



# **The Appeals Process under REACH/BPR and the Work of the ECHA Board of Appeal (BoA)**

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## Andrew Fasey

- Technically Qualified Member of the Board of Appeal
- Summary CV (and other members):  
<http://echa.europa.eu/about-us/who-we-are/board-of-appeal/the-board-of-appeal/the-list-of-the-members-of-the-board-of-appeal-and-the-alternate-additional-members>
- N.B. A non-lawyers presentation regarding a 'quasi-judicial' system

# Presentation

- The Appeals Process
- Story So Far
- Story To Come?
- Personal Reflections & Conclusions

## Key Messages

- The system for appeals, the BoA, Registration, Evaluation etc are all part of the system for REACH/BPR
- BoA is independent and impartial
- Appeals are good for the system
  - Clarify grey areas
  - Opportunity to correct mistakes
- BoA decisions may impact how REACH & BPR are implemented; BoA decisions are therefore potentially important to their operation

# The Appeals Process



# Scope – BoA Competence (REACH)



- **Pre-registration**      ➔ Closed; **no decisions**
- **Data sharing**      ➔ ECHA arbitration; **BoA authority**
- **Registration**      ➔ Rejections; **BoA authority**

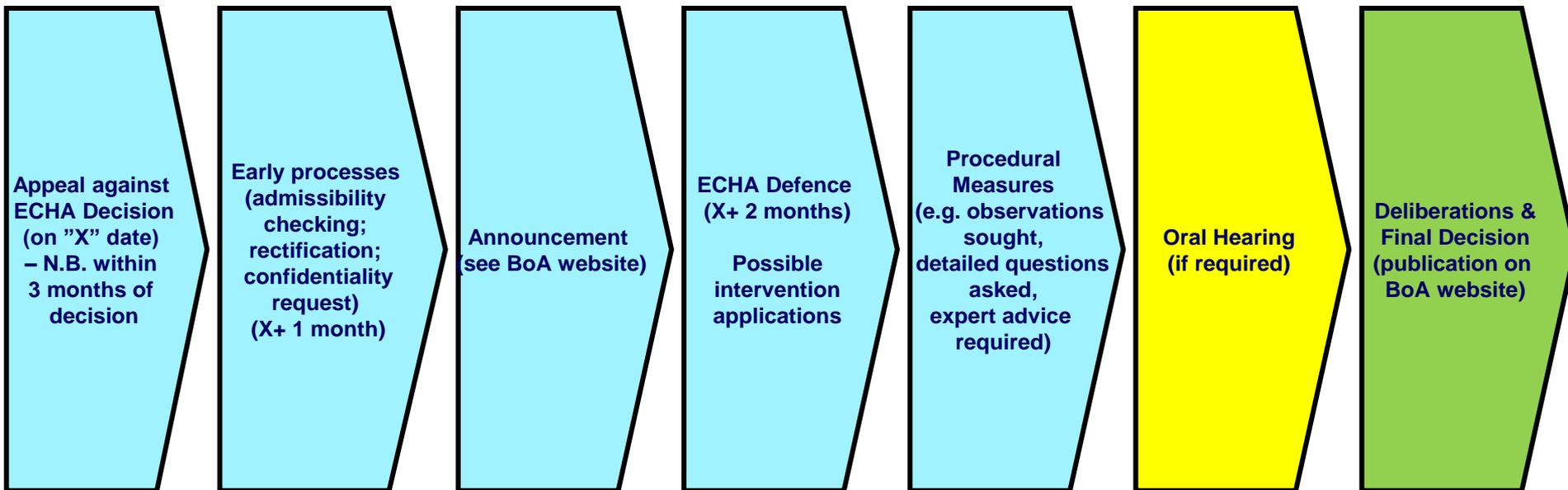


- **Evaluation**  
• **Dossier evaluation**
    - Testing proposals
    - Compliance checks
  - **Substance evaluation**
- BoA authority**  
Only decisions based on unanimity between all MS may be subject to appeal



- **Authorisation**
  - **Restriction**
  - **Classification & labelling**
- Outside BoA authority**

## The Appeals Process in a 'Nutshell'\*



\*over 40 separate steps identified (applies to REACH & BPR)

