Substance and dossier evaluation

A company case

André Aarts
Solutia Europe sprl/bvba
20 June 2013

Solutia and REACh

- Subsidiary of Eastman Chemical Company
- Lead registrant for currently 13 Solutia substances (phase-in and NONS)
- Lead registrant for two substances on the 2012 CoRAP and for one substance on the 2013 CoRAP
- Focus is on 2012 Substance evaluation experience

EASTMAN

Substance and dossier evaluation

- Comparison of substance and dossier evaluation
- Substance evaluation
  - Process
  - Interaction with evaluating member state competent authorities (eMSCA)
  - Dossier updates
  - Draft decisions
  - Cooperation with co-registrants
- Conclusions

EASTMAN

Substance vs. dossier evaluation
Evaluation phase

- Substance evaluation:
  - Concern/issue driven
  - Focuses on the science and facts in the (lead) dossier
  - Announced upfront in draft CoRAP and published
  - Review period: 1 year from date of publication
  - Covers the substance and all registration dossiers
  - Handled by a member state competent authority
  - Interaction with evaluating authority possible and desirable (ECHA leaflet)

- Dossier evaluation:
  - Compliance driven
  - Focuses on compliance and on specifics in your dossier
  - Not communicated to registrants
  - Review period: may happen any time
  - Covers your specific dossier
  - Handled by ECHA staff
  - No interaction possible during evaluation phase

EASTMAN

Substance vs. dossier evaluation Decision phase

- Substance evaluation:
  - Draft decision issued by ECHA, based on submission by the eMSCA
  - Draft/preliminary substance evaluation report to support the decision (not available to registrants)
  - Draft decision issued to all registrants
  - No informal interaction during the first commenting period
  - Lead or contact to respond on behalf of all registrants, but individual response is possible
- Dossier evaluation:
  - Draft decision issued by ECHA
  - No other justification for decisions available than what's in the decision
  - Issued to one specific registrant
  - Possibility of informal call during first commenting period (except for targeted CCH)
  - Lead to respond on behalf of concerned registrants (tonnage band)

EASTMAN

Substance evaluation: 2012 CoRAP

- Two p-phenylenediamine substances listed:
  - 7PPD by Austria
  - 77PD by Belgium
- Overall issue: suspected PBT + exposure (wide dispersive use/high aggregated tonnage)
- Dossiers rely significantly on read-across
- Data from other PPD substances used to fill critical data gaps
- Substances covered by PPD Consortium
- Three registrants for 77PD but only one for 7PPD

2012 CoRAP: Start-up actions

- At date of publication no outlined process known to ECHA, member states or registrants
- PBT concern difficult to understand:
  - Substances are not stable and hydrolyse quickly to non-bioaccumulative degradation products
  - Why PBT concern ?
- Felt need for direct contact with the evaluating member state
- Contacted both Belgium and Austria by mid-March, and received quickly positive feedback

2012 CoRAP: Kick-off meetings

- Meetings set up at eMSCA location soon
  - Establish personal contact with experts/evaluators
  - Obtain clarification of initial concerns (PBT), but also other issues raised in the initial communications
  - Understand the process and timelines of the member state
- PBT concern was not clarified
  - Due to concern for soil and/or sediment ?
- eMSCA evaluates the full dossier, not limited to the initial concerns
- Target date for eMSCS: submit drafts (draft decision and evaluation report) to ECHA by early/mid December 2012
- eMSCA would keep registrants updated

2012 CoRAP: The months after kick-off

- eMSCA requested full reports and provided by registrants
- Dossier updates prepared by lead registrant:
  - CSA/CSR thoroughly reviewed
  - Error corrections and consistency improvements
  - Updated exposure scenarios
  - Further elaboration of read-across justification
- Draft updated CSR provided to eMSCA for review/comments
  - Comments received over several months (July – October) for each expert area (tox, ecotox, exposure, risk characterisation)
  - Not obvious how to coordinate
  - On several occasions needed to contact eMSCA expert for clarification and discussion

EASTMAN

2012 CoRAP: The months after kick-off (2)

- Frequent and intensive discussions in particular with Austria
- Comments reviewed and incorporated in CSR and Iuclid
- Further updates of read-across justification
- Updated registration dossier submitted within timeline agreed with eMSCA
  - 77PD/Belgium: mid October 2012
  - 7PPD/Austria: end November 2012

2012 CoRAP: The months after kick-off (3)

- Dossier reviewed highlighted potential shortcomings in data items and/or waivers
- Non-vertebrate testing initiated to strengthen the dossier
  - Ionisable substances: determine pKa's
  - Read-across of hydrolysis study from other PPD compound
  - Soil toxicity
  - Analytics for determination of parent compound and known metabolites in soil
- Aligned with eMSCA

2012 CoRAP: Final months

- Follow up with eMSCA:
  - Belgium: no further discussions needed
  - Austria: continued discussions
  - No draft documents (decision and/or evaluation report) were received
- February 2013:
  - Additional information requested by Austria, including full studies of information published in summary format
  - Evidently no opportunity to discuss, clarify or address concerns

