

Follow-up of appeal decisions

Agenda point 10.5

38th Management Board meeting

17-18 June 2015, Helsinki

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What makes ECHA improve its practices

- Continuous process development
- Stakeholder feedback
- Nonconformities

- Complaints (incl. Ombudsman complaints)
- Court cases
- Appeals

Appeals in total June 2014 – June 2015

- Registration appeals: 2
 - 1 dismissed (A-020-2013)
 - 1 pending (A-022-2013)

- Data-sharing appeals: 4
 - 1 inadmissible, 1 dismissed (A-005-2013, A-017-2013)
 - 2 pending (both on biocides)

- “SME” appeals: 6
 - 4 withdrawn
 - 2 pending (stayed until Court judgment)

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Appeals in total June 2014 – June 2015

- Dossier evaluation appeals: 21
 - 5 withdrawn (A-007-2014, A-016-2014, A-001-2015, A-002-2015, A-006-2015)
 - 15 pending
 - 1 decision annulling ECHA's decision (A-001-2014)

- Substance evaluation appeals: 6
 - 6 pending

7/3/2015

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Final BoA decisions June 2014 – June 2015

- Procedural decisions on confidentiality, interveners etc.
- 8 withdrawal decisions
- A-005-2013 dismissed as inadmissible
- A-017-2013 dismissed, data sharing decision now final
- A-020-2013 dismissed, revocation decision now final
- A-001-2014 annulling a testing proposal decision

Impact of final decisions – examples of confirmation of ECHA's position

- The right to proceed to a registration despite a pending data sharing dispute stems directly from the REACH Regulation (A-005-2013)
- ECHA does not need to cross-notify information submitted by the parties in a data-sharing dispute (A-017-2013)
- Every registrant has the duty to act diligently and prudently (A-020-2013)
- For administrative efficiency, a cut-off point in the procedure can be set for dossier updates (A-001-2014)

Impact of final decisions – examples of items requiring/recommending action from ECHA

- ECHA's letter informing about a data sharing dispute was misleading concerning a contingency procedure (A-005-2013): all related letter templates withdrawn and reviewed before the 2018 deadline
- Poor administrative practice to assign the same reference number to two separate letters (A-005-2013): to be avoided
- Separate invoices are not ancillary to the decision, if deadline for payment is not mentioned in the decision (A-020-2013): invoices now sent together with the decision

Impact of final decisions – examples of items requiring/recommending action from ECHA

- Weaknesses identified in the notification of decisions through REACH-IT (A-020-2013): REACH-IT changed, Terms and Conditions changed [see also A-005-2012]
- Although public consultations on testing proposals have been run correctly, BoA recommends making them more explanatory (A-001-2014): Practice changed already in 2014
- Where a cut-off point in the procedure is used, it has to be balanced e.g. with the need for animal testing to be a last resort (A-001-2014): ECHA needs to restart the procedure from the MSCA referral if relevant and substantial new information arrived before sending the decision that could have changed its content

Other effects of proceedings

- Items are flagged for guidance update
- Items are flagged for update of IT tools
- Practical Guides, FAQs, Fact Sheets are improved
- Letter and decision templates are improved
- Justifications are improved
- Practices are simplified to make them clearer for registrants

Conclusions

- The BoA decisions have an impact on how ECHA operates
- The BoA requires ECHA to balance its efforts for efficiency in evaluation decision-making with animal testing considerations
- BoA proceedings in general feed to improving ECHA's processes and documentation