[http://echa.europa.eu/documents/10162/17207/procedure\\_appeal\\_proceedings\\_before\\_the\\_boa\\_v01\\_new\\_coverpage\\_en.pdf](http://echa.europa.eu/documents/10162/17207/procedure_appeal_proceedings_before_the_boa_v01_new_coverpage_en.pdf)

## Possible Outcomes

- ✓ Rejecting the appeal ('Appeal Dismissed')
- ✓ Supporting the appeal partly or totally ('Appeal Upheld'):
  - Annul (part of) the ECHA decision and
    - Remit the case back to the competent body of ECHA
    - or
    - Replace the ECHA decision
- ✓ N.B. BoA may exercise any power which lies within the competence of the Agency
- **ALWAYS:** Suspension of the contested decision's effects while the appeal is pending
- BoA decisions are ECHA decisions; **can be challenged by Appellant** at EU General Court

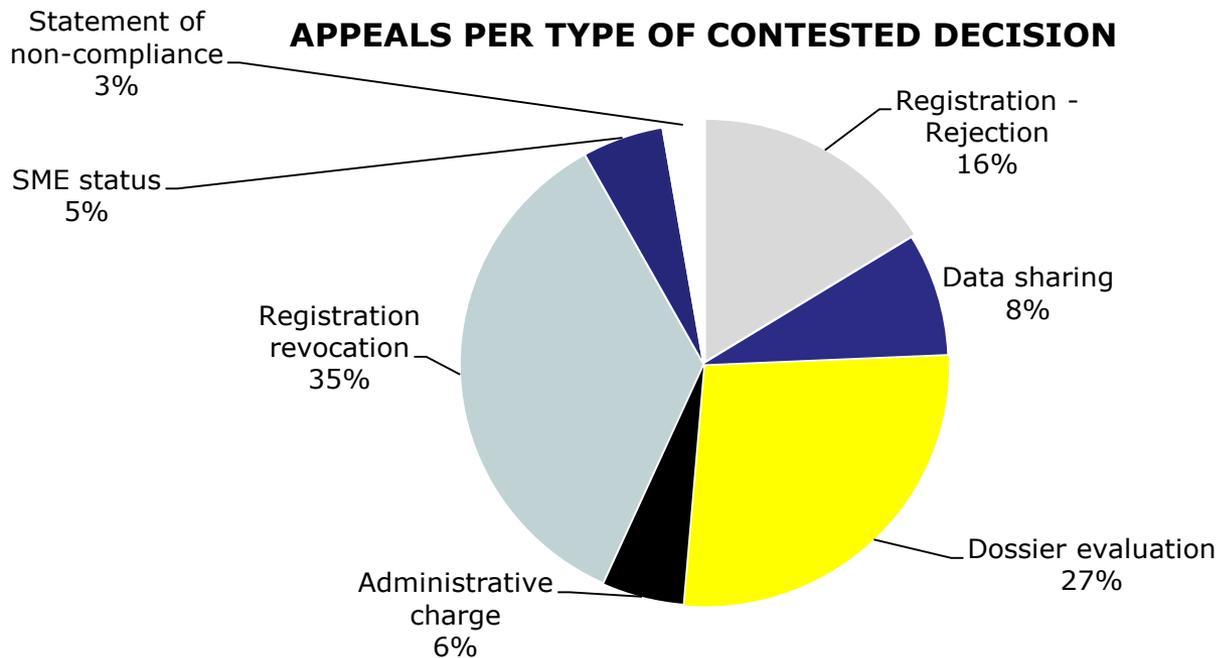
# The Story So Far



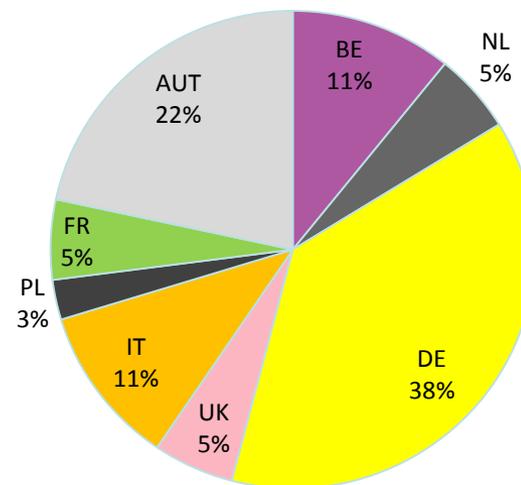
## Statistics (09/12/2013)

