Commission's proposal on transparency and sustainability of the EU risk assessment model in the food chain

Brussels, 11 April 2018

Questions & Answers

Why is the Commission making a proposal on transparency and sustainability of the EU risk assessment model?

This proposal is a direct follow-up to:

- The Commission's reply**[1]** to the European Citizens Initiative on glyphosate, and specifically to peoples' concerns regarding the studies to be used in the evaluation of pesticides. In order to address these concerns, the Commission is now strengthening the transparency in the risk assessment process and it provides additional guarantees of reliability, objectivity and independence of the studies used by EFSA in risk assessments.
- The Commission's commitment to Better Regulation which included a fitness check of the General Food Law Regulation.The checkidentified the need to improve the transparency in the EU decision-making cycle as well as the need to safeguard European Food Safety Authority (EFSA) ability to get access to a sufficiently high number of qualified and multidisciplinary scientific experts. An important element is also the need to reinforce the co-operation between EFSA and national scientific bodies, increasing Member States' involvement in EFSA's operation**[2]**;

A public consultation, running between 23 January and 20 March 2018, showed that citizens and stakeholders acknowledge the importance of improving the public access to the industry studies used by EFSA in its risk assessments, as a significant element to ensure trust in the EU food safety risk assessment.

On this basis we are coming forward with a proposal which foresees the proactive disclosure of industry studies. The ability of EFSA to be able to recruit the needed scientific expertise will be guaranteed by reinforcing the resources of the Authority and giving it access to a large pool of scientific experts nominated by Member States.

Which EU legal acts are concerned?

This proposal is arevision of the General Food Law Regulation, focusing on transparency in EU risk assessment, on strengthening the reliability, objectivity and independence of the studies used by EFSA, and revisiting the governance of EFSA in order to ensure its long-term sustainability.

To ensure legal consistency across EU food law, it is also necessary to amend, in addition to the General Food Law Regulation, 8 sectorial legislative acts dealing with 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[3].

How will the new system increase the transparency of scientific studies?

The Commission proposes that all studies and supporting information that are submitted to EFSA for risk assessments are made public proactively and automatically, at the very early stage of the process. Confidential information will be protected in justified circumstances, to be verified by the Authority.

Studies should be made publicly available and easily accessible in an electronic format via EFSA's website, with the possibility to search, download and print them.

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

- **A register 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 to base its 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);

- **Controls and audits 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 submitted evidence.

Intellectual property rights, data exclusivity and data protection will be guaranteed in line with the applicable EU legislation.

This proposal covers the entire agri-food chain.

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. The proposal sets out the type of information that may be considered significantly harmful for the commercial interests concerned (positive lists of confidential items). Applicants will have to provide verifiable justification for their possible confidentiality claims on the acceptance of which EFSA will decide

In any case confidential information could be disclosed in two cases:

- When urgent action is essential to protect public health, animal health or the environment;
- When the information is part of the conclusions of the EFSA opinion and relates to foreseeable health effects.

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, 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.

Without delay, EFSA would make the non-confidential version of the submitted studies and information public. In parallel, within a short period from the date of receipt, EFSA would assess the confidentiality claim. Once the 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.

Why risk communication is important?

Ensuring a coherent communication throughout all 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 guaranties 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 consumers.

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.

How will the proposal improve risk communication?

The proposal addresses the challenges around risk communication by setting out a framework of the objectives and general principles that it should pursue and comply with. Based on this, the Commission in its capacity as risk manager is empowered to draw up a general plan on risk communication. This general plan will identify the key factors that need to be taken into account when considering the type and level of communication activities needed. It will ascertain the tools and channels for the relevant risk communication initiatives depending on the specificities of the various target audience groups and establish the appropriate mechanisms to ensure coherent risk communication.

The main objective is to enhance coordination between EU and national risk assessors, in order to achieve an effective communication to the public.

Which are the key elements improving the governing of EFSA?

The Commission considers that 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 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 proposal 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 remains 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

The appointment of experts to EFSA's scientific panels will be made from a pool of nominations put forward by Member States, thus formally involving them in making available the right expertise. Member States' representatives in the new Management Board will be required to meet specific requirements in risk assessment. They will not be risk managers. Strict criteria of independence will have to be fulfilled and the EFSA Executive Director, whose function is in particular to ensure EFSA's scientific excellence and independence, will have a decisive role in the selection of Panel experts proposed to the Management Board.

- Commission of studies

EFSA will be able to commission studies on a case by case scenario for verification purposes linked to exceptional circumstances, such as high level of controversies on a substance. The request will be triggered by the Commission and it will be financed by the EU budget. However, this is without prejudice to the responsibility of applicants for providing the scientific evidence needed by EFSA for the risk assessment process.

- Reinforcement

Member States will be represented in the Management Board, thus taking more responsibility for supporting EFSA and ensuring an increased scientific cooperation. Member States will also propose independent and top quality experts for EFSA Scientific Panels' membership with the view to gather a large pool of experts from which the best experts - meeting EFSA's strict criteria for independence and excellence - will be selected, ensuring the appropriate multi-disciplinary expertise needed for each of the 10 EFSA Panels.

For more information

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

[1] Communication from the Commission on the ECI "Ban glyphosate and protect people and the environment from toxic pesticides". C(2017) 8414 final :

http://ec.europa.eu/transparency/regdoc/rep/3/2017/EN/C-2017-8414-F1-EN-MAIN-PART-1.PDF

[2] Commission Staff Working Document, 'The REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002), SWD (2018)38 final, dated 15.1.2018, to be found at: https://ec.europa.eu/food/safety/general_food_law/fitness_check_en.

[3] 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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