European Commission

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

PLENARY MEETING OF THE ADVISORY GROUP ON THE FOOD CHAIN AND ANIMAL AND PLANT HEALTH
7 MAY 2019

DG SANTE, *Food chain science and stakeholder relations*

Health and Food Safety

European Commission

A few introductory words about the 'Transparency rules'…

Health and Food Safety

European Commission

How has it all begun?

Health and Food Safety

European Commission

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

European Commission

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

Health and Food Safety

European Commission

'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

European Commission

Four Pillars

Sustainability & governance of EFSA

Quality & reliability of studies

Improved risk communication

Transparency of EU risk assessment

Health and Food Safety

European Commission

1st pillar: Quality and reliability of studies

Health and Food Safety

European Commission

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

European Commission

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

European Commission

2nd pillar: Transparency of EU risk assessment

Health and Food Safety

European Commission

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

European Commission

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

European Commission

3rd pillar: Risk communication

Health and Food Safety

European Commission

Improved risk communication

- ✓ Definition of general objectives and general principes
- ✓ 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 communiation activities
  - ✓ Types and levels of risk communication activites 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

European Commission

4th pillar: Sustainability and governance of EFSA

Health and Food Safety

European Commission

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

European Commission

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

European Commission

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

European Commission

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?)

European Commission

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

European Commission

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

European Commission

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

European Commission

Thank you for your attention!

Health and Food Safety