



DECISION

<p>EFSA – European Food Safety Authority</p>	<p>Decision of the Management Board laying down practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006</p>	<p>Decision No.: wp200327-a2</p>
	<p>Effective Date: 27/03/2020</p>	<p>Supersedes: EFSA Decision of 16 September 2003 concerning access to documents</p>

Approvals	Signature	Name
Originator		Bernhard Url
Management Board	See Decision	Jaana Husu-Kallio (Chair of the Management Board)

<p>Introduction</p>	<p>Following the amendment of Regulation (EC) No 178/2002 by Regulation (EU) 2019/1381, the EFSA Management Board is required to adopt practical arrangements implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006. The present Decision on practical arrangements is adopted in accordance with Article 41(2) of Regulation (EC) No 178/2002, as amended, and repeals the previous Management Board Decision on access to documents of 16 September 2003. The present Decision takes account of case law developments on the interpretation of Regulation (EC) No 1049/2001 as well as Articles 6 and 7 of Regulation (EC) No 1367/2006.</p>
<p>Description</p>	<p>The present practical arrangements provide information regarding the process for the handling of applications for access to documents held by EFSA. It lays down detailed procedures highlighting the steps required at each stage for replying to applications for access to documents. The conditions for applying exceptions to disclosure are described as well as the manner in which all legal rights and obligations are reconciled throughout the entirety of the process.</p>
<p>References</p>	<p>Directive 2003/4/EC Regulation (EC) No 1049/2001 Regulation (EC) No 178/2002 Regulation (EC) No 1367/2006 Regulation (EU) 2018/1725 Regulation (EU) 2019/1381</p>
<p>Abbreviations</p>	<p>EFSA: European Food Safety Authority EU: European Union CJEU: Court of Justice of the European Union TEU: Treaty on the European Union TFEU: Treaty on the Functioning of the European Union</p>



Decision of the Management Board of the European Food Safety Authority
laying down practical arrangements for implementing Regulation (EC) No 1049/2001
and Articles 6 and 7 of Regulation (EC) No 1367/2006
repealing the Decision of the Management Board concerning access to documents of
16 September 2003

The Management Board of the European Food Safety Authority ('EFSA' or 'the Authority')

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 15 thereof,

Having regard to the Charter of Fundamental Rights of the European Union, and in particular Articles 8, 41 and 42 thereof,

Having regard to Regulation (EC) No 178/2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety¹, and in particular Article 41 thereof, as amended by Regulation (EU) 2019/1381 of the European Parliament and the Council on the transparency and sustainability of the EU risk assessment in the food chain²,

Having regard to 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 documents³,

Having regard to 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 (hereinafter the 'Aarhus Regulation'), and in particular Articles 6 and 7 thereof⁴,

Having regard to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies, and in particular Article 9 thereof⁵,

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.

² 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, OJ L 231, 6.9.2019, p. 1–28.

³ 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.

⁴ 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.

⁵ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98.

Whereas:

- (1) EFSA was established as an independent source of scientific advice, information and communication in order to enhance consumer confidence in matters relating to food safety.
- (2) Openness forms part of EFSA's key values, which the Authority is committed to upholding in all areas of its work. Openness contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in Article 6 of the Treaty on European Union (TEU) and in the Charter of Fundamental Rights of the European Union. Openness helps to foster trust in EFSA and contributes to greater citizen participation in decision-making.
- (3) The rights provided by Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006 should not be limited in any manner by the provisions on proactive dissemination laid down in Regulation (EU) 2019/1381 and the relevant assessment of confidentiality requests. This assessment will be carried out in line with the EFSA practical arrangements concerning confidentiality and transparency in accordance with Article 39d(5) and Article 38(3) of Regulation (EC) No 178/2002, as amended by Regulation (EU) No 2019/1381 which applies as from 27 March 2021.
- (4) Increased public access to environmental information and the dissemination of such information contribute to a greater awareness of environmental matters, a free exchange of views, and facilitating the involvement by the public in environmental decision-making.
- (5) Directive 2003/4/EC on public access to environmental information is applicable to Member States and not to EFSA. However, that Directive, as interpreted by the Court of Justice of the European Union (CJEU), may be taken into consideration where appropriate with respect to the interpretation of Regulation (EC) No 1367/2006 of the European Parliament and of the Council.
- (6) Pursuant to Article 41(2) of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381, which applies as from 27 March 2021, the Management Board of EFSA is required to adopt practical arrangements for implementing Regulation (EC) No 1049/2001 of the European Parliament and of the Council and Articles 6 and 7 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council, ensuring the widest possible access to documents in its possession by 20 March 2020.
- (7) EFSA is required to process applications for access to all documents which it holds, namely documents drawn up or received and in its possession in all areas of the activities of the EU. This comprises documents in existing version and format as outlined in Article 10(3) of Regulation (EC) No 1049/2001. As such, the possibility for creating documents in response to applications for access to documents is not foreseen.
- (8) EFSA is committed to multilingualism and ensuring that Europe's cultural and linguistic diversity and heritage is safeguarded and enhanced. As such, EFSA should make every effort to reply to applications for access to documents in the language in which they are submitted.
- (9) In its handling of applications for access to documents, EFSA takes full account of the case law of the CJEU, including its latest developments.
- (10) If an application for access to documents is received concerning documents to which the applicant already enjoys access under another legislative framework or if these are

