ECHA Board of Appeal: Function, Powers, and Decision-making

4 June 2014

Marcus Navin-Jones

32(0)2 645-5097
navin-jones@khlaw.com

www.khlaw.com
Preliminary word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual’s specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depend on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the author’s alone and not those of the author’s clients.
Overview

1. Legal status of ECHA BOA
   - Administrative body Vs Judicial authority
   - Functional independence

2. Legal powers and authority of ECHA BOA

3. ECHA BOA and EU Courts of Law
   - Legality and lawfulness
   - Substitution
   - *de novo* review and the principle of Administrative Continuity

4. ECHA BOA Decision-making
   - Honeywell Vs Dow
   - Evolution of ECHA BOA decision-making

5. Concluding remarks
Acronyms

- NoA – Notice of Appeal
- App – Appellant
- OH – Oral Hearing
- WP – Written Procedure
- GC – General Court
- RoP – ECHA BoA Rules of Procedure Reg 771/2008
- ECHA BoA Fee Reg – Reg 340/2008 as amended Regulation 254/2013
- PD – ECHA BoA Practice Directions
- HCD – Historical Control Data
- REACH – Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (1907/2006)
- ECHA – European Chemical Agency
- ECHA BoA – ECHA Board of Appeal
- Rapporteur - Member of ECHA BoA responsible for case
- MSCA – Member State Competent Authority
- MS – Member State
- EU – European Union
Legal status of ECHA BOA
ECHA BOA – Administrative body Vs Judicial authority (1/2)

- EU Boards of appeal relatively new legal construct
  - The Agency for the Cooperation of Energy Regulators (ACER) Board of Appeal est. approx. 2009
  - The European Chemicals Agency (ECHA) Board of Appeal established approx. 2007
  - The European Aviation Safety Agency (EASA) Board of Appeal established approx. 2002
  - The Community Plant Variety Office (CPVO) Board of Appeal established approx. 1994
  - The Office for Harmonisation in the Internal Market (OHIM) Boards of Appeal est. approx. 1994

- Legal status: OHIM BsOA - Administrative bodies of OHIM
  - OHIM Boards of Appeal
    “…still OHIM bodies and not courts…” Case T-298/10 Arrieta D. Gross v OHIM [2012] para 105

  “…while the [OHIM] Boards of Appeal enjoy a wide degree of independence in carrying out their duties they constitute a department of the Office [i.e. the OHIM] responsible for controlling […] the activities of the other departments of the administration to which they belong…”
  Case T-63/01 Procter & Gamble v OHIM (Soap bar shape) [2002] ECR II-5265, para 21-22

  “A procedure is, initially, a matter for OHIM, its Opposition Divisions first of all and, then, on appeal, its Boards of Appeal which in spite of the independence enjoyed by those departments and their members, remain nonetheless departments of the OHIM”
  Case C-29/05 P OHIM v Kaul [2007] ECR I-2213, para 51
OHIM BsOA solely administrative bodies of OHIM?
- Case T-163/98 Procter & Gamble v OHIM (BABY-DRY) [1999] ECR II-2383 para 23
  Sunrider: OHIM argued:
  - Because OHIM Boards of Appeal are merely a “…final authority of the OHIM…”
  - Because an appeal to the OHIM Boards of Appeal “…more an internal administrative remedy than a judicial remedy…” para 51
  - Appellant could not benefit from rights under Article 6 ECHR (Right to a fair trial)
  CFI held:
    - “decisions must be adopted within reasonable time” Article 41(1) Charter of Fundamental Rights of the European Union regarding administrative proceedings

EU BOAs solely administrative bodies of their affiliated agencies/offices?
- Intention of legislator to establish an appeal body where rights of the Appellants were not protected and can be ignored?
- NB Degree of autonomy and independence from affiliated EU Agencies and Offices
- NB Significant legal powers as compared to (i) affiliated EU Agencies/Office and (ii) judicial authorities
ECHA BOA – Functional independence

- EU Boards of Appeal form part of affiliated Agencies / Offices

- However, members of EU Boards of Appeal generally operate independently.
  
