How to dispute decisions under Regulation 1107/2009

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Summary

When is a decision challengeable?

- What is a “decision” under 1107/2009?
- Criteria / conditions and type of decisions

How to dispute a “decision”?

- EU level
- Zonal level
- National level

Where to dispute a decision

- Arbitration / Court / Other?

When is a "decision" challengeable?

Conditions

- Binding act producing "legal effects" (not preliminary opinion, position…)
- "Decision" must bring about a distinct change in appellant's legal position
  - Example: decision rejecting an application after completeness check; decision rejecting confidentiality application; non-approval / non-authorisation decisions …
  - NB: the form of the act is immaterial, what counts is the substance (letters can be a "decision")
- Addressed to the appellant or be of "direct concern" to him
- Violation of relevant law (TFEU, Reg. 1107/2009, AIR etc.) and/or
- Manifest error of assessment and/or
- Violation of fundamental principles of law (e.g., duty to state reasons; right of defence; principle of proportionality etc.)

How to dispute a decision

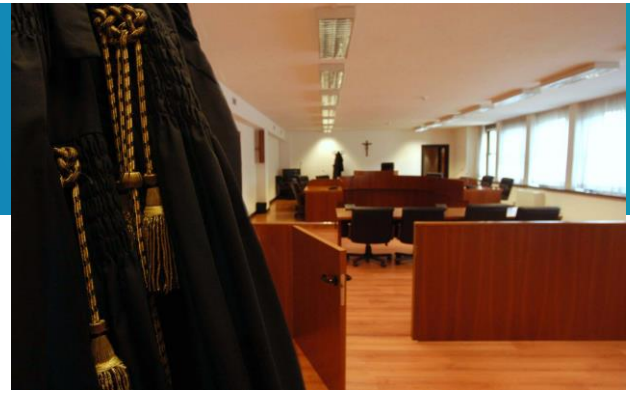
- Assess the level where decision is taken, and by whom
- Three main levels for disputes:
- EU level : decisions taken by European Commission or EFSA
- Mid-level: decisions taken by MS in their capacity as RMS or zonal RMS
- MS level: decisions taken by MS in their capacity as national authority
- Fourth level:
- Commercial level: disputes between companies on data sharing, LoA, Task Force agreements etc.
- Some commercial disputes may involve authorities
  - Example: access to documents held by competent authority, data sharing disputes, failure to cancel registration, etc.
  - Example: assessment of technical equivalence

Where to dispute a decision

EU level decisions

- Institutions (Commission) and Agencies (EFSA)
- Challengeable before EU General Court in Luxembourg
- Two months from notification to the addressee
- If publication, deadline starts 14 days thereafter
- Plus ten days to take account of distance from EU Court in Luxembourg
- NB: be cautious in calculation of deadlines (dies a quem / dies a quo)
- NB: Court application has no automatic suspensory effects
- → a request for interim relief needed (urgency to prevent irreparable harm)

Where to dispute decisions



MS level decisions

- MS decisions are typically taken at product authorisation level
  - Example: registration refusals; conditions of use / label restrictions/use extensions, etc.
- Some 'hybrid' decisions may be challenged at national level
  - Example: zRMS draft registration report
- BUT, not all MS decisions are necessarily a "MS decision"
  - Example: RMS draft assessment report is not national decisions (nor a "final" decision)
- Court challenges
  - Traditional way to challenge MS decisions
  - Lodged before national Admin Courts (tribunal adminsitratif, TAR Lazio, Conseil d'Etat, etc.)
  - Usually do not suspend decision automatically – request interim relief needed (urgency to prevent irreparable harm)
- Administrative review possible in some jurisdiction depending on the decision
  - Example: request for internal review (UK CRD), recours gracieux (ANSES) etc.
  - NB: may suspend deadlines for Court actions / not always the case

Where to dispute a decision

Alternative out-of-Court options

- Request for internal review (e.g. publication of EFSA Conclusions)
- Letter to EC asking intervention to ensure correct application of EU law
  - Example: cases where RMS is not respecting legal principles, deadlines etc.
  - Example: grey area of law and need to have a legal position clarified (AIR deadline, lack of response from zRMS, lack of criteria for assessment etc.)
  - Example: request for access to docs held by an Institution (general duty to disclose environmental information vs confidentiality/trade secrets)
- Ombudsman in case of EC maladministration (excessive delay in dealing with administrative matters)
- NB: above not always fully "alternative" to Court / Admin challenges
- NB: Do not suspend Court deadlines

Where to dispute decisions

- Commercial disputes between companies regarding data generation / sharing
- General duty to avoid repetition of studies (in general)
  - EU level: renewals under AIR a joint submission is preferable
  - MS level: product authorisation → data sharing options
- Vertebrate animal studies cannot be duplicated
  - Separate renewal submissions under AIR but no separate vertebrate studies
  - Mandatory data sharing unless studies were available previously to the applicants for other reasons (to be documented)
- Data sharing
  - Studies are protected / Necessary for evaluation
  - GLP/GEP / Not protected previously (also on another substance)
- Disputes
  - No EU-level arbitration / Court
  - Disputes arise at MS level → no uniform rules!

