

Transparency and sustainability of the EU risk assessment model in the food chain

Cefic welcomes the Commission legislative proposal of 11 April aiming at increasing transparency and independence in the EFSA risk assessment process. We support transparency for better risk management. However, where transparency is not needed to prevent harm to human and animal health or the environment, there should be room for businesses to protect commercially valuable information (CBI).

❖ Review of Confidentiality Requests lacks procedural safeguards

The Commission proposes that for confidentiality to be preserved, the applicant has to provide a “verifiable justification”¹ that disclosure would “*significantly* harm the interests concerned”.

This requirement implies that harm to commercial interests is not enough; it should be *significant*. Combined with the need for ‘verifiable’ proof, this may effectively bar industry from any sort of confidentiality protection. Indeed, as long as the data is confidential, the harm remains only potential and cannot be verified.

In turn, if the request for confidentiality is rejected by EFSA, the operator will only have the opportunity to express disagreement with such decision; not to request for internal review.

Article 39, b), paragraph c, of the proposal only grants the operator requesting a confidentiality treatment a right to be heard. This is confirmed pursuant the provision of Article 39c on the review of confidentiality.

Given the significant impact that a decision rejecting a confidentiality claim can have, additional procedural safeguards should be foreseen: this could be achieved by including a ‘request for review’; similar to that existing under REACH², where the operator has the right to contest a negative decision at a higher administrative level within the Agency. The access to such remedy, i.e. the right to bring an administrative appeal before the high level of EFSA, would allow the applicant to ask the Authority for a review of the rejection decision³. As a result, the protection of CBI would be improved, preserving this way the interests of the industry, if so required.

Without such remedy, the uncertainty relating to CBI protection is likely to discourage potential applicants and hamper the stimulation for economic growth in the EU market.

¹ See [Article 39 \(2\) on Confidentiality](#) of the proposal for an amendment of the General Food Law.

² Article 3 ‘Request for review’: [Decision establishing remedies for reviewing a partial or full rejection of a confidentiality request pursuant to article 118\(3\) of REACH Regulation.](#)

³ Registrant’s right to ask ECHA to review the rejection decision (<https://echa.europa.eu/regulations/reach/registration/publishing-information-from-dossiers>)

❖ Aarhus Emissions Rule⁴ risks undermining Sector-specific confidentiality safeguards

The Commission proposes including a reference to the Aarhus Emissions Rule in Article 41 of the General Food Law.

In the light of recent EU case law⁵ and remaining uncertainties around the concept of *'information on emissions into the environment'*⁶, the chemical sector is concerned that such reference will give away any possibility to protect CBI submitted for regulatory purposes⁷.

Such reference risks rendering ineffective the existing confidentiality safeguards under sector-specific legislation. We therefore invite the co-legislators to weigh the risks entailed by this reference to the Emissions Rule for the protection of CBI. Likewise, we kindly request that a reconciled interplay between the aimed increased transparency and the CBI protection⁸ is considered to avoid sector-specific legislation turning ineffective.

❖ Early publication of studies

Cefic is concerned that proactive automatic disclosure on EFSA website of confidential and non-confidential business information at the time the application is submitted would reveal individual business strategies to all competitors in the market.

The separation of risk assessment and risk management, and the independence of the scientific risk assessment is at stake; publication of studies will likely foster a public – or even political - debate, before the scientific risk assessment has started.

❖ Importance of CBI protection for industry innovation and competitiveness

Operators⁹ are required to submit dossiers to EFSA in view of the applications for authorization, including very detailed data packages. These dossiers may contain commercially sensitive information, which is a significant component of a company's valuable business assets.

The possibility that CBI submitted to EFSA may be disclosed to the public at an early stage of the risk assessment process, and so become available to unfair use, can be a disincentive for innovation and investment in research and development - and can detract from a more structured sharing of data between interested parties.

This may lead to lower competitiveness of the industry and can even jeopardize the survival of companies by providing competitors with an unfair competitive advantage

In our view, transparency of regulatory data should be fostered in line with the following key principles:

Predictability

Industry needs to know in advance if, how and when the data submitted will be disclosed to third parties.

⁴ Article 6.1 of the EU Aarhus Regulation (1367/2006), regarding the definition of 'information on emissions into the environment'.

⁵ CJEU ruled for a broader interpretation of the definition of 'information on emissions' ([C-673/13 P](#))

⁶ 'Glyphosate Case' ([C-545 11/RENV](#)), whereby the EU General Court is now requested to re-assess the definition provided by the CJEU in the case of Appeal, as well as to define the application of such concept.

⁷ Under the Aarhus Emissions Rule, an overriding public interest in disclosure shall be deemed to exist where the information requested relates to emissions into the environment, even if this is considered CBI.

⁸ Similarly, to what it was mentioned by Advocate General Kokott in her Opinion on Case, C-673/13 P. See [para. 60](#): "The emissions clause cannot thus be applicable to the information referred to in Article 63(2) of the Plant Protection Regulation. A decision on access to such information must therefore be taken pursuant to the third sentence of Article 4(2) of Regulation No 1049/2001 and Article 6(1) of the Aarhus Regulation based on an assessment of the individual case."

⁹ Operators also referred to as applicants for an authorization procedure carried out under EFSA's remit.

Fairness

A fair balance between the right of the public to access to the information and the right to confidentiality and protection of professional and business secrecy and of property rights is highly important, as reflected under EU law¹⁰. Hence, the protection of confidentiality is particularly relevant for data submitted by companies in the context of regulatory procedures.

Proportionality

The scope and manner in which data is disclosed to the public or to a third party should be proportional to the interests at stake. The risk of commercial harm is more immediate where the data is proactively disseminated to the public (typically on a website) upon their request¹¹.

Coherence

The implementation of the proposed amendments to the confidentiality provisions of Article 39 (a) to (g) of the General Food Law (hereinafter GFL), and which also concern the eight sectoral legislative acts tackled by this initiative, should be coherent with other areas of EU law and with international agreements concluded by the Union. Thus, such implementation should not undermine the protection of confidentiality as provided in other sector-specific EU legislation.

Finally, it should be consistent with the TRIPS agreement¹², and in particular Art. 39(3) thereof, which requires the EU to protect the secrecy of undisclosed data subject to two exceptions: where disclosure is necessary to protect the public or where steps are taken to ensure the data is protected against unfair commercial use.

For more information please contact:
Susana-Beatriz Lores Tercero, Legal Manager, Cefic,
+32 2.436.93.23 or slt@cefic.be

About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies in Europe, which provide 1.2 million jobs and account for 17% of world chemicals production.

¹⁰ See provisions in Art. 339 TFEU, Art. 7, 15, 16, 17 and 41(2)(b) Charter of Fundamental Rights of the EU.

¹¹ Dissemination of data through the Internet increases the risk of unfair commercial use by competitors, as it will be extremely difficult for companies to control the use that is made of published data. If the data is not protected by IP rights but contains CBI, it will often lose its value upon publication.

¹² International legal agreement on Trade-Related Aspect of Intellectual Property Rights between all the member nations of the World Trade Organization (WTO).