

**Opinion of the European Economic and Social Committee on ‘Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 (on general food law), Directive 2001/18/EC (on the deliberate release into the environment of GMOs), Regulation (EC) No 1829/2003 (on GM food and feed), Regulation (EC) No 1831/2003 (on feed additives), Regulation (EC) No 2065/2003 (on smoke flavourings), Regulation (EC) No 1935/2004 (on food contact materials), Regulation (EC) No 1331/2008 (on the common authorisation procedure for food additives, food enzymes and food flavourings), Regulation (EC) No 1107/2009 (on plant protection products) and Regulation (EU) 2015/2283 (on novel foods)’**

(COM(2018) 179 final — 2018/0088 (COD))

(2018/C 440/27)

Rapporteur: **Antonello PEZZINI**

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Section responsible	Agriculture, Rural Development and the Environment
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Outcome of vote (for/against/abstentions)	176/2/2

## 1. Conclusions and recommendations

1.1. The EESC has always been a proponent of an EU policy to protect health throughout the food chain at every stage of production, from farmer to consumer. This policy should avoid contamination and food risks with a view to promoting safety and hygiene and clear, transparent and safe product information.

1.2. The EESC supports the Commission's initiatives aimed at addressing the challenges of transparency, sustainability and effectiveness in the entire food supply chain monitoring system to help give the public, the media and civil society as a whole a better perception of reliability and safety.

1.3. The EESC strongly advocates the need to strengthen EFSA to make sure risk managers have the best possible scientific advice through clear and transparent communication and to ensure greater cooperation with the Member States and other bodies operating in the social ambit in order to provide a coherent, secure and reliable food safety system.

1.4. The EESC has previously pointed out that ‘the EFSA has proved that it is competent throughout its existence. There is no doubt that it plays a very important role in preventing health risks in Europe’<sup>(1)</sup>.

<sup>(1)</sup> OJ C 268, 14.8.2015, p. 1.

1.5. The Committee believes that it is vital to maintain both a high level of independence from external influence and optimal scientific expertise within EFSA, maximising risk analysis capacities in order to guarantee a sustainable EU assessment system, which is considered one of the best in the world.

1.6. The EESC believes that EFSA and the Member States, working as a network, should be enabled to develop, in the best possible way, appropriate risk communication capacities — independently but mutually consistent and coordinated between assessors and risk managers — using a clear, interactive approach so that users can grasp the findings and conclusions, while ensuring appropriate levels of confidentiality and protection of intellectual property rights.

1.7. The EESC is strongly in favour of setting up a register of studies, easily accessible online, that includes identification of certified experts and laboratories, sworn declarations of absence of conflict of interest, descriptions of aims, technical and financial resources allocated and sources.

1.8. The Committee believes that a significant improvement is needed in consumers' perception of the risk they face in relation to food, through a targeted food and nutrition culture and selective analysis capacity in relation to the risk.

1.9. In the EESC's view, the forthcoming general European strategic risk communication plan — if conceived in full harmony with, and respecting the independence of, EFSA — is the lynchpin on which the efforts of the bodies responsible must focus, the aim being to give an effective, unequivocal, timely, interactive and appropriate response to the public's needs regarding the safety, transparency and reliability of the food chain.

1.10. The EESC suggests boosting structured and systematic dialogue with civil society in which the EESC, with its Sustainable Food Systems bodies, could contribute in a useful and tangible way.

1.11. As far as EFSA governance is concerned, the EESC wholeheartedly backs the proposal for greater Member State and civil society involvement in the management structure and scientific panels, aligning the composition of the management board with the standards established by the Common Approach on Decentralised Agencies.

1.12. The EESC believes that the agreement between EFSA and the Joint Research Centre should be followed up, especially regarding joint activities on food and feed and framing a harmonised scientific quality analysis methodology that ensures transparency, comparability, inclusiveness and fairness for all stakeholders.

## 2. Background

2.1. General food law (EU legislation on food and feed safety throughout the production chain) is the cornerstone of the EU's legislative framework on the entire food chain — from producer to consumer.

2.2. This law states that the rules on feed and food must have a scientific basis. This is known as the risk analysis principle, which comprises three separate but interconnected components: risk assessment, risk management and risk communication.