  “…while the Boards of Appeal form an integral part of the [OHIM] […] and there is continuity in terms of their functions between the Board of Appeal, the examiner and/or the competent division […] Boards of Appeal and their members have functional independence in carrying out their tasks. The [OHIM] cannot therefore give them instructions”
  
  Case T-107/02 GE Betz v OHIM para 33.

- ECHA BOA:
  
  - “The members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions” (Article 90(2) REACH)
  
  - “The members of the Board of Appeal may not perform any other duties in the Agency” (Article 90(3) REACH)
  
  - “Members of the Board of Appeal may not take part in any appeal proceedings if they have any personal interest therein, or if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal” (Article 90(5) REACH).
Legal powers and authority of ECHA BOA
ECHA BOA – Legal powers and authority

ECHA BOA

- “The Agency shall comprise: […] a Board of Appeal, which shall decide on appeals against decisions taken by the Agency” (Article 76(1)(h) REACH).
- “A Board of Appeal should be set up within the Agency to guarantee processing of appeals for any natural or legal person affected by decisions taken by the Agency” (para 106 REACH Preamble).

ECHA BOA legal powers and authority

- “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” (Article 93(3) REACH)
- “If the Board of Appeal remits the case to the competent body of the [ECHA] in accordance with Article 93(3) [REACH], the [ECHA] shall be bound by the reasoning in the decision of the Board of Appeal save in so far as a change in the circumstances occurs” (Article 18 RoP)
ECHA BOA – Scope of authority

- [REACH] establishes a Board of Appeal to decide on appeals against the decisions referred to in Article 91(1) REACH (para 1 RoP Preamble)

- ECHA Dossier Evaluation Decisions requiring, for example, new data (Art 51)
- ECHA Decisions on data sharing of REACH registration data within the SIEF; i.e. granting permission to refer to VAT study etc (Art 30(5)(2)-(3))
- ECHA Decisions on granting permission to refer to full study report for non phase-in and non preregistered phase-in substances (Art 27(7)(6))
- ECHA Decisions rejecting registration dossiers which fail completeness check (Art 20(5) and 20(2))
- ECHA Decisions on extending PPORD exemptions to REACH register and ECHA Decisions on conditions of PPORD exemptions granted re use (Art 9(10)(4) and (7) REACH)
- NB BPR
ECHA BOA – Scope of authority

- Generally, ECHA BOA has no legal authority to hear appeal cases concerning other issues.
- E.g. ECHA BOA cannot hear cases challenging legality or lawfulness of REACH provisions themselves.
- Dow Benelux B.V. Vs ECHA A-001-2012
  - DEv procedure itself not compliant with TEU and TFEU as constituted breach of the legal principle of institutional balance and therefore illegal
  - ECHA BOA not competent to address claim
  - Pleas regarded as inadmissible (para 58)
- Kronochem GmbH Vs ECHA A-004-2011, para 66
ECHABOA and EU Courts of Law
ECHA BOA – Legality, lawfulness and admissibility

- EU Courts of Law review legality or lawfulness of decision taken by initial decision maker

- “…the Court of First Instance and the Court of Justice, where it sets aside the judgment of the Court of First Instance and gives judgment itself on the action, carry out a review of the legality of the decisions of the OHIM bodies. If they hold that such a decision, called into question in an action before them, is vitiated by illegality, they must annul it…”
  Case T-402/07 Kaul GmbH v OHIM, para 49

- Lanxess Deutschland GmbH v ECHA A-004-2012

- No legal prerequisite for ECHA BOA to identify legal breach or legal infringement in order to hear or annul an ECHA Decision.
  - Consistent with underlying objective of ECHA / ECHA BOA
  - Evaluations of appeals must be “balanced […] from a legal and technical point of view…” (para 3 Preamble of RoP)
  - ECHA BOA includes a technical member.
  - ECHA BOA forms part of ECHA. ECHA decision-making requires consideration all relevant issues not merely technical

- Thor GmbH v ECHA A-003-2012
ECHA BOA – Substitution

Core legal doctrine that, generally speaking, EU Courts of Law may not substitute the assessment of the relevant factual matters, the reasoning, or the judgment of the initial decision maker.

