The EU Commission proposal on transparency and sustainability of the EU risk assessment in the food chain[1]

EuropaBio Position – a summary version is available here.

14 June 2018

To build trust in food safety, let's promote science

We fully support the Commission's objective to increase trust and confidence in the EU's procedure for risk assessment in the food chain, by making it more transparent and sustainable. The EU's risk assessment system is robust, but looking ahead, we agree that it should become more efficient, consistent, and transparent to help ensure consumer confidence and the system's viability in the long term. Much can be learned from other risk assessment systems in the EU and around the world.

Comprehensive transparency should not be limited to regulatory studies, but include more transparency in EFSA's processes and a step change in communication. Let the science speak loud and clear! The focus of this initiative should be on informing the wider public about real versus perceived health threats, and on tackling disinformation and misperceptions, so that consumers can rest assured that their food is safe. Europe's citizens deserve to know the truth: modern food and agriculture have brought unprecedented levels of food safety to Europe, and food security to the world.

Certain elements of the Commission proposal such as improved risk communication can help to achieve the stated objectives of increasing transparency and sustainability. We also strongly support the idea of making certain procedural aspects of EFSA more like in the European Medicines Agency (EMA), including the introduction of pre-submission activities. On the other hand, the proposed processes for publishing regulatory studies and conducting verification studies require clarification to ensure that they meet the aim of enhancing trust without having a counter-productive impact on the decision-making process and on competitiveness. Given that the risk assessment system is critical for food safety, innovation and all regulated industries, it is regrettable that the Commission has decided not to produce an impact assessment.

We therefore recommend to:

1. Build on EFSA's robust risk assessment;
2. Increase transparency of internal processes;
3. Adopt good practices from EMA for more efficiency;
4. Improve communication and tackle misinformation.

[1] Proposal for a regulation on the transparency and sustainability of the EU risk assessment in the food chain (COM(2018) 179)

1. Build on EFSA's robust risk assessment

Summary: The current risk assessment system provides a very high level of public safety, with adequate checks to ensure the quality and reproducibility of the data submitted by applicant companies. We support measures to strengthen the reliability and objectivity of studies, such as complementary audits and controls. To ensure the highest scientific standards also in the future, it is important for the EFSA to attract and retain expertise. We welcome the proposed extension of the term for the Panel members from three to five years.

High standards and adequate checks to ensure quality and reproducibility of data: **The current system is very robust** ensuring the highest level of data integrity. There are three complementary mechanisms in place in the food safety area (including GMOs) safeguarding the quality and integrity of the data provided by company applicants:

- Mandatory compliance with EU legislation and internationally agreed guidelines such as the Codex Alimentarius[2];
- Quality assurance processes, such as Good Laboratory Practice (GLP)[3] and ISO;
- Independent review process carried out by EFSA, including applicant studies and available peer-reviewed literature.

Attracting dedicated experts: EFSA's procedures on selection of scientific experts should ensure the enrolment of the best professionals in the risk assessment process. **We welcome the proposed longer terms of office** (Art. 28 para. 5) of the experts in the Scientific Panels (five years instead of currently three years), which should improve the continuity of the risk assessment and avoid unnecessary delays. The same level of scrutiny should apply to candidates for the membership in EFSA Scientific Panels from industry and other stakeholder groups. Strict scientific and independence criteria for the experts in Scientific Panels need to be applied to avoid any politicised selection of experts by Member States

Risk assessment training: The scientific work of EFSA should continue to be driven by risk assessment principles and not by academic curiosity. The scientific experts of EFSA, both staff and Panel members, should be provided with **comprehensive training in risk assessment.** Unfortunately, the Commission has not proposed any provisions to this effect.

An appeal system for applicants is missing in EFSA. Such a system **exists in most national authorities and in the other two major EU risk assessment bodies** (EMA and ECHA), to enable error correction and clarification of processes, and to ensure the robustness of the scientific assessment. Unfortunately, the Commission has not proposed any provisions to this effect for EFSA.