- 37 appeals lodged:
  - 4 decided in favour of Appellant
  - 4 decided in favour of Agency
  - 5 rectified by Executive Director
  - 3 withdrawn
  - 21 on-going
- Types of Appeals:
  - 6 registration rejections and 13 revocations
  - 3 data sharing
  - 11 compliance check
  - 4 administrative charge/SME

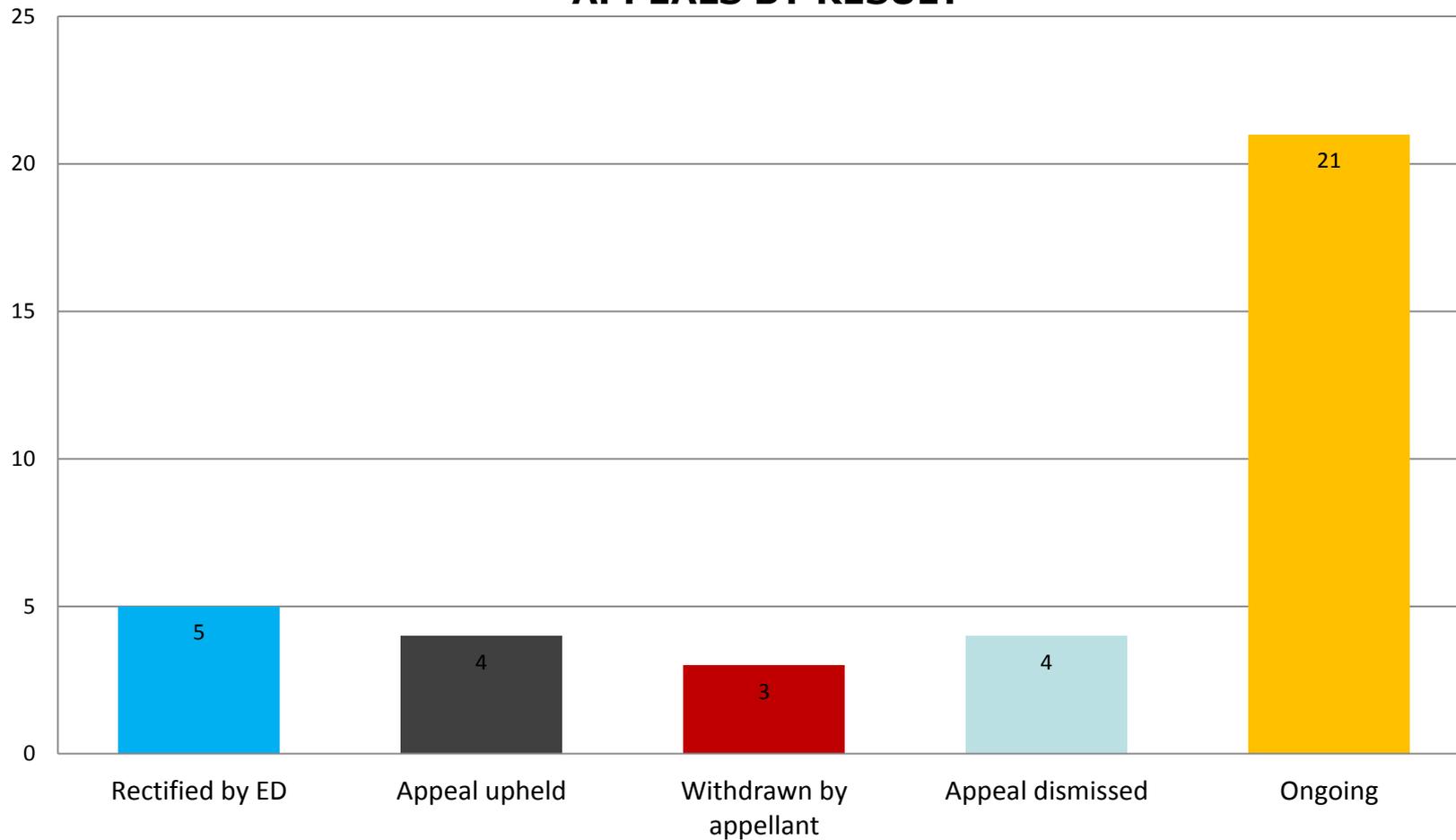
### APPEALS PER TYPE OF CONTESTED DECISION



### APPEALS PER COUNTRY



## APPEALS BY RESULT



## What Does This Tell Us?

- Do not read too much into this
- 50/50 chance?
  - No
  - And even if it did?
- Every decision taken on its merits
- The Appeals system appears to work:
  - Clarification of some issues
  - Some companies get what they want
  - Some ECHA decisions and approaches are confirmed
- Someone will always be unhappy, 'nature of the beast'
- BoA is independent and impartial?

