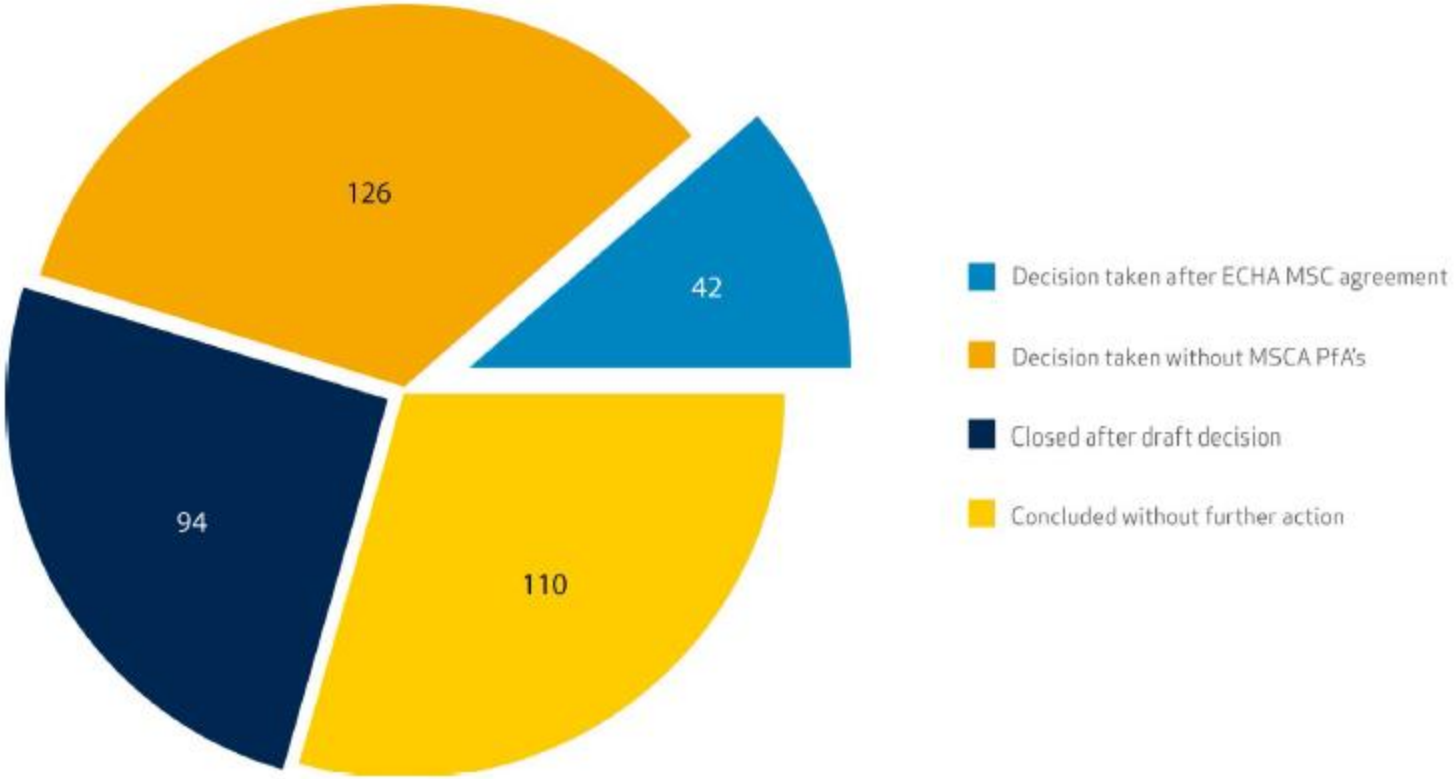
Dossier Evaluation Outcome

Targets of Compliance Checks

- Substance identity issues (often necessary before initiating a testing proposal examination).
- Areas of concern: endpoints considered highly relevant to risk management and chemical safety.
- Substances listed in the Community rolling action plan (CoRAP).