Verification Studies already exist: The Commission proposed 'verification studies' (Art. 32e), whereby the Commission "may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process." **This provision appears superfluous** taking into account previous EU research projects. Over the past 25 years, the EU has spent well over €300 million on over 50 complementary studies on GMOs alone, consistently confirming the worldwide scientific consensus that all safety assessed

[2] Biotech topics covered by the Codex Alimentarius: http://www.fao.org/fao-who-codexalimentarius/thematic-areas/biotechnology/en/

[3] The application of GLP is required for all regulated products within EFSA's remit. Directive 2004/9/EC requires that the OECD Guides for Compliance Monitoring Procedures for GLP, as well as the OECD Guidance for the Conduct of Test Facility Inspections and Study Audits, be followed during laboratory inspections and study audits. The Directive also lays down the obligation of EU countries to designate the authorities responsible for GLP inspections in their territory.

GM crops are at least as safe as conventionally bred crops[4]. Yet, public perception has not improved. In addition, **EFSA already re-conducts certain studies** provided by applicants in the GMO area through procurement projects, such as bioinformatic studies and statistical analyses. Additional complementary studies are **unlikely to increase public trust in the risk assessment**. If conducted, they would have to follow the same regulatory requirements and quality principles (i.e. GLP and in some cases ISO, internationally agreed testing guidelines), to ensure reliable and reproducible results. We regret that the Commission has not proposed any qualifiable and justifiable criteria for triggering the conduct of verification studies.

Reduce Animal Testing: The EU has made good progress on this in fields such as cosmetics, and it is now time to enshrine the "Replacement, Reduction and Refinement" approach also in the General Food Law. Scientifically unjustified legal requirements for animal tests should be removed in order to reduce animal testing.[5]

2. Increase transparency of internal processes

Summary: We would like the internal rules of procedure for risk assessment at EFSA to be more transparent, as well as the voting of Member States on authorising products which EFSA confirms to be safe. We support the disclosure to the public of information supporting applications for product authorisations, where this does not undermine the integrity of the decision making process and the legitimate protection of company interests. The timing and modalities of disclosure should be appropriate not to jeopardise innovation in the EU and the competitiveness of companies selling their products in and outside of the EU because of a lack of protection of their legitimate interests. We emphasise that disclosure of technical information, on its own, is unlikely to improve public understanding of science and trust in the risk assessment process. Improved risk communication that provides the necessary context to the technical information is therefore essential for building trust (see point 4). We can share technical regulatory studies, but the **focus should be on informing the wider public** about real versus perceived food safety threats, and on tackling disinformation and misperceptions. Europe's citizens deserve to know the truth: modern food and agriculture have brought unprecedented levels of food safety to Europe, and food security to the world.

Transparency on regulatory data: When it comes to GMOs, a detailed summary of the application is already made publicly available upon submission to EFSA. Additional non-confidential information is already being disclosed to any citizen of the EU upon request by e-tools.[6] The type of information protected by confidentiality is very limited. Experience has shown that **disclosure of information, on its own, is unlikely to improve public understanding** of science and trust in the risk assessment process. There have been cases where disclosed information such as the location of field trials even facilitated criminal actions, such as the vandalisation of GM field trials.

[4] "EU Commission-sponsored Research on Safety of Genetically Modified Organisms'' (1985-2000): "The use of more precise technology and the greater regulatory scrutiny probably makes GMOs *even safer than conventional plants and foods*." "A decade of EU-funded GMO research'' (2001-2010). 50 EU projects, more than 400 independent research groups, European research grants of some EUR 300 million; "Biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies."

[5] Such an unjustified requirement is being maintained in the GMO legislation, against the recommendations of EFSA and against the scientific advice resulting from three publicly funded research projects GRACE/G-TwYST/GMO90+ (€15 million of taxpayers' money invested). See recent policy brief from the research programmes (May 2018), EuropaBio press release (April 2018), Opinion article in Parliament Magazine.

[6] Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents

Controlled disclosure mechanism to limit the risk of misuse: **Effective transparency** is achievable through a robust and controlled mechanism for access to regulatory data, which does not allow for the unfair commercial use of the disclosed data and supports innovation and competitiveness. Insufficient protection of regulatory data and potential misuse thereof for commercial purposes threatens innovation, investments and jobs in the EU and beyond.

The modalities of information disclosure should **not interfere with the risk assessment process**. We support the general principles on transparency - predictability and legal certainty, fairness, proportionality and coherence.[7] Precise terms and conditions for granting access to non-confidential information should be set out to **minimise the risk of misuse both inside and outside of the EU** (Art. 38 para. 1) where data protection provisions do not substantially exist. This can best be achieved by a well-managed and controlled system of disclosure (requestor identification needed), whereby the information would be virtually downloaded within the system, but not physically transferred to the requestor's computer. The disclosed studies should not be printable and should be available in the system for a limited period of time.

