More transparency and certainty

Information session on changes in dossier evaluation

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Laurence Hoffstadt
Scientific Officer - Evaluation

What will change?

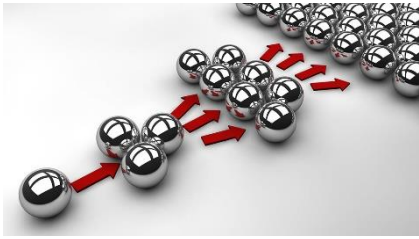
Scope of compliance

- **Bring the whole joint submission into compliance**

- Dossier evaluation decisions will be addressed to **all registrants** having obligations to comply with respective testing or required information

Why change?

- Support collaboration and data/cost sharing within joint submission
  - End of operation of SIEFs as of 1 June 2018
- Improve compliance and data quality
  - Greater certainty and clarity on regulatory obligations for all
  - Help ensure that everyone able to comply
  - Opt-outs addressed more systematically – ensure level playing field
- Support avoiding unnecessary animal testing
  - Tests and information requested to support compliance across whole joint submission
- Ensure all registrants get timely information to make business decisions on their portfolio



Who receives our decisions?

- Currently: mostly lead registrant of a joint submission
  - Lead requested to inform members
  - In some cases, individual registrants (opt-out)
  - Mostly registrants with highest tonnage dossiers (> 100 tpa)

- From January 2019: Active registrants with obligations to comply with respective requirements
  - Not necessarily only the lead
  - Not necessarily all registrants of a joint submission
  - Can be a registrant with opt-out, for one or more endpoints
  - Can be a registrant at any tonnage

What will be checked?

- Substance identity
  - Consistency of information across joint submission: "one substance, one registration"
  - Before initiating hazard assessment: non-compliance related to substance identity addressed and resolved

- Information on intrinsic substance properties
  - Must meet requirements for highest tonnage within joint submission
  - Must be compliant for all registrants at all tonnages
    - Non-compliance at lower tonnage also addressed in decision

    e.g. if 90-day study requested for Annex IX registrants, may address Annex VIII registrants, if 28-day study is not compliant
    - Triggers for higher level information requirements at a lower Annex level also considered

Output of Evaluation

- All relevant dossiers for the same substance
  - Lead and member dossiers
  - Dossier with opt-outs

- Draft decision with requests per Annex
  - Specifies for which tonnage bands obligations apply
  - Same decision addressed to all registrants that have obligations to comply
  - Separate decision to address evaluation of opt-outs

New decision template - Example

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that the information listed below is generated and submitted, with a test material representative of the Substance:

A. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471);

B. Requirements applicable to all the Registrants subject to Annex VIII of REACH

1. Bioaccumulation in aquatic species (Annex I, Section 4; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous/ dietary exposure)

2. *In vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487);

3. Only if both studies requested under Section A.1 and B.4 have negative results, *in vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490);

4. Justification for an adaptation of the Short-term repeated dose toxicity (28 day), (Annex VIII, Section 8.6.1.) based on the study requested under Section C.1;

C. Requirements applicable to all the Registrants subject to Annex IX of REACH[1]

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route.

[1] Testing required under this Annex can only be started or performed after the decision has been adopted (Article 51)

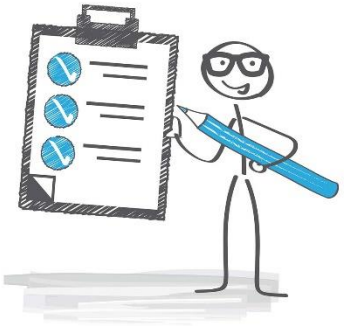
D. Requirements applicable to all the Registrants subject to Annex X of REACH[1]

1. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rat or rabbit), oral route.

Conditions to submit the requested information

A detailed justification for the information requested can be found in the Appendices below.

Decision-making:
Getting organised



- Ensure communication and coordination between recipients during decision-making
  - Same procedural and legal guarantees for all

- Identify representatives
  - To help coordinate and submit comments
  - To be involved in preparation and attend Member State Committee meeting, where relevant

Decision-making: Commenting

- Comments on draft decision
  - Preferably one set of consolidated comments
  - Focus on content of draft decision, e.g. flag an error of assessment by us
  - Avoid lengthy comments

- Comments on proposals for amendment
  - Preferably one set of consolidated comments
  - Focus on proposals for amendments

After decision is adopted

- Adopted decision sent to same recipients as in draft decision
  - Exception: if you cease manufacture or import upon receipt of draft decision and your registration was revoked, you will not receive adopted decision
- Members who are not directly concerned are informed
  - Link to adopted decision on our website

After decision is adopted (2)

- Agree on who shall perform requested tests and inform us within 90 days
  - If we are not informed, we will designate one of you to perform the test
- Agree who will update dossier, including chemical safety reports where relevant
- Ensure requested data is submitted by deadline indicated in the decision

