

## 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  - 4 withdrawn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  - 5 withdrawn (A-007-2014, A-016-2014, A-001-2015, A-002-2015, A-006-2015)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a data sharing dispute was misleading concerning a contingency procedure (A-005-2013): all related letter templates withdrawn and reviewed before the 2018 deadline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