Workshop: The Board of Appeal for REACH & Biocides

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Topics for Today

1. Procedural considerations
2. Decisions so far – any conclusions on the merits?
3. Focus on data sharing
4. The BoA and the BPR
5. Practical considerations – why introduce an appeal?
6. Expected forthcoming issues in the near future
7. Some Conclusions
8. Q & A

Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.

Procedural Considerations

What is the BoA?

- BoA: a body of the European Chemicals Agency (see art. 76 REACH), established by art. 89 REACH (Regulation No 1907/2006)
- Chairman, the members and alternates are appointed by ECHA's Management Board, for five years (extendable once)
  - appointed on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates adopted by the Commission
  - One Chairman (Chairwoman), one technically qualified member, one legally-qualified member
- Independent members, may not be removed from office, unless serious grounds: Commission decision upon opinion of Management Board
- Members cannot take part in appeal proceedings if they have any personal interest therein: replaced by an alternate

Nature of BoA Proceedings

- Appeal against ECHA decisions exclusively, under REACH or BPR
- Administrative review of decisions: written procedure, with a possibility of oral hearing
- After consultation with Chairman, Executive Director may rectify ECHA's decision (art. 93(1) REACH)
- Powers equivalent to ECHA's decisions: it 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 (art. 93(3) REACH)
- Decisions on admissibility may be taken either after 30 days of lodging the appeal – or with the final decision
- If appeal is admissible the BOA may annul and refer back to ECHA for renewed decision
- Possibility of challenge before the General Court or the Court of Justice of the EU, to contest BoA decision or for failure to act

Activities of the BoA

Decision date	# appeals	#decisions	#withdrawals	#pending
2009	1		1 rectification	
2010	1	0		
2011	6	1 annulled 1 dismissal	2 withdrawals 2 rectification	
2012	8	0	1 rectification	
2013	22	3 annulled 2 dismissals 1 inadmiss	2 withdrawals	4
2014	18	1 inadmiss 4 dismissals 2 annulled	1 rectification 2 withdrawals 12 settlements	14
TOTAL	**56**	**15**	**23**	**18**

What Decisions Can Be Challenged Before the BoA?

Type of REACH decision:	15	Type of BPR decision: 0
Data sharing:	1	Data sharing
Substance evaluation:	6 pending	Active substance approval (and renewal)
Examination of testing proposals:	3	Assessment of the technical equivalence of active substances
Compliance check of registrations / intermediate:	10 + 6 pending (1 intermed)	Union authorisation (and renewal) of a biocidal product
Rejections of registrations (SMEs / appropriate fee)	13	
PPORD exemption	0	

Implementing Texts

- Procedure: Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency – OJEU L 206 of 2.8.2008
- REACH appeal fees: Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) – OJEU L 107 of 17.4.2008 – amended by Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013 – OJEU L 79 of 21.3.2013
- BPR appeal fees: Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products – OJEU L 167 of 19.6.2013

ECHA Fees for Appeals Before the BoA (REACH)

Fees for appeals under Article 92 of Regulation (EC) NO 1907/2006

Table 1

Standard fees

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	EUR 2 356
Article 27 or 30 of Regulation (EC) No 1907/2006	EUR 4 712
Article 51 of Regulation (EC) No 1907/2006	EUR 7 069

