



Commission Initiative on the transparency and sustainability of the EU risk assessment model in the food chain

67th meeting of the Advisory Forum of the European Food Safety Authority

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Péter Bokor

Head of Unit D1: Science, stakeholders, enforcement

DG SANTE



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Outline

- Background of the initiative
- Overall objectives of the initiative
- Consultation activities

Background for the initiative

- **Tackle findings of the Fitness Check of the General Food Law:**
 - **Transparency** of risk analysis: an issue in terms of perception, particularly in the context of authorisations.
 - Negative signals identified on the EFSA's capacity to **maintain high level of scientific expertise**, need to **engage with Member States**.
 - **Risk communication** has not always been effective.
- **Address the Commission's reply to the European Citizens' Initiative "Ban glyphosate":**
 - To come forward a legislative proposal **by May 2018** covering the transparency in scientific assessment and decision-making, quality and independence of scientific studies and the governance of EFSA (drawing on GFL Fitness Check and after open public consultation).

Challenges on transparency

- Citizens perceive the risk assessment process opaque and demand more transparency thus **trust is adversely affected**, because:
 - EFSA's evaluations of authorisation dossiers being essentially based on industry studies (burden of proof of safety of products on the applicant).
 - Recent debates raised concerns on transparency and independence of industry-generated studies and data.
- Several different transparency and confidentiality rules applicable to risk assessment and decision-making process: **complex and non-uniform rules.**

Challenges to sustainability

EFSA's high level of independent scientific expertise is linked to its capacity to pool expertise from Member States. This is **challenged by**:

- **difficulties to attract new Experts** (recognition, financial compensation, etc.);
- despite progress, **there are future challenges in ensuring full engagement of Member States in scientific cooperation.**



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Challenges to Risk Communication

Key finding of the Fitness Check:

- Risk communication: **not effective enough.**

Objectives targeted by the initiative (I)

- Improve and clarify **the rules on transparency** (scientific studies supporting RA).
- Increased **reliability, objectivity and independence of studies used by EFSA** in its risk assessment (mainly **authorisation dossiers**).

In particular the **reply to the ECI highlighted** the need to:

- involve more public authorities in the process of deciding which studies need to be conducted;
- enhance auditing of compliance with GLP principles;
- measures increase transparency while respecting confidential business information;
- exceptionally commission ad-hoc studies in specific cases.

Objectives targeted by the initiative (II)

- Improve **governance** and strengthen the scientific cooperation **and more involvement of** Member States in EFSA
- Address **the limitations affecting the long term scientific capacity of EFSA** and its ability to maintain a high level of scientific expertise
- Develop a **more effective and transparent risk communication** with public, in collaboration with Member States

Related links

- **Roadmap**

<http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6265773>

- **Open Public Consultation**

https://ec.europa.eu/info/consultations/public-consultation-transparency-and-sustainability-eu-risk-assessment-food-chain_en

- **Fitness Check**

https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

- **Communication on the European Citizens' Initiative (ECI)**

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyp_hosate_eci_final.pdf

Consultation activities on the initiative

- Open Public Consultation of the Commission's Roadmap (from 20 December 2017 to 17 January 2018)
- Open Public Consultation via questionnaire (from 23 January to **20 March**)
- Advisory Group on the Food Chain, Animal and Plant Health (on 5 February)
- EFSA's Advisory Forum (6 February)
- EFSA's Scientific Committee (15 February)
- Expert Group on General Food Law (5 March, tentative)



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Thank you!



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Open discussion

- How should **the transparency of the risk assessment process** of regulated products **be increased** without compromising confidential data?
- How should, if at all, **public authorities/agencies**, like MSs, EFSA, Commission, **get more involved** in the process of **deciding which studies are needed**?
- What could be done further to **enhance the auditing system of laboratories' compliance with GLP principles**?
- How can the **commissioning of ad hoc studies**, that could be foreseen in case of serious controversies and widely used substances, be organised?
- How can **Member States be further involved in the risk assessment system to ensure its sustainability**, including support to Expertise needed by EFSA?