

Data Disclosure: Will The New GFL Ensure Transparency Without Jeopardizing EU Competitiveness?

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The controversy surrounding the safety evaluations of glyphosate by public European bodies, in particular the European Food Safety Agency (EFSA), has had its impact on the EU General Food Law reform, Katia Merten-Lentz, partner at Keller and Heckman, suggests. On June 13th, following the approval by the European Parliament on 17 April 2019, the Council formally adopted a new Regulation on the transparency and sustainability of the EU risk assessment in the food chain.

The new Regulation aims at increasing the transparency of the EU risk assessment in the food chain and strengthening the reliability, objectivity and independence of the studies used by EFSA. Harmonization appeared as a priority, given that transparency and confidentiality rules vary depending on the sub-area concerned. However, some raised concerns concerning competitiveness, innovation and jobs in the EU agri-food sector.

Transparency commitments and access to document policy

The new Regulations amends the General Food Law Regulation to ensure that the Authority carries out its activities with a high level of transparency.

As a result, EFSA shall make public, without delay: agendas and minutes of the Scientific Committee and the Scientific Panels; scientific opinions and the information on which they are based; declarations of interest by members; results of its scientific studies; the annual report of its activities; and requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification¹. EFSA will also shows its commitment to openness and transparency by proactively seeking stakeholders' input² and opening meetings of its Scientific Committee and Panels to observers.

However, EFSA documents which are not publicly available can only be accessed upon request to the Executive Director. The applicant must specify a request in a sufficiently precise manner to enable EFSA to identify the requested document(s)³. EFSA may refuse access to documents for various reasons, such as when disclosure of that information might seriously harm the commercial and financial interests of the applicant. EFSA could also consider that there is no overriding public interest justifying disclosure or that access was not necessary to verify the scientific risks assessment carried out.⁴

Openness and transparency rules guarantee legal certainty for any food business operator willing to place new innovative products on the EU market.

Discussion on the publication of studies at an early stage

The European Parliament supported the view that all supporting data and information relating to applications for authorization should be made public by EFSA upon receipt.⁵ Members of Parliament (MEPs) discussed whether



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studies would be published in full at the beginning or the end of the authorization process and exact details of what information can be kept private. Divisiveness among them resulted in Rapporteur Sommer's resignation in December 2018.

According to the Council, all supporting data and information linked to an application for authorization should be made public by EFSA after the assessment of the validity of the application. EFSA would consider the validity of a confidentiality request and communicate the results to the applicant. If the applicant disagrees with EFSA's position, it could file a confirmatory request. In this case, the information cannot be made public until a final word is said

Finally, all studies and information supporting a request for a scientific output by EFSA will automatically be made public when an application is validated or found admissible. This must be done at the very early stage of the risk assessment process.

Public access to information and competitiveness

In 2017, in response to a European Citizens' Initiative (ECI) concerning glyphosate, the European Commission agreed with the request to ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry.⁶

The new rules will grant EU citizens greater and easier electronic access to information submitted to the food safety authority, with the possibility to search, download and print the studies.

Such an "open" transparency is seen as a strong incentive for companies to provide accurate and up-to-date data. However, third countries competitors could also easily check the Internet for copying innovative product developments in the food sector in the EU. Given the comparatively long approval procedures at EFSA, they could even launch a product copy on the international market during this time.⁷

Even if confidential information can be protected in duly justified circumstances, data protection remains a strategic issue when applying for an authorization. Here the EU food industry relies only on EFSA's willingness and accuracy when assessing confidentiality claims and requests to access documents. Early stage publications require rather a strong legal framework and legal certainty to balance both industry and citizen interests.

The new Regulation is expected to be published in the Official Journal on **6 September 2019**. Following its entry into force 20 days after publication, it will become applicable 18 months later (**by end of March 2021**).

This article was written with support from Caroline Commandeur, legal consultant at Keller and Heckman.

[1] Article 38 of Regulation No 178/2002

[2] Stakeholder Consultative Platform and an annual Stakeholder Conference

[3] EFSA, Decision concerning access to documents, MB 16.09.2003

[4] Article 4 of Regulation (EC) No 1049/2001 and Judgment in Cases T-716/14 Anthony C. Tweedale v European Food Safety Agency (EFSA) and T-329/17 Hautala and Others v EFSA

[5] except for duly justified confidential information

[6] January 25th, 2017 - Ban glyphosate and protect people and the environment from toxic pesticides, ECI(2017)000002

[7] See Gerardo Fortuna, MEPs ready to negotiate EFSA's transparency rule, but need to find a new negotiator, EURACTIV.com, Dec 2019.

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