Transparency and Information Access

View expressed by Regulated industries

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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 (SOP s) 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 artifical 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)