Conclusion - What to do ...

Identify “decisions” producing legal effects which may be challenged

Assess if, when, where and by whom they can be challenged

Consider all options and try to avoid litigation, if possible

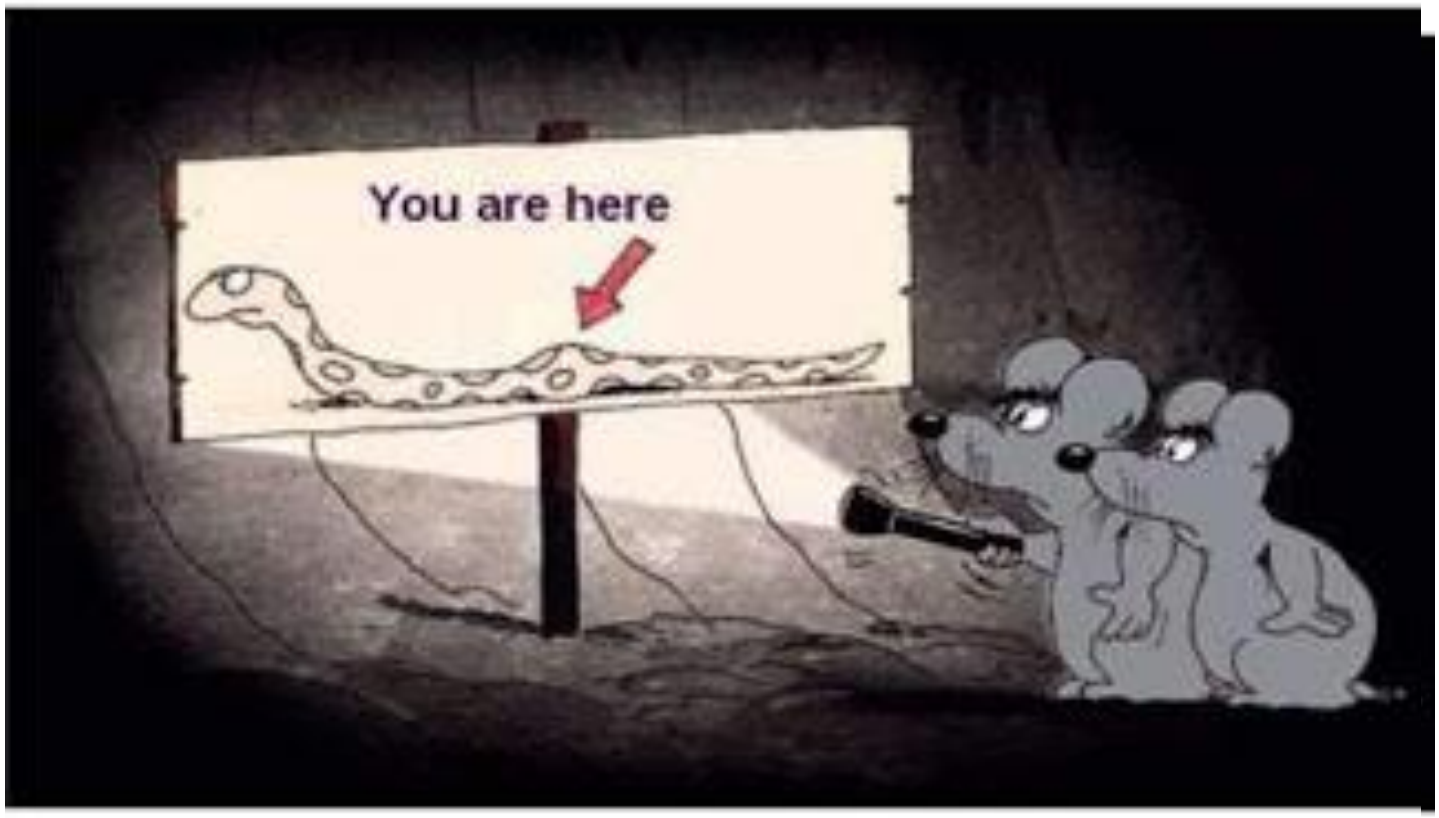
But do not discard litigation, if needed …

Sometimes it can help setting the scene and timeframe for settlement

Seek advice and try to discuss alternative options with EU/MS regulatory authorities

BUT be mindful of deadlines to bring legal actions!

Make sure you know where you are in the process



Q&A

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