## Decisions to Date

- Winners and losers?
  - Yes, but...
- Every decision tells us (all stakeholders) something about
  - interpretation of REACH and
  - its implementation
- Stakeholders will of course focus on those elements favourable to their interests
- Please consider our decisions carefully and in full

## BoA: Success & Failure?

- BoA cannot be judged on its popularity
- Someone will always be unhappy
- The test is the quality, soundness and robustness of our decisions
- Feedback is positive so far but limited
- We welcome fair and analytical feedback on our decisions
- We can learn
- We can get better

## Time Taken to Process Appeals

- Frequent requests for oral hearings
- Procedural complexity arising from e.g:
  - confidentiality requests
  - applications to intervene
  - change of language requests
  - translations
  - applications to extend deadlines, etc.
- Scientific and legal complexity of evaluation (and other) decisions
- Balance the rights of the parties with need for speed
- Personnel factors; a BoA of 3 is vulnerable to any unavailability

## Time Taken to Process Appeals

- Too long?
- How to best balance the need for expediency against the rights of the parties?
- Too cautious so far?
- Role of oral hearings?
- Importance of Notice of Appeal
  - See Practice Directions
  - BoA has no access to REACH-IT
  - Feedback on Practice Directions welcome
- Accuracy and completeness; sometimes taken a while to get the full and complete picture

## Effect of BoA Decisions

- Not BoA's job to audit changes
- Previous BoA decisions will inform future ones
- Changes appear to have been made as a result of appeals and BoA decisions, for example:
  - Invoicing
  - Evaluation decisions
  - Anecdotal evidence
- You may be able to judge better than us
- Changes seen?

# The Story To Come?



## Story to Come?

- Substance Evaluation
  - Complex?
  - Political?
  - New process and procedure
- Biocides
  - Something of an unknown
  - Data sharing?
  - SME decisions?
  - We are prepared as far as we can be
- Dossier Evaluation
  - Intermediates
  - RAAF
- Rejection of registration numbers?

## Story to Come?

- ECHA decisions?
- Quicker decisions?
- Balance of quality and certainty against speed and cost?
- Future of the BoA?

# Personal Reflections & Conclusions



## Breaking New Ground

- Procedural, legal, scientific and technical issues are often being considered for the first time
- Many of the BoA's tasks have no analogues elsewhere from which to draw experience
- As issues are addressed and resolved in turn the BoA should get more efficient.
- Every case, so far, brings with it something new or different

## Challenges Ahead

- 1) Balancing legal versus technical considerations in light of the objectives of REACH
- 2) Explore ways of working effectively in ECHA without compromising impartiality and independence
- 3) Managing new appeals derived from the BPR with the similar resources as available for REACH appeals
- 4) Substance evaluation
- 5) Planning with an unpredictable workload
- 6) Maintaining high level of knowledge on legal and scientific developments
- 7) Procedural efficiency
- 8) Better understanding by stakeholders of the appeals process

## Points to Note

- Case-by-case; every case is different
- Every appeal so far seems to have been 'legitimate'
- Could some appeals have been avoided through better communication?
- Continue to explore methods to facilitate dispute settlement leading to withdrawal of appeals
- Decisions can be complicated
- Read the full decision to understand why the BoA has acted as it has
- BoA decisions based on the information made available to it during the case proceedings
- All final decisions published

## Conclusions

- Appeals process gives potential for effective access to legal redress to support the implementation of a complex piece of legislation with some grey areas...
- The appeals process is part of the system for REACH/BPR
- A vital role in the effective functioning of REACH/BPR
- BPR and SEv to come
- Relatively early days still for BoA, ECHA & stakeholders
- Safety net for both ECHA and stakeholders
- Cases tend to be complicated; legally and/or scientifically
- Numbers of appeals are outside BoA control
- **We will be impartial and independent**

