



Improving the transparency and sustainability of the EU risk assessment in the food chain

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'Transparency' Regulation

- Formal endorsement: EP (April) and Council (June)
- Publication: **6 September 2019**
- Entry into force: 20 days following publication
- Entry into application: 18 months following entry into force (**end of March 2021**):
 - ***Exception: New EFSA MB and appointment of experts in panels: as of 1 July 2022***
- ***Transitional measures: The new rules will not apply to requests for scientific output submitted to EFSA before its entry into application***



Four Pillars

Sustainability &
governance of EFSA

Quality & reliability
of studies

Improved risk
communication

Transparency of EU
risk assessment



1st Pillar - Quality and reliability of studies

- ✓ General **pre-submission** advice
- ✓ Notification of **commissioned studies**
- ✓ **Public consultations** of planned studies (only for renewals) and all submitted studies
- ✓ **Fact-finding missions** to laboratories carrying out studies to take place **within 4 years** after entry into application
- ✓ Commissioning of **verification studies** in exceptional circumstances of serious controversies or conflicting results



2nd pillar - Transparency of EU risk assessment

- ✓ **Studies/data** supporting any request for a scientific output, including applications for authorisations, are
 - ✓ to be made public **proactively and automatically**, in an easily accessible format through EFSA's website,
 - ✓ **early on** in the risk assessment process i.e. when an application is found valid or admissible)
 - ✓ **except for duly justified confidential information.**
- ✓ No prejudice to existing **IPRs** and **data exclusivity** rules
- ✓ **Standard data formats** for applications to be developed by means of implementing acts



3rd pillar – Improved risk communication

- ✓ Definition of general objectives and general principles
- ✓ General plan on risk communication to be adopted by means of an implementing act (IA):
 - ✓ Key factors to be taken into account when considering risk communication activities
 - ✓ Types and levels of risk communication activities and the appropriate tools and channels
 - ✓ Appropriate mechanisms of coordination and cooperation amongst risk assessors and risk managers
 - ✓ Appropriate mechanism for open dialogue amongst interested parties



4th pillar - Sustainability and governance of EFSA

- ✓ MS representatives in the Management Board + Commission + EP + civil society and food chain interests
- ✓ An active involvement of MS to stimulate experts in contributing to EFSA's work (promotion of EFSA's call for experts to Scientific Panels and Scientific Committee):
 - ✓ Criteria of excellence and independence to be respected



What is next? (1)

- A **considerable budget increase** is also proposed in the Multi-Financial Framework (MFF) Programme:
 - EUR 62.5 million; and,
 - 106 additional posts
- However, the negotiations on the MFF are still ongoing



What is next? (2)

- **In those 18 months (2019-early 2021), preparatory work must be carried out both by EFSA and by the Commission in close co-operation:**

By EFSA (1):

- Set up practical arrangements/infrastructure for:
 - the general pre-submission advice;
 - notification of commissioned studies;
 - public consultations of planned and submitted studies;
 - the implementation of the transparency rules (e.g. proactive public disclosure of studies); and,
 - the implementation of the confidentiality rules.



What is next? (3)

By EFSA (2):

- Draw up draft standard data formats for further adoption by the Commission (IA)
- Develop new and/or align existing guidance in conformity to the new transparency rules (esp. in sectoral legislation)
- Prepare a smooth transition to the new EFSA governance model (MB) and selection process for experts in Panels



What is next? (4)

- **By COM:**

- Align existing COM guidance/implementing acts in sectoral legislation to the new rules
- To adopt the general plan on risk communication (IA)
- To adopt standard data formats for applications (IA)
- To carry out the fact-finding missions (within 4 years following entry into application) – findings to be presented in an overview report



Thank you for your attention!