factually in the public domain, such an application may be handled without the need to make reference to either Regulation (EC) No 1049/2001 or this Decision.

- (11) The concept of a 'document' defined in Article 3(1) of Regulation (EC) No 1049/2001 is to be interpreted according to the case law of the CJEU.
- (12) EFSA should take into account its internal rules relating to document management and information security.
- (13) As regards the exception to disclosure relating to the protection of the privacy and the integrity of the individual, Regulation (EU) 2018/1725 is applicable in its entirety, in particular Article 9 thereof. In this regard, EFSA takes full account of the case law of the CJEU, including its latest developments.
- (14) If EFSA considers that an exception to disclosure is applicable to a requested document, EFSA should provide the applicant with a statement of reasons explaining how disclosure of that document would specifically and actually undermine the interest protected by the exception upon which it is relying. It is settled case law that exceptions to disclosure laid down in Article 4 of Regulation (EC) No 1049/2001 should be interpreted and applied strictly.
- (15) The CJEU has recognised general presumptions of confidentiality with respect to the accessibility of certain categories of documents requested under Regulation (EC) No 1049/2001.
- (16) The grounds for refusal as regards to environmental information should be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions into the environment. The notion of 'information which relates to emissions into the environment' should apply as interpreted by the CJEU.
- (17) The distinction between the reactive transparency obligations of EFSA in terms of responding to applications for public access to documents and the proactive transparency obligations of EFSA laid down in Article 38 of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381, should be taken into consideration. The evolving case law on common concepts of the legal framework regarding access to environmental information should be taken into account when handling applications for access to documents submitted under this Decision.

Has adopted the following Decision.

Article 1 – Purpose

The purpose of this Decision is to give the fullest possible effect to the right of public access to documents held by EFSA by laying down the practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006 in order to ensure the widest possible access to documents held by EFSA as provided for by Article 41 of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

Article 2- Scope

This Decision shall apply to all documents held by EFSA in accordance with Article 2(3) of Regulation (EC) No 1049/2001, that is to say, documents drawn up or received by EFSA and in its possession at the moment an application for access to documents is received, in all areas of activity of the European Union.

Article 3 – Definitions

For the purpose of this Decision, reference is made to the definitions laid down in Article 3 of Regulation (EC) No 1049/2001 and Article 2 of Regulation (EC) No 1367/2006.

Article 4 – General principles for public access to documents processing

1. In accordance with Article 6 of Regulation (EC) No 1049/2001, applications for access to documents shall be made in written form to EFSA in one of the official languages of the EU, preferably in the way suggested in the practical guidance for applicants referred to in Article 10(2).
2. Applications for access to documents shall be submitted in a sufficiently precise manner in order to enable EFSA to identify the documents within their scope. Applicants are not obliged to state the reasons behind the submission of their application.
3. If an application for access to documents is not sufficiently precise, EFSA shall ask the applicant to clarify the application and shall assist the applicant in doing so, as referred to in Article 6(2) of Regulation (EC) No 1049/2001, for example by providing additional information allowing the identification of documents. The deadline for reply shall run only from the time when EFSA receives the necessary clarifications from the applicant.
4. If an applicant does not reply to a request for clarification or if the reply received is unclear, EFSA shall reply to the application for access to documents taking into consideration the elements at its disposal. The applicant may submit a new application for access to documents at any time in case any of the documents originally intended to form part of the scope of the initial application for access to documents were not explicitly identified. In the event that, following the request for clarification, the applicant intends to include additional documents in the initial application, the new documents requested will be treated as a new application for access to documents.
5. EFSA shall reply to applications for access to documents in the official language of the EU in which they are received. In order to ensure timely processing of applications for access to documents, EFSA may seek the consent of applicants to receive replies from EFSA in English, the working language of EFSA, when the application for access to documents is submitted in another official language of the EU.
6. Pursuant to Article 2(2) of Regulation (EC) No 1049/2001, EFSA shall make every effort to process applications for access to documents originating from citizens of third countries not residing in the territory of an EU Member State.
7. In the event of complex or voluminous applications for access to documents, EFSA may extend the deadline to reply. Reasons must be given for any extension of the deadline and it must be notified to the applicant in writing beforehand.