Table 2

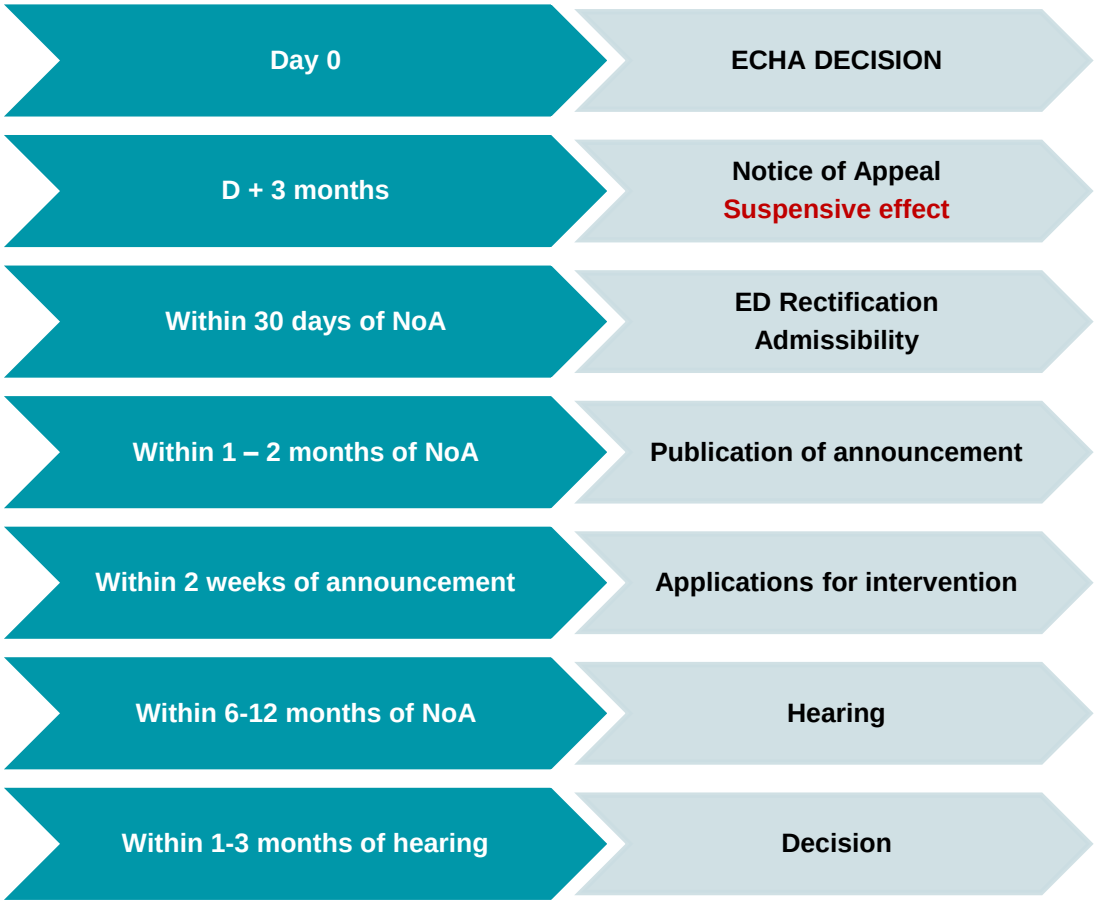
Reduced fees for SMEs

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	EUR 1 767
Article 27 or 30 of Regulation (EC) No 1907/2006	EUR 3 534
Article 51 of Regulation (EC) No 1907/2006	EUR 5 301'

ECHA Fees for Appeals Before the BoA (BPR)

- € 2,500
- No reduction for SMEs
- Decisions appealed will have been the subject of the levying of fees

Typical Timeline of BoA Proceedings



Typical Proceedings

- Notice of appeal
- ECHA Defence
- At BoA discretion: Reply submitted by Appellant
- At BoA discretion: Rejoinder submitted by ECHA
- Decision on applications to intervene and submission of observations by interveners
- Submission of observations by Appellant and ECHA on statements in intervention
- Closing of written procedure
- Hearing: Optional, unless requested by Appellant
- BoA Decision (published)

Issues of Confidentiality

- Confidentiality
  - vis-à-vis ECHA
  - vis-à-vis third party interveners
  - vis-à-vis public: announcement, hearing, and final decision of the Board of Appeal
- What can deserve confidential treatment:
  - Personal data
  - Substance
  - Appellant
  - All reference numbers (communication, registration, submission #)
  - Confidential business information

Who Can Lodge an Appeal?

- Who can be an appellant? Individual or joint appeal?
- What are the effects of the appeal? On whom?
- Who can intervene? What are the consequences of intervention?

Who Can Be an Appellant?

- "Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former" (Article 92(1) of REACH)
  - Addressees of a decision
  - Persons who are "*directly and individually concerned* "

Who Can Be an Appellant?

- Addressees of a decision
  - Registration completeness check: concerned registrant
  - Data sharing dispute: concerned data owner / concerned applicant
  - Dossier evaluation: Registrant and co-registrant if on joint submission
  - Substance evaluation: all registrants who received the Agency's draft decision for comments

Who Can Be an Appellant?

- Persons who are "directly and individually concerned"
- Direct concern
  - The Contested Act must directly affect the legal situation of the Appellants; and the addressees of the Contested Act must be left with no discretion in implementing the Contested Act.
- Individual concern
  - "[…] *if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed*". (see for example Case C-583/11 P – *Inuit Tapiriit Kanatami and Others v Parliament and Council*, not yet published, paragraph 72.)

Who Can Intervene? What are the Consequences?

