My substance is under evaluation. What should I know and do? ECHA Stakeholders' day – Helsinki – 26 March 2013

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Evaluation - Overview

ECHA
EUROPEAN CHEMICALS AGENCY

MSCAs
Member State Competent Authority

Dossier evaluation

Substance evaluation

Examination of Testing Proposals

Compliance Check

Examine any information on a substance

ECHA Decision requesting information, quality observation letter (for CCH) or no further action

Follow-up of decisions

Examination of testing proposals

- Legal text gives time periods in Art 43
  - Non phase-in substances draft decision within 180 days after receiving registration
  - Phase-in substances
    - Within 2 years for the 2010 registration deadline
    - Within 3 years for the 2013 registration deadline
    - Within 4 years for the 2018 registration deadline

Examination of testing proposals

- Learnings of industry
  - The test proposal is not evaluated in isolation
  - Substance identity is checked before
  - In case of multi-constituent substance or UVCB define clearly the substance that will be tested and explain why this is the most relevant one
  - Other gaps in the information requirements can be picked up
  - Although compliance check is different from the examination of testing proposals, there is a potential interference

Examination of testing proposals

- Learnings of industry
  - The lead registrant receives the draft decision
  - Possibilities for commenting are embedded in the process with strict deadlines to respect
  - Up to the lead registrant to inform the other SIEF members – no legal obligation
  - Expert(s) is/are invited by the Member State Committee. They can play an important role in further clarification of the strategy that has been followed
  - Updates of the registration dossier at the end of the process can't be considered
  - Limited number of decisions resulted in an appeal

Compliance check

- **Legal text**
  - **No legal timeframe given in the legal text when this has to be started, but within 12 months of the start of the compliance check, ECHA has to come with a draft decision.**
  - **The Agency shall select not less than 5% of the registration dossiers for each tonnage band, for compliance check**

Compliance check

- Learnings of the industry
  - The 5% relates to formal compliance checks. In reality the targeted compliance checks screen all registration dossiers
  - Substance identity
  - Use of assessment factors deviating from the ECHA guidance to derive the Derived No Effect Level and the Predicted No Effect Concentration needs a good justification
  - Industry considers the guidance values and the application of the ECHA Committees as very precautionary

Compliance check

- Learnings of the industry
  - The justifications for using read-across and the use of Annex XI in general require much more justification than industry got in mind
  - Consumer exposure is seen very broad
  - Long-term toxicity testing in invertebrates, plants and sediment organisms is taken very seriously by the Member State Committee
  - Still no solution for the two generation reproductive toxicity study

Substance evaluation

- Completely different process compared to dossier evaluation
- Starting with Community Rolling Action Plan (CoRAP)
  - Covers a period of three year
  - Draft annual updates presented to Member States by 28 February
  - This is not a precursor of the Candidate List!
  - For the majority of industry selection criteria not well understood
  - Mentions initial ground(s) of concern, the evaluating Member State and justification document

Substance evaluation

- **Evaluating Member State**
  - **Will not only look at lead registrant dossier, but as well joint submitters' dossier**
  - **Is not limited to the initial ground(s) of concern**

Substance evaluation

- What should industry do?
  - Contact the SIEF members and nominate a representative, organise the upcoming work
  - Check your dossier and update, if necessary, as soon as possible
  - Contact the evaluating Member State
    - Better understanding of their concern
    - Inform on planned updates by registrant(s)
      - Different situation if substance comes immediately in first year or only in the second or third year
      - Understand that at a certain moment in time updates can’t be taken into consideration

Substance evaluation

- Potential outcome of substance evaluation
  - No further information is needed
    - No regulatory action is needed, all uses are adequately controlled
    - Regulatory action is required
  - Further information is needed
    - Additional hazard information requiring additional testing outside the information requirements described in the Annexes
    - Further information on exposure
    - Further information on uses

Substance evaluation

- **Further steps**
  - **30 days to comment the draft decision by registrant(s) or downstream user(s) concerned**
  - **Procedure and timing described in Articles 52 and 51**
  - **Ultimate decision with a given deadline to be respected by registrant(s)**
  - **Request for additional information will always require update chemical safety report**
  - **Evaluating Member State has 12 months to draft any appropriate decision within 12 months of the information being submitted**
  - **Appeal is possible**

Conclusions

- **For industry**
  - **Your dossier is your business card, major parts of it are already disseminated**
  - **Organise yourself well, the work of the SIEF is not stopping when you got/get a registration number**
  - **Learn from the evaluation reports**
  - **Interact in an efficient way with ECHA and with evaluating Member State**
- **For ECHA**
  - **Substance evaluation is not on cruise speed yet, the processes are not well understood yet by the majority of companies**
- **For evaluating Member States**
  - **An early and organised contact with industry can only be beneficial and was a recommendation of a workshop**

Thanks for your attention