Outcome of “Targeted” Compliance Checks

- Outcome of the 372 ‘targeted’ compliance checks performed in 2014



Source: ECHA’s Evaluation report 2014

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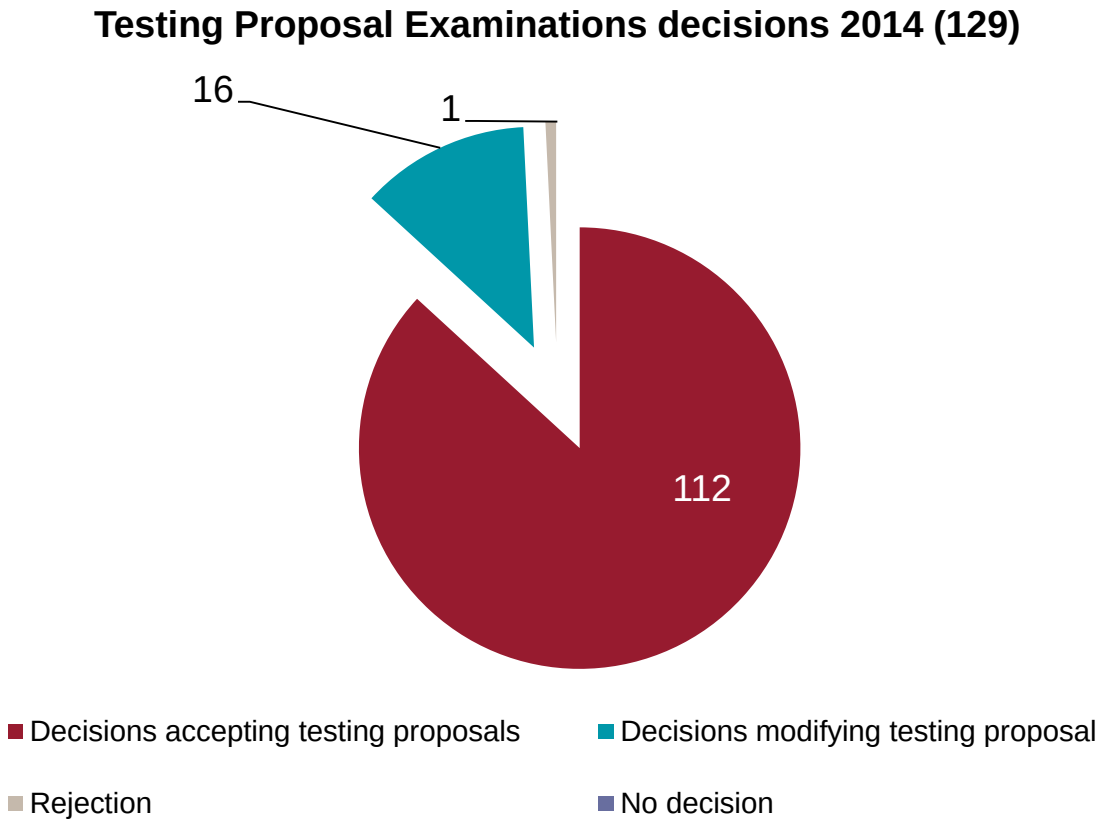
Outcome of TPE Evaluation