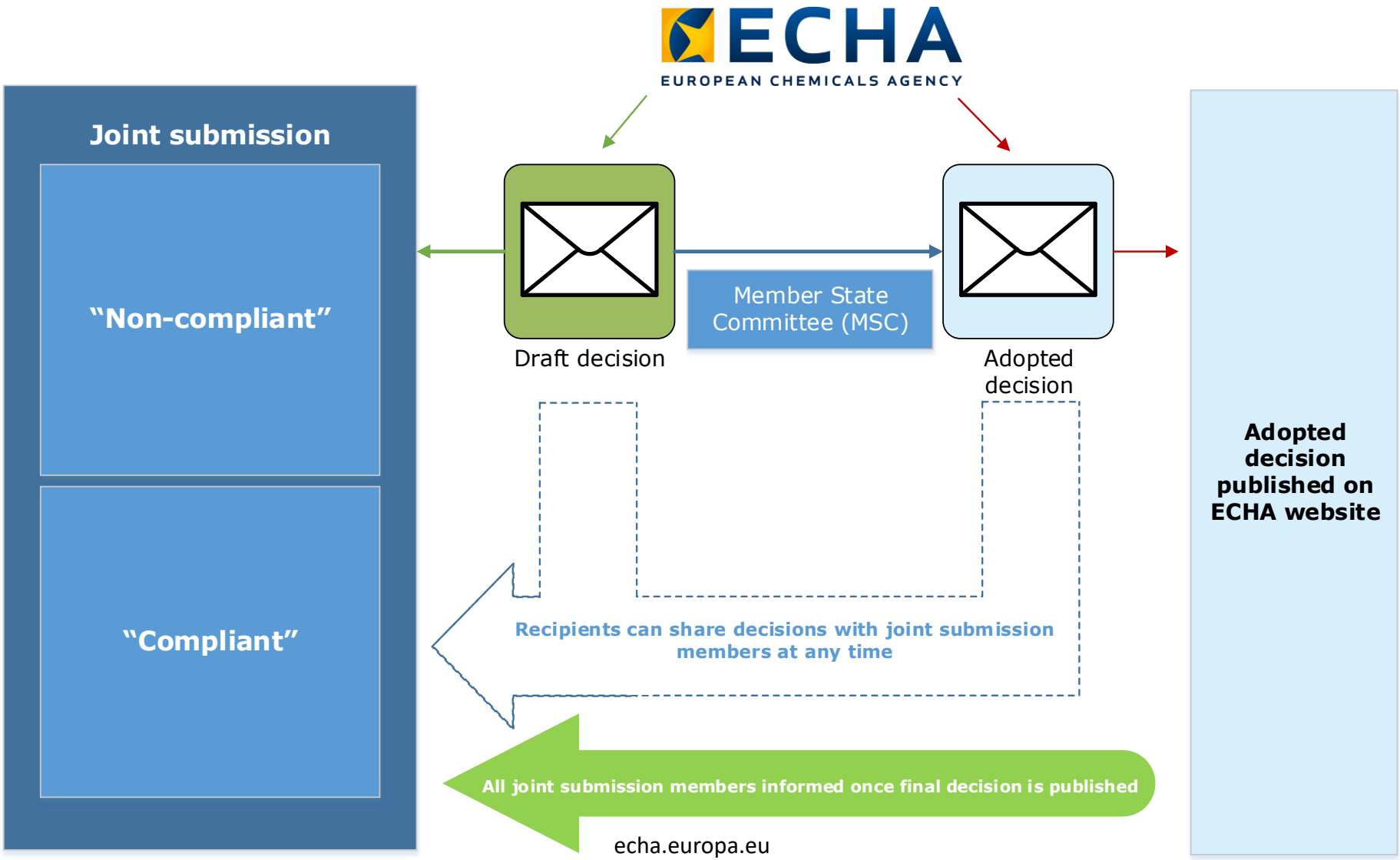
After deadline has passed

- In case of non-compliance
  - New (draft) decision issued

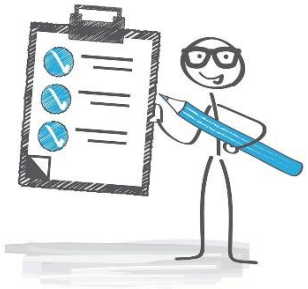
  or

  - Relevant Member States and recipients informed
    - ➢ Member States' enforcement authorities invited to consider enforcement action
- If in compliance,
  - Notification to Member States and Commission
  - For information to all recipients of the decision

When am I informed? - Summary



Take home messages



Same evaluation decision addressed to all registrants having obligations to comply with the same information requirements

- Separate decisions for opt-out dossiers

Need for increased coordination and cooperation among recipients to ensure smooth process

- From receiving draft decision until submitting information
- Keep all informed of requests and progress, i.e. recipients of the decision and other registrants