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## Appeal of Decisions under REACH

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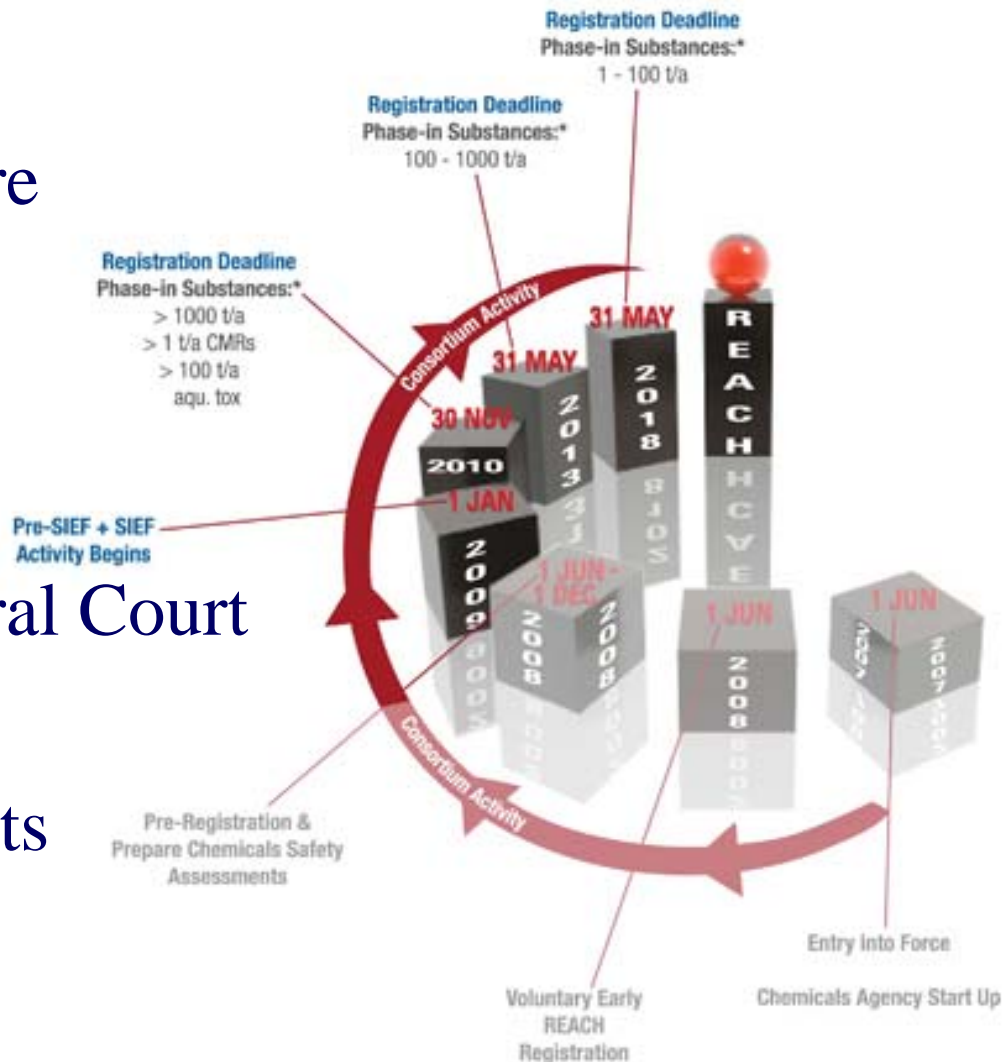
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# TOPICS COVERED

1. Appeals Architecture
2. Board of Appeal
3. Appeal to the General Court
4. Access to Documents
5. Recommendations



\* Principally substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)

# 1. APPEALS ARCHITECTURE

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ECHA exercises considerable decision making power affecting your rights and obligations throughout the operation of the REACH regime.

The REACH Regulation provides an express Appeal mechanism:

- Board of Appeal
- Appeal to the General Court (formerly “CFI”)

However the potential for legal recourse is wider. Don't think, if the Regulation doesn't specifically permit an appeal of an ECHA decision, you can't do it.

## **2. BOARD OF APPEAL**

# BoA COMPOSITION

A **multi-disciplinary panel** appointed on the basis of experience and expertise in fields of chemical safety natural sciences, regulatory or judicial procedures. Candidates list drawn up by Commission. BoA is housed within ECHA but required to be **independent** and not take instructions from any source. **Not permitted to hold any other role in ECHA**. 5 years terms (can be extended once).

Chairman	Mercedes ORTUÑO
Legally qualified member	Mia PAKARINEN
Technically qualified member	Henricus SPAAS
Alternate Chairman	Andreas BARTOSCH
Legally qualified alternate/additional members	Barry DOHERTY, Rafael Antonio LÓPEZ PARADA and Marc PALLEMAERTS
Technically qualified alternate/additional members	Carlo LUPI, Jonna SUNELL-HUET and Arnold VAN DER WIELEN

# BoA'S JURISDICTION

Article 91(1) REACH Reg. lists reviewable ECHA decisions. For those listed you must challenge via the Board of Review in the first instance.

