

**Voluntary Report** – Voluntary - Public Distribution

**Date:** April 21, 2021

**Report Number:** E42021-0039

**Report Name:** EU Transparency Regulation Enters Into Force

**Country:** European Union

**Post:** Brussels USEU

**Report Category:** SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

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**Report Highlights:**

On March 27, 2021, the EU's Transparency Regulation (2019/1381) went into force. The Regulation intends to enhance transparency of risk assessment in the food chain by increasing the independence of scientific studies, strengthening the governance of the European Food Safety Authority, and developing comprehensive risk communication. This Regulation amends the General Food Law and impacts eight sectoral legislative acts across the agri-food industry. To improve transparency, the Regulation also allows the public disclosure of scientific information and studies early in the risk assessment process, a significant confidential business information concern of U.S. companies registering products in the EU.

## General Information:

The European Commission developed the “Transparency Regulation” (TR) – [Regulation \(EU\) 2019/1381](#) with the intent to improve risk assessment transparency in the food chain for products that undergo authorizations or receive “Scientific Opinions” from the European Food Safety Authority (EFSA). Enforcement of the Regulation began on March 27, 2021. It includes an amendment to the General Food Law in response to a European Citizen’s Initiative (ECI) that called for greater EFSA risk assessment transparency. The TR intends to enhance the independence of studies, strengthen the EFSA regulatory governance, and develop comprehensive approaches to risk communication. For background on the TR, please see the following GAIN reports:

- [June 2018: Proposed New Rules on Transparency and Risk Communication](#)
- [May 2019: EU Adopts Regulation on Transparency in Food Chain Risk Assessments](#)

The TR addresses four pillars:

1. The **sustainability and governance** of EFSA to strengthen the scientific capacity of the risk assessment body, including throughout the Member States and their representation in EFSA’s management board as well. The organizational changes at EFSA will apply as of July 1, 2022.
2. **Improve risk communication** on how the risk management body (European Commission) takes decisions based on the outcome of the risk assessment authority (EFSA). The Commission will have to come up with a general plan on risk communication by means of implementing acts, but there are no further details yet regarding content or timelines.
3. Concerns about the **quality and reliability** of studies used in the evaluation of plant protection products, especially for any bias in the studies from industry or companies. The applicants must notify in advance all the studies for EFSA review to ensure that all relevant information is provided and deter against unfavorable studies being omitted from a submitted dossier.
4. Increasing the **transparency** of EFSA’s risk assessment process by disclosing information early in the risk assessment process, immediately after the acceptance of the applicant’s submission dossier. EFSA may grant confidential treatment of business information from a horizontal list of items (Article 39.2 of the TR) for which the applicant can demonstrate that the disclosure of information would potentially harm its interests to a significant degree.

On March 30, 2021, the European Commission, EFSA, and the Portuguese Council Presidency jointly organized a [celebratory virtual event](#) initiating the TR and focusing on the potential next steps in the transformation of the EU risk assessment process of the food chain.

## Implementation of the TR in the Agri-Food Sectors:

The TR amends the General Food Law and impacts eight sectoral legislative acts across the agri-food industry. As of March 27, 2021, the Commission has reviewed almost all relevant sectoral acts in order to be in line with the TR.

The eight legislative acts and the respective revised implementing regulations are:

- 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:
  - [Commission Implementing Regulation 2020/1773 on the assessment and the authorisation of 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;
  - [Commission Implementing Regulation 2020/1823 establishing a common authorisation procedure for food additives, food enzymes and food flavourings](#)
  - [Commission Implementing Regulation 2021/148 for the re-evaluation of approved food additives](#)
- Regulation (EC) No 1107/2009 on plant protection products, and
  - [Commission Implementing Regulation 2020/174 for the implementation of the renewal procedure for active substances](#)
- Regulation (EU) No 2015/2283 on novel foods:
  - [Commission Implementing Regulation 2020/1824 concerning traditional foods from non-EU countries](#)
  - [Commission Implementing Regulation 2020/1824 for applications referred to in Article 10 on novel foods](#)

EFSA provides for “Practical Arrangements” that explain how it implements the legal framework provided by the TR and can be found on the [their website](#). Also, on the website, there is further information on transparency and confidentiality. For plant protection products, additional details are also set out in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 on confidentiality.

### **Key Changes for Applicants of the New Implementing Regulations:**

- The applicant needs to notify the intended studies during the pre-submission phase and seek advice on them from EFSA.
- The full dossier will be made publicly available – the whole content is disclosed for public access.
- There will be a public consultation on the dossier.
- The online submissions are happening via a central submission system using the IUCLID software package (standard data formats).
- There is also a new window for applicants to submit comments and information at the end of the peer review and they can submit comments to EFSA on the draft conclusion.

### **Concerns:**

Stakeholders welcome greater transparency, but there are some notable applicant concerns over the disclosure of scientific information and studies submitted to EFSA. Other issues concern the timing of the disclosure and the nature of the data to be released publicly. The EFSA review process will disclose information at a very early stage of the risk assessment process. The Commission’s reasoning is that this will allow for greater public scrutiny of the data that EFSA uses in its risk assessments.

Regulation (EU) 2019/1381 also introduced requirements for transparency and rules for the submission of confidentiality requests. Applicants can submit a “verifiable justification” for a list of categories provided in the regulation in order to protect Confidential Business Information (CBI), but claims need to be assessed and then approved on a case-by-case basis.

In addition, some criteria allow CBI documents older than five years to be made available for public release; however, in some cases industry argues that CBI protections should be permanent. An applicant also needs to demonstrate ‘significant harm’ when sensitive information is disclosed. However, quantifying the actual damage of public exposure for CBI and other sensitive information is difficult. U.S. companies are likely to be affected - particularly those with European affiliations and especially as applications are submitted to EFSA for approval of substances or products in Europe.

For more information on the implementation of the TR:

[https://ec.europa.eu/food/safety/general\\_food\\_law/implementation-transparency-regulation\\_en](https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en)

**Attachments:**

No Attachments.