“The Court of Justice and the Court of First Instance cannot under any circumstances substitute their own reasoning for that of the author of the contested decision”
Case C-164/98 P DIR International Film and Others v Commission [2000] ECR I-447, para 38

However, ECHA BOA is not restrained by this legal doctrine

“…in relation to the ‘manifestly inappropriate’ criterion set by the EU Courts when conducting a judicial review of the proportionality of a measure, the Board of Appeal underlines the clear differences between itself and the EU Courts. In particular, the latter refrain from substituting their own assessment for that of the EU Institution whose decision is being reviewed […]. However, under Article 93(3) of the REACH Regulation, the Board of Appeal ‘may exercise any power which lies within the competence of the Agency […]’. Thus, the Board of Appeal can inter alia replace a decision under appeal with a different decision”
Honeywell Belgium NV v ECHA, A-005-2011, paragraph 117 emphasis added
Generally: When reviewing the legality of an act or decision of an initial decision-maker, EU courts are not legally able to conduct a wholly new investigation and assessment (i.e. a *de novo* review) of the factual issues and circumstances.

However: “Not only must the Community courts, *inter alia*, establish whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complete situation and whether it is capable of substantiating the conclusions drawn from it” Case C-12/03 P *Commission v Tetra Laval* [2005] ECR I-987

Contrasts starkly with doctrine of ECHA BOA

ECHA BOA not only legally able to conduct a *de novo* review of all the factual circumstances of a dispute

Suggestion that ECHA BOA is legally bound to conduct a *de novo* review of all the factual circumstances behind a particular dispute
ECHA BOA – de novo review and admin. continuity

- N.V. Elektriciteits – Produktiemaatschappij Zuid-Nederland EPZ v ECHA A-001-2010

- ECHA argued that ECHA BOA
  (i) could not rely on evidence which was not submitted by one of the parties to the dispute – but which was obtained by the ECHA Board of Appeal “on its own initiative” (para 30) and
  (ii) that “it would be inappropriate for the [ECHA BOA] to raise new grounds for possible annulment of the contested decision which have not be invoked by the Appellant (para 30).

- In response, ECHA BOA rejected the pleas submitted by ECHA and, ultimately, found in favour of the Appellant, ordering the refund of the fee.

- “…the [ECHA] Board of Appeal can carry out a new, full examination as to the merits of the appeal, in terms of both law and fact…”, and that: “Consequently, when called to decide on an appeal related to a registration pursuant to the REACH Regulation, the [ECHA] Board of Appeal is conducting an ex parte procedure and it may, contrary to the Agency’s claims, consider all circumstances and facts applicable during the administrative procedure that led to the adoption of the contested decision. As such, and by reason of the concept of administrative continuity, the examination of the appeal is not limited to the arguments of the facts and law raised by the parties” para 36-37
ECHA BOA – de novo review and admin. continuity (3/4)

- ECHA BOA found legal authority for conducting de novo review of facts and evidence ‘by reason of the concept of administrative continuity’ para 36

- ECHA BOA initially drew comparisons between its legal powers of those of OHIM BsOA

- ECHA BOA stated that the General Court had already ruled that administrative continuity existed between the OHIM and the OHIM BsOA

- ECHA BOA cited the definition of ‘administrative continuity’ from General Court’s judgment in Henkel KGaA v OHIM [2003] ECR II-03253 para 29

- “the examination which the Board [of OHIM] must conduct is not, in principle, determined by grounds relied on by the party who has brought the appeal. Accordingly, even if the party who has brought the appeal has not raised a specific ground of appeal, the Board of Appeal [of OHIM] is none the less bound to examine whether or not, in light of all relevant matters of fact and of law, a new decision with the same operative part as the decision under appeal may be lawfully adopted at the time of the appeal ruling”
In EPZ case, ECHA BOA found legal authority to conduct de novo review. Also legal requirement to conduct de novo review?

Significant difference between EU Courts of Law and ECHA BOA

EU Courts of Law more passive in their role – review evidence before them

ECHA BOA more independent and proactive in investigating facts

Outstanding questions (i) to what extent is ECHA BOA legally required to conduct de novo review; and
(ii) to what extent has ECHA BOA discharged this obligation in any particular circumstance?