Appeal can be brought by any natural or legal person against a decision:

- addressed to that person, *or*
- of 'direct and individual concern' but addressed to another person

(Art. 92(1))

# BoA'S JURISDICTION

**3 month time limit** to bring appeal from date of notification *or* (if not notified) date on which it became known. (Art. 92(2)) **This is not long.**

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

**Interveners** (on either side) may participate to echo the parties' positions.

# BoA'S JURISDICTION

- **PPORD substance registration exemption** - completeness check of notifier's information or decision to **impose conditions** limiting handling and control conditions (Article 9)
- **Rejects an incomplete registration** - where missing information not supplied by registrant within deadlines (Article 20). This generated the only Appeal to date: *Specialty Chemicals Coordination Center s.a.*, Case A-001-2009
- **Evaluates dossier** as regards **testing proposals** or overall compliance of **registration dossier**, or request **further information** and **examination** of that information. (Article 51)

# BoA'S JURISDICTION

- Permits data referral by potential registrant for registered substances to existing information - where parties fail to agree on sharing information (Article 27(6))
- Designates *which* SIEF member will carry out testing for new studies not available in SIEF (Article 30(2)) where members can't agree
- Permits other registrants to refer to vertebrate testing study where study owner in SIEF will not provide it and blocking of uncooperative Data Owner's registration (Article 30(3))

# BoA: DATA SHARING & GENERATION

	PROSPECTIVE REGISTRANT		DATA OWNER	Compensation Terms
Data	Inquire before testing whether a relevant study is available	Request Access from Data Owner (if data is protected)	Provide Access	
<b>Existing Study Involving Vertebrate Animal Tests</b>	Must Art 30(1) para. 1	Must Art 30(1) para. 1	Must ECHA will give access if Data Owner refuses to provide (i) proof of costs or (ii) the study, and block Data Owner's Registration. Art. 30(3)	Calculated 'in a fair, transparent and non-discriminatory way'  If agreement cannot be reached on the amount of compensation 'the cost shall be shared equally'  Art 30(1) para. 1
<b>Existing Study does <u>not</u> involve testing on vertebrate animals (wider than just animal i.e. non-animal as well)</b>	Must Art 30(1) para. 1	May Art 30(1) para. 1	May ECHA has no power to oblige access but if a study is requested by a SIEF member, and a data owner refuses to share, the other SIEF participants can proceed as if the study did not exist. Art. 30(4)	
<b>Any new study involving tests which is required for Registration and is not available</b>	One SIEF participant conducts one new study (for the purpose of fulfilling a Registration information requirement) on behalf of all other SIEF participants. The SIEF participants need to agree on (or ECHA will impose on them) which party should secure the new testing.  Art 30(2) (see Art 29(3) also)			Costs for 'the elaboration of the study with a share corresponding to the number of participating registrants'. (This does not necessarily mean that equal shares will be borne by each of the SIEF members.)  Art 30(2)

# BoA APPEAL FEES

Fees depend on *what* you challenge:

Article(s)	Standards fee	SME fee
9 or 20	2,200	1,800
27 or 30	4,400	3,600
51	6,600	5,400

Becomes **more expensive** the close you get to challenging an Evaluation.