2.3. Regulation (EC) No 178/2002 set up the European Food Safety Authority (EFSA), an autonomous scientific agency tasked with providing the scientific opinions underpinning the measures adopted by the EU throughout the food chain.

2.4. On 6 October 2017, a European Citizens' Initiative based on a total of 1 070 865 statements of support from 22 Member States was forwarded to the European Commission. The 'Ban Glyphosate and Protect People and the Environment from Toxic Pesticides' initiative <sup>(2)</sup> called on the European Commission to propose a number of measures to the EU Member States. These included 'ensuring that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry'. The

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<sup>(2)</sup> See <http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002>

Commission undertook to present this legislative proposal by May 2018, in order to improve the transparency of scientific assessments and the quality and independence of the scientific studies.

2.5. The assessment of whether the regulation on General Food Law (GFL, No 178/2002) was fit for purpose <sup>(3)</sup> was completed on 15 January 2018.

2.6. The assessment indicates that the GFL Regulation is still decisive and appropriate for tackling the bulk of current trends.

2.6.1. Overall, the GFL's main objectives have been met: a high level of protection of human health, the interests of consumers with regard to food and the smooth running of the single market.

2.6.2. Establishing EFSA has improved the scientific basis for the measures taken by the EU. Significant improvements have been made to EFSA's scientific capacity, the standard of its scientific findings, the gathering of scientific data and the development and harmonisation of risk assessment methodologies.

2.6.3. EFSA has stepped up both cooperation with national and international scientific bodies and the exchange of information between the Member States.

2.6.4. No systemic inconsistency in the application of the risk analysis principle as such has been identified at EU level.

2.6.5. EFSA's rigorous independence and transparency policies have been finetuned and reinforced on a regular basis. Nonetheless, since not all the Member States are represented on EFSA's board, the agency's governance appears not to be in line with the common approach to the EU's decentralised agencies.

2.6.6. In some cases, the food safety framework established by the GFL Regulation has been a source of inspiration to non-EU countries when framing their own national legislation.

2.6.7. As regards risk assessment, EFSA is bound in the area of authorisation dossiers by confidentiality rules and analytical procedures, which recommend that all available evidence or studies be taken into account. As a result, EFSA not only takes industry studies into account in its opinions, but also bases its scientific findings on a literature review that is as comprehensive as possible. Industrial applicants, on the other hand, must provide their own studies, as part of the dossier, when applying for authorisation.

2.6.8. Recent evaluations <sup>(4)</sup> indicate that some limitations have been identified in EFSA's current system:

- there have been difficulties in attracting new panel members;
- scientific expertise comes from just a few Member States;
- shrinking budgets for the public administration;
- limited funds for outsourcing EFSA tasks.

2.6.9. What is more, the lengthy authorisation procedures in some sectors slow down the process of bringing new products onto the market. Nonetheless, the centralised authorisation system is more efficient than using a number of different national food authorisation systems.

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<sup>(3)</sup> See Executive Summary of the Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002){SWD(2018) 38 final}

<sup>(4)</sup> See SWD(2018) 37 final, 15 January 2018.

2.7. The EESC has previously pointed out that ‘the EFSA has proved that it is competent throughout its existence. There is no doubt that it plays a very important role in preventing health risks in Europe’<sup>(5)</sup>.

2.8. In one of its previous opinions, the EESC, taking into account the influence of scientific studies which do not always agree, recommended that EFSA ‘pay special attention to this practice, since scientific literature is an important reference point for the assessment procedure’<sup>(6)</sup> and asked the Commission to systematically publish both the statutory studies used and the related raw data that led to the findings on the agency’s website.

2.9. The EESC has also pointed out<sup>(7)</sup> that EFSA assessment is based on a scientific study which should demonstrate that a particular product is harmless. Under current legislation, this baseline study has to be presented by the company wishing to put the product on the market. This is the most sensitive aspect, because the findings of scientific studies can differ at times depending on their sources of funding and the methodologies used.

2.10. More generally speaking, the EESC has recently called for a food policy fit for the 21st century that meets a whole raft of criteria: food quality, health, environment, social and cultural values, sound economics, decent jobs, fully internalised costs and good governance<sup>(8)</sup>.

