Taking action to ensure compliance

Safer chemicals – ECHA conference

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REACH: First principles

Hazard & Use Info

Safety Assessment

e-SDS

Safe use
More than 10 years of evaluation – what we achieved so far?

- More than 2700 dossiers checked for compliance (to various degrees)
  - Non-compliance in one or more endpoints identified in more than two thirds of the dossiers checked
- About 25% of substances registered above 1 000 tonnes checked
- Improved knowledge on chemicals
  - Generation of information to clarify CMR and PBT properties for more than 1 000 substances
- Support to other processes
  - 96 substances flagged for harmonised classification and 3 for substance evaluation after data generation
- Improving safe use
  - Substance no longer produced after generating information which led to Carc 1B classification

Main reasons for non-compliance

- Waiving of data requirements not correctly justified
- Adaptations (read-across, QSAR, WoE) failing due to incorrect justification or lack of documentation – leading to data gaps for higher tier information requirements
- Documentation insufficient - e.g. insufficient level of detail in robust study summaries to allow for an independent assessment
Feedback on compliance

- Annual evaluation reports (2010-2018) - advice on how to improve compliance
- Evaluation decisions available on ECHA website
- Workshops, MSC meetings
- Reports on the use of animal tests
Increase impact and transparency

✓ Address substances in **groups**
  • Coordinate with on-going processes on analogue substances

✓ **Expand** dossier evaluation to the whole joint submission
  • As of 2019, dossier evaluation decisions sent to all co-registrants that are not compliant with their respective information requirements, incl. opt-out members

✓ Dossier evaluation **progress visible** on ECHA’s website
  • Progress tracked from draft to final decision
  • Tool for registrants... but also to the public at large
ECHA-Commission joint action plan
Why an action plan?

- Despite efforts, still major compliance and quality issues with registration dossiers
- REACH review by Commission (2017)
  - “REACH is effective but not efficient”
  - “Significantly improve evaluation procedures…”
- Study by German Federal Institute for Risk Assessment:
  - Data gaps and inappropriate waiving/adaptations identified
  - ≥1000 tpa: 12-61% of the examined endpoints “non-compliant”
- Media and stakeholder attention
REACH compliance – a priority

- Direct impact on ensuring that REACH delivers its objectives
- Commitment to take action: joint ECHA-Commission action plan
  - To be finalised by June
  - Will propose concrete actions to improve compliance
Objectives

- Address all substances
- Improve clarity of legal provisions
- Accelerate decision making
- Improve follow-up and enforcement of evaluation decisions
Address all substances

- 16 500 substances registered in full in 66 000 dossiers as of end 2018

**IT screening → Grouping → Regulatory pools**

- Put all substances above 100 tonnes in regulatory pools by end of 2020
- Develop a plan to enable similar conclusions for lower tonnage bands

- Preliminary timelines as market is dynamic
  - New registered substances, tonnage down(up)grades, cease of manufacture
Regulatory pools

**Priority for regulatory risk management**
- In the process of being regulated
- Pending action

**Low priority**
- Already regulated
- Concluded as low priority in the assessment

**Priority for data generation**
- Need more data for a judgement to be made on the need for risk management or low priority
  - Candidates for compliance check and substance evaluation
New compliance check targets

- Currently 5 % of dossiers per tonnage band – REACH Article 41(5)
- **Proposed new target: 20 % of dossiers**
  - corresponding to ~30 % of substances
    - ~ 35-40 % - above 100 tonnes
    - ~ 20 % - below 100 tonnes
- Commission Regulation to modify the target
Other actions to improve compliance

• Improve clarity of **legal text**
  • Revise information requirements and adaptations; no new requirements added

• Accelerate the **decision making** process
  • Simplify compliance check decisions
  • Resolve different views among Member States to reduce the number of proposals for amendments
  • Better integrate substance evaluation and compliance check

• Improve **enforcement**
  • Harmonisation
Last, but not least

- **Industry takes on the compliance challenge**
  - Companies with large portfolio to consider programmes for addressing multiple substances
  - Optimise testing strategies
  - Refine information on use and exposure

- **Working arrangements between ECHA and big industry associations**
  - To facilitate action plans by industry for addressing compliance
What to expect from now on?
Increasing the number of compliance checks

- Chances to receive a CCH decision increase
  - As all substances will be addressed
  - ...and two thirds are non-compliant

- How to get prepared?
  - Consider regular updates, remove information which is no longer relevant
  - Update is a legal obligation – this is the law but also the proof for safe use of chemicals
  - Implementing Act on dossier updates – to stimulate updates
Be pro-active

• Most likely, you will need to generate further information
• Consider submitting testing proposals
  • Especially when using read-across/category approaches
Compliance checks vs testing proposals

• If category/read-across fails, ECHA will reject the category and request data for each substance
  • Less possibility to refine/incorporate strategy during process

• Testing proposals
  • Can incorporate a strategy
    • Sequence of tests for a substance, and within a category
    • Some tests could be initiated immediately (e.g. toxicokinetics)
  • You will save money and perform less animal tests
  • Need to be realistic with regard to how compliance could be achieved within reasonable timelines
Real example – registrant’s testing plan to build read across

Testing proposal:

- **Bioavailability Absorption**
  - Evaluate using gut sac model
  - Confirm with targeted in vivo absorption studies
  - Inform on potential role of toxicokinetics in tox tests
  - Use to support read-across
  - Testing underway

- **Metabolism**
  - Metabolic case for category
  - Substance selection for screening toxicity

- **Screening studies on selected substances**
  - Confirm hypothesis
  - Test hypotheses of read across in 422 with representative substances for RDT and repro
  - Selection of substances for higher tier tests
  - Testing underway

- **90 day, Developmental Reproductive toxicity**
  - Complete higher tier information requirements on representative samples
  - Confirm hypothesis

- Testing underway
In summary

- A lot has been achieved... still many challenges ahead for all players
- Being compliant with REACH is not only an obligation but also an act of social responsibility to use chemicals safely
- To instil confidence of citizens, we all (ECHA, MSCAs, registrants) need to play our role properly
Thank you!
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