Other differences:
- Suspensive effect (Article 91(2) REACH)
- Duty of disclosure
- Interveners
- Deadlines
ECHA BOA Decision-making
Honeywell A-005-2011
Background to A-005-2011

- ECHA required a study under Section 8.6.4 Annex X

  Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 in case of:
  - toxicity of particular concern (e.g. serious/severe effects), or
  - indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or
  - particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).

- Contested Decision required Appellant to carry out:

  “90-day repeated dose toxicity study (sub-chronic toxicity study) in the rabbit, by inhalation (method B.29 of Regulation (EC) No 440/2008 or OECD 413). The study protocol shall be modified with additional clinical pathology and histopathological evaluations to evaluate effects on reproductive organs; specifically as described in OECD 416, paragraphs 29-32, 39, 41-45”.

Summary of Appellant legal arguments

1. Breach of Article 41 REACH and Annex X REACH (ECHA Authority to request and require animal testing).

2. Inconsistent with Article 13(3) REACH (Testing proposals)

3. Inconsistent with Article 13(2) REACH (Testing protocols)

4.1 Breach of, and inconsistent with, Article 25(1) REACH (Animal testing)

4.2 Proportionality

5. [New plea] Contested Decision adopted in breach of Article 51(6)-(7) REACH
Summary of Decision in A-005-2011

- ECHA Decision to require 90-day test annulled on grounds that:
  1. ECHA failed to ensure that testing on vertebrate animals was a last resort i.e. Acted in breach of Article 25(1) REACH (Animal testing)
  2. ECHA failed to ensure that testing involved the minimum number of vertebrate animals i.e. Acted in breach of Article 25(1) REACH and Directive 2010/63/EC, etc.
  3. Test was not appropriate or necessary i.e. ECHA act was not proportionate.

Common to each: ECHA failed to assess “…all the information which must be taken into account in order to assess a complex situation” (Case C-12/03 P Tetra Laval [2005] ECR I-987, para 39) – A-005-2011 para 76

- Case remitted to ECHA for “re-examination” [ECHA Evaluation Unit]
- Appeal fee refunded (Article 10(4) of Fee Regulation 340/2008)
Appellant successful – Decision did not merely annul Contested Decision – went further and assessed multiple issues to assist the ECHA in preparing a new decision:

“The appeal could be decided on [any one of the 3 grounds] alone. However, the board of Appeal considers it necessary, to assist the Agency in preparing a new decision…” (A-005-2011 para 172)

ECHA BOA expressly acknowledged that it was not an EU court of law and that its legal powers of review are, in some instances, more extensive

“…the Board of Appeal underlines the clear differences between itself and the EU Courts. In particular, [the EU courts] refrain from submitting their own assessment for that of the [initial decision maker]” whereas the ECHA BOA “…can inter alia replace a decision under appeal with a different decision” (A-005-2011 para 117)

Legal powers of review and legal scrutiny applied in full.

Tests applied in reviewing ECHA Decision – identical to EU court of law?
Dealt with application of principle of proportionality in ECHA decision-making and animal welfare issues: Generally very comprehensive particularly on ‘appropriate’ criterion
  • Unprecedented study
  • Lack of historical control data
  • Choice of species: Most significant for human risk assessment
  • Rabbits susceptibility to stress and generation of false negatives
  • Problems related to commissioning of the study

NB ECHA BOA did not address some issues at all in the ECHA BOA Decision – particularly claims regarding ECHA adoption of Contested Decision (procedural irregularities and questionable practices)

Procedurally significant:
  • First to proceed to Oral Hearing
  • Case management changed in wake of Honeywell - More efficient and less time consuming (HW – WP more than 1 year - closed 22 Aug 2012, OH 12 Dec 2012), Oral Hearing now recorded, Questions at end of written procedure, Disclosure of ECHA internal documents, etc
ECHA BOA – Evolution of decision-making

- Generally ECHA BOA has conducted a de novo review of all the factual and legal issues underlying appeal cases brought before ECHA BOA – some exceptions