2.11. The European Ombudsman has carried out investigations and initiatives on the EU’s model of risk assessment in the food chain. In a letter to the Commission dated 15 March 2018, the Ombudsman flagged up a number of guiding principles for improving this model, specifically:

- independence and transparency;
- the commitment to publish ‘guideline studies’ when it carries out its scientific assessments;
- greater public scrutiny of its risk assessment duties at an early stage in the process;
- capacity to involve the public and its stakeholders in the process of risk assessment<sup>(9)</sup>;
- enabling stakeholders to take part in meetings. This measure should extend beyond the plenary meetings which are currently open, and clearly uphold confidentiality requirements.

2.12. The Ombudsman also pointed out that ‘The public information tools that EFSA uses to raise awareness about the risks associated with certain substances or products should be available in all 24 official EU languages’, ensuring that ‘the rights of people with disabilities are respected, and that risk communication takes account of their needs’<sup>(10)</sup>.

### 3. The Commission proposals

3.1. The Commission has proposed a revision of the regulation on general food law and eight sectoral legislative rules to make them compatible with general rules, boost transparency and increase the guarantees of reliability, objectivity and independence of the studies.

3.2. To improve governance, the proposal is to involve Member States more broadly in EFSA’s governance structure and scientific panels and to step up contributions from national scientific bodies to the provision of data and scientific studies.

3.3. Lastly, the launch of a general communications plan is intended to achieve more and better risk communication to the public, with joint measures to boost consumer confidence and promote public awareness and understanding.

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<sup>(5)</sup> OJ C 268, 14.8.2015, p. 1.

<sup>(6)</sup> OJ C 268, 14.8.2015, p. 1.

<sup>(7)</sup> Ibid.

<sup>(8)</sup> OJ C 129, 11.4.2018, p. 18.

<sup>(9)</sup> Letter of the European Ombudsman

<sup>(10)</sup> Ibid.

#### 4. General comments

4.1. The EESC has always been a proponent of an EU policy to protect health throughout the food chain at every stage of production. This policy should avoid contamination and food risks with a view to promoting safety and food hygiene, transparent and truthful product information, plant health and animal health and wellbeing.

4.1.1. The EESC is a strong supporter of the requirement for the EU to guarantee maximum safety standards for the European food chain, by working via EFSA to provide risk managers with the best scientific advice possible, communicating clearly and transparently with the general public about risks, and cooperating with the Member States and other stakeholders to guarantee a consistent and reliable food safety system. It would be beneficial to:

- review the arrangements for authorisation procedures, with a view to making them more consistent and efficient and speeding up market access;
- review exemptions and simplified rules for micro-enterprises, in line with a high level of protection of human health;
- reassess the impact of existing authorisations which exacerbate EFSA's workload;
- simplify processes to ensure greater transparency.

4.2. The EESC believes that it is vital to maintain both a high level of independence from external influence and optimal scientific expertise within EFSA, maximising its ability to assess risk in order to guarantee a sustainable EU assessment system.

4.3. The EESC would point out that thanks to EU legislation, Europeans have the benefits of one of the highest food safety standards in the world. The EESC therefore believes that it is absolutely essential not only to ensure high levels of reliable and independent scientific analysis, full transparency and interactive communication during the entire risk assessment process with the full involvement and shared responsibility of all Member States, but also — and above all — to take forceful and determined action on the mechanisms of risk perception by civil society.

4.4. The EESC considers that it is crucial to provide consumers with safe food and to maintain confidence in order to sustain a positive and reliable relationship with the public and have a beneficial impact on the agrifood market.

4.5. The scientific community must have confidence in EFSA's food safety role and its opinions must constitute key benchmarks to guarantee that the food placed on the market is safe.

4.6. The EESC believes that EFSA is best placed to develop an appropriate risk communication capability, using easily understandable reports and a clear, transparent approach so that users are able to grasp the findings and conclusions, while ensuring appropriate levels of confidentiality and protection of intellectual property rights to avoid hindering innovation and competitiveness.

4.7. A prerequisite — though not sufficient in itself — for guaranteeing that risk communication regarding specific foods is understandable, appropriate, timely and consistent for all target audiences is to reinforce coordination between the risk assessor, the risk manager, the Member States and the stakeholders on the basis of agreed communication principles.

