



REACH Post Registration: Next Challenges

Jim Searles & Darren Abrahams

Appeals under REACH

STEPTOE & JOHNSON LLP

step toe.com

15 February 2011

Topics Covered

- Appeals architecture
- Board of Appeal
- The role of the General Court
- Access to documents
- Recommendations

Appeals Architecture

ECHA has **wide decision-making powers** affecting your rights and obligations (both powers exercised already before the first registration deadline and powers it will exercise in the future).

The REACH Regulation – unusually for EU laws – provides an **express administrative Appeal mechanism**:

- Board of Appeal
- followed by Appeal to the General Court (formerly 'CFI')

Potential for recourse is wider than expressly stated in the Regulation. Other ECHA action is potentially subject to challenge.

Beyond litigation: our experience post first registration deadline is that ECHA may be open to constructive engagement to minimise the need for appeals.

BoA Composition

BoA is housed within ECHA but required to be **independent** and not take instructions from any source. Members not permitted to hold any other role in ECHA. A **multi-disciplinary** 3-person panel:

- **Chairman** (legally qualified)
- **Legally** qualified member
- **Technically** qualified member

One of them acts as *Rapporteur*, carrying out a preliminary study of the appeal.

BoA's Jurisdiction

Six types of reviewable ECHA decisions for which the BoA route must be followed *in the first instance*.

Appeal can be brought by **any natural or legal person** against a decision (applying old style Art. 230 EC test):

- addressed to that person, *or*
 - of '**direct and individual concern**' but addressed to another person (potential for competitors, downstream users, etc.)
1. **Rejects an incomplete registration** – where missing information not supplied by registrant within deadlines (Article 20)

This generated the only Appeal decision to date: *Specialty Chemicals Coordination Center s.a.*, case A-001-2009 and the only pending *N.V. Elektriciteits – Produktiemaatschappij Zuid-Nederland EPZ, Borssele*, case A-001-2010

BoA's Jurisdiction

2. Evaluates dossier as regards **testing proposals** or overall compliance of registration dossier and requires, e.g., **testing / information** to bring registration into compliance (Articles 40, 41, 51)
3. **PPORD substance registration exemption – completeness check** of notifier's information or decision to **impose conditions** limiting handling and control conditions (Article 9)
4. Designates **which SIEF member will carry out testing for new studies** not available in SIEF (Article 30(2)) where members can't agree (someone to inform ECHA using form available on website)

BoA's Jurisdiction

(ECHA 'last resort' Decisions on data sharing disputes; mandatory underlying dispute settlement procedure)

5. Re data sharing under 'inquiry' rules for **already registered non-phase-in or non-pre-registered substances**, ECHA permits potential registrant to refer to existing data where parties have failed to arbitrate or otherwise agree on sharing (Article 27(6))
6. Re data sharing for **phase-in substances**, ECHA permits potential other registrant to refer to vertebrate testing study where study owner in SIEF will not provide proof of cost or the study itself, and ECHA **blocks the uncooperative Data Owner's registration** or, if substance already registered, effectively obliges owner to **turn over full study report** to obtain compensation (Article 30(3))

Appears that BoA getting drawn into assessing if proposed costs or conditions respect the sharing rules ('fair, transparent and non-discriminatory')

- ❑ Financial penalties (Article 126) on uncooperative data owner imposed by national authorities, not ECHA (→ national appeal)
- ❑ Uncooperative data owner(s) may face competition law claims, again via national authorities or Commission in Brussels, not ECHA

BoA's Jurisdiction

Note: mandatory ECHA dispute settlement procedure prior to ECHA Decision on data sharing dispute

- Most likely scenario: substance already registered, e.g., 2013 or 2018 registrants needing LoA for whole set of studies from Joint Submission; dispute on LoA cost
- Responsibility of all parties to make every effort to reach agreement on sharing of data and costs (fair, transparent and non-discriminatory)
- Strict documentary requirements to show each party's position (or use of 'available information')
- ECHA Decision follows receipt of information from all parties and entails balancing and respect of interests of all parties
 - Beware: ECHA interaction may involve just Lead Registrant, so data owners need to clarify rights / obligations on their studies vis-à-vis Lead Registrant

BoA Timing

3-month time limit to bring appeal from:

- date of notification *or*
- (if not notified) date on which it became known.

