Dossier- and Substance evaluation: Continuous process

Cefic REACH Implementation workshop XI

Topics

Evaluation relates to two processes

- **Dossier Evaluation by ECHA**
  (Started in 2011)
  •Industry experiences

- **Substance Evaluation by Member States.**
  (New process since 2012, as specified in the CoRAP)
  •Industry expectations

Introduction : Dossier evaluation

- Compliance check & examination of testing proposals.

- Direct interaction between **Registrant** and **ECHA**

- The process confirms/ checks the content compliance of the registration dossiers
  - Outcome of evaluations:
    - No action required by Registrant
    - QOBL: **Q**uality **Ob**servation **L**etters
    - Draft Decision ➔ Final Decision

Quality **Ob**servation **L**etters (QOBL)

- Received via the Message box of REACH-IT.
  - Message : "**Communication concerning a compliance check under Regulation (EC) No 1907/2006"**
- The QOBL gives indications on how to improves the quality of the dossier.
  - Can refer to the company specific part as well as the joint part of the dossier.
- QOBL is also sent to the Member States of the Registrants country.
- In the letter a deadline for the 'voluntary' update is suggested
  - Normally between 6 and 12 Months.

Draft decision

- Received via the Message box of REACH-IT.
  - Message : "**Notification of a draft decision on a compliance check under Regulation (EC) 1907/2006"**

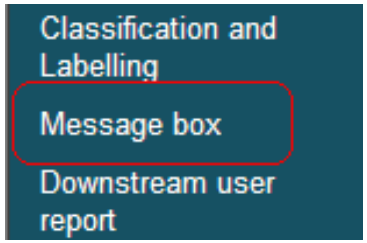
- The Draft - decision start a well described process with explicit timelines.

- Member States of the Registrants country receive a copy of the Draft decision letter.

- You need to respond to this Draft –decision with 30 days after date stamp.

Lessons learned : Message Box

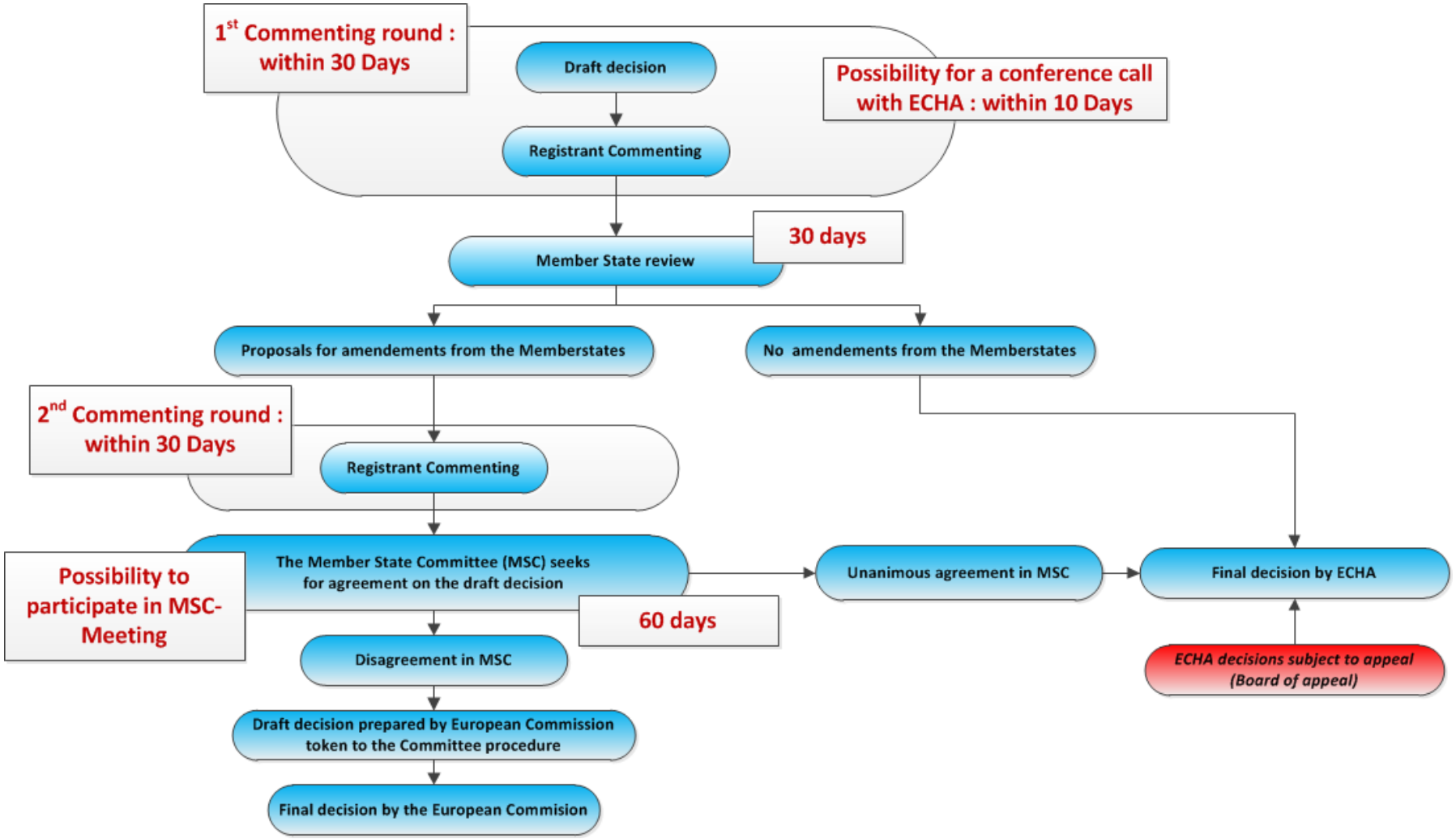
- **Ensure frequently monitoring of the mailbox.**