4.7.1. The EESC sees the need to substantially improve consumer perception of the risks of food consumption in terms of harmfulness, cultural eating habits and food consumption patterns.

4.7.2. The EESC maintains that the forthcoming general European strategic risk communication plan — if accompanied by a range of operational measures suitable for individual situations — is the lynchpin for assessing the capacities of all actors at each level, in order to respond in an effective, timely and appropriate manner to people's expectations regarding the safety, transparency and reliability of the food chain.

4.7.3. Uncertainties have to be recognised and described, with any shortcomings in data or non-harmonised methodologies noted. It is essential here that the communicators deliver messages that do not contradict one another and that communication channels are interactive, verifiable and subject to continuous monitoring of their effectiveness.

4.7.4. The EESC also considers it essential that communication measures be accompanied by campaigns to combat misinformation and misconceptions in order to prevent proper risk analyses being misused to block innovations, particularly those of SMEs.

4.7.5. It is important to step up coordination with the authorities and the national agencies in order to have an effective warning system, to ensure consistency in communication and to set up structured and systematic dialogue with civil society, within which the EESC, with its Sustainable Food Systems bodies, could contribute in a useful and tangible way.

4.7.6. Lastly, international coordination and cooperation with our biggest trading partners should be stepped up, especially in relation to free trade agreements, to ensure common risk assessment guidelines and to frame methodological assessment criteria that are harmonised and consistent with the coverage of global risks under the Codex Alimentarius.

4.8. EFSA must also undertake to provide clear instructions and information which will establish a stable and predictable framework for businesses submitting applications.

4.9. In order to ensure that EFSA has access to all the key information on a given dossier, it should be more open to dialogue with the businesses when analysing a given dossier, setting out the initial data available to it and supplementing them with information provided by the businesses involved.

4.10. The EESC feels that regulators, which support EFSA's work, should be made more independent to remind decision makers and the general public of the importance of high quality data, regardless of the source. Greater public scrutiny of EFSA's risk assessment operations from an early stage of the process, as happens through the Stakeholder Engagement Approach, currently ensures a better relationship with all stakeholders.

4.11. The EESC calls for increasingly streamlined and transparent procedures which will go hand in hand with the challenges to be faced in terms of the intellectual property rights of the owners of the data.

4.12. The EESC supports the recent request from EFSA's Advisory Forum for more public investment in research on food safety, so that industry-sponsored research does not give preference to interests other than the public interest and to ensure that consumers have complete confidence in the EU's food risk assessment.

4.13. Where EFSA governance is concerned, the EESC supports the proposal for greater involvement of the Member States in EFSA's governance structure and scientific panels, thereby aligning the composition of EFSA's management board with the Common Approach on Decentralised Agencies and at the same time strengthening structured dialogue with civil society.

## 5. Specific comments

5.1. The EESC welcomes the proposal for a register of studies, provided that it is easily accessible online and includes the identification of the certified experts and laboratories involved, sworn declarations of absence of conflict of interest, the description of the aims and the complexity of the study, the technical and financial resources allocated and their sources, the timescale and procedures for interactive communication adopted, and any verification studies required.

5.2. The reference legislation for laboratory standards is Directive 2004/10/EC, based on the Good Laboratory Practice (GLP) standards drawn up by the OECD<sup>(11)</sup>. The legislation regarding — and operation of — food safety laboratories<sup>(12)</sup> should be accompanied by audit systems on data processing to ensure that the studies reflect reality.

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<sup>(11)</sup> OECD Principles of Good Laboratory Practice.

<sup>(12)</sup> See Regulation (EC) No 882/2004.

5.3. The EESC believes that the agreement between EFSA and the Joint Research Centre should be followed up, especially regarding joint activities on food and feed, alternative methods for protecting animals, combined exposure to chemical substances and mixtures and the collection of basic data for risk assessments. In particular, EFSA and the JRC should develop harmonised scientific methodologies that ensure quality, transparency, comparability, inclusiveness and fairness towards all stakeholders.

Brussels, 19 September 2018.

*The President*  
*of the European Economic and Social Committee*  
Luca JAHIER

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