EASTMAN

2012 CoRAP: Draft Decisions

- Draft decisions received at the dates indicated by the ECHA
- No opportunity for informal contact with ECHA
- Comments drafted for review within PPD Consortium
- Issued after consultation/agreement from co-registrants
- Now in the pipeline …
  - Follows the normal Decision process
  - Upon completion the information needs (x years from now):
    - Evaluation report finalised
    - Regulatory action may be proposed (SVHC, Restriction, C&L)

2012 CoRAP: Lessons learned

- Substance is evaluated by a member state due to specific initial concerns, but …
- eMSCA may evaluate any aspect of the substance and the dossiers
  - Not limited to initial concern
  - Not limited to the REACh annexes VI to X
  - Can review exposure data and CSR
- Lead dossier must be in good shape at the start
  - Early review is recommended
  - Submit update preferably before the CoRAP publication or soon after
  - Align timing with the evaluating member state

2012 CoRAP: Lessons learned (2)

- Establish the contact with the member state and cooperate:
  - Knowledge of the substance is limited
  - Experts focus on narrow aspects in their area of expertise
  - Don’t expect that eMSCA experts know your substance
    - Make all assumptions explicit and justify scientifically
    - Provide strong read-across justification
- Cooperate with co-registrants:
  - Start as soon as possible
  - Identify the resources you need: experts, time, money
  - Be aware of organisational and competitive issues

EASTMAN

2013 CoRAP: Putting lessons into practice

- Lead registrant for 2013 CoRAP substance
- Started cooperation with co-registrants upon publication of the draft in October
  - Agreed on form of cooperation
  - Update of the dossier agreed
- Contacted the eMSCA (several e-mail addresses provided) early December - no reply

2013 CoRAP: Putting lessons into practice (2)

- Completed update of the dossier and submitted in REACh-IT in March
- Re-contacted the member state early March; positive response received but no further follow-up or questions
- Informed the member state of the update and proposed kick—off meeting – no response yet received
- Conclusions:
  - Not everything is under our control
  - Member states are approaching SEV in very different manners

EASTMAN

Maintain your registration dossiers

- Submit good quality dossiers
  - Use the guidance and the TCC plug-in
- Keep your dossier up to date
  - Keep track of your tonnages and submit timely updates
  - Review, maintain and update your uses as applicable
  - Monitor the activities of the Lead Registrant on e.g. C&L and PBT assessment
- Monitor the CoRAP and get ready if one of your substances is listed
- Monitor actions on your dossier
  - Use the e-mail warning setting of REACH-IT
  - Check your REACH-IT inbox timely
- Cooperate with the other registrants

EASTMAN

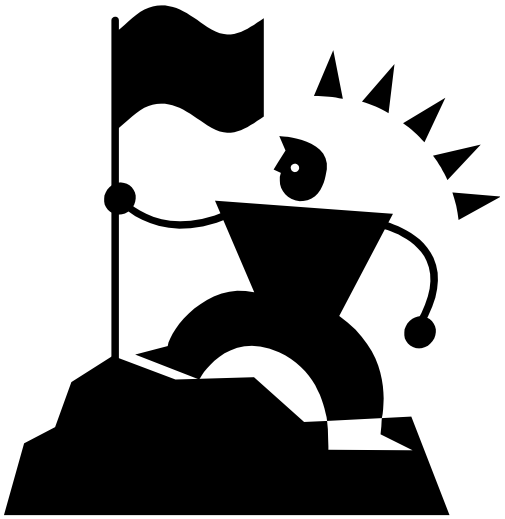
Further information

- ECHA website:
  http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation
- ECHA Q&A:
  http://echa.europa.eu/documents/10162/13626/qa_corap_en.pdf
- ECHA Tips on substance evaluation:
  http://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf
- CEFIC Tips on dossier evaluation:
  http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Cefic%20guidance%20on%20Dossier%20Evaluation.pdf

EASTMAN

Conclusion

- Registering a substance feels like this …



EASTMAN

Conclusion

- But you should feel like this

- Registration is a long-term commitment
  - Remember this yourself; don’t loose sight of your dossier
  - Tell your boss that registration is never finished

Thank you for your attention

Backup slides

Dossier evaluation

- Test Proposal Evaluation (TPE) or Compliance check (CCH)
- Dossier evaluation by ECHA
- Draft Decision send to Registrant
  - Make use of the opportunity for informal call within 10 days (except for Targeted CCH)
  - Provide comments within 30 days
  - If comments from MSCA's received, comment again within 30 days
- Final Decision follows 6 to 9 months later and sets deadline for submitting updated dossier

Compliance check (CCH)

- May concern any aspect of the dossier:
  - Substance identity (any dossier)
  - Waivers (lead dossier)
  - Information requirements
  - Intermediates
  - Etc.
- No specified timing but ECHA must evaluate 5 % of the dossiers submitted
- If requiring additional testing, to be coordinated with all registrants
- Note: targeted compliance checks with focus on specific areas of concern