# Scope of review by the Courts and Board of Appeal

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# Review of REACH decisions - personal reflections from ECHA's point of view

# Commission REACH decisions so far challenged

- Fee Regulation 340/2008: T-392/13 La Ferla – inadmissible
- Listing in the Authorisation Annex: T-360/13 Vecco – dismissed, under appeal C-651/15 P
- Harmonised classification: T-689/13 Bilbaína – dismissed, under appeal C-691/15 P
- Authorisation decisions – pending cases T-837/16 and T-108/17

# ECHA's REACH decisions challenged in two fora

- Interpretation of "intermediates" in Article 3(15) REACH
  - ECHA's interpretation confirmed in a case on a Substance of Very High Concern T-268/10 RENV, under appeal C-650/15 P
  - Literal interpretation taken in dossier evaluation case A-010-2014
- In follow-up to a decision having required testing, is ECHA's communication a decision?
  - A-019-2013 and another, pending case T-283/15
- Right forum for company size verification decisions
  - BoA : SME verification process not as an autonomous process outside the scope of review of the Board of Appeal but as part of the completeness check pursuant to Article 20(2) of the REACH Regulation which ultimately leads to a registration decision, which is under the scope of review of the Board of Appeal (A-002-2013)
  - General Court: The Court has jurisdiction … notwithstanding the appeal …also lodged by the applicant before the Board of Appeal of the ECHA (T-620/13) [A-016-2013 stay of proceedings and withdrawal after the judgment]

