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

Expert Group of the General Food Law
5 March 2018

DG SANTE - EFSA Team
Unit D1: Science, stakeholders, enforcement
Unit E1: Food information and composition, food waste

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Timing:

foreseen adoption of the proposal on 11 April 2018

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Consultation activities on the initiative

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

- ***Expert Group on General Food Law (5 March)***

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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).

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Challenges on transparency

Citizens perceive the risk assessment process opaque and demand more transparency, because:

- **Several different transparency and confidentiality rules applicable** to risk assessment and decision-making process: complex and non-uniform rules. Recent debates raised concerns on transparency and independence of industry-generated studies and data;
- EFSA's evaluations of authorisation dossiers are essentially based on **industry studies**: burden of proof of safety of products on the applicant.

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Challenges on 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 on Risk Communication

Key finding of the Fitness Check:

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

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How could we tackle these challenges?

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By ensuring Transparency, Quality and Independence of Studies in application dossiers

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Ensuring Transparency

How could we do this?

- The European Food Safety Authority (EFSA) should be required to **make public any studies** accompanying a request for authorisation **upon receipt**, except for **confidential data**

- A **list of confidential data** should be established at horizontal level (General Food Law Regulation) - to be further supplemented **by additional lists,** where necessary, at sectorial level (7 acts to be amended)

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Ensuring quality and independence of studies

- 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:

  1. involve more public authorities in the process of deciding which studies need to be conducted,
  2. enhance auditing of compliance with Good Laboratory Practice (GLP) principles ,
  3. exceptionally commission ad-hoc studies in specific cases

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Choice of studies

- Sectorial regulation and EFSA guidance to applicants on how to submit application dossiers are already existing

- What can be foreseen **in addition**, taking into account the concerns of NGOs:
  - Doubts about industry not submitting all studies performed
  - Stakeholders not enough informed and involved

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Studies: possible options?

At the pre-submission stage:

- **Planned studies will be included in an EU register**. Industry will have to notify EFSA of any safety study commissioned to a test facility. Test facilities to also notify?
- **Pre-submission procedure on planned studies**: EFSA providing clarifications on planned studies. **Only in case of renewals**, it is coupled with a mandatory public consultation.

At the submission stage**:**

- **Public consultation (full? call for data?)** on submitted studies in the application file.

Overall, need to ensure transparency and ,where needed, confidentiality on these procedures

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Enhance auditing of compliance with GLP principles

- OECD auditing system already existing on GLP
- What could be done to strengthen system, options?
  - Introduce an extra-guarantee in the EU: to verify compliance of MSs with requirements of Directive 2004/9/EC and 2004/10/EC, to involve EU inspectors?

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Ad hoc studies in exceptional cases

Possible options?

- Objective should be "for verification purposes" of studies submitted in application dossier
- Upon request of the Commission?
- EFSA to fund/coordinate the commissioned studies

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By reforming EFSA's Governance

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Governance/MS involvement

To address the limitations affecting EFSA ability to maintain a high level of scientific expertise in particular by improving **governance** and strengthening the **involvement of** Member States in EFSA.

What can we do?

- Align the composition of EFSA Management Board on to the Inter-institutional model (with all MS).

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Governance/MS involvement

Need to improve **governance** and strengthen the **involvement of** Member States in EFSA: MS involved in nomination of members for EFSA Panels?

Considerations:

- Need to maintain the high level of independence and scientific expertise.
- Need to take account of EFSA specificities (10 Panels of 21 members), so 210 experts to appoint. Each Panel with different tasks and each requiring specific multidisciplinary expertise. EFSA considers it needs an initial pool of 900 high level experts to meet these needs.
- Limited risk assessment capacity in several MS.

How could MS be more involved?

Possible options?

- EFSA Executive Director provides to the MS details on the needs for multidisciplinary expertise for each Panel;
- MS nominate a large pool of experts in order to meet criteria for excellence, independence and multidisciplinary expertise in each Panel;
- Executive Director selects and proposes final list of experts for Panels to MB for appointment;
- Possibility for EFSA to co-opt if expertise missing.

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By developing a more effective, consistent and transparent risk communication

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Improve Risk Communication

What could be done?

- To lay down general principles of shared risk communication between risk assessors and risk managers;

- Empower the Commission to develop a 'general plan on risk communication' covering the entire agri-food chain in close co-operation with EFSA and the Member States.

Financial needs - tasks generating costs in EFSA (staff and operational)

- **Transparency** (registers of studies, publication of studies, public consultation activities, confidentiality screening of authorisation' dossiers)

- **Higher reliability of studies** used in Risk Assessment (new pre-submission procedure, GLP audit, additional studies)

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Financial needs - tasks generating costs

- **Strengthening EFSA scientific capacity and better involve MSs** (changes of MB and Panels, MS & experts nomination, experts & MS better compensated, increased internal scientific capacity of EFSA, training)

- **More effective risk communication** to reach wider audience.

The implementation of these tasks will require substantial additional resources for EFSA

Thank you!