Evaluation post 2018
Changes in the evaluation processes to further improve compliance

REACH Compliance – A workshop on data quality in registration dossiers

BfR-Workshop
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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...
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
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)
• **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
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