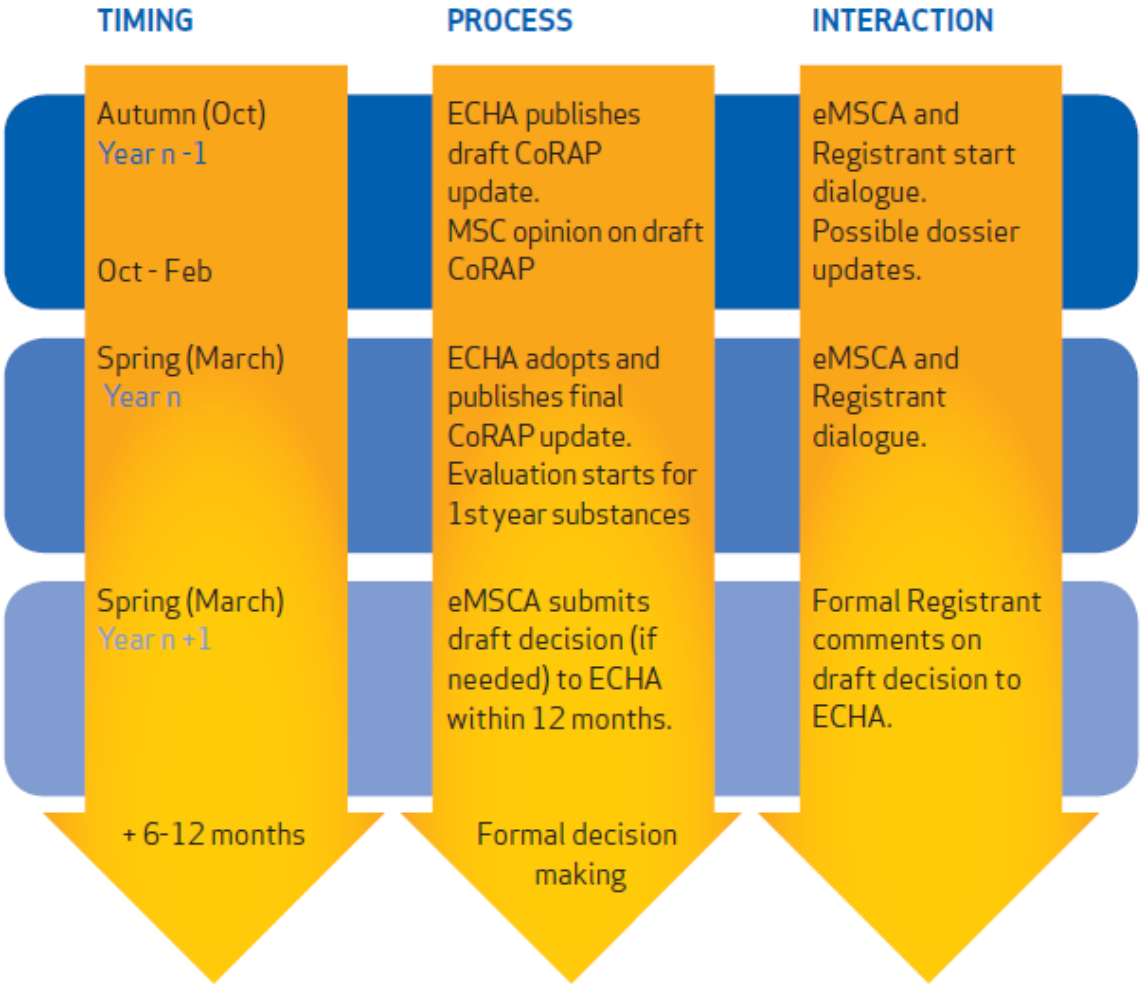
Source: ECHA and Steptoe & Johnson LLP

Substance Evaluation

Substance Evaluation

- Evaluation of substance throughout registrants' dossiers for the "same" substance, to clarify whether the manufacture or uses of a chemical substance poses a risk to human health or the environment
- Community Rolling Action Plan
  - Prioritisation of substances: criteria of Article 44(1) REACH
  - Proposals by Member States
  - Legal impact
  - Latest CoRAP list update: 17 March 2015 for 2015-2017
  - 48 substances are being evaluated in 2015 by 20 Member States
- Carried out by the Member States, while ECHA has a coordinating role in the substance evaluation process and remunerates the Member States for the task

