

Consultation strategy for the Commission initiative on the transparency and sustainability of the EU risk assessment model in the food chain

1. Background information

The General Food Law Regulation ([Regulation \(EC\) No 178/2002](#)) was adopted in 2002, setting out a comprehensive harmonised legal framework, addressed to EU institutions and Member States as well as to food business operators. It covers the entire food chain, i.e. all stages of production, processing and distribution of food and feed, including import ('farm to fork' approach). It follows a framework approach, providing the basis for developing both EU and national food law. The General Food Law Regulation established the European Food Safety Authority (EFSA) as the independent EU risk assessment body for matters relating to the food chain.

This initiative follows from the findings of the [Fitness Check of the General Food Law](#) and the [Commission Communication on the European Citizens' Initiative \(ECI\) "Ban glyphosate and protect people and the environment from toxic pesticides"](#).

According to the findings of the Fitness Check of the General Food, despite overall considerable progress, transparency of the EU risk analysis process remains an important issue in terms of perception. With respect to the EU risk assessment in the context of regulated products and substances, EFSA is bound by strict confidentiality rules and by the legal requirement to primarily base its assessment on industry studies, laid down in the General Food Law and in the multiple authorisation procedures in specific EU food legislation. These elements lead civil society to perceive a certain lack of transparency and independence. Furthermore, risk communication has not always been effective. The Fitness Check has also identified a number of negative signals on the capacity of EFSA to maintain a high level of scientific expertise and to fully engage all Member States in scientific cooperation.

These findings are further complemented by the Commission's reply to the ECI mentioned above. One of the ECI petitioners' requests was to modify the EU pesticide approval procedure to tackle the perceived lack of transparency and independence of the scientific studies used to support authorisation dossiers. In the Communication replying to the ECI, the Commission acknowledged that "transparency in scientific assessments and decision-making is vital to ensuring trust in the regulatory system. It also attaches continued importance to the quality and independence of the scientific studies that are the basis of the EU risk assessment carried out by EFSA". The Commission therefore committed to come forward with a legislative proposal by May 2018 covering these and other aspects such as the governance of EFSA, drawing on the results of the Fitness check of the General Food Law and following a public consultation.

[Roadmap "Transparency and sustainability of the EU risk assessment model in the food chain"](#)

2. Consultation scope and objectives

The consultation strategy builds on previous consultations that have taken place, amongst others, on issues to be addressed by the present initiative in the context of the recent Fitness Check of the General Food Law ([SWD \(2018\) 37 of 15 January 2018](#)). Extensive consultations have taken place involving consumer organisations at EU and national level, organisations/associations representing food and feed businesses at EU and national/regional level active in the entire food chain, small- and medium-sized enterprises (in particular the small- and micro-enterprises) given their significant importance in the food chain, Member States' competent authorities, NGOs and other associations representing other interests in the food chain (e.g. animal welfare associations), selected non EU countries and EFSA.

The objective of the planned consultations is to collect views from the relevant stakeholders including the general public on three main aspects:

1. the transparency and independence of the EU risk assessment system with respect to the underlying industry studies and information on which EFSA's risk assessment/scientific advice is based in particular in the context of authorisation procedures;
2. risk communication; and,
3. the governance of EFSA, in particular the involvement of the EU Member States (MS) in the EU risk assessment system.

3. Mapping of stakeholders

Citizens and consumers' associations. Citizens as consumer are end-users. There is an increasing consumer interest in the area of food safety and the public consultation is expected to attract considerable attention from civil society. Consumers' associations will be part of targeted consultation.

EU/national/regional associations representing interests in the food chain. There are numerous associations with high interest in the area of food safety. Main EU associations are members of the Advisory Group on the food chain, animal and plant health and will be part of targeted consultation.

Public authorities. Member State Competent Authorities (MS CA) are important actors as agencies in Member States directly involved in the risk assessment process. MS CA act also as risk assessors, are responsible for enforcement on national territory and also act as risk managers in the framework of comitology together with the Commission. The level of interest, support and influence varies from Member State to Member State.

Food and feed business operators. The interest of food and feed industry, including SMEs, is strong as businesses are directly affected when ensuring compliance with the Regulation. The food industry is global and affected businesses are located both within and outside the EU. There are important EU level associations representing different sectors of food businesses. Therefore, particular emphasis will be given to ensure their views are collected and taken into consideration. Different sectors of industry are concerned, more specifically:

- Food industry
- Feed industry

- Pesticides industry
- Other sectors related under General Food Law: flavourings, additives, nutrients, food contact material, etc.

Third countries. Third countries have high stakes in terms of trade in food and feed and are directly affected by any changes in the Regulation.

Scientific Community. These stakeholders are indirectly affected as they are involved in developing the scientific methods used in the risk assessment. This category includes experts, either from the academia or the private sector who are subcontracted to develop methodologies or assessments of technologies for industry or public authorities.

The European Food Safety Authority (EFSA). The Authority will be directly affected. EFSA being the EU independent risk assessor for the food chain, there will be close consultation and cooperation all along the preparation of the initiative between the Commission and EFSA.

EU agencies. Other EU risk assessment agencies, i.e. European Centre for Disease Prevention and Control (ECDC), European Medicines Agency (EMA), European Chemicals Agency (ECHA), may be impacted since they cooperate on issues of scientific interest with EFSA.

4. Selection of consultation activities & their accessibility

1. The public consultation on the initiative via web based questionnaire was launched on 23 January 2018 and will be open for 8 weeks (deadline 20 March 2018). The questionnaire is available in 23 official EU languages and can be answered in all official EU languages. The consultation is open to all EU and non-EU citizens and stakeholders, and the respondents need to be identified. The data will be anonymised, if so requested, in the synopsis report about the consultation.
2. A targeted consultation of European stakeholder associations with interest in the food chain was carried out through a dedicated meeting of the Advisory Group on the food chain, animal and plant health, on 5 February 2018.
3. A targeted consultation of Member States will be carried out through a dedicated meeting of the Expert Group on General Food Law on 5 March 2018.
4. The questionnaire of the public consultation will be presented and discussed with EFSA's Advisory Forum which is composed of national bodies undertaking tasks similar to those of EFSA and EFSA Scientific Committee which has a general coordination role on scientific advice in EFSA. The meeting dates are 6 February 2018 and 15 February 2018.

5. Summary /overview on consultation activities by stakeholder groups

Targeted stakeholders	Public Consultation	Targeted meetings
Citizens	x	
Consumers' associations	x	x
EU/national/regional associations representing interests in the food chain	x	x
Public authorities	x	x
Food and Feed business operators	x	x
Third countries	x	
Scientific Community	x	
European Food Safety Authority	x	x
EU Agencies	x	

6. Consultation webpage & communication activities

Dissemination of information on the public consultation is being done – amongst others – via:

- The Advisory Group on the food chain, animal and plant health and its sub-groups
- Animal Welfare platform
- The European Consumer Consultative Group
- Civil Society Dialogue Groups (DG TRADE, DG AGRI)
- The Commission SANTE's webpage
- The High-Level Forum for a better functioning food chain
- EFSA's webpage

The webpage for the public consultation is: https://ec.europa.eu/info/consultations/public-consultation-transparency-and-sustainability-eu-risk-assessment-food-chain_en