

A close-up photograph of a microscope's objective lenses and eyepiece, rendered in a blue-tinted, semi-transparent style. The text is overlaid on the upper left portion of this image.

STEPTOE & JOHNSON LLP

When Experience Matters®

Appeal of Agency Decisions

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OVERVIEW

The Agency will exercise considerable **decision making power affecting your rights and obligations.**

The REACH Regulation provides an **express Appeal mechanism:**

- Board of Review (3 person multi-disciplinary panel)
- Appeal to the Court of First Instance

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

EXPRESS RIGHT OF APPEAL

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Appeal can be brought **against an Agency decision** 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))

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

EXPRESS RIGHT OF APPEAL

Article 91(1) lists reviewable Agency decisions.

For those listed you must challenge via the Board of Review (cannot jump to the ECJ):

- to impose conditions on PPORD substances re limiting handling and control conditions (Article 9(4))
- to reject an incomplete registration where missing information not supplied by registrant within deadlines (Article 20(2), (5))
- to permit potential registrant (non-pre-registered phase-in substances or non-phase-in substances) to refer to existing information where data owner does not agree to share information (Article 27(6), (7))

EXPRESS RIGHT OF APPEAL

Article 91(1) reviewable Agency decisions:

- which SIEF member will carry out testing for new studies not available in SIEF (Article 30(2)) where members can't agree
- to permit other registrants to report on vertebrate testing study where study owner SIEF will not provide it or to refer to info in the registration dossier where already a registration with information needed (Article 30(3) and (4))
- to amend a draft decision on examination of testing proposals, compliance of registration dossier, or request further information and examination of that information. (Article 51, 40 and 41)

EXPRESS RIGHT OF APPEAL

- 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 ECJ where suspensive effect is very difficult to achieve.)
- **Admissibility** is assessed within 30 days. (Contrast with position before ECJ.)
- If admissible and well founded, **Agency may rectify its decision within 30 days** of appeal filed.
- 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 the Agency or remit the case** to the Agency for further action”.

GENERAL RIGHT TO APPEAL

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ECJ can be used not only to appeal Board of Review decisions.

Also where no express right of appeal to the Board for Agency activities:

- Article 230 EC Treaty - annulment action
- Article 232 EC Treaty - failure to act action

Art. 94 circumvents the problem of challenging an Agency (contrast with EFSA cases).

GENERAL RIGHT TO APPEAL

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'?

ACCESS TO DOCUMENTS

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Right to **ECJ** challenge to Agency 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

PRACTICAL STEPS

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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.
- 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.).
