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

2018/0088(COD) - 11/04/2018 - Legislative proposal

PURPOSE: to improve the transparency of scientific studies in the field of food safety.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EC) No 178/2002 on general food law (the GFL Regulation) established the principle of risk analysis as a general principle in EU food law. Risk assessment at EU level is carried out by the European Food Safety Authority (EFSA), independently of the risk management function, which is entrusted to the EU institutions, and more particularly to the Commission.

The GFL Fitness Check and recent public debates have shown that certain aspects of the current legislative framework need to be addressed.

Citizens demand that the risk assessment process in the area of food law (and the decision-making based on it) be more transparent. Transparency and confidentiality rules currently vary depending on the sub-area of regulation concerned. Many stakeholders and citizens complain that the EFSAs evaluations of authorisation applications are essentially based on studies, data and information generated (and paid for) by the applicant for authorisation. Risk communication was also found not to be effective enough.

As announced in the Communication replying to the European Citizens Initiative Ban glyphosate and protect people and the environment from toxic pesticides, this proposal is a targeted revision of the GFL Regulation (and other measures adopted in that framework) in order to improve transparency in risk assessment, reliability, objectivity and independence of studies used by EFSA in its risk assessment, risk communication, and governance of EFSA.

CONTENT: the proposal seeks to amend not only the GFL Regulation but also eight additional sectoral legislative acts relating to the food chain. The main objectives of the proposed amendments are:

- ensure greater transparency by ensuring that scientists and citizens have access to key safety related information being assessed by EFSA at an early stage in the risk assessment. All supporting data and information relating to applications for authorisation are to be made public by EFSA upon receipt, including additional information, with the exception of information for which confidentiality is duly justified;
- improve citizens confidence in the credibility of scientific studies by:
    - i. establishing a Union register of commissioned studies on substances subject to a food law authorisation system, to be managed by EFSA; the register of commissioned studies will have a positive impact on the objectivity of the evidence submitted by industry since it will provide additional guarantee that applicants submit all studies they have performed on a substance whatever their results;
    - ii. providing a pre-submission procedure, by which EFSA may provide advice to an applicant, such advice being made public;
    - iii. providing that at the stage of submission of authorisation application, when all studies are made public according to the new provisions on transparency, a consultation of third parties will be launched with the aim to identify whether other relevant scientific data or studies are available;
    - iv. providing for controls and audits by Commission inspectors in relation to studies;
    - v. introducing the possibility for the Commission to request EFSA to commission studies in exceptional circumstances (e.g. controversies) for the purpose of verification.
- better involving Members States in EFSAs governance structure and scientific panels without touching on its independence: the proposal aligns the composition of EFSAs Management Board with the Common Approach on decentralised agencies by including representatives of all Member States. It will also increase the involvement of Member States in the nomination process of Panels members. The existing strict criteria on independence are maintained and specific provisions require Member States to set up specific measures ensuring that the experts have concrete means to act independently as required by the proposal.
- strengthen risk communication: the proposal ensures a develop a comprehensive and effective risk communication strategy, involving the Commission, Member States and the EFSA throughout the risk analysis process, combined with open dialogue amongst all interested parties.

BUDGETARY IMPLICATIONS: the Commission considers that by strengthening the EFSAs governance and making risk assessment more sustainable, EFSA will continue to play a fundamental role in the Union food safety system and to contribute to the health and well-being of Union citizens and to an innovative and competitive Union agri-food industry.

To address these issues, the Commission has come up with a wide ranging and ambitious proposal requiring a significant increase in the resources available to the EFSA to enable it to discharge its existing and proposed new responsibilities. Member States that provide the EFSA with expertise also need to receive more compensation.

The impact on EFSA's expenditure is estimated at EUR 256.270 million for the period 2020-2024 (staff costs: EUR 56.276 million; operational expenditure: EUR 199.994 million).