OVERVIEW OF SUBSTANCE EVALUATION PROCESS



Source: Echa

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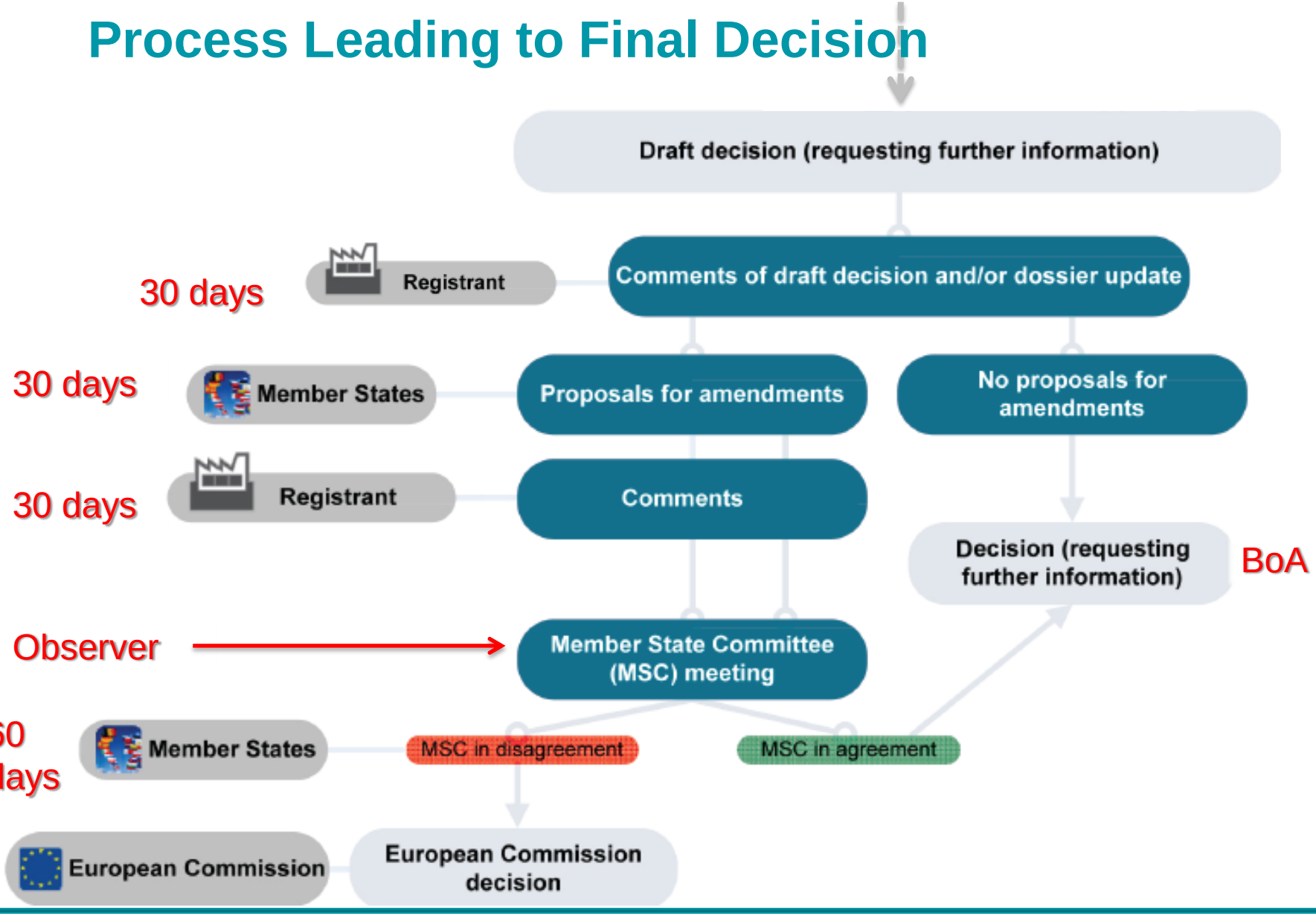
Process Leading to Final Decision