- "Any person establishing an interest in the result of the case submitted to the Board of Appeal" (Article 8(1) of the BoA Rules of Procedure)
- Precedents so far
  - Member States
    - Substance evaluation: evaluating Member States, other Member States
  - Other registrants
    - Dossier evaluation: registrants other than the Lead registrant
  - NGOs
    - Animal rights groups

Analysis of Decisions So Far

Analysis of Decisions So Far

A few principles can be derived from previous experience and BoA decisions (mainly dossier evaluation)

- ECHA's margin of discretion
- ECHA creates legitimate expectations – the Agency's actions cannot frustrate these expectations
- Registrants must present their comments through dossier updates and formal comments

ECHA's Margin of Discretion

- ECHA must assess
  - If the evidence relied on is factually accurate, reliable and consistent,
  - If it contains all the information that must be taken into account in order to assess a complex situation and
  - If the evidence can sustain the conclusions drawn from it
- ECHA is under a duty to examine carefully and impartially all the relevant elements of the individual case
- Different standard than the standard applied by the EU Courts to the European Commission in cases involving scientifically and technically complex cases

ECHA Creates Legitimate Expectations

- Legitimate expectations (that cannot be frustrated) are created through Agency guidelines, fact sheets, guidance documents, or direct communication to registrants
- ECHA's actions must then be consistent with these expectations
  - See ECHA practice of engaging in dialogue with registrants

Registrants' Comments

- The BoA held (Case A-004/2012) that
  - the Appellant "did not clearly put forward adaptation or waiving arguments in the appropriate section of its registration dosser" and the Agency "should not be required to compile adaptation arguments on behalf of registrants from the information set out in other parts of the registration dossier."
  - "The Agency is not required to examine the registration dossier of its own initiative to look for information that may justify an adaptation or waiving."
- The BoA held Case A-004/2012 that
  - "whilst registrants can expect a certain level of expertise within the Agency, it is not the task of the Agency to develop, or improve, read-across adaptations on their behalf."
- Registrants must present their arguments, and should not expect ECHA to develop them

BoA Decisions – Other Conclusions

The BoA decisions so far provide background for dossier evaluation for example on:

- Read across justification
- Waiver justification
- Provision of a second species reprotoxicity study
- Article 41 compliance check do not necessarily cover all end points of a registration
- Communication with the Agency during the dossier evaluation procedure

Focus on Data Sharing

Lessons from the BoA

- **1st decision on a data sharing dispute**, under REACH (Art. 30) issued on December 17, 2014 (Case A-017-2013).
- Key elements giving rise to the dispute:
  - 10% *per annum* increase post-2010 registration deadline (to pre-finance LR's efforts), subject to later reimbursement i.e. deposit (ECHA decision characterized increase as "manifestly discriminatory" but BoA said it did not have sufficient evidence to reach this conclusion, noting the reconciliation)

    No detailed description of what discrimination means in this context.
  - €1,000 handling (one off) (ECHA and BoA held this was not explained with sufficient clarity – did not say it was inappropriate)

Lessons from the BoA (cont'd)

DATA SHARING TERMS

- BoA confirmed that ECHA:
  - Should not assess if the "actual and precise cost of a letter of access is reasonable or justified" (as in Data Sharing Q&A)
  - May make an assessment of whether each of the parties made "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way"
- BoA takes a holistic approach to "every effort" test without separating the three subcomponents:
  - A fact/case driven analysis as to whether every effort is taken based on the "arguments presented during the data sharing negotiations between the parties" (word for word)
  - Only communications between the parties during data sharing negotiations are examined (confirms ECHA practice on DSD, published in August 2014)

Lessons from the BoA (cont'd)

- Reconciliation clauses "may, in certain circumstances, be considered to be an important point in assessing whether every effort has been made" (10% per annum increase was not judged to have been clearly subject to reconciliation)
- Ever-present clarification burden: an effective reversal of burden on data owner to respond to concerns (not fully articulated) and provide unrequested evidence (*e.g. reconciliation mechanism*)?

Lessons from the BoA (cont'd)

ADMISSIBILITY CRITERIA

- BoA held that ECHA must clarify the scope of requests with a data accessor
- BoA held there is a presumption that those requested data are for all V-data in the substance dossier for the tonnage band (if cherry picking then will need to state expressly vis-à-vis the data owner):
  - Willingness to infer "common understanding" (contrast with need for declarative clarity required for cost sharing information)
  - Willingness to deduce scope from absence of questions (so ask questions, include conditional qualifiers to avoid certainty being imputed – or risk being found not to have made every effort)

Lessons from the BoA (cont'd)

NEGOTIATING PRACTICES

- BoA guidance on other aspects:
  - Early circulation of SIEF agreements is "good practice" but analysis really begins at the moment when active negotiations start (what is stored up for 2018?)
  - Repetition of positions is credited if the response is not judged adequate (after the event/by the data accessor?) When are concerns "adequately addressed?"
  - Negotiations close to a registration deadline are not a per se indication of failure to make "every effort." The reason for failure to agree is more important.