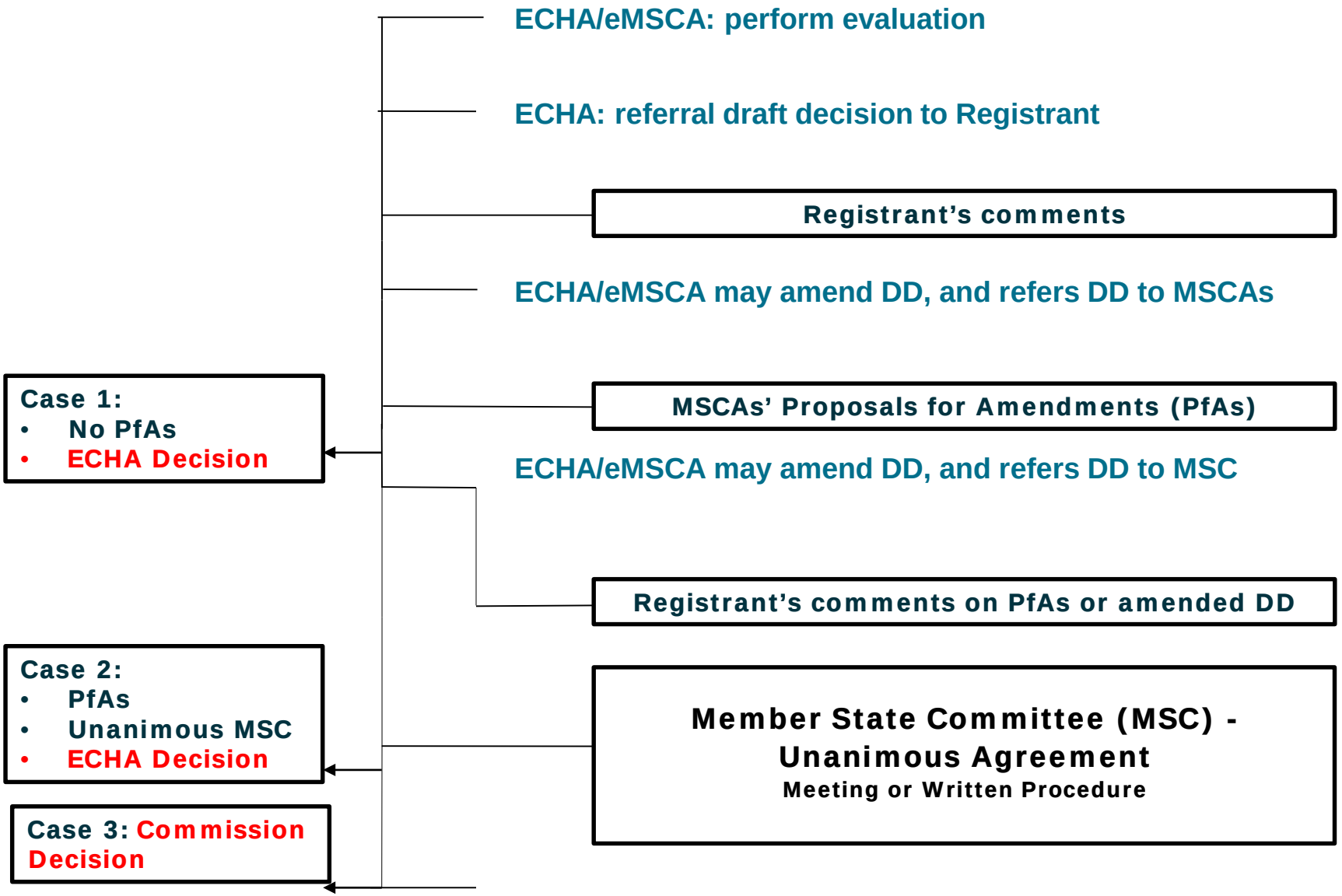
# The case of evaluation decisions

- COM(2003)644: Member States perform all evaluation and draft all decisions, decision-making procedure the same
- Explanatory memorandum p. 31: “This Article creates a procedure for securing agreement on evaluation decisions among Member State competent authorities before such decisions are taken by the Agency, without the necessity for a time consuming and resource intensive comitology procedure in every case. In case of disagreement, the Agency's Member State Committee provides a technical forum to resolve differences, again without the need for comitology. […] Any Member State can require that a decision be taken by comitology.”
- Final REACH text:
  - Agency performs dossier evaluation
  - Member States perform substance evaluation
  - Decision-making procedure *mutatis mutandis* the same

# Rectification of evaluation decisions

- Prerogative of the Executive Director
- Member States' agreement need to be respected
- ECHA can only rectify where
  - Formal error in the decision, e.g. wrong text in the decision, erroneous omission
  - Factual circumstances for taking the decision were wrong

# Procedural steps Articles 50, 51 REACH



# Legal review of evaluation decisions

- Court: manifest error of appreciation
- Board of Appeal:
  - Appropriateness, good administrative practice, proportionality?
  - How to maintain equality of arms for both parties?
  - How to take institutional balance into account?
  - No “functional continuity” at least in REACH evaluation?

Follow case T-125/17

# Scenario

- Registrant registers substance X in January 2010
- In substance evaluation of 2017, eMSCA finds substance X poses a concern for human health and proposes that a registrant has to perform study A within 2 years and, depending on the outcome of that study, also study B within another 3 years (7+1 year)
- Despite the Registrant's comments all Member States agree, and ECHA sends the decision to the Registrant (+1 year)
- The Registrant appeals (+3 m) with automatic suspensive effect
- ECHA's BoA annuls the decision regarding study B as not properly justified and modifies the testing conditions of test A (+ 16 m)
- eMSCA brings an appeal against the BoA decision in the Court (+2 m)
- Court comes to a decision finds the first decision was correct (+16 m)
- Registrant does not appeal further. Data for study A arrives in September 2023 and for study B in April 2028.

# Scope of review

What is the Court going to review?

- Grounds not limited to lack of competence, infringement of an essential procedural requirement, infringement of the Treaty, infringement of [REACH] or misuse of power?
- Whether the BoA made a manifest error of assessment in annulling test B?
- Whether ECHA made a manifest error of assessment in imposing test A or both tests?
- How to conclude which testing conditions for test A are correct?

What if the Member States did not agree unanimously? The Commission takes the decision in April 2020 and the Registrant brings an action in Court in June 2020 together with an action for interim measures not to start the studies. The Court finds no manifest error of assessment in the Commission decision and gives its judgment in September 2021. The Registrant does not appeal further. The last study results arrive in 2026, two years earlier than in the first scenario but still 16 years later than the substance was registered.

# THANK YOU