European Food Safety Authority

Staff Working document

Non-paper

This non-paper outlines key concepts of the forthcoming Practical arrangements implementing Articles 38(1) and 39d(5) of Regulation (EC) No 178/2002 with the aim of gathering input and comments from Member States' experts. It sets out the position of EFSA's services on 18.02.2020 and may not be interpreted as representing EFSA's position.

1. Background and procedure

Openness and transparency of the EU risk assessment process in the food chain contributes to greater legitimacy of the Authority in pursuit of its mission, strengthens confidence in the Authority's work and, ultimately, ensures its democratic accountability *vis-à-vis* consumers, business operators and the public.

The Authority is fully committed to carrying out its mission taking as a basis the highest possible standards of transparency, while protecting the legitimate interests and rights of business operators.

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[1] (hereinafter "Transparency Regulation") further enhances the Authority's ability to carry out its risk assessment functions in accordance with the highest transparency standards in a proactive manner.

To ensure the highest level of transparency, legal certainty and accessibility, the present practical arrangements should take the form of a decision of the Authority's Executive Director.

2. Subject matter

In view of the interconnected nature of EFSA's proactive public disclosure obligations and confidentiality requirements, and to offer all interested parties including business operators a comprehensive overview of the applicable regulatory framework and the relevant procedures, the Authority considers it appropriate to adopt a single document laying down practical arrangements applicable to both proactive-transparency-related and confidentiality-related processes.

[1] 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, PE/41/2019/REV/1, OJ L 231, 6.9.2019, p. 1–28.

3. Proactive disclosure and IT standards

Information, documents and data listed under Article 38(1) of the GFL Regulation should be made publicly available by the Authority in a proactive manner in a dedicated section on its website with the exception of information awarded confidential status.

That dedicated section of the website must be publicly available and easily accessible. The information, documents and data to be publicly disclosed pursuant to Article 38(1) of the GFL Regulation must be available to be downloaded, printed and searched electronically.

Where information, documents and data are submitted by business operators in support of an application/notification or any other request for scientific output by EP/COM/Member States, such information, documents and data are to be made publicly available first in non-confidential version as submitted by the business operators, and later updated with documents implementing EFSA's decisions if confidentiality requests are submitted.

Prior to obtaining access to the information or data in question, interested users should provide clear undertakings or signed statements that disclosure should not be considered to be explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules.

4. Confidentiality requests

Article 39 of the GFL Regulation sets out specific requirements as to the types of information that may qualify for confidential treatment under certain conditions and only with regard to items inserted in the closed list in paragraph 2 of this Article. To address sectoral specificities, sector specific closed positive lists are outlined in Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 1935/2004, Regulation (EC) No 1331/2008, Regulation (EC) No 1107/2009, Regulation (EU) 2015/2283 and Directive 2001/18/EC.

5. Scope of Practical Arrangements for confidentiality decision making

These arrangements should be applicable, amongst others, to all business operators submitting scientific data, studies and other information, including supplementary information to the Authority in support of applications or notifications or in support of, or accompanying, requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, where appropriate mutatis mutandis.

Where such scientific data, studies and other information are submitted by business operators, they should be submitted electronically and be compatible with certain minimum IT requirements, including machine-readability, to allow the Authority to proceed with the public disclosure of the submitted information, in accordance with Article 38(1).

These arrangements regulate all EFSA confidentiality decision making processes, except for:

1. confidentiality requests submitted to, and assessed by the national competent authorities, under Article 25 of Directive 2001/18/EC, or under Article 7 of

Regulation (EC) No 1107/2009. The latter shall be assessed by the Member States in light of the Authority's practical arrangements for national competent authorities adopted in accordance with Article 7(3) of the aforementioned Regulation;

2. Where an opinion by the Authority is not required in accordance with Article 3(2) of Regulation (EC) No 1331/2008, the present decision does not apply to information submitted in support of applications under the latter Regulation. In those instances, it is for the Commission to assess the relevant confidentiality requests, while the information remains accessible under Regulation (EC) No 1049/2001;
3. Where an opinion by EFSA is not requested by the Commission under Regulation (EU) 2015/2283.

6. Proactive dissemination of environmental information

The provisions on proactive dissemination laid down in the GFL Regulation and the relevant assessment of confidentiality requests should not affect the rights stemming from Regulation (EC) No 1049/2001[2] and, where environmental information is concerned, the rights enshrined in Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (henceforth the "Aarhus Regulation").[3]

Any information falling under the definition of "environmental information" pursuant to Article 2 of Aarhus Regulation should not be treated as confidential since, in accordance with Article 4 of that Regulation, the Authority is required to make such information available to the public.

