

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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## **EU-28**

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### **Proposed New Rules on Transparency and Risk Communication**

#### **Report Categories:**

SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports  
Agriculture in the News

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#### **Report Highlights:**

The European Commission proposed new rules “on the transparency and sustainability of the EU risk assessment model in the food chain” for products that undergo authorizations or receive scientific opinions from the European Food Safety Authority (EFSA). The proposal also sets out a risk communication framework for outreach, seeking to embrace transparency while trying to avoid unintended consequences to consumer confidence.

**General Information:**

The European Commission published [a proposal](#) for a Regulation “on the transparency and sustainability of the EU risk assessment model in the food chain.” This is a revision of Regulation (EC) 178/2002 on the [General Food Law](#). The Commission’s proposal aims to enhance risk communication around EFSA’s work through greater public disclosure and also to strengthen EFSA’s reach and resources. These new disclosure provisions would affect parties requiring EFSA review.

Established by the General Food Law, EFSA is an autonomous agency that undertakes risk assessments for EU-wide food and agricultural product (re)-authorizations. EFSA provides scientific opinions on issues affecting food and feed safety, animal health and animal welfare, plant health, human nutrition, and Genetically Modified Organisms (GMOs) at the request of the European Commission, EU Member States and the European Parliament. In recent years, EFSA has been operating in an environment where many of its science-based regulatory decision-making processes are under intense public scrutiny, particularly for products regulated by the GMO and plant protection regulations. There are eight sectoral legislative acts that would be re-aligned with this proposal:

- Directive 2001/18/EC on the deliberate release into the environment of GMOs;
- Regulation (EC) No 1829/2003 on the use of GMOs for food and feed;
- Regulation (EC) No 1831/2003 on feed additives;
- Regulation (EC) No 2065/2003 on smoke flavorings;
- Regulation (EC) No 1935/2004 on food contact materials;
- Regulation (EC) No 1331/2008 on food additives, food enzymes and flavorings;
- Regulation (EC) No 1107/2009 on plant protection products, and
- Regulation (EU) No 2015/2283 on novel foods.

**Seeking to Strengthen Scientific Engagement by Member States:**

The Commission’s proposal calls for strengthening the scientific cooperation between EFSA and national scientific bodies of the Member States. Only a handful of the 28 EU Member States contribute the bulk of EFSA experts, most of whom come from Italy, the United Kingdom, Germany, France, Netherlands, and Spain. If the Parliament and Council adopt the Commission’s proposal, the appointment of EFSA experts will be made from a pool of nominations put forward by all Member States. The proposal aims to further strengthen the connection between EFSA’s work with national scientific bodies throughout the EU by setting out a standardized framework for risk communication at the Member State level. The proposal calls for harmonizing Member States’ data collection efforts so that it is easier to analyze and compare Member States’ data.

**More EU-funded Studies Envisaged:**

In its proposal, the Commission acknowledged the growing disconnect between 1) the public’s negative perceptions of applicant-funded studies and 2) the value of having industry primarily bear the costs of proving a particular food or feed is safe rather than directing public monies to prove they are unsafe.

This proposal envisages more government-funded studies—highly controversial applications, but commits to keeping the existing system where the applicant bears the costs of proving product safety to access the EU market.

### **Changes to Public Disclosure:**

The Commission proposed several actions it says will find an appropriate balance between greater transparency and protecting commercial interests, e.g. applicants' proprietary information. EFSA would manage a web-based public register of all commissioned scientific studies to facilitate greater public scrutiny of the data EFSA may use in making its risk assessment determinations. The EFSA review process would pro-actively disclose non-confidential data associated with EFSA applications; as such, the Commission would develop a positive list identifying sections of the EFSA applications that are to be public or confidential. EFSA would make non-confidential data available and accessible in an electronic format via its website, with the possibility to download and print. Applicants can challenge the positive list by providing a "verifiable justification" for their confidentiality claims, after which EFSA makes the final decision on the request's validity. EFSA would also introduce a pre-submission procedure so that applicants are aware of all the requirements in the review; this, too, will be publicly available.

### **Next Steps in the Legislative Review Process:**

This legislative proposal falls under the EU's ordinary legislative procedure, whereby the European Council and Parliament will debate and likely amend the proposal. The European Commission aims for this proposal to be adopted by mid-2019. Once adopted, the measure would become applicable 18 months after its publication in the Official Journal of the EU. The Commission's comment period runs through June 19, 2018.

### **Background:**

In 2017, the Commission officially registered the European Citizens' Initiative (ECI) to ban the plant protection product glyphosate. The ECI is a tool for citizen participation and agenda-setting at the EU level. For the Commission to respond, an initiative must receive a minimum of one million signatures, which the glyphosate initiative garnered in mid-2017. In response, the Commission committed to present a legislative proposal in 2018 to increase the transparency and the quality of studies used in the scientific assessment of food and feed. The Commission sought to address public mistrust of scientific studies used in the evaluation of plant protection products, since many European citizens are increasingly uncomfortable with [industry-funded research](#). From January to March 2018 the Commission held a public consultation on this legislative proposal. The Commission affirmed the importance of improving public access to industry studies used by EFSA in its risk assessments. These findings complemented other ongoing efforts by the Commission to improve transparency in the decision-making process, including a "fitness check" of the General Food law. This **fitness check** or Regulatory Fitness and Performance program ([REFIT](#)) is an ongoing program to keep all EU legislation under review and ensure that it is "fit for purpose." The review process of the General Food Law identified the need for sufficient scientific capacity by having a wider range of scientific experts for EFSA, as well as enhanced scientific cooperation with national scientific organizations to increase the involvement of the Member States.

### **For More Information:**

[https://ec.europa.eu/food/safety/general\\_food\\_law/transparency-and-sustainability-eu-risk-assessment-food-chain\\_en](https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en)