There is no mechanism for extending the time limit. This is not long to prepare a properly formulated appeal (need to include all of the pleas in law and arguments of fact and law relied upon, plus any evidence offered). **'No Fee No Appeal'**: Appeal fee (max 6,600 Euro) must be paid to ECHA within time limit and is not considered lodged until this is done (reimbursed if decision rectified or appeal successful).

ECHA defence within 2 months of service of notice of the appeal.

Interveners (on either side) may participate to echo the parties' positions within 2 weeks of publication of ECHA website announcement that notice of appeal submitted.

BoA Procedure

- An appeal has a '**suspensive effect**': contrast with situation for legal challenges before General Court where suspensive effect is rarely granted. **Admissibility** is assessed within 30 days. (Contrast with position before ECJ.)
- If admissible and well founded, **Executive Director of ECHA may rectify Decision within 30 days** of appeal being filed (as in *Specialty Chemicals Coordination Center*).
- If admissible (and no rectification) there is a **right to an oral hearing upon request by either party**.
- Board of Appeal can **exercise any power** which lies within the competence **of ECHA or remit the case** to the responsible body of ECHA for further action. (Article 93(3)) Chair has cited wide powers to call meetings, request expert testimony, etc. at any time during the appeal.

General Court

General Court actions:

- Article 263 TFEU – annulment action

‘within two months of the publication of the measure, or of its notification to the plaintiff, or, in the absence thereof, of the day on which it came to the knowledge of the latter, as the case may be’

- Article 265 TFEU – failure to act

Consider Court action under REACH:

1. to challenge BoA decisions (must be done within 2 months)
2. **where no express right of appeal** to the BoA for ECHA action and/or Commission action

Issues to consider for challenges: is it a decision susceptible to challenge? Does it have legal effects [IBM case]? Standing?

General Court: New Rules

Old Article 230

Any natural or legal person may...institute proceedings against a decision **addressed to that person** or against a decision which, although in the form of a regulation or a decision addressed to another person, **is of direct and individual concern** to the former.

New Article 263

Any natural or legal person may...institute proceedings against an act **addressed to that person** or which is of direct and individual concern to them, **and against a *regulatory act* which is of direct concern to them and *does not entail implementing measures*.**

Discussions about whether a REACH chamber will have to be established in the Court to deal with the volume of cases expected.

Different *standing* tests before the BoA and General Court means companies might have a chance to challenge issues which they are not able to bring before the BoA (as well as those not subject to the BoA).

General Court

To date there have already been a number of actions where no express right of appeal to the BoA, focused on whole or partial annulment of ECHA decision to place substances on candidate list:

- various borates (Case T-343/10 Etimine SA and Ab Etiproducts Oy, and Case T-346/10 Borax Europe Ltd)
- acrylamide (Case T-268/10 Polyelectrolyte Producers Group GEIE (PPG) and SNF SAS)
- pitch, coal tar, high temp. (Case T-93/10 Bilbaína de Alquitranes and Others)
- anthracene oil (Case T-94/10 Rütgers Germany and Others) and anthracene oil low (Case T-95/10 Cindu Chemicals and Others), anthracene oil paste (Case T-96/10 Rütgers Germany and Others)

Access to Documents

Right to ECJ challenge to ECHA decisions on access to documents (under Regulation (EC) 1049/2001) held by it (Art. 118(1)).

Alternative right to complain to **Ombudsman**.

Consider **exemptions** (including):

- commercial interests of a natural or legal person, including intellectual property
- court proceedings and legal advice
- a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution...if disclosure would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure

Access to document is useful in itself, and useful in any later appeal.

Recommendations

- If you are an appellant, be alive to **short deadlines** for bringing actions. Immediate work needs to begin as soon as you are aware of a problem.
- **Add BoA and General Court to your strategic toolkit** of responses to any problem.
- If data owner, ensure protection of rights if Lead Registrant gets into data sharing dispute covering your study(ies).
- Ensure that you **monitor appeals** being lodged.
- **Intervene** in proceedings which are important to your business.
- **Do not hesitate to find out** if you have a good case: the BoA procedure is relatively quick and efficient.

Recommendations

- This is not about a 'day in Court': ECHA procedure builds in the **opportunity to avoid an appeal and reverse a decision**.
- Legal action may provide **short-term suspensive benefit** (where available on appeal to Board of Review).
- Where you must go through the Board, this will **protect your position** for an appeal to Court (damages etc.) Ensure you are making the best legal and technical arguments available.