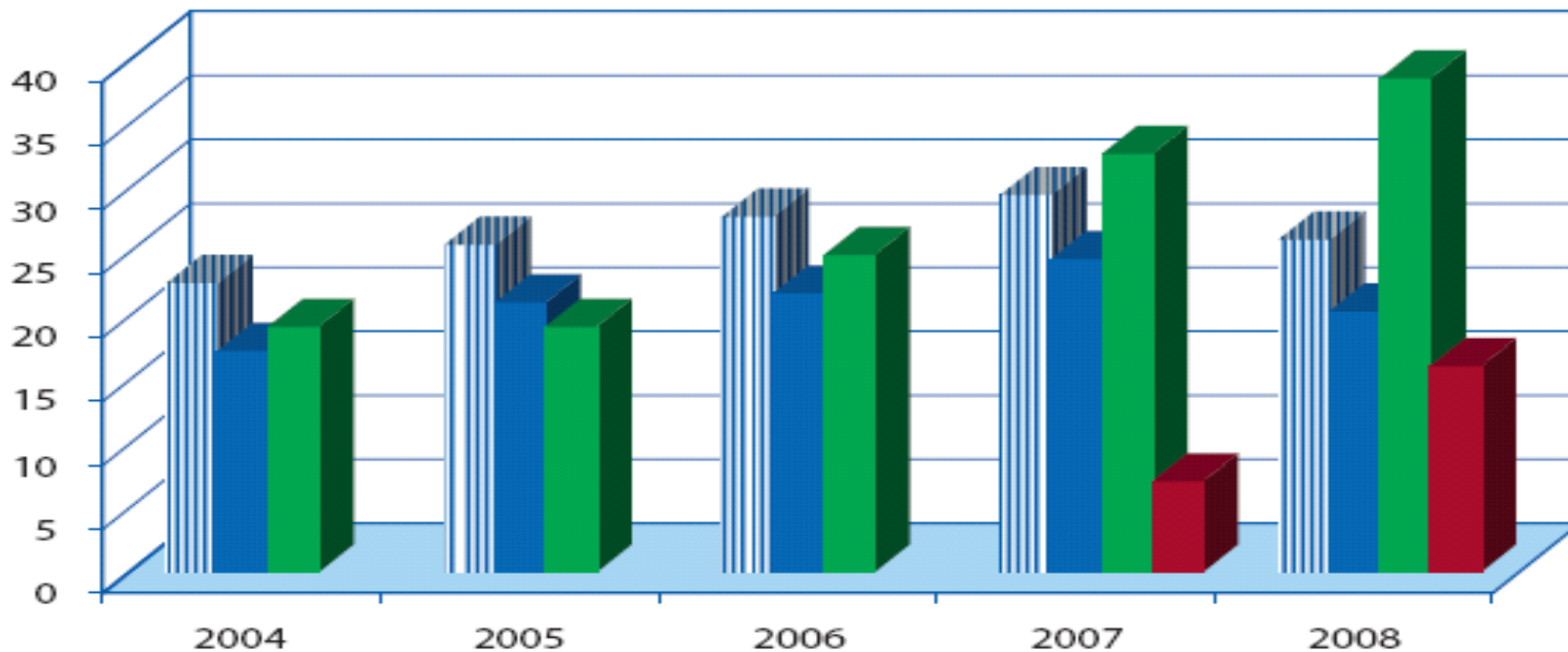
For evidential costs each party bears its own generally but BoA can make an exceptional costs award against ECHA ‘*where the evidence taken proved necessary and decisive for the outcome of the proceedings and such a decision is in the interest of the proper administration of justice*’.

# BoA PROCEDURE

- An appeal has a “**suspensive effect**” (Art. 91(2)): Possible unwanted ramifications e.g. delay to potential registrants who want data from reluctant data owner. (Contrast with situation for legal challenges before General Court (CFI in the past) where suspensive effect is very difficult to achieve.)
- **Admissibility** is assessed within 30 days. (Contrast with position before ECJ.)
- If admissible and well founded, **ECHA may rectify its decision within 30 days** of appeal filed (as in *Specialty Chemicals Coordination Center*).
- If admissible (and no rectification) there is a **right to an oral hearing**.
- Board of Appeal can **exercise any power** which lies within the competence of **ECHA or remit the case** to the ECHA for further action.

# COMPARE WITH CFI

**Completed cases — Duration of proceedings in months (2004–08)**  
*(judgments and orders)*



	2004	2005	2006	2007	2008
Other actions	22.6	25.6	27.8	29.5	26.0
Intellectual property	17.3	21.1	21.8	24.5	20.4
Staff cases	19.2	19.2	24.8	32.7	38.6
Appeals				7.1	16.1

**APPEAL TO THE GENERAL COURT**

# GENERAL COURT

General Court can be used to challenge BoA decisions: Art. 94.

- Article 263 TFEU - annulment action (formerly 230 EC Treaty)
- Article 265 TFEU - failure to act action (formerly 232 EC Treaty)

Also where no express right of appeal to the BoA for ECHA activities!

Issues to consider for challenges:

- is it a decision susceptible to challenge?
- does it have legal effects [IBM case]?
- standing - are you an addressee of decision or ‘directly or individually concerned’?

# 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.

Because of the different *standing* tests before the BoA (old 230 language) and under the new 263 language for direct challenges – might some companies have a chance to challenge issues which they are not able to litigate before the BoA?

# ACCESS TO DOCUMENTS

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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
- 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

# RECOMMENDATIONS

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- Be alive to **short deadlines** for bringing actions.
- Do not hesitate to find out if you have a good case.
- However, possible **rapid remedies** too, which must be seized upon.
- 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 ECJ (damages etc.). Ensure you are making the best legal and technical arguments available.

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# QUESTIONS ?

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STEPTOE & JOHNSON LLP

REACH SERVICES

#### What is REACH?

The Regulation (EC) 1907/2006 on Registration, Evaluation and Authorisation of Chemicals (REACH) establishes a new EU chemicals regime. The central policy objective is to transfer responsibility for the generation of data on the safety of chemical substances from governmental authorities to industry. It is expected to affect some 30,000 existing chemical substances, most of which will need to be Pre-Registered by 1 December 2008. Time limits apply and must be respected in order to maintain market access. Substances of Very High Concern may need to be Authorised. Other Restrictions may also apply. REACH also forces a new approach to the sharing of data and to supply chain relationships.