Transparency and Information Access

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View expressed by Regulated industries
Overview

Regulated industry groups have always been:

- Open and positive to appropriate levels of transparency
  - if it genuinely serves the public interest without undermining legitimate private interests
  - However, transparency is not only related to “access to data”, but also to the assessment process

BUT!:

- Recent examples have brought to the fore legitimate concerns about how transparency initiatives are implemented, and what impact they may have.
- Current implementation does not always acknowledge legitimate rights and disregards other processes
Key issues in transparency

• How to achieve a balance between transparency and other legitimate interests
  ➢ Preserving EU industry competitiveness, by protecting Confidential Business Information and intellectual property rights
  ➢ Ensuring a positive investment climate in EU
  ➢ Integrity and effectiveness of decision making process
Areas requiring discussion

• Goals to be achieved through providing greater transparency
• Understanding “overriding public interest”
• Legal and treaty issues
• Manner and format information is made available
• Negative impacts of undue data disclosure, including misuse or unfair commercial use of information made public.
Principles that should underlie transparency in assessment

- Consistency within panels
  - Same level of scientific scrutiny should be applied for all applications
  - Training of (new) experts and implementation of dedicated procedures to ensure consistency across opinions and working groups

- Consistency among panels
  - Cooperation among panels to ensure consistency (e.g. same product to be evaluated by different panels, e.g. feed vs food)

- Consistency needs transparency and training

- Consistency of EFSA opinions needs a (peer?)-review
  - Scientific outputs should follow dedicated quality procedures (SOPs) and (peer-)reviews
Principles that should underlie ‘access to data’

- Procedure should allow for a fair weighting of interests exercise (as required by law)
- Predictability & legal certainty for applicants should be a basic principle
- Public access to study reports should be on request only
- Applicants should be given opportunity to review data to be made public
- Applicants should be informed who has requested data, and when it will be released
- Need for consistency of general principles and procedural rules between EU agencies
- Access should be non-discriminatory – equal treatment for all – applicants and requesters
- Ensure actions are in line with EU & international legal obligations
- EFSA should take reasonable precautions to ensure that released data is not misused by others
Industry viewpoint

• Common concerns but different legislative challenges

• Looking at:
  - Relevant legislation for each sector
  - Key concerns of the sector
Crop protection

• Relevant legislation
  - Regulation 1107/2009, Article 60 (information normally deemed to be confidential)

• Key issues for the sector
  - Protection of valuable business information
  - Data access should not provide commercial advantage for competitors
  - Reading room would allow public access & protect business information
Biotechnology

• Relevant legislation
  • Directive 2001/18/EC, Art 25
  • Regulation 1829/2003 Article 30

• Key issues for the sector
  - Protection of valuable business information - access should not provide commercial advantage for competitors
  - When data is released pre-approval, misuse of the data as a means of slowing/stopping approval
  - Misuse and copying by others in geographic areas where there is no stewardship or IP protection
  - In the EU, where there is no commercial market due to political blockage, why take the risk of submitting data if it is made freely available to copycats?
Food additives

• Relevant legislation
  ➢ Regulation 1331/2008

• Key issues for the sector
  ➢ access to the full documentation may disclose extremely valuable know-how developed by the applicant (e.g. food application know-how, design of specific studies)
  ➢ the need for close dialogue between notifier & EFSA to ensure effective & efficient risk assessment
Feed additives

• Relevant legislation
  • Regulations 1831/2003 and 429/2008

• Key issues for the sector
  ❯ Transparency of the process is key
  ❯ Accessibility of the assessment process to all stakeholders (inc. consumer groups & scientific experts beyond EFSA)
  ❯ Scientific discussion cannot be replaced by guidance documents
  ❯ Lack of scientifically sound justification to applicants in case their argumentation or data are not accepted
Health Claims on Foods & Supplements

- **Relevant legislation**
  - Regulation (EC) No 1924/2006

- **Key issues for the sector**
  - 5-year exclusive claim use for applications based on proprietary data – but not granted after publication
  - Dis-incentivises publication, decreasing transparency
  - Discourages funding of academic studies: academics are measured on their publication record - creates artificial conflict of interest
Recommendations for EFSA

- More communications efforts to increase stakeholder understanding of risk assessment processes
  - Communicate and explain role of transparency and mechanisms that already exist for data access

- EFSA should clarify:
  - Which data, at what stage in the product review process
  - the criteria (to whom, for what reason)
  - the conditions for release (how the data can & cannot be used)
  - Notification warning of data to be released
  - in what format, using what tools (CDs, reading room, internet, etc.)

- Structured dialogue between EFSA and regulated industries to ensure transparency of the process
Conclusions

- Regulated industries have different challenges but a common view:

  - We support appropriate levels of transparency
  - Transparency means dialogue and access to data
  - We oppose data access for commercial gain
  - We oppose data access pre-approval of a product

- There are existing alternatives (esp. reading room concept)