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EU Adopts Regulation on Transparency in Food Chain Risk Assessments

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Report Highlights:
During its last plenary session in April 2019, the European Parliament has adopted the draft regulation to increase transparency and sustainability of risk assessment in the food chain. Following the Council's formal adoption, the publication of the regulation in the Official Journal will happen over the summer according to a Commission official. If so, it will enter into force 18 months later, which means by the end of 2020 at the earliest. The main elements of the agreement aim at ensuring more transparency, increasing the independence of studies, strengthening the governance of the European Food Safety Authority as well as developing a comprehensive risk communication.

Background:
In April 2018, the European Commission presented its proposal for a Regulation "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 Commission's proposal is an amendment of the General Food Law and is a result of a review of the regulation as well as a response to a European Citizen's Initiative (ECI)[1] that called for greater transparency of the risk assessments carried out by the EFSA. The main elements of the agreement aim at ensuring more transparency, increasing the independence of studies, strengthening the governance of EFSA as well as developing comprehensive risk communication. The regulation will have an influence on eight sectoral legislative acts across the agri-food industry, including:

- 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.

Considering the political pressure following the controversial debate on glyphosate, the European Commission pushed the European Parliament (EP) to move the proposal forward in order to finalize the procedure before the end of its term in April 2019. By February 2019, the European Council and Parliament reached a provisional agreement on the text. The complete legislative procedure has taken about a year, since the EP has now formally adopted the draft regulation during its last plenary session. The only step left is the formal adoption by the Council of Ministers. The regulation is expected to be published in the Official Journal in the summer. It will enter into force 18 months later, at the earliest by the end of 2020. The organizational changes at EFSA will only apply as of July 1, 2022.

The Four Pillars
The draft regulation will address four pillars:

- The **sustainability and governance** of EFSA in order to allow the risk assessment body to continue to do its job by strengthening its scientific capacity throughout the different Member States including their representation in EFSA's management board as well.

[1] 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.

- Concerns about the **quality and reliability** of the commissioned studies used in the evaluation of plant protection products, with regard to the independence of studies from industry or companies. The Commission sought to address public mistrust of these scientific studies, since many European citizens are increasingly uncomfortable with industry-funded research. The applicants need to notify all the studies to EFSA in advance to ensure that companies will submit all relevant information and not hold back unfavorable studies.

- The concerns of the general public to show how EFSA performs risk assessments by increasing the **transparency** of its risk assessment process. It means that applicants will have to disclose information early in the risk assessment process, immediately after the acceptance of their submission dossier by EFSA. However, EFSA may grant confidential treatment of business information from a horizontal list of items (Article 39.2) included in the draft regulation for which the applicant can demonstrate that the disclosure of information would potentially harm its interests to a significant degree.

- **Improve risk communication** on how the risk management body (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 they have no further details yet regarding content or timelines.

Concerns for Applicants

Although stakeholders, in general, welcome greater transparency, there are some major concerns about the disclosure of scientific information and studies from the EFSA applications submitted by individual companies, especially with regard to the timing of the disclosure and the nature of the data to be published.

The EFSA review process would pro-actively disclose non-confidential data associated with EFSA applications, as soon as EFSA has considered an application valid or admissible. This is 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. However, there are concerns that this could lead to false interpretations of scientific data by non-scientists and therefore politicize the EFSA outcome even before the final decision is made.

In addition, companies have some concerns about the protection of commercial interests, such as the applicants' proprietary business information. Although the idea is that EFSA would only disclose non-confidential data, applicants will have to provide a "verifiable justification" for their confidentiality claims, after which EFSA makes the final decision on the request's validity. The disclosed information will be accessible in an electronic format via the EFSA website, with the possibility to download and print. Competitors or copycats may have access to valuable information for their own business development. Article 39 of the draft regulation lists the items for which the applicants can request confidential treatment when demonstrated that the release of such information could potentially harm its interests to a significant degree. Stakeholders are pleased that this list of items has been broadened with some additional specifications during the negotiations, but it is still too early to tell whether and how this will affect their approach to innovation. These items are referring to the manufacturing process, including methods and innovative aspects, as well as other technical industrial specifications and the

quantitative composition of the subject matter. In addition, some commercial links and information regarding market shares, business strategy may also be considered confidential. This is reflected in all sectoral legislations. It will be protected under "Union law" instead of "Union food law", also broadening the scope of information that can be protected.

This could potentially affect the U.S. companies with European affiliations as well, especially within the agrochemical industry, since they submit applications to EFSA for approval of substances or products in Europe. The companies themselves are rather skeptical about the current outcome given the uncertainty surrounding business disclosure, while the European Crop Protection Association (ECPA) reacted positively. ECPA, who represents the European agrochemical industry in Europe, welcomes transparency but also believes that the outcome of the negotiations could have been a lot worse for their members in terms of disclosure of confidential business information. In other agri-food sectors in the EU, stakeholders seem to be carefully optimistic as well about the final text of the regulation, but it is still too early to draw conclusions before its actual implementation.

For More Information on the content:
https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en
GAIN report: Proposed New Rules on Transparency and Risk Communication