



Improving the transparency and sustainability of the EU risk assessment in the food chain – Regulation (EU) 2019/1381

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European Parliament

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**Regulation (EU) 2019/1381 on the
transparency and the sustainability of the
EU risk assessment in the food chain – “the
‘Transparency Regulation’” –**

A few introductory words...

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



‘Transparency Regulation’ –

Main features

The Transparency Regulation

- Procedural aspects:
 - Negotiated within 10 months with the European Parliament and the Council (April 2018 – February 2019)
 - Adopted in June 2019 and published in the Official Journal in September 2019.
- A targeted revision of 9 acts – but the impact is far greater!

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

Implications for the European Parliament

- **Proactive public disclosure of studies/data** supporting any request for a scientific output, including applications for authorisations

- **Public consultation**

- **Governance of EFSA**

Two members appointed by EP in the new EFSA Management Board as of 1 July 2022

- **General Plan on risk communication**

To be adopted by IA on the basis of consultation with EFSA and Member States. EP involvement will be valuable



What is next – Budget ?

- Considerable budget increase proposed in the MFF proposal:
 - EUR 62.5 million; and,
 - 106 additional posts
- **Budget negotiations still ongoing!**

Key dates

- Publication: 6 September 2019
- Entry into application: **27 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**

Implementation of the new Transparency Regulation

What is next by COM ? (1)

- Align existing **COM guidance/implementing acts** in sectoral legislation to the new rules – this alignment needs to be coordinated with the alignment of EFSA guidances: **By 27 March 2021**
- To ensure IT infrastructure to accommodate new requirements in close cooperation with EFSA/MS (e-submission system for the transparency/confidentiality provisions): By 27 March 2021
- To carry out the fact-finding missions to laboratories for checking compliance with applicable standards when carrying out studies supporting EFSA's risk assessment (2021-2025)– findings to be presented in an overview report

What is next by COM ? (2)

- To adopt the general plan on risk communication (IA) – not subject to a deadline
- To adopt standard data formats for applications (IA) - not subject to a deadline
- Contribute to ensure a smooth transition to the new EFSA governance model (MB) – New EFSA MB will consist of representatives of 27 MS, COM, EP and representatives of civil society and food chain interests – to take office as of 1 July 2022



What is next by EFSA ?

- Develop new and/or align existing guidance in conformity to the new transparency rules (esp. in sectoral legislation) – **By 27 March 2021**
- To ensure IT infrastructure to accommodate new requirements in close cooperation with SANTE/MS – **By 27 March 2021**
- Draw up draft standard data formats for further adoption by the Commission (IA)
- Prepare a smooth transition to the new EFSA governance model (MB) and selection process for experts in Panels - applicable as of 1 July 2022

For more information

- Transparency Regulation:
https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en
- Implementation of Transparency Regulation:
https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en
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Thank you



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