New legislation on transparency and sustainability of the EU risk assessment model in the food chain *

Brussels, 13 June 2019

What has been adopted today?

Today, following the approval by the European Parliament on 17 April 2019, the Council has formally adopted a new Regulation on the transparency and sustainability of the EU risk assessment in the food chain. This new Regulation is based on aEuropean Commission's proposal tabled in April 2018 and mainly amends the General Food Law Regulation[1]. It 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.It is a direct response to a successful European Citizens' Initiative and builds upon the findings of the fitness check of the General Food Law Regulation , a comprehensive evaluation, completed in January 2018.

Which EU legal acts are concerned by the adopted legislation?

It covers the review of the General Food Law Regulation 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**[2]**.

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

The Regulation stipulates that all studies and information supporting a request for a scientific output by EFSA are to be made public automatically when an application is validated or found admissible. This will 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 robust, independent and transparent risk assessment process are:

- **A notification obligation for applicants and laboratories when studies are commissioned and creation of 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;
- **Consultation** 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);
- **Pre-submission advice** on the applicable rules and the required content of an application dossier, to be provided by EFSA upon request to potential applicants;
- **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 or signed statements are obtained to that effect, prior to disclosure of documents,

without, however, jeopardizing the proactive character of, or the easy access to the disclosed information.

Are sanctions or penalties foreseen for non-compliant studies?

The legislation must be enforceable, therefore negative temporary stop in the risk assessment are foreseen to sanction applicants who have not complied with the notification obligation of commissioned studies.

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 EFSA in advance the studies it plans to carry out for the renewal request along with the proposed study design. EFSA will then launch a consultation of third parties regarding these planned studies, and will be able to provide tailor-made advice to the applicant on the content of the renewal dossier as well as on the design of the studies.

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, based on the positive lists of confidential items, 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 (that are included in the positive lists of confidential items) to be kept confidential, with the condition that verifiable justification for this request is provided demonstrating that disclosure of the relevant information would potentially harm its interests to a significant degree. 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, as submitted by the application, 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:

- **contributing to EFSA acquiring greater legitimacy** in pursuing its mission and
- **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 Regulation 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.

To this end, the new Regulation sets out objectives and general principles of risk communication. Based on these objectives and general principles, the Commission is empowered to set out a **general plan on risk communication** by means of an implementing act, to promote an integrated risk communication framework for all risk assessors and risk managers on all matters relating to the food chain.

The general plan on risk communication should:

- **identify the key factors** to be taken into account when considering the type and level of risk communication activities needed, (e.g. different level of risks, nature of risk, risk perceptions etc.);
- **determine the tools and channels** to be used as well as the appropriate mechanisms of coordination and cooperation between the risk assessors and risk mangers; and,
- **launch an open dialogue** amongst all interested parties.

What is next?

The new Regulation is expected to be published in the Official Journal on **6 September 2019**. Following its entry into force 20 days after publication, it will become applicable 18 months later (**by end of March 2021**).

The Commission and EFSA will work closely to ensure the proper implementation of the new Regulation.

For more information

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

* updated 13/06/2019, 12:00

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

[2] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1); Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1); Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22

September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29); Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1). Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4); Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1); Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1); Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

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