Timing of information disclosure: Access to non-confidential information, including to regulatory studies, should be **granted after the authorisation process has been completed**. This is consistent with the current practice in EMA where the clinical trials' reports are disclosed 60 days after the authorisation has been granted. Disclosure preceding the scientific opinion of EFSA would threaten the integrity of the risk assessment and would be inconsistent with EU legislation on public access[8] and EU case law. This would also put the EFSA Panel experts under pressure, thus affecting their independence and the quality of their work. Even studies re-conducted by EFSA in the GMO area, such as bioinformatic studies and statistical analyses, are disclosed only once the EFSA opinion has been adopted and published.

Need for appropriate and transparent risk management: **A clear separation** between risk assessment and risk management is crucial. Political interference with risk assessment undermines trust. The risk assessor should deliver an independent opinion based exclusively on scientific knowledge, which facilitates the decision-making process of risk managers. Transparency is also important for the risk management phase. We support the idea to publish the **voting behaviour of Member States**.[9] Voting of risk managers against the scientific evidence from the EU's own risk assessment body has been significantly undermining trust in the EU's risk assessment, innovation and food safety. Equally, risk managers should refrain from undermining EFSA's reputation when the scientific evidence does not support political preferences.

Transparency on EFSA processes: EMA's processes provide a much higher level of predictability and certainty to applicants than those of EFSA. As an example, the expected timeline for each step of the risk assessment is specified on the EMA website to the exact amount of days. Another example is that EMA publishes its delays in its annual reports.

[7] Letter "*Principles for Balanced Transparency of Risk Assessment Data Made Available to EFSA*" of 15 November 2016 sent to EFSA and signed by 17 European associations.
[8] Article 4(3) of Regulation (EC) No 1049/2001
[9] This was proposed in the Commission's "comitology proposal" COM(2017) 85 final, on which EuropaBio has published a position paper.

3. Adopt good practices from EMA for more efficiency

Summary: More should be done to improve efficiency of the risk assessment process, because "lengthy authorisation procedures in some sectors (…) slow down the market entry process"[10]. We strongly encourage additional streamlining of the different risk assessment practices across EFSA and compared to the other EU risk assessment bodies. We support the proposed provisions that are inspired by the existing good practices in the European Medicines Agency (EMA). EMAs' excellence is globally recognised, combining the highest scientific quality with efficient administrative procedures. The introduction of pre-submission advice is an important step in the right direction, and we hope that the proposed reform of the EFSA Management Board will motivate Member States to take more responsibility and defend a streamlined EFSA and its scientific outputs.

Delays affect innovation and competitiveness: The proposal addresses not just the transparency, but also the sustainability of the risk assessment system, which implies, inter alia, an efficient process. Lengthy risk assessment processes cast doubts over the quality and the scientific excellence of the regulatory decision-making. Similarly, innovation suffers from lengthy authorisation procedures. The Commission's Fitness check for the General Food Law has confirmed: "Lengthy authorisation procedures in some sectors (e.g. feed additives, plant protection products, food improvement agents, novel foods, health claims) slow down the market entry process. This affects the innovation potential and the competitiveness of the EU food and drink industry as well as its capacity to address future challenges."[11] The listed product groups constitute the majority of the product groups evaluated by EFSA. Similarly, the risk assessment timelines for GM import have almost tripled since 2010, amounting to well over five years for products authorised in 2017[12] - despite the fact that all GMOs have been found to be at least as safe as conventionally bred plants. This data indicates that the GMO Panel systematically fails to meet its **legally envisaged timeline** of six months[13], while EMA exceeds its legally envisaged timeline on human medicines by just over 40%[14,15]. The delays in both agencies are justifiable, but only to some extent, by the 'stop the clock' mechanism, which is applied when the agency sends questions for clarification to the applicants. While the structures and responsibilities of EFSA and EMA are different, the particular good practice examples below should be easy for EFSA to take over.

