

NEW LEGISLATION ON TRANSPARENCY AND SUSTAINABILITY OF THE EU RISK ASSESSMENT MODEL IN THE FOOD CHAIN

- **Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 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**

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→ **Entry into force:** 26/9/2019

→ **Date of application:** 27/3/2021

(1/7/2022 for amendments to Articles 25 and 28 of Reg. 178/2002 concerning EFSA's Management Board and Scientific Committee & Scientific Panels)

→ **Amendments** to Regulation (EC) No 178/2002 ("General Food Law") and to 8 EU legal acts dealing with specific sectors of the food chain, including the Feed Additives (Regulation (EC) No 1831/2003)

➤ **Why this new Regulation ?**

→ Fitness check of the General Food Law:

- Perception by civil society of lack of transparency / independence as regards evaluation procedures of regulated products
- Need to maintain a high level of scientific expertise in EFSA
- Need to improve risk communication

→ European Citizens' Initiative "Ban glyphosate" (2017)

- Concerns on transparency in the EU risk assessment and on quality/independence of scientific studies
- Commission's commitment (December 2017) to introduce a legislative proposal – Proposal submitted in April 2018

➤ **The new Regulation contains 4 pillars:**

→ Sustainability & Governance of EFSA

→ Quality & Reliability of studies

→ Improved risk communication

→ Transparency of EU risk assessment

➤ **Pillar “Quality & Reliability of studies”**

→ General pre-submission advice on the applicable rules and the required content of an application dossier, to be provided by EFSA upon request by an applicant

→ Notification of commissioned studies: obligation for applicants and laboratories when studies are commissioned + creation of a database of commissioned studies (allowing double-check by EFSA on submission of studies)

→ Public consultations:

- on all submitted studies during the risk assessment
- for renewal of existing authorisations: on planned studies at pre-submission phase. EFSA to give tailor-made advice to applicant on the content of the renewal dossier/design of the studies

→ Fact-finding missions by the Commission to ensure compliance of laboratories and studies with relevant standards (within 4 years after entry into application: 28/3/2025)

→ Possibility for the Commission to ask EFSA to commission studies (“verification studies”) in exceptional circumstances to verify evidence used in the risk assessment process

➤ **Pillar “Transparency of the EU risk assessment”**

→ Studies/data supporting any request for a scientific output (including applications for authorisation) are

- ✓ To be made public **proactively and automatically**, in an easily accessible format through EFSA’s website
- ✓ **Early on** in the risk assessment process (when an application is found valid or admissible)
- ✓ **Except** for duly justified confidential information

→ This is without prejudice to existing intellectual property rights and data exclusivity rules

→ Standard data formats for applications to be developed (and to be adopted through implementing acts)

→ Confidentiality claims will be assessed by EFSA:

- ✓ **Closed positive lists** of information that may be treated as confidential, upon verifiable justification proving significant harm to commercial interests
- ✓ **Specific procedure** is laid down for confidentiality decision

➤ **Pillar “Sustainability and governance of EFSA”**

→ Each Member State will nominate a representative to the Management Board of EFSA, meeting specific requirements and selected on the basis of relevant experience and expertise in the field of the food chain legislation and policy, including risk assessment + strict criteria of independence.

→ Strengthening of scientific cooperation between EFSA and national scientific organisations

→ Amendments to Articles 25 and 28 of the General Food Law

- Provisions of the Animal Nutrition legislation which are directly affected by Regulation (EU) 2019/1381

1. Regulation (EC) No 1831/2003 (Feed Additives)

• New Article 7(1):

*“An application for an authorisation as provided for in Article 4 of this Regulation shall be sent to the Commission, **in accordance with standard data formats; where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply mutadis mutandis.** The Commission shall without delay inform the Member States and forward the application to the European Food Safety Authority (hereinafter referred to as the “Authority”).”*

• New Article 7(2)(c):

*“[The Authority shall:]
(...) (c) **make public the application and any information supplied by the applicant, in accordance with Article 18.**”*

(Current text: “(...) make the summary of the dossier mentioned in paragraph 3(h) available to the public, subject to the confidentiality requirements laid down in Article 18(2).”)

- **New Article 18 on Transparency and confidentiality:**

“1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.

2. In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and in this Article, the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification. The Authority shall assess the confidentiality request submitted by the applicant.

3. In addition to the items of information referred to in Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following items of information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:

(a) the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) of, and Annex I to, this Regulation; and

(b) specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.

4. *This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.* [= Rules on access to documents]

2. Commission Regulation (EC) No 429/2008 (“Guidelines”)

- Will need to be aligned to the new rules
- Examples: the form used for the application for authorisation will have to comply with the future “standard data format” – modification of the procedure and rules concerning confidentiality of application dossiers – provisions on renewal of authorisations

3. EFSA’s guidance documents

- Will need to be aligned to the new rules

→ Preparatory work by the Commission and EFSA has started in order to be ready by the date of application of the new Regulation (27/3/2021).

→ Further information on SANTE/EUROPA:

https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en