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

2018/0088(COD) - 06/09/2019 - Final act

PURPOSE: to improve the transparency of scientific studies supporting marketing authorisation applications in the field of food safety.

LEGISLATIVE ACT: Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

CONTENT: this Regulation amends Regulation (EC) No 178/2002 on General Food Law (GFL Regulation) and eight additional sectoral legislative acts relating to the food chain. Its objective is to make the scientific information on which risk assessment in the food chain and food safety communication are based more transparent and accessible to citizens.

The Regulation originates from the European Citizens' Initiative on Banning Glyphosate and Protecting People and the Environment from Toxic Pesticides, which confirmed concerns about transparency with regard to studies commissioned by industry and submitted as part of authorisation procedures.

Improved risk communication

The Regulation shall ensure transparent, continuous and inclusive risk communication throughout the risk analysis, involving Union and national risk assessors and risk managers.

Risk communication shall aim to:

- raise awareness and understanding of the specific issues under consideration, including in cases of divergences in scientific assessment, during the entire risk analysis process;

- ensure consistency, transparency and clarity in formulating risk management recommendations and decisions;

- provide a sound basis, including, where appropriate, a scientific basis, for understanding risk management decisions;

- improve the overall effectiveness and efficiency of the risk analysis;

- foster public understanding of the risk analysis, including of the respective tasks and responsibilities of risk assessors and risk managers to enhance confidence in its outcome;

- ensure appropriate involvement of consumers, feed and food businesses, the academic community and all other interested parties;

- ensure appropriate and transparent exchange of information with interested parties in relation to risks associated with the food chain;

-ensure the provision of information to consumers about risk prevention strategies; and

- contribute to the fight against the dissemination of false information and the sources thereof.

The Commission shall adopt, by means of implementing acts, a general plan for risk communication in order to achieve the objectives.

Verification studies

The amending Regulation introduces the possibility for the Commission to request the European Food Safety Authority EFSA to commission scientific studies, in exceptional circumstances, to verify the evidence used in its risk assessment process. It also gives a more active role to Member States to help EFSA to encourage more and better scientists to participate in scientific panels.

Protection of confidentiality

Supporting data and information related to an application for authorisation shall be made public by EFSA after an assessment of the validity of the application, unless the applicant demonstrates that such publication could potentially harm his interests and requests confidential treatment by EFSA. The applicant may submit a confirmatory application if he/she disputes EFSA's assessment of confidentiality. In this case, the information shall not be made public until a final decision has been made.

Enhanced governance of the EFSA

The Regulation reinforces the role of the Member States and the efforts and commitment of all parties involved in the EFSA Management Board. In addition to the members and alternates, the Management Board shall comprise: (a) two members and two alternates appointed by the Commission, with the right to vote; (b) two members appointed by the European Parliament, with the right to vote; (c) four members and four alternates with voting rights, representing the interests of civil society and the food chain sector.

The selection of members of the Scientific Committee and Scientific Panels of the Authority by the EFSA Executive Director and their appointment by the Management Board shall be based on strict criteria ensuring the excellence and independence of the experts while ensuring the multidisciplinary expertise required for each Scientific Panel.

Pre-submission advice

The amending Regulation provides for the implementation of a new pre-submission advisory procedure that shall allow EFSA to advise applicants on how to correctly submit their application for authorisation, thus making the process more reliable.

Database and notification of studies

EFSA shall establish and manage a database of studies commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion.

Fact-finding missions

Commission experts shall carry out fact-finding missions to Member States to assess the application by laboratories and other test facilities of the standards applicable to the performance of tests and studies submitted to the Authority in the context of a request.

Those fact-finding missions shall allow the Commission to identify, and to aim to correct, possible weaknesses in the systems and non-compliance and to provide an additional level of guarantees to

reassure the general public on the quality of studies. Based on the conclusions of such fact-finding missions, the Commission may propose appropriate legislative measures aimed at improving compliance with the relevant standards.

ENTRY INTO FORCE: 26.9.2019.

APPLICATION: from 27.3.2021.