

Regulatory Fitness and Performance Programme (REFIT) and the General Food Law Regulation

PARI-EFSA COALITION OF INDUSTRY ASSOCIATIONS

INDUSTRY ROUNDTABLE, 13 JUNE 2018

EC proposal on the transparency and sustainability of the EU risk assessment

- We support the establishment of EFSA with clear separation of risk assessment vs risk management
- We acknowledge the need to improve the transparency, sustainability, and efficiency of the risk assessment process to increase trust in the EU risk assessment
- We regret that **no impact assessment has been initiated**
- Transparency of the risk management process is equally important for public trust

Need for balanced transparency

- Respect for predictability, legal certainty, proportionality and coherence
- Innovation and competitiveness cannot be compromised
- Transparency applicable to all parties and processes

Data disclosure “without delay”

- Early disclosure of business strategic and commercial information
 - Need to distinguish data
 - Supporting an authorization request (e.g. efficacy-related feed additives)
 - Not supporting authorization request (e.g. contaminants)
 - Risk of misinterpretation
 - Limited data protection from competitors
 - Threatened integrity of the risk assessment
- *Not consistent with Regulation 1049/2001 on public access to EU institution documents*

Modalities of data disclosure

- Only relevant data to be disclosed in a controlled way not earlier than before the publication of the EFSA opinion
- Prevent unfair exploitation of data in and outside the EU
- Need for a better protection against misuse of data

Confidentiality of data

- Extension of EFSA remit beyond risk assessment
- No possibility to appeal against EFSA decision
- No responsibility for guaranteeing exploitation of data made public by EFSA by third parties

General Advice

- Supportive of pre-submission advice to applicants from all industry branches
- Ensure robustness, adequacy and proportionality of data package
- The scientific aspects of the application should be also covered
- Outcome should not be published before the publication of the EFSA opinion

EFSA Governance

- Supportive of MS involvement in the Management Board & the longer term for members of the Scientific Panels
- Training in risk assessment for Scientific Panels to be considered
- Need to provide EFSA with sufficient resources for additional tasks

Appointments of EFSA Panel Members

Nomination by Member States should not lead to:

- Political appointments
- Lower quality of experts (not all MS may be able to nominate 12 high quality experts)
- Lower quality of EFSA's scientific output
- Possibly jeopardising strict separation of risk assessment and risk management

Risk Communication

- We welcome the general plan and objectives for risk communication
- Improved risk communication, providing the necessary context is essential

Communication should:

- Prioritize quality and comprehensibility to the broader public
- Highlight the integrity and quality of the risk assessment process
- Combat the spread of misinformation
- Strengthen collaboration between Member States and the Commission to avoid different or contradicting messages

Conclusions

- Effective and balanced transparency shall not compromise:
 - *Innovation and competitiveness in the EU*
 - *Protection of legitimate business interests*

- Timing and modalities of disclosure shall:
 - *Not interfere with risk assessment*
 - *Protect CBI and business strategic and commercial information until the publication of the EFSA opinion*

- The impact of the proposed mechanism should be duly assessed by the EC ([Better Regulation Guidelines](#))

Conclusions

- Both data pertaining to an authorisation or not should be duly considered
- Comprehensive and comprehensible communication, both in risk assessment and risk management, facilitates transparency and builds trust