# Thanks for Listening

See

<http://echa.europa.eu/web/guest/about-us/who-we-are/board-of-appeal>

Contact information:

<http://echa.europa.eu/web/guest/about-us/who-we-are/board-of-appeal/contact>

## Oral Procedure

- Held if requested by one of the parties or considered necessary by BoA
  - Must be requested within 2 weeks of being informed of closure of written procedure
- Public unless BoA decides otherwise for serious reasons
- Times and dates published on website
- Videoconference possible depending on the technical compatibility
- Last 2 hearings in November and December

## Oral Proceedings (cont.)

- Offers parties the opportunity to express their arguments directly before the BoA while allowing BoA to ask questions of the parties and interveners
- 7 have been held - 6 in Helsinki & 1 by teleconference
- Pros: effectively communicate on relevant issues, ensures the views of the parties are expressed and understood, chance for in-depth Q&A
- Cons: considerably lengthens the proceedings, cost

# Confidentiality Claims

- Most procedural decisions are taken by BoA
- Decisions on confidentiality made by the Chairman
- Examples of requests:
  - Appellant's identity (so far not granted);
  - Substance name (granted and not granted);
  - Business information related to research (granted);
  - Tonnage (granted);
  - The uses of the substance (granted and not granted);
  - Studies (not granted);
  - Blanket requests (mainly rejected)
  - Personal data are always protected and are not made public
- Considered case-by-case (i.e. the above is not an indication of what will be decided in a specific case)
- Some confidentiality decisions published

## Applications to Intervene

- Case by case basis consideration
- Animal welfare NGOs: applications both accepted and rejected
- Co-registrant accepted as intervener in two cases
- Basis for rejection: applicant had not demonstrated an interest in the result of the specific case (x2), while in another the applicant was not a proven legal entity
- Pros: useful and constructive contributions to the case from a different perspective, transparency
- Cons: extra workload for all involved in the process
- Some decisions on applications to intervene published

# Decisions - Examples

## **A-003-2012**

- Subject: ECHA decision requesting 3 tests and a robust study summary for a test that had already been conducted.
- Decision: ECHA had not clearly and precisely communicated information, in due time, to the Appellant on the deadline for updates to the registration dossier to be considered in ECHA's decision-making process.
- Result: The ECHA decision was annulled and the case was remitted to ECHA for re-evaluation of the registration dossier as updated by the Registrant.

## **A-001-2012**

- Subject: ECHA decision rejecting the read-across approach proposed to satisfy certain information requirements.
- Decision: ECHA had acted within its margin of discretion.
- Result: BoA dismissed the appeal. Due to the suspensive effect of appeals, and considering the circumstances of the case, the BoA decided to set a new time limit for the submission of the requested information.

## **A-005-2011**

- Subject: ECHA decision requiring a Registrant to conduct a 90-day repeated dose toxicity study in the rabbit by inhalation.
- Decision: The Agency had breached the REACH requirements for testing on animals to be a last resort and for the least number of animals to be used if testing on vertebrate animals is required. The decision was also disproportionate as the appropriateness of, and necessity for, the requested study had not been demonstrated nor was the requested study shown to be the least onerous option to achieve the objectives of the Contested Decision.
- Result: The ECHA decision was annulled and the case was remitted to ECHA for re-examination.

## **A-004-2011**

- Subject: ECHA decision rejecting a registration due to late payment of the registration fee.
- Decision: ECHA confirmed that the Agency had acted correctly in rejecting the registration. In reaching its decision, the Board of Appeal found that there was nothing in the specific facts of the case to suggest that ECHA should not have applied the provisions in REACH.
- Result: BoA dismissed the appeal as ECHA had no alternative but to reject the registration dossier in question.

## **A-001-2010** (similar but...)

- Subject: ECHA decision rejecting a registration due to late payment of the registration fee.
- Decision: The Board of Appeal found there were shortcomings in ECHA's handling of the case. ECHA had not fulfilled all the requirements of good administration, particularly in regard to the requirement for clarity of the information it provided to the Appellant.
- Result: The Board of Appeal found in favour of the Appellant and ordered ECHA to refund both the registration fee and the appeal fee.