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

2018/0088(COD) - 11/12/2018 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 427 votes to 172, with 67 abstentions, **amendments** to the 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 and amending and amending eight sectoral legislative acts in terms of transparency and confidentiality.

The matter was referred back to the committee for interinstitutional negotiations.

As a reminder, the proposal for the revision of Regulation (EC) No 178/2002 on general food law (the GFL Regulation") aims to (i) strengthen the transparency rules applicable to the European Food Safety Authority (EFSA), (ii) increase the reliability, objectivity and independence of the studies on which EFSA relies for risk assessment and (iii) improve EFSA's governance and (iv) strengthen risk communication.

The main amendments adopted in plenary concern the following issues:

Risk communication: Members believe that risk management, risk assessment and communication actions shall be based in particular on the thorough application of the precautionary principle. To regain public confidence, they called for a transparent, independent, continuous and inclusive process of risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers.

Parliament indicated that risk communication shall:

- provide information on how the risk management option chosen reflects the degree of uncertainty of the risk assessment, and the level of consumer and animal health and environmental protection it would achieve;
- foster **public understanding** of the risk analysis process, in particular by providing clear and consistent information on the respective tasks, powers and responsibilities of risk assessors and risk assessors;
- promote the **balanced involvement of all interested parties**, including economic operators in the food chain as well as consumers and civil society organisations;
- inform consumers about risk prevention strategies;
- combat the dissemination of false information and sources thereof.

In order to ensure transparent risk management, the Commission and the Member States shall be required to **make public** the draft risk management measures envisaged and the agenda and detailed minutes of the meetings of the Member States' working groups at which the risk management measures are discussed.

Risk assessment: Parliament proposed that the European Chemicals Assessment process shall be carried out as part of a coordinated approach for all sectors concerned. In addition, evaluators shall integrate the assessment of ‘cocktail effects’ into their work.

Studies, including test data, submitted by business operators in support of applications for authorisation shall be based on accessible scientific literature or comply with internationally recognised principles and good laboratory practice (GLP) principles. Data from a test commissioned but not registered shall not be used in a risk assessment.

A **Union register of studies commissioned by business operators** seeking to obtain an authorisation or renewal under Union food law is hereby established. In order to provide an additional level of guarantee ensuring that the Authority can have access to all relevant scientific data and studies available on a subject matter of an authorisation procedure, it is appropriate to provide for a consultation of third parties in order to identify whether other relevant scientific data or studies are available.

To increase the effectiveness of the consultation, the consultation should take place immediately after the studies submitted by industry included in an application for authorisation have been made public, under the transparency rules of this Regulation.

Confidentiality: the amended text introduces a set of criteria for deciding what information may be considered confidential, such as the brand under which the substance will be marketed, and the trade name of the preparations, materials or articles in which it will be used, if any.

Except for information that is considered **toxicologically, ecotoxicologically or environmentally relevant** , the applicant may request certain information submitted under this Regulation to be kept confidential, accompanied by adequate and verifiable justification. The justification shall include verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

Organisation: the Management Board shall be selected in such a way as to secure the highest standards of competence and commitment to the protection of health and the environment and a broad range of relevant experience available amongst the representatives of the Member States, the European Parliament and the Commission.

It shall include (i) **two full and alternate members** appointed by the Commission, (ii) **two representatives appointed by the European Parliament**, and (iii) six full members representing the interests of civil society and the food chain sector, including one representative of public non-governmental organisations specialised in health, farmers' organisations and agrochemical organisations. The maximum term of office for members would be **2.5 years**.

Members of the Scientific Panels shall be appointed by the Management Board for a **renewable 5-year term**. The Executive Director, after consulting the Management Board, shall publish a call for expressions of interest in the Official Journal of the European Union, in the relevant scientific publications concerned and on the EFSA website, and inform the Member States accordingly. This call would set out the specific multidisciplinary expertise needed within each scientific group and indicate the number of experts required.

As 20% of the current national experts are British, the system shall be strengthened, while encouraging applicants to apply, in order to ensure that a sufficient pool of independent experts is available. In order to ensure the effectiveness of risk assessment, EFSA's staffing and financial resources shall be strengthened.

Lastly, using the model of the Board of Appeal of the European Chemicals Agency (ECHA), a **Board of Appeal of EFSA** shall be established by means of delegated acts.