



Dossier evaluation: Industry expectations
Cefic REACH Implementation workshop IX



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Introduction



Dossier evaluation is a new process:

- puts **companies in direct contact with ECHA**
- **key process under REACH** as it confirms the compliance of the registration dossiers (checks during the submission were on completeness)
- gives the **opportunity to all parties to align on expectations**
- **Dossier evaluation** = compliance check & examination of testing proposals. This presentation will focus on compliance check.

It has just started, still not many cases available, but some feedback to share...



Compliance check: outcome

ECHA staff carries out the evaluation of the compliance of the dossiers with three possible outcomes:

- No action
- QOBL: Quality Observation Letters
- (Draft) decision

Currently, there is no way to know that your dossier has been selected for evaluation. It would be useful to be able to know if and when the process is started by ECHA ₃



Compliance check: no action

- currently this result does not trigger information to the registrant
- It would be useful for companies to know when ECHA finds no issue with the dossier
- acknowledge that the dossier may be re-opened in the future with different outcome



Compliance check: QOBL

- Although not part of the legal text, pragmatic approach as it gives indications to registrants on how to improve
- Sent by email to the REACH-IT mailbox
- Member States are informed
- The follow-up by the registrant is monitored by ECHA and keeps MS informed

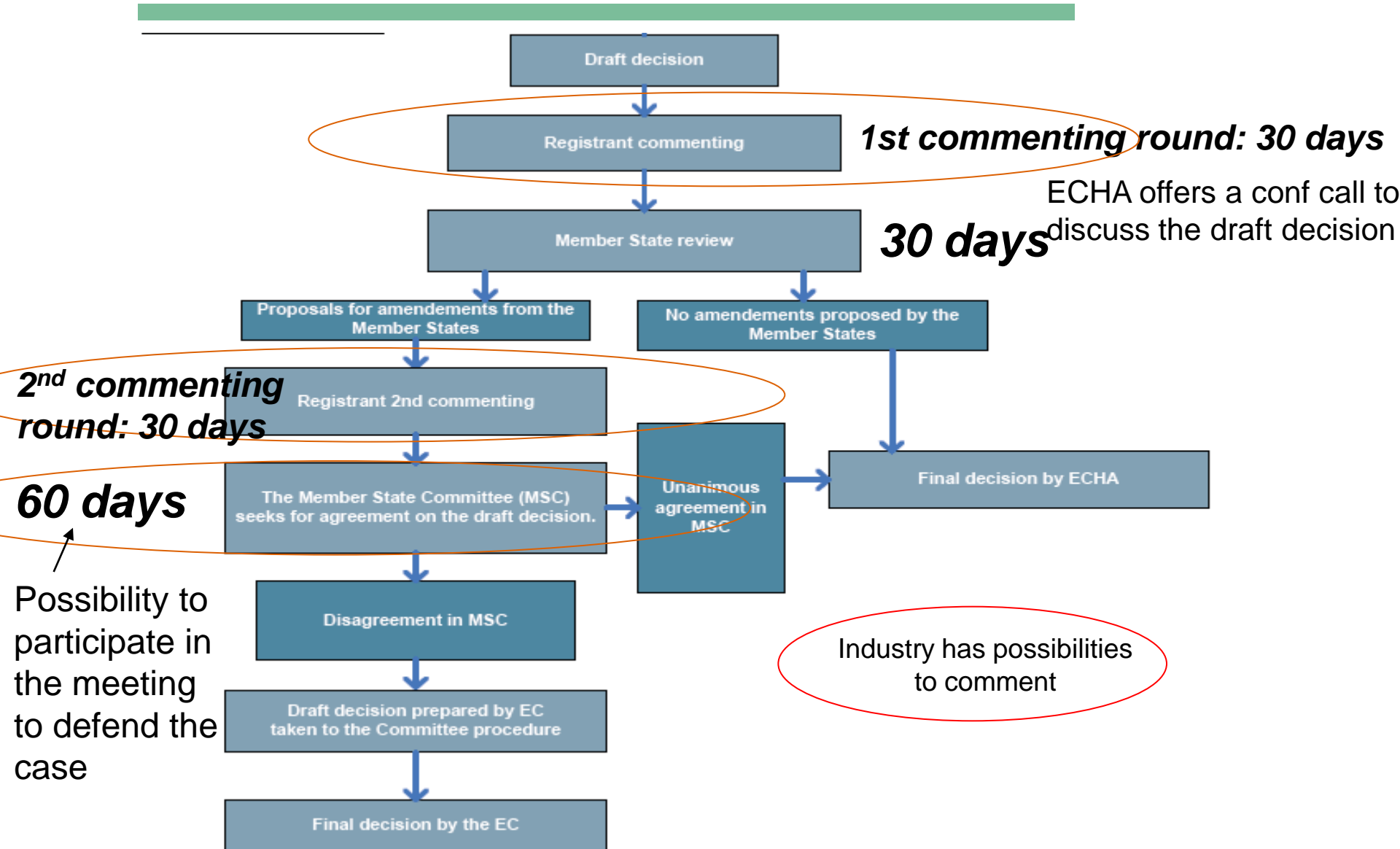


Dossier evaluation: draft decision

- This outcome triggers the ‘formal’ process
- Sent by email to the REACH-IT mailbox to all users of the legal entity (company account)
- Member States are informed



Dossier evaluation: draft decision





Dossier evaluation: draft decision

If the Lead Registrant receives a draft decision, he **should inform the members of the Joint submission (JS):**

- Asap after receiving the draft decision
- 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)



Dossier evaluation: draft decision

1st commenting round:

- 30 days since reception of the draft decision
- Using webform specified in the cover letter of the draft decision (keep copy for your records!)
- The registrant may opt for an update of the dossier
- This round includes the option to have a conf call with ECHA within 10 days (time critical)



Dossier evaluation: draft decision

2nd commenting round:

- Only triggered if