The BoA and the BPR

The BoA and the BPR

- **History of EU-level biocides litigation is unhappy**:
  - (i) procedural barriers to justice ('standing' and the *Plaumann* doctrine)
  - (ii) ultimate failure (common with much past chemicals litigation)
    - T-339/00 and C-258/02 P (First Review Regulation cases)
    - Joined Cases T-75/04 and T-77/04 to T-79/04 (Second Review Regulation cases)
    - Joined Cases T-400/04, T-402/04 to T-404/04 (Legislative Amendment cases)
    - Case T-120/08 (Third Review Regulation case)

- **The BoA provide some light at the end of the tunnel.**

ECHA: The BoA and the BPR

BoA remedies apply against ECHA, which has roles which are:

- (1) Advisory
- (2) Decision-Making – BoA remedy
- (3) Coordination

ECHA: The BoA and the BPR

BPR Interlocutor	Potential Action
ECHA	• Legal Advocacy
	• **BoA in specific areas + Ability to rectify**
	• **ECJ (i) on appeal from BoA** and (ii) for ATD and Dissemination
Commission	• Legal Advocacy (even on unchallengeable ECHA action which underlines its own Decisions)
	• General Court
	• ECJ on appeal from General Court
Member States Authorities	• Legal Advocacy
	• National Courts + Preliminary Ruling to ECJ

ECHA Decision-Making and the BoA

Fees∞	Data Sharing	Technical Equivalence
Validation of AS applications - rejection of application for non payment of fees within 30 days (Art 7.(2))	**Mandatory where parties don't agree** (Art 63(3))	**Decision on technical equivalence** (Art 54.(4))
Renewal of AS applications - rejection of application for non payment of fees within 30 days (Art 13.(3))	**Referral to unprotected data when technically equivalent** (Art 64(1))	**Rejection of application where further information requested** for technical equivalence but not provided so rejected (Art 54.(5))▲
Validation of Union Authorisation - rejection of application for non payment of fees within 30 days (Art 43.(2))		
Renewal of Union Authorisation - rejection of application for non payment of fees within 30 days (Art 45.(3))		
Rejection of application for Technical Equivalence for non payment of fees within 30 days (Art 54.(3))		
Rejection of AS applications under Art. 95 Transitional Measures - rejection of application for non payment of fees for submission of a dossier within 30 days (Art 95(1) 4th sub-paragraph. **No explicit BoA Appeal.**		

∞▲*Same remedy for fees non-payments and /or failure to provide requested information under Reg. (EU) 613/2013, Reg. (EU) 564/2013 (also on SME status) and Reg. (EU) 354/2013.*

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ECHA Decision-Making and the BoA

Although not actionable before the BoA, the ATD regime may support BoA claims.

- Free-standing right to challenge **ECHA decisions** on access to documents (under Regulation (EC) 1049/2001) before General Court. Consider applicability of Article 4 exceptions including commercial interests of a natural or legal person, including intellectual property. **Access to document is useful in itself**, and useful in any later appeal.
- Alternative right to complain to **Ombudsman.**

Take-Home Messages

- Resolving legal issues under the BPR is not all about a 'day in Court' or even before the BoA. Showing you understand the limits on power need not be a hostile gesture. Sound decision-making is not an issue for 'one side'.
- The BPR framework expressly includes a mechanism for ECHA to avoid an appeal before the BoA and reverse a decision. This should set the tone for all interaction under the BPR.
- Failing to address legal issues with all three Interlocutors (ECHA, Commission and Member States) is to store up conflict, generate poor decisions and allow procedures to escalate to conflict when early articulation of messages might have avoided this (before positions harden).

Practical Considerations – Why Introduce an Appeal?

Practical Considerations – Why Introduce an Appeal?

- For a partial or complete annulment of the decision
- Suspensive effect - vis-à-vis the appellant only?
- To be heard:
  - Opens a window of opportunity for a rectification by the Executive Director
  - Opens a further window of opportunity for settlement
- For establishment of best practices?

Expected Forthcoming Issues in the Near Future

Types of Cases

- 2010 – 2013:
  - A large number of fees/SME-related cases
  - A few precedent-setting decisions on dossier evaluation (compliance check and testing proposals)
- 2014:
  - Continuing cases introduced against dossier evaluation decisions
  - First cases against substance evaluation decisions
- 2015:
  - Continuation of cases against dossier evaluation decisions
  - More cases against substance evaluation decisions
  - What about ad hoc ECHA decisions?

Types of Issues

- PBT-testing
- Scope/margin of discretion
- Nano-related issues
- New issues related to endocrine disruption?
- Procedure?
- Others?

BoA Appeals

TO BE CONTINUED!

Some Conclusions

- Real substantive issues are pending, or will be addressed in the near future
- Lack of precedents combined with potential lack of clarity in the law means that real changes can be made to current practices
- The appeals procedure must be used

Questions?