- **Activate the message alert function**
  - **You will be automatically informed of new messages.**

- **Setup multiple user accounts for access assurance.**

Dossier evaluation: draft decision



Draft decision : First Round

- “Lead” Registrant receives a draft decision :
  - Directly inform joint-submission members of draft decision
  - Share content related to joint part of the submission-dossier
    - The SIEF agreements include provisions to cover this: the LR has the duty to inform JS members (art. V.1 model SIEF agreement)
    - JS members have the duty to contribute to potential costs arising from the evaluation
      (art. IX.6 SIEF agreement).
  - Possibility of conference call with ECHA in the first 10 days (! This possibility may no longer be available for targeted compliance checks)
  - Comments have to be submitted within 30 day’s via specified WEB-Form

Draft decision : Second Round

- When :
  - Disagreement by ECHA with comments from registrant

    or
  - Additional requirements from Member States

- Comments have to be submitted within 30 days via specified WEB-Form.

- At the end of this second communication round, the registrant maybe invited to meeting of the Member States committee meeting.

Lessons learned : First/Second Round

- When sharing the information of the draft decision with joint submission members :
  - Setup conference call to discuss content and next steps
  - Specify deadlines for responses
  - Achieve agreement on the approach
  - ***30 Days are really short !!***
- Use the Conference Call (First round) is very useful, can resolve issue easily
- Keep copy of your submitted WEB-Form.
  - You will not receive a copy from the ECHA system
- Timing for Test proposals to be discussed at this point: ensure sufficient/realistic time including update of the dossier, CSR, etc.

Draft decision : Part. in MSC meeting

- The working procedure rules were updated in Feb. 2011 to allow ‘case owner’ to participate in initial discussions

- If the case is considered confidential, the registrant can express their wish to have the Cefic observer present during the discussions

- This needs to be communicated to ECHA upon acceptance to participate.

Lessons learned : MSC Meeting.

- Check the agenda of MSC meeting if your substance is on the agenda
  - Benefits your planning.

- Be well prepared your time is limited
  - Do not make long introductions. Focus on the endpoint and your arguments
  - Submit a subject matter expert related to questions and a case owner.

- Review the draft minutes received from the meeting on the accuracy

Tip to registrants

- **Verify your other submitted dossiers if the QOBL or Draft decision has implication on their content.**
- **If the QOBL is related to the Classification and Labeling all the SIEF members have to be informed.**
- **Keep your dossiers up to date because it case always be reviewed again.**
- **Read carefully the ECHA evaluation report as it provides concrete suggestions on what to improve:**

http://echa.europa.eu/web/guest/regulations/reach/evaluation

Substance Evaluation

- New process , evaluation by Member States.
  - Initiated by the Community Rolling Action Plan (CoRAP)
  - Every Year Updated in February

First experiences & industry expectations

- Lack of harmonisation among countries on how to carry out the S Evaluation and in particular how to involve industry → ECHA should play a firm role in coordinating this activity to ensure harmonisation of practices and consistency of decisions among all MS.

- Some MS are asking registrant to provide copies of all full study reports: practical and legal issues (e.g. copyright) as well as practical → robust study summaries should be sufficient. Additional information can be provided on specific endpoints but not on all information.

Substance Evaluation

- MS should not ‘redo’ all the work done in the registration process by industry → focus on the particular concern identified in the CoRAP.

- Recommendation for the Evaluating MS to contact LR using the contact from REACH-IT at a very early stage of the process and again before publication: A face to face meeting is preferred

Currently we don’t have many experience on this process but will closely monitoring the developments.

Thank you for your attention!

Any questions?