



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

Ad hoc meeting of the Advisory Group on the Food Chain and Animal and Plant Health

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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?