 - ECHA does not agree with comments from registrant or
 - Additional requirements from Member States
- Using webform specified in the cover letter of the draft decision (keep copy for your records!)
- At the end of this round, registrant can be invited to meeting of the Member States committee to explain his comments



Dossier evaluation: draft decision

Participation 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.



Dossier evaluation: draft decision

- **High interaction between companies, ECHA and Member States**
- **Extremely short deadlines:** 10 days for the conference call, 30 days to react, etc.
- **Transparent process:** need to see how this works in practice but process involves all parties, possibilities to hear all views and discuss...



In summary: Tip to registrants I

- **Spontaneously update registration dossier** in case of identification of shortcomings
- **Check regularly your REACH-IT inbox** including holidays/absences!
- Accept ECHA's invitation for an **informal conference call** on the draft decision. Make sure you have your experts present in the call.



In summary: Tip to registrants II

- When you submit your comments to ECHA make sure you **keep a copy of your submission** for your own records (screenshots, copy/paste, etc.)
- Check the calendar of **meetings of the ECHA MS Committee** to plan meeting in Helsinki
- Prepare meeting of the MS Cttee with relevant experts. There is only time for a brief exposition of your case so be clear, concise and ready to answer questions.



In summary: Tip to registrants III

If the joint part is subject to evaluation:

- the **LR should involve asap** the members of the consortium or the SIEF leadership team, if any
- In an ad hoc conf call the draft decision should be discussed and further steps launched (technical, admin, financial aspects, wording of answer, persons to involve in meetings with ECHA/ MSC)
- Keep the members of the Joint submission informed on the progress of the dossier evaluation process



In summary: Tip to registrants IV

If the joint part is subject to evaluation:

- Ask the JS members, if relevant, for input
- In particular, inform them of each step of the decision process and its outcome
- If the QOBL or draft decision concerns the harmonised classification, all SIEF members should be informed.

→ Cefic Evaluation TF is preparing guidance document explaining the process and tips in detail



In short: ***deadlines are very tight so be aware of the process and plan in advance!***

Thank you for your attention!
Any questions?