# Agreement on the Commission's proposal on transparency and sustainability of the EU risk assessment model in the food chain – Questions and Answers

**What has been agreed today?**

Today, the European Parliament and the Council reached a provisional agreement on the European Commission's proposal tabled last April to amend General Food Law Regulation . The proposal follows-up on the European Citizens' Initiative and aims at increasing the transparency of the EU risk assessment in the food chain, on strengthening the reliability, objectivity and independence of the studies used by European Food Safety Authority (EFSA), and revisiting the governance of EFSA in order to ensure its long-term sustainability. The proposal also responds to a fitness check of the General Food Law, completed in January 2018.

**Which EU legal acts are concerned by the agreement?**

The agreement covers the review of the **General Food Law Regulation**[1], and the amendment of eight legislative acts dealing with specific sectors of the food chain: GMOs (cultivation and for Food/Feed uses), feed additives, smoke flavourings, food contact materials, food additives, food enzymes and flavourings, plant protection products and novel foods.

**Once the new Regulation applies, how will the transparency of the EU risk assessment and the independence of scientific studies be increased?**

The agreement reached today stipulates that all studies and information supporting a request for a scientific output by EFSA are made public automatically when an application is validated or found admissible. This has to be done at the very early stage of the risk assessment process, in an easily accessible electronic format with the possibility to search, download and print the studies. Confidential information will be protected in duly justified circumstances. Confidentiality claims will be assessed by EFSA.

Other measures which will also ensure a more independent and transparent risk assessment process are:

• **A database of commissioned studies.** This will provide a mechanism by which EFSA will be able to double-check whether all studies commissioned by an applicant in the context of its application for an authorisation, have been submitted;

• **Consultations** of stakeholders and of the general public on submitted studies to ensure EFSA's comprehensive access to existing evidence underpinning its risk assessment;

• **A specific procedure**, including consultation of stakeholders and the general public on planned studies in the case of renewals of already authorised substances (see below);

• **Fact-finding missions by the Commission** to ensure the compliance of laboratories/studies with standards;

• **Possibility for the Commission to ask EFSA to commission studies** in exceptional circumstances to verify evidence used in its risk assessment process. Intellectual property rights, data exclusivity and data protection will be guaranteed in line with the existing Union and national rules concerning intellectual property rights, which set out limitations on certain uses of the publicly disclosed documents or their content. EFSA will ensure that clear undertakings are obtained to that effect, prior to disclosure of documents.

**Are sanctions or penalties foreseen for non-compliant studies?**

The legislation must be enforceable, therefore negative temporary stop in the risk assessment will be foreseen to sanction those applicants who would not notify studies. This stop must be dissuasive but shouldn’t put in jeopardy the whole process.

**Do these changes concern also the procedure for the renewal of already authorised substances?**

Yes. The changes will affect the renewals of authorisations of substances that are already on the market. The applicant will have to notify in advance the studies it plans to carry out for the renewal request. EFSA will then launch a consultation of third parties regarding these planned studies, and will be able to provide advice to the applicant on the content of the submission dossier.

**Will confidential information be disclosed?**

No, as long as this is duly justified. Applicants will have to provide verifiable justification for their possible confidentiality claims on the acceptance of which EFSA will decide.

**How will the studies be disclosed and how will confidential information be processed in practice?**

When the applicant submits a dossier, it may request certain parts of the submitted studies and other information to be kept confidential (that are included in the positive list of confidential items), with the condition that verifiable justification for this request is provided. To this end, it should submit a non-confidential version and a confidential version of the submitted studies and other information. When the application is validated or found admissible, EFSA will make the non-confidential version of the submitted studies and information public. In parallel, within 10 weeks from the date of receipt, EFSA would assess the confidentiality claim. Once this assessment is completed, any additional data and information for which confidentiality requests has been considered as unjustified would also be made public.

**Does the proposal protect personal data?**

Yes. Any processing of personal data would be carried out in accordance with the applicable Union legislative framework. On this basis, no personal data will be made publicly available unless it is necessary and proportionate for the purposes of ensuring the transparency, independence and the reliability of the risk assessment process, and preventing conflicts of interests.

**Is the agreement reinforcing EFSA?**

Since it is crucial to strengthen the EU risk assessment model which includes EFSA but also EU national scientific bodies contributing to EFSA's work, the text agreed today will lead to greater transparency of the risk assessment process by:

o contributing to EFSA acquiring greater legitimacy in pursuing its mission and

o increasing citizens' confidence in EFSA's work.

The EFSA model, as it is also the case for the other EU scientific agencies (EMA, ECHA), is dependent on its capacity to pool expertise from Member States. In particular, national scientific organisations contribute to EFSA's work by allowing their experts to work in EFSA as experts in its Scientific Panels and by providing EFSA with scientific data and studies. These contributions should be further supported to avoid increasing current difficulties in attracting sufficient candidates for EFSA's Scientific Panels.

The agreement addresses these limitations by reinforcing EFSA's own scientific capacity and by strengthening the scientific cooperation with national scientific organisations.

The key elements concern:

**Independence**

EFSA will remain independent. EFSA is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (i.e. Commission, Council, and European Parliament) as well as the Member States. The rules whereby members of the Management Board and members of the Panels have to act independently and – publicly – make an annual declaration of interest are maintained and reinforced. EFSA Management Board will also continue to hold its meetings in public.

**Role of Member States**

Each Member State will nominate a representative to the Management Board, thus taking more responsibility for supporting EFSA and ensuring an increased scientific cooperation. Member States' representatives in the new Management Board will be required to meet specific requirements and will be selected on the basis of their relevant experience and expertise in the field of the food chain legislation and policy, including risk assessment. Strict criteria of

independence will have to be fulfilled.

**What has been agreed on risk communication?**

Ensuring a coherent communication throughout the risk assessment process is key for two reasons. First, it enables to avoid divergences that could have an adverse impact on public perception as regards safety in the agri-food chain. Second, it guarantees a more comprehensive and continuous process throughout the risk analysis process, by actively involving all the relevant parties (i.e. the Commission, EFSA, Members States, stakeholders and the public). Both elements are very relevant for European citizens.

The Fitness Check of the General Food Law also made clear that risk communication could and should be improved via the open dialogue amongst all interested parties.

**For more information**

Transparency and sustainability of the EU risk assessment in the food chain

[1] https://ec.europa.eu/food/safety/general_food_law_en