

# The standard of review by the Board of Appeal

**Seminar on 10 years of REACH  
Litigation**

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## Outline

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2. Standard (intensity) of review - other BoAs
3. Analogy to the ECHA BoA?
4. Standard of review in substance evaluation cases
5. Conclusion

# The ECHA Board of Appeal ('BoA')

## Composition

- 3 members, two lawyers and one scientist

## Procedure

- Rules of Procedure (Commission Reg. No 771/2008, as amended) based on Rules of Procedure of the General Court
- Adversarial procedure, with ECHA as defendant
- Pleas in law, rules on evidence
- Usually 2 rounds of written pleadings + hearing
- Target time for a decision: 15 months from filing the case

## Decisions subject to appeal

- Registration, registration exemptions and data sharing
- Dossier evaluation (testing proposals and compliance check)
- Substance evaluation

## Standard (intensity) of review - other BoAs

- So far, case-law on EUIPO/OHIM, CPVO, EASA BoAs
- *'Continuity in terms of functions'* – common factors:
  - Possibility to *'exercise any power which lies within the competence'* of the relevant Agency
  - *'The scheme'* established by the relevant Regulation
- Such BoAs *'are therefore called upon to carry out a new, full examination of the merits [of a decision], in terms of both law and fact.'*

(e.g. C-29/05 P, OHIM v Kaul, para. 56-57)

## Analogy to the ECHA BoA? (1)

- Can the case-law on functional continuity and *de novo* review be transposed 1:1 to the ECHA BoA?

### Elements to consider

➤ Art. 93(3) REACH:

*'The Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.'*

- But are the REACH processes underlying appealable decisions sufficiently similar to those of other Agencies?

## Analogy to the ECHA BoA? (2)

### Variables

- Margin of ECHA discretion varies depending on the process
- Different procedures followed ('democratic' unanimous agreement of the Member State Committee, or assessment only by ECHA secretariat)

Contested decision	Margin of discretion	Participative procedure (MSC)	Analogy to other BoAs?
PPORD, registration, data-sharing	Narrow	No	✓
Dossier evaluation (testing proposals, compliance check)	'Medium'?	Yes	~
Substance evaluation	Broad	Yes	✗

## Substance evaluation

- ECHA and its Member State Committee have broad discretion concerning both:
  - the identification of a potential concern, and
  - The choice of means to clarify it.
- E.g. evidence shows that a substance may be an endocrine disruptor, and there are several testing options. No 'right' answer.

## Substance evaluation - ECHA

- Highly complex subject matter and lack of information – there may be no such thing as a scientific ‘truth’
- Highly specialised knowledge
- Thousands of pages of information, dossiers, studies
- Years of work by Member States and/or ECHA on a substance
- Unanimous agreement between Member States: scrutiny/analysis by 28 MS + ECHA + registrants
- If no unanimous agreement between Member States the decision is taken by the Commission through comitology

## Substance evaluation - BoA

- If the legislator intended to have a second tier of scientific evaluation, the composition and size of the BoA should have been entirely different?
- Why the participative decision-making procedure if the assessment should then be repeated by the BoA (i.e. the Technically Qualified Member)?
- What to do if there is no scientific 'truth', only uncertainty and different views?
- Need to find a 'third way' between *de novo* examination and the limited review of the EU Courts?

## How to strike a balance? – Examples

### Case A-004-2014, *MCCP Registrants*, para. 74-84

- ECHA required testing certain constituents of a substance for bioaccumulation in fish.
- The Appellants argued that there was a more appropriate way to test the substance.
- Detailed scientific debate, but ECHA showed that it had taken all relevant elements into account in a detailed scientific assessment.
- BoA held that there was a difference in scientific opinion not leading to annulment.

### Case A-009-2014, *Albemarle and others*, para. 99-105

- ECHA required information on the potential endocrine disruptive properties of a substance (vitellogenin induction).
- The Appellants argued that the underlying concern was based on an study the results of which were unreliable for several reasons.
- ECHA did not rebut the substance of these arguments.
- BoA held that the study was too weak to establish the existence a potential concern, and annulled the decision in this regard.

## Conclusion

- BoA approach so far in **substance evaluation** cases: ‘high intensity’ review of legality
  - Review based on pleas in law (typically proportionality and errors of assessment)
  - Detailed scientific assessment in the context of reviewing ECHA’s scientific assessment (~~manifest~~ error of assessment, ~~manifest~~ inappropriateness to achieve the objective pursued).
- The scientific review is detailed, but not necessarily reflected in the final decision.
- Ultimately, if an appellant cannot show that ECHA made an error, but only that there are different views in a context of scientific uncertainty, it will not succeed.

**Thank you.**