Pre-submission activities for obtaining scientific advice from EFSA regarding the specific characteristics of the product, including the study design, as well as the completeness of the safety data are efficient tools to ensure compliance and efficiency, as evidenced by current good practice in EMA and ECHA. This would enhance the quality of applications and facilitate efficiency through better use of resources. **We welcome the proposed**

[10] Fitness check of the General Food Law https://ec.europa.eu/food/safety/general_food_law/fitness_check_en
[11] Executive Summary of the REFIT evaluation, SWD(2018) 37 final: https://ec.europa.eu/food/sites/food/files/gfl_fitc_executive_summary_2018_en.pdf
[12] For the risk assessment, from submission to the publication of the scientific opinion. This is then followed by the 'comitology' process, in which the Commission puts EFSA-assessed products to the Member State vote. In 2016, undue delays in the comitology process on GMOs were condemned by the European Ombudsman.
[13] Article 5.4 of Regulation 182/2011: "In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in par. 2."
[14] EMA's founding legislation foresees a risk assessment timeline of 6 months (Article 6.3 of Regulation (EC) No 726/2004): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf
[15] Average EMA assessment in 2017 took 10 months in practice (EMA annual report 2017 p. 64).: http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2018/04/WC500248201.pdf

provision to introduce pre-submission advice (Art. 32 a) as a step in the right direction, but ideally the provision should be more closely aligned with EMA's good practice.

Member States on board: The disconnect between some Member States' risk assessment experts and their representatives at the policy level is an impediment to the trust and functioning of the overall authorisation process. Therefore, we hope that the proposed reform to the EFSA Management Board (Art. 25) will **motivate Member States to take more responsibility** and defend a streamlined EFSA and its scientific output. This reform would bring EFSA structures more in line with those of EMA and ECHA.

Innovation Principle: The General Food Law should take into account both the innovation principle and the precautionary principle. The abuse of the precautionary principle has been repeatedly criticised by the European Court of Justice, the WTO and other bodies. This means recognising that innovation provides benefits and that the **absence of innovation includes risks**. The innovation principle has been endorsed by most EU institutions[16].

4. Improve communication and tackle misinformation

Summary: We strongly recommend a step change in communication, addressing the broad public in an easily understandable way. Unfortunately, despite ensuring high levels of public safety, the current system is not well communicated or understood by the public. We welcome the provisions reinforcing risk communication, and are looking forward to supporting the envisioned 'general plan for risk communication', provided that it ensures that risk assessors and risk managers communicate with one voice. We regret that the Commission has not proposed any actions to combat the spread and sources of misinformation that severely undermine science-based risk assessment and the credibility of EFSA.

We welcome the proposed provisions on risk communication (Art. 8a - 8c) as steps in the right direction. But we would like to see a higher level of ambition, and consider that the proposed objectives (Art. 8a) and principles (Art. 8b) should be more clearly tailored to address public perceptions and misperceptions. The most important principles missing from the proposal are that risk communication should enable consumers to minimise risk, and should include approaches to combat misinformation.

The minimisation of risk is a key component of risk communication strategies of many other institutions, such as the World Health Organization (WHO). This requires a focus on priority risks, and on enabling consumers to adopt practices and habits to minimise their exposure. For example, illnesses caused by *Salmonella* can be much reduced by simple practices in the kitchen.

[16] For example: EU Competitiveness Council (May 2016), The EU Political Strategy Centre (EU Commission's think tank) concluded in June 2016 that the Innovation Principle is not inconsistent with existing EU legislation – including the precautionary principle. European Parliament report on technological solutions for sustainable agriculture in the EU, adopted June 2016. Commission's Industrial Policy Strategy (September 2017).

Towards a general plan: We warmly welcome the provision on the **general plan for risk communication** (Art. 8c), including the proposed involvement of EFSA, the Commission and Member States, and the proposed involvement of stakeholders. We consider that the plan should be adopted swiftly and should aim, inter alia, to:

- **Relevant information** should be provided in an understandable manner to the consumer and should be tailored to consumer questions (e.g., salmonella in baby formula). Quality and relevance of information to citizens should be prioritised over quantity of information.
- Risk assessors and risk managers including Member States should **communicate coherently**.
- **Highlight the integrity and quality** of EFSA's scientific opinions in an understandable manner, and communicate the **strength and robustness** of the current system to increase both understanding and trust in the risk assessment process as well as decision-making processes.
- **Combat the spread and sources of misinformation** and conspiracy theories, especially insofar as they receive funding from taxpayers. Holistic efforts must address concretely the sources of unscientific information, their business models and funding sources. If misinformation is allowed to flourish and expand, science-based risk assessment and the credibility of EFSA and national risk assessment authorities will continue to be undermined.