- Honeywell Belgium N.V. Vs ECHA A-005-2011
- ECHA BOA reconfirmed that:
  "…in conducting its administrative review of Agency decisions, the Board of Appeal possesses certain technical and scientific expertise which allows it to enter further into the technical assessment made by the Agency than would be possible by the EU Courts. As a result, when examining whether a decision adopted by the Agency is proportionate, the Board of Appeal considers that it should not be limited by the need to establish that the decision is ‘manifestly inappropriate’ to the objective pursued…” para 117

- ECHA BOA did not merely annul the ECHA Decision. ECHA BOA went on in its Decision and assessed, and then annulled, the ECHA Decision on several, separate and legally independent grounds to “… assist the Agency [ECHA] in preparing a new decision…” para 172

- Legal principles applied in HW by ECHA BOA same legal principles that apply as in EU Court of Law
- Irony: precisely because the ECHA BOA is not an EU Court of Law but an administrative body of ECHA – it has more investigative powers of review which means, in turn, that it is all the more self-empowered as a semi-judicial authority to review ECHA Contested Decisions than some judicial authorities.
Concluding remarks
Number of ECHA BOA appeal cases initially predicted

Estimation of ECHA BOA appeal cases 2007*
*Estimations in 2007 for ECHA Staff Model purposes

*NB Statistics taken from ECHA 2007 staff model document
Number of ECHA BOA cases lodged
### ECHA BOA – Significant cases to-date

<table>
<thead>
<tr>
<th>Company</th>
<th>Register No.</th>
<th>Date</th>
<th>Type</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPZ</td>
<td>A-001-2010</td>
<td>October 2011</td>
<td>A</td>
<td>Registration fee</td>
</tr>
<tr>
<td>Honeywell</td>
<td>A-005-2011</td>
<td>April 2013</td>
<td>A</td>
<td>Animal welfare</td>
</tr>
<tr>
<td>Dow</td>
<td>A-001-2012</td>
<td>June 2013</td>
<td>E</td>
<td>Read-across</td>
</tr>
<tr>
<td>Thor</td>
<td>A-003-2012</td>
<td>August 2013</td>
<td>A</td>
<td>Update to dossier</td>
</tr>
<tr>
<td>Italcementi</td>
<td>A-007-2012</td>
<td>September 2013</td>
<td>A</td>
<td>Substance ID UVCB</td>
</tr>
<tr>
<td>Lanxess</td>
<td>A-004-2012</td>
<td>October 2013</td>
<td>E</td>
<td>Waivers/Justification</td>
</tr>
<tr>
<td>Momentive</td>
<td>A-006-2012</td>
<td>February 2014</td>
<td>E</td>
<td>Read-across</td>
</tr>
<tr>
<td>Infineum</td>
<td>A-001-2013</td>
<td>April 2014</td>
<td>E</td>
<td>UVCB / ‘Stabiliser’</td>
</tr>
</tbody>
</table>
ANNEX VIII

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

Table 1: **Standard fees**

<table>
<thead>
<tr>
<th>Appeal against decision taken under:</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 9 or 20 of Regulation (EC) No 1907/2006</td>
<td>EUR 2 356</td>
</tr>
<tr>
<td>Article 27 or 30 of Regulation (EC) No 1907/2006</td>
<td>EUR 4 712</td>
</tr>
<tr>
<td>Article 51 of Regulation (EC) No 1907/2006</td>
<td>EUR 7 069</td>
</tr>
</tbody>
</table>

Table 2: **Reduced fees for SMEs**

<table>
<thead>
<tr>
<th>Appeal against decision taken under:</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 9 or 20 of Regulation (EC) No 1907/2006</td>
<td>EUR 1 767</td>
</tr>
<tr>
<td>Article 27 or 30 of Regulation (EC) No 1907/2006</td>
<td>EUR 3 534</td>
</tr>
<tr>
<td>Article 51 of Regulation (EC) No 1907/2006</td>
<td>EUR 5 301’</td>
</tr>
</tbody>
</table>

[Extract from Regulation 254/2013]
Thank you

Marcus Navin-Jones

32 2 645 5097
navin-jones@khlaw.com


www.khlaw.com

Washington, D.C. ● Brussels ● San Francisco ● Shanghai ● Paris