7. Submission of confidentiality requests

When submitting confidentiality requests, the concerned individuals should do so by:

1. submitting confidentiality requests only via the IT tool(s)
2. avoiding modifying or complementing confidentiality requests

Without prejudice to the possibility of charging certain costs to requestors, submission of confidentiality request is not subject to the payment of a fee.

8. Minimum content of confidentiality requests

When submitting confidentiality requests, the concerned individuals should provide:

1. a clear identification of the relevant parts of the submitted information that, in their opinion, qualify for a confidential treatment.

[2] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43–48.
[3] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies OJ L 264, 25.9.2006, p. 13–19.

2. a text explaining why the information should be granted confidential status. This shall include at least an explanation or justification as to why the following cumulative requirements are deemed to be satisfied:
    a. the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons;
    b. the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree;
    c. explanation or evidence demonstrating to the satisfaction of the Authority that the harm that may be caused is of a significance corresponding at least to 5% of their total turnover for legal persons, or earnings for natural persons. If the harm is quantified as not reaching this percentage, the person shall provide a specific reason on why they considered that any public disclosure would potentially harm their interests to a significant degree.
    d. the document, information or data for which confidentiality treatment is requested is worthy of legal protection in the form of the award of the confidentiality status;
    e. the confirmation that the document, information or data for which confidentiality status is requested does not fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation.
    f. the confirmation that the document, information or data for which confidentiality status is requested has not been finalised more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason on why public disclosure of that information would still potentially harm its interests to a significant degree.

9. Working Languages

In making proactively available on its website the information items listed in Article 38(1) of The GFL Regulation, the Authority should comply with its Decision on the Linguistic Regime applicable to its operations.

The Authority is committed to multilingualism and ensuring that Europe's cultural and linguistic diversity and heritage is safeguarded and enhanced. As such, the Authority should make every effort to reply to applications in the language in which they are submitted, when requested to do so.

10. EFSA confidentiality decisions

EFSA shall assess confidentiality requests in accordance e.g. with the following principles:

1. Case-by-case analysis of requests;
2. Non-disclosure of information claimed confidential pending the assessment of confidentiality requests;
3. Notification of decisions via the IT tool;

4. Moment of receipt of request - completeness of application;
5. Assessment of confidentiality requests submitted in reply to requests for additional information of clarifications in a single decision when scientific evaluation is over.
6. The following information, with the exceptions for names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information deemed to significantly harm the privacy and the integrity of those persons, is made public:
    i) name and address of applicant,
    ii) the names of authors of published or publicly available studies supporting such requests; and
    iii) the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the subject matter.

11. Legal remedies against negative decisions

Effective legal remedies should be made available to applicants affected by the Authority's decisions on confidentiality requests. Confirmatory applications are made available to recipients of negative or partially negative confidentiality decisions.

The possibility to submit a confirmatory application with respect to a confidentiality decision of the Authority should be deemed to represent a more recent, and more specific, provision replacing the option of triggering an administrative review of the Authority's decision by the European Commission, pursuant to, respectively, Article 36 of Regulation (EC) No 1829/2003, Article 19 of Regulation (EC) No 1831/2003, Article 14 of Regulation (EC) No 1935/2004, Article 13 of Regulation (EC) No 396/2005[4] or Article 6 of Regulation EC No 1937/2006.

Recipients of a decision in response to a confirmatory application may file an action for annulment under Article 263 TFEU or, in the alternative, for any citizen of the Union or any natural or legal person residing or having its registered office in a Member State, a complaint for maladministration to the European Ombudsman pursuant to Article 228 TFEU.

12.EFSA decisions on confirmatory applications

In assessing confirmatory applications, EFSA shall comply with the following principles:

1. It will consider only points of law only, thereby excluding submission of new requests or changes to the factual background initially submitted;
2. Confirmatory applications shall have suspensive effect on the confidentiality decision against which they are submitted;
3. EFSA will ensure that staff working on its decisions on confirmatory applications did not work on the confidentiality decision against which it was submitted;
4. The possibility to submit a confirmatory application is deemed to represent *Lex specialis vis-à-vis* "administrative review clauses" available in certain EU Food Regulations and internal review under the Aarhus Regulation

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OL 70, 16.3.2005, p. 1–16.

13. Personal data and regulatory data sanitisation

Applicants and business operators are required to provide EFSA with versions of the documents with personal data already pre-sanitised.

14. Withdrawal of applications

Applicants have the possibility of withdrawing their applications which, depending on the moment this is done, has different effects on the confidentiality and transparency processes:

Withdrawal prior to the adoption of the corresponding confidentiality decision by EFSA results in:

a. Deletion from the EFSA website of information, documents or data already disclosed;
b. No further disclosure of information, documents or data.

Withdrawal after the confidentiality decision is adopted by EFSA results in:

a. Implementation of, and compliance with, the confidentiality decision;
b. No deletion of published information, documents or data.