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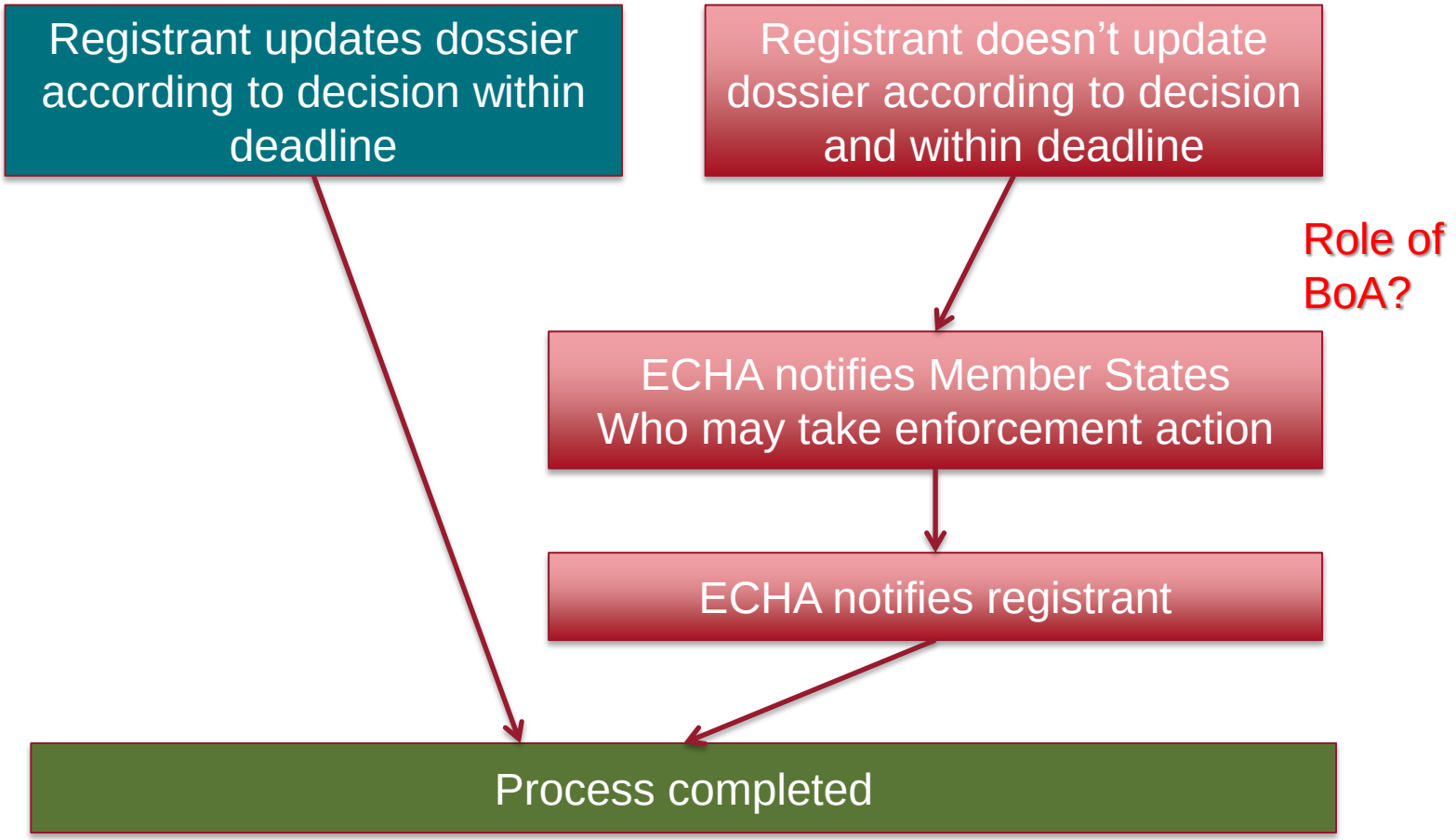
Outcome of Substance Evaluation



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Outcome of Evaluation

- Additional information requested:
  - Limited to REACH annexes in case of dossier evaluation
  - May result in a decision ordering additional testing beyond standard REACH information requirements in substance evaluation
- Information used
  - For other evaluation processes, e.g. for substance evaluation
  - For harmonised classification
  - For restrictions or authorisations
- New concerns identified

How Do the 3 Processes Interlink?

