Evaluation post 2018

Changes in the evaluation processes to further improve compliance

REACH Compliance – A workshop on data quality in registration dossiers

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Session 4

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Content

- 10 years of Evaluation
- Evaluation post 2018 – challenges ahead
- Changes to the evaluation processes
- Other changes foreseen
- Concluding remarks

10 years of Evaluation
What we achieved so far?

- ✓ Well-established, solid processes, delivering well towards the intentions of the legislator
  - Dossier Evaluation, CoRAP, Substance Evaluation, Common Screening
- ✓ Enhanced consistency of assessments and evaluation decisions
- ✓ High number of decisions under dossier and substance evaluation
  - Focus on high tonnage dossiers
- ✓ Generation of information for an important number of substances
  - **Thereby clarifying the concern, especially with regard to higher tier endpoints**
- ✓ Capacity building
  - ECHA-Member States- Registrants

…and the journey continues…

Evaluation post 2018

- Finalise evaluation of high tonnage chemicals – meeting the WSSD 2020 goals
- Plan and evaluate the lower tonnage dossiers
- Tackle the outcome of the REACH review
- ...

REACH review action 2:
Improve evaluation procedures

- Identify the main reasons for non-compliance and develop remedies
- Where appropriate, apply evaluation procedures in parallel
- Systematically implement a grouping approach, where this is possible
- Improve work-sharing across evaluation activities with Member States
- Improve decision-making procedures

Many challenges ahead… how to respond?

- Build upon the work done so far
- Develop remedies
  - To improve efficiency, effectiveness and impact of evaluation work
- Consolidate the collaboration and work sharing with relevant stakeholders

Changes proposed to evaluation processes

Dossier evaluation

Expanding decisions to all members of a joint submission

- Change from sending the decision to the lead registrant to sending it to **all registrants** that are non-compliant with the respective information requirements
- Applied for **both** compliance check (CCH) and testing proposal evaluation (TPE)

Why?

- **Support collaboration and data/cost sharing within joint submissions**
  - in the absence of SIEFs as of 1 June 2018
- **Improve the level of compliance and data quality**
  - greater certainty and clarity on regulatory obligations for all member registrants
  - helps ensuring that all registrants within a joint submission become compliant
  - opt-outs addressed in a more systematic manner – supports the level playing field
- **Support registrants in respecting their legal obligation to avoid unnecessary testing**
  - tests requested aim to bring the whole joint submission to compliance; e.g. lower tier tests may not be necessary if higher tier tests need to be performed
- **Ensure that the concerned members get more timely information they need to make business decisions on their portfolio** (e.g. upgrade their tonnage)

What will be checked?

- Consistency of SID information across the joint submission “one substance, one registration”
- Assessment would be performed against the requirements for the highest tonnage within the joint submission – focus on the 8 super-endpoints
- Triggers for higher level information requirements at a lower Annex level will also be considered, as well as non-compliance at lower tonnage
  - Example, if ECHA requests a 90-day study at Annex IX, also Annex VIII registrants should be addressed if the 28-day study is not compliant
- Evaluation will be performed on all relevant dossiers within a joint submission
  - Including (partial) opt-outs

Content of the (draft) decision

- The same (draft) decision addressed to all members obliged to comply with it
  - The decision will list requests per Annex and specify to which tonnages the obligations apply
- Reminder that the registrants need to agree on who shall perform the requested test(s) and inform ECHA thereof within 90 days.

Decision-making

- **Registrants comments** (on DD/ PfAs)
  - Expectation that only one set of consolidated comments is sent
  - Related to the content of the decision, short and targeted

- **MSC meetings and adopted decision**
  - Same procedural guarantees for all registrants subject to the decision
  - Informal steps in the process (possible informal interaction, participation in the MSC-meeting) would require concerted action by the registrants
  - Selected representatives of the addressees to be invited to the MSC-meeting
- **After the deadline has passed** (Follow-up)
  - In case of non-compliance, enforcement action would be triggered against all registrants “concerned”

Implementing the change

- Envisaged as of 1 January 2019
- Stakeholders views sought in CARACAL (June 2018)
- Webinar with industry on 19 September 2018

Other changes to the dossier evaluation process

To support effectiveness of the process

- **Informal Communication**
  - Will no longer be offered “by default”
  - May be replaced sometimes with an earlier interaction, e.g. when addressing large categories or groups of substances
- **Tonnage downgrade or change of status (e. intermediate)**
  - No longer considered after a draft decision is sent
- **Pre-alerts for compliance check**
  - May be discontinued and replaced by a new page containing more information on the “dossier evaluation lifecycle”

! Registrants to maintain the dossiers up to date with regard to information on tonnage, uses and exposure consideration

- To avoid unnecessary, bureaucratic steps

! Cease of manufacture (or import)

- No further information requested if performed before adoption of the decision; otherwise the requests still stand if e.g. cease of manufactures happens upon receiving the (final) decision

Substance evaluation

- Running substance evaluation and compliance check in parallel
  - May bring efficiency gains which should be further explored
  - Pilot cases soon to be initiated with the Member States
- Further support for evaluating MSCAs
  - Improved decision template and instructions for drafting shorter, more concise decisions

Grouping

- Whenever feasible, substances will be addressed/considered in groups
  - Along all processes – screening, dossier evaluation, substance evaluation, risk management
- ECHA will explore ways to support registrants in developing intelligent testing strategies
  - To avoid unnecessary testing and achieve compliance within reasonable timelines
  - Early interaction (e.g. COLLA or similar) to be considered case by case

Enforcement

- Closes the loop – provides the regulatory stick for compliance
- Align and sharpen the line on enforcing dossier update obligations (Article 22) and ECHA's evaluation decisions,
  - where appropriate, **setting penalties for the period of (established) non-compliance**
- Not within ECHA's remit – requires good collaboration among authorities at national level

What else?

Communication

- “Dossier life-cycle” – improve transparency on the evaluation processes
  - Status update on ECHA/dissemination website
- ECHA will further streamline the content of evaluation decision
  - Adapting the content to the learnings from decision making and litigation decisions
- ECHA to provide clear messages on which adaptations are not acceptable in any circumstances
  - e.g. QSAR predictions on higher tier endpoints
  - in relevant support material (i.a. ECHA website)
  - by the end of 2019

Exposure information

- Very valuable for company level risk management
- Evaluation processes not well equipped to obtain such information
  - Keep the processes efficient and provide legal certainty towards registrants
  - Difficult to enforce
- Consider other processes - restriction?
  - Further discussions foreseen in CARACAL on the ways to get the necessary exposure information

Concluding remarks

Collaboration of all actors is key in achieving good regulatory outcome

- **Registrants** – update the dossiers with the most recent information
  - it may avoid unnecessary work in formal processes (e.g. in case of tonnage downgrade or cease of manufacture)
- **Authorities** – further improve collaboration and working together
- **Enforcement** – consider taking a stronger role

Thank you!

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