



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

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A few introductory words about the 'Transparency rules'...



How has it all begun?



Fitness Check of General Food Law

- The system was found to work well!
 - **No systemic failures identified**
 - **EFSA significantly improved the scientific basis of EU measures**
 - **International recognition of EU safety standards**
- Opportunities for improvement:
 - Civil society perceived a **certain lack of transparency** and independence in the context of regulated products
 - **Need to ensure the long-term sustainability of EFSA** to maintain **high level of scientific expertise**
 - **Risk communication was** not always effective enough



European Citizens' Initiative 'Ban glyphosate' – Autumn 2017

Concerns raised:

- Transparency of the EU risk assessment;
- Quality and independence of scientific studies

Commission's commitment (December 2017) to introduce a legislative proposal



New rules on the “transparency and sustainability of the EU risk assessment in the food chain”



'Transparency' rules: Proposal and provisional agreement

Commission's legislative proposal on the transparency and sustainability of the EU risk assessment in the food chain

- Adopted by the College on 11 April 2018
- Targeted revision of the GFL and - as regards transparency – of eight other related sectorial legislative acts
- **Provisional agreement reached on 11 February 2019 – within 10 months!**
- The new rules expected to be published in the OJ over summer and enter into application in early 2021



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



Quality and reliability of studies (1)

- ✓ General pre-submission advice
- ✓ Notification of commissioned studies
- ✓ Public consultations:
 - ✓ **For renewals only:** public consultation of **planned studies** at pre-submission phase
 - ✓ **For all submitted studies:** Public consultation during the risk assessment



Quality and reliability of studies (2)

- ✓ **Fact-finding missions** to laboratories carrying out studies (at EU and in 3rd countries where relevant agreements) to take place **within 4 years** after entry into application:
 - ✓ Reporting of non-compliance and appropriate follow up
 - ✓ Outcome to be presented in an overview report – possible legislative proposal if appropriate
- ✓ **Commissioning of verification studies** in exceptional circumstances of serious controversies or conflicting results



2nd pillar: Transparency of EU risk assessment



Transparency of EU risk assessment (1)

- ✓ **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



Transparency of EU risk assessment (2)

- ✓ Closed positive lists of information that may be treated as confidential, upon verifiable justification proving significant harm to commercial interests:
 - ✓ GFL and other 7 sectoral acts
 - ✓ Generally, EFSA to make the confidentiality assessment (some exceptions apply)
 - ✓ Procedure outlined
 - ✓ Exceptions for duly justified confidential information
- ✓ Protection of personal data



3rd pillar: Risk communication



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



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



Other elements (1)

- Transitional measures:
 - The new rules will not apply to applications under Union law and requests for scientific output submitted to EFSA before its entry into application (early 2021?).
 - The new MB will take over as of 1 July 2022.
- Review clause:
 - Regular review of the GFL Regulation as such
 - Every 5 years, COM review of EFSA's performance



Other elements (2)

- 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? (1)

- Publication in OJ over summer 2019
- Entry into force 20 days after publication
- Entry into application: 18 months later (early 2021?)



What is next? (2)

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

By EFSA (1):

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



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!