- The processes are independent of each other but are interlinked with regard to scope and procedure. Furthermore, these processes may run in parallel.
- ECHA has indicated that it intends to conduct compliance checks for all substances included in the CoRAP.
- Compliance checks may be open for various types of concern, in sequence.
- In cases where substance evaluation and testing proposal examination would run in parallel, the latter could be suspended by ECHA, pending the conclusion of the substance evaluation process.

Procedural Challenges

Procedural Challenges

- Right to comment
- Right to update the registration dossier
- Participating to MSC meetings
- Actions after receipt of the final decision – consequences
- Interactions with other registrants

Right to Comment

- Accepted in relation to the draft decision
  - Informal discussions may be organized with ECHA desk officers
- Accepted in relation to Proposals for Amendments (if any)
- Not accepted for
  - Revised draft decision
  - Comments of Member States during the MSC meeting
- Depends on discretion and practice of individual Member States during the 12 months period of assessment by MS during substance evaluation

Right to Update the Registration Dossier

- Throughout the procedure, but are updates taken into account?
  - Practice before end of January 2015

  (see ECHA information on 28 January 2015)

  - Practice after end of January 2015 - consequences

Participating to MSC Meetings

- Who participates?
- Formalities
- Discussions with Member States
- Follow-up – minutes, confidentiality

Actions After Receipt of the Final Decision - Consequences

- Informing ECHA of agreement as to the company performing the tests
- Undertaking the test
- Updating the dossier
  - Test results / Improved waiver, read-across
- ECHA actions
  - Possible statement of non-compliance, consequences

Interactions with Other Registrants

- Informing co-registrants throughout the process
- There is no imposed mechanism for cost sharing after a requested study is conducted and submitted by the Lead registrant as a result of an ECHA evaluation decision
  - What if co-registrants refuse payment? ECHA actions
- The contribution by co-registrants to costs of requested studies may differ for dossier *v* substance evaluation

Specific Observations – Initial Grounds for Concerns

- Criteria for Substance Evaluation – ECHA and Member States shall cooperate to develop them – harmonized approach, based on:
  - Hazard information (properties of concern)
  - Exposure information
  - Aggregate tonnage
- Substances meeting the criteria get prioritized for Evaluation - Risk based approach
- Final Community Rolling Action Plan (CoRAP) is based on opinion of the Member State Committee – annual updates covering three years
- Any substance not on the CoRAP list could be recommended for Evaluation by a MS – prioritization based on opinion of the Member State Committee
- During Evaluation further information can be required – if justified

Specific Observations – Initial Grounds for Concerns

- Substance Evaluation is based on all relevant information submitted on that or a structurally related substance
- (Draft) Agency Decision justifies the need for further information
- Registrant shall submit the information by the deadline set – or appeal
- If information is submitted the evaluation is finished in 12 months
- The indication of the initial grounds for concern does not limit the evaluation made by the Member States, since the Member States may also focus their assessment into other concern areas they find relevant during the evaluation. Yes, but:
- **Can further information be required for other (newly defined) concerns in case the initial concern on the substance, triggering CoRAP prioritization has not been confirmed?**

Specific Observations – Communication with Registrants

- Interaction between the registrant and the evaluating Member State is encouraged by ECHA.
- Individual Member States may have different practices; however:
- It is crucial to document discussions and potential agreements during these dialogues

CoRAP Update for Years 2015 – 2017

- Lists 134 substances for evaluation by the Member State Competent Authorities under the substance evaluation process.
- The plan contains 66 newly allocated substances and 68 substances were already published in the previous CoRAP in March 2014.
- 48 substances are being evaluated in 2015 by 20 Member States
- Many suspected PBT/vPvBs, CMRs and sensitizers with potentially wide, dispersive uses.

Questions?