

ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

TITLE OF THE INITIATIVE	Transparency and sustainability of the EU risk assessment model in the food chain
LEAD DG – RESPONSIBLE UNIT	SANTE – Unit D1 and E1
LIKELY TYPE OF INITIATIVE	Interinstitutional legislative file
INDICATIVE PLANNING	Q2 2018
ADDITIONAL INFORMATION	https://ec.europa.eu/food/safety/general_food_law_en

This Roadmap is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Roadmap, including its timing, are subject to change.

A. Context, problem definition and subsidiarity check

Context

The General Food Law Regulation 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 EU risk assessment body for food and feed safety.

This initiative follows from the findings of the Fitness Check of the General Food Law¹ and the Commission Communication on the European Citizens' Initiative (ECI) "Ban glyphosate and protect people and the environment from toxic pesticides".²

One of the ECI petitioners' requests was to modify the EU pesticide approval procedure to tackle the transparency and independence of the scientific studies used to support authorisation dossiers.

In the Communication, 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 after a public consultation to be launched shortly.

Problem the initiative aims to tackle

The Fitness Check of the General Food Law and recent public debates surrounding specific substances (e.g. the renewal of the authorisation of glyphosate, also subject of the ECI mentioned above) have shown some aspects in the current legislative framework that need to be addressed. In particular:

- Citizens perceive the risk assessment process (and the decision-making based on it) as opaque and demand more transparency; trust in the process itself is adversely affected as a result of the perceived insufficient transparency. In addition, a variety of transparency and confidentiality rules is applicable to the risk assessment and decision-making process depending on the sub-area concerned. Similar (but not uniform) rules on confidentiality exist in the multiple authorisation procedures laid down in EU sectorial legislation, in the General Food Law Regulation and in Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

¹ The results of the Fitness Check of the General Food Law will be available on the following website by 12 January 2018: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en.

² Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", dated 12.12.2017, C(2017)8414, to be found at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_eci_final.pdf.

- Negative perceptions are also the result of EFSA's evaluations of authorisation dossiers being essentially based on studies, data and information generated (and paid for) by the applicant for authorisation. Current procedures are based on the principle that it is for the applicant for an authorisation to provide the scientific evidence supporting it, and that public money should not be used to commission costly studies (several thousand to several million Euros) that will eventually help industry put a product on the market. While this principle remains valid, recent debates have raised concerns regarding the transparency and independence of industry-generated studies and data.
- Risk communication is, overall, considered not to be effective enough, especially in light of the difficulty of communicating science-based risk assessment decisions in an environment characterised by increasing scepticism about the objectivity of scientific findings.
- EFSA's high level of scientific expertise is linked to its capacity to pool expertise from Member States. This capacity is adversely impacted by a number of factors:
 - difficulties encountered to attract new experts due to, among other: insufficient recognition for the scientists' career, financial compensation for the experts and their employers considering the amount of time required for their contribution to EFSA's work;
 - the fact that more than two thirds of EFSA's Scientific Panels' experts (69%) originate from six Member States only and the difficulties encountered by EFSA in receiving sufficient support from many Member States to its scientific work (e.g. via studies, provision of data) clearly point to future challenges in ensuring a long term sufficient expertise and in fully engaging all Member States in scientific cooperation.
- In contrast with other EU Agencies, Member States are not represented in EFSA's Management Board and its governance has not been aligned with the Common Approach on EU decentralised agencies³.

Basis for EU intervention (legal basis and subsidiarity check)

The legal bases are Articles 43,114,168(4)(b), and 207 of the Treaty on the Functioning of the EU.

To address the emerging challenges in the area of food law in light of the experience gained to date (Fitness check of the General Food Law is to be published by mid-January 2018) and the ECI Communication, any actions in this area would need to take place at EU level and primarily within the existing EU legislative framework established by the General Food Law Regulation and where necessary in other relevant sectorial legislative acts.

B. What does the initiative aim to achieve and how

The initiative acknowledges that the challenges and areas of concern to EU citizens in the food domain have shifted over time and aims to respond to the new challenges by increasing the transparency, the accountability and the sustainability of the related risk assessment process. Its main objective is to adjust the current process so as to:

- improve and clarify the rules on transparency, especially with regard to the scientific studies supporting the risk assessment;
- increase the guarantees of reliability, objectivity and independence of studies used by EFSA in its risk assessment, in particular in the framework of authorisation dossiers;
- improve the governance and strengthen the scientific cooperation and 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 across the different areas of the agri-food sector; taking also account of the related financial and budgetary aspects, and
- develop a more effective and transparent risk communication with the public in collaboration with Member States.

C. Better regulation

Consultation of citizens and stakeholders

Extensive consultation has taken place on the issues to be addressed by the present initiative in the context of the recent Fitness Check of the General Food Law, expected to be finalised and published by early 2018. The ECI, albeit its scope was limited to the pesticides sector, refers to some of the critical elements addressed by this initiative.

While a public consultation will be carried out, it will exceptionally last 8 weeks (as opposed to the normal standard of 12 weeks) due to the limited time available to follow up on this proposal. It will be launched in January 2018 and will be addressed to stakeholders and citizens. It will be carried out in all official EU languages and will be published on the Commission's central portal for consultations⁴. To ensure the best possible outreach, targeted consultation activities will also be carried out in parallel.

The results of all consultation activities will be summarised in a synopsis report that will also be published on the

³ https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

⁴ https://ec.europa.eu/info/consultations_en

consultation's webpage.

Evidence base and data collection

The Fitness Check of the General Food Law relied, amongst others, on an external study on the general provisions of the General Food Law. With respect to the operation of EFSA, an external evaluation was conducted in 2012, covering the period January 2006 to December 2010 and updated by the Commission with more recent data for the purposes of the Fitness Check.

Throughout the Fitness Check exercise, the Commission was assisted by the Expert Group on the General Food Law composed of experts from the competent authorities of Member States. A wide range of stakeholders participated in the exercise through the special Working Group of the Advisory Group on the Food Chain and Animal and Plant Health. Participation in the Working Group was expanded beyond statutory membership to ensure the broadest possible representation of the interests concerned.

Data collection for the Fitness Check included extensive surveys, case studies and workshops as well as in-depth interviews with relevant stakeholders.

While the explanatory memorandum of the legal proposal will identify and analyse relevant impacts and provide justifications for the proposed measures, no full-fledged impact assessment will be carried out for this initiative, as the measures to achieve the identified objectives should in essence concern the transparency and the way the Commission as risk manager and the EFSA as risk assessor acquire the evidence needed to make decisions on the basis of unchanged criteria. Such measures are therefore not expected to have significant socio-economic and environmental impacts that are clearly identifiable ex ante.