



# **Commission Proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain**

68<sup>th</sup> EFSA's Advisory Forum, Sofia, Bulgaria, 6 and 7 June

**DG SANTE Units D1 and E1**

# Why this proposal?

- **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:

  - **Transparency** in scientific assessment.
  - **Quality and independence** of scientific studies.
  - **Governance** of EFSA.

## Consultation activities

- Open Public Consultation of the Commission's Roadmap (December 2017 to January 2018)
- **Open Public Consultation via a questionnaire (8 weeks – from 23 January to 30 March)**
- AG on the Food Chain, Animal and Plant Health (5 February) – all the main stakeholders
- EFSA's Advisory Forum (6 February) – National food safety bodies
- EFSA's Scientific Committee (15 February) – Scientists
- Expert Group on General Food Law (5 March) – Member States

# The Commission proposal

- **Commission proposal on the transparency and sustainability of the EU risk assessment in the food chain.**
- Adopted by College on 11 April.
- Proposes targeted changes to the EU General Food Law and eight related sectoral legislative acts.
- Presented to Member States in AGRIFISH Council on 16 April, and to the ENVI Committee of the European Parliament on 26 April.

# The four pillars of the proposal

- 1. Transparency of risk assessment***
- 2. Quality and reliability of studies***
- 3. Sustainability and governance of the EFSA system***
- 4. Improved risk communication***

## ***1. Transparency of risk assessment***

- ✓ Studies/data supporting applications for authorisation to be made public proactively and early on in the risk assessment process, except for confidential info.
- ✓ Lists the info that may be considered as confidential.
- ✓ No prejudice to IPR and data exclusivity.

## ***2. Quality and reliability of studies***

- ✓ EU register of commissioned studies.
- ✓ Pre-submission procedure.
- ✓ Consultation on planned studies (renewals only) and submitted studies (renewals and new requests).
- ✓ Commissioning of verification studies in exceptional cases.
- ✓ Control and audit of laboratories carrying out studies.

### ***3. Sustainability and governance of the RA system***

- ✓ Alignment with the common approach on decentralised agencies (MS representatives in the Management Board).
- ✓ MS involved in the Panel Members selection process: pool of experts (criteria of excellence and independence to be respected).



## ***4. Improved risk communication***

- ✓ Definition of precise objectives.
- ✓ General principles.
- ✓ General Communication Plan.

## Other elements

- Reinforcement of EFSA's own scientific capacity.
- Strengthening cooperation with national scientific organisations.
- A budget increase coherent with our ambition to meet citizens' expectations on food safety.
- Transitional measures.

## What is next?

- Adoption by ordinary legislative procedure.
- Coordination with ongoing Bulgarian and future Austrian presidencies of the Council.
- Coordination with European Parliament.
- Aiming at adoption **by mid-2019.**



European  
Commission

**Thank you for your attention!**