8. Without prejudice to the possibility of extending deadlines to reply to initial and confirmatory applications for access to documents under the relevant provisions of Regulation (EC) No 1049/2001, EFSA may confer with applicants, to find an arrangement which is agreeable to them, in accordance with Article 6(3) of Regulation (EC) No 1049/2001. In particular, in order to reconcile the interests of the applicant with those of good administration, EFSA may reply to applications for access to documents in batches, request the applicant to provide a priority list of documents and/or further extend time-limits to reply to applications for access to documents by taking into consideration the resources involved and striking an appropriate balance with the proper functioning of EFSA.
9. Documents shall be released by EFSA in response to an application for access to documents in electronic form by any technical means as detailed in the practical guidance for applicants referred to in Article 10(2).

Article 5 - Processing of initial applications for access to documents

1. Upon receipt of an application for access to documents and as soon as that application is registered, a written acknowledgement of receipt shall be sent to the applicant informing them of the deadline to reply.
2. Applicants shall be informed in writing of the response to their applications for access to documents.
3. Any decision which is even partly negative shall state the reason for the refusal based on one or more exceptions listed in Article 4 of Regulation (EC) No 1049/2001.
4. In the event of a total or partial refusal, applicants shall be informed of their right to make a confirmatory application, in accordance with Article 7(2) of Regulation (EC) No 1049/2001, within 15 working days of receiving EFSA's reply, asking EFSA to reconsider its position.
5. In the event that EFSA does not reply within the indicated deadline, this shall be considered as a negative reply and therefore entitle the applicant to make a confirmatory application.

Article 6 – Processing of confirmatory applications

1. Upon receipt of a confirmatory application and as soon as that application is registered, a written acknowledgement of receipt shall be sent to the applicant informing them of the deadline to reply.
2. Any argumentation accompanying the confirmatory application shall be duly taken into consideration by EFSA.
3. Decisions following confirmatory applications shall constitute an independent review of initial decisions.
4. In the event of a total or partial refusal, the relevant decision may be challenged in accordance with Article 8(3) of Regulation (EC) No 1049/2001. Therefore, EFSA shall inform the applicants according to Regulation (EC) No 1049/2001 of the remedies open to them, namely lodging an action for annulment of EFSA's decision before the General Court of the European Union pursuant to Article 263 of the TFEU within two months of its receipt

and/or making a complaint to the European Ombudsman pursuant to Article 228 of the TFEU, in case the applicant believes that EFSA committed maladministration, within two years of receiving EFSA's final position on the matter.

5. Failure by EFSA to reply within the indicated time limit shall be considered as a negative reply and shall entitle applicants to institute court proceedings against EFSA pursuant to Article 263 of the TFEU and/or make a complaint to the European Ombudsman pursuant to Article 228 of the TFEU.

Article 7 – Consultations

1. As regards documents held by EFSA originating from a third party and which form the subject of an application for access to documents, EFSA shall verify whether one or more of the exceptions of Article 4 of Regulation (EC) No 1049/2001 apply. Unless it is clear that the document shall or shall not be disclosed, EFSA shall consult with the third party with a view to assessing whether an exception in Article 4(1) or 4(2) of Regulation (EC) No 1049/2001 is applicable. EFSA shall grant access to the requested documents where, *inter alia*, documents have been published or have already been disclosed to another applicant and none of the interests referred to in Article 4 of Regulation (EC) No 1049/2001 would be obviously affected by the disclosure.
2. As regards documents originating from Member States, EFSA shall assess whether one or more interests protected by Article 4(1), (2) or (3) of Regulation (EC) No 1049/2001 could be undermined. If after this assessment, EFSA concludes that certain documents shall be partially or fully disclosed, it shall engage with the Member State from which those documents originate. As clarified by the law, the particular position of Member States allows them to request EFSA not to disclose documents originating from them without their prior agreement, providing justification for the application of one or more exceptions of Article 4 of Regulation (EC) No 1049/2001.
3. When consulting, EFSA shall indicate a deadline to reply which allows EFSA to abide by its own deadlines to reply. In the absence of an answer within the indicated deadline or in case the third party is unreachable or not identifiable, EFSA shall decide in accordance with the provisions of Regulation (EC) No 1049/2001 taking into account the interests at stake in accordance with the case law of the CJEU.
4. Following consultation, as detailed in the paragraphs above, if EFSA intends to provide access to documents against the explicit opinion of the relevant third party or Member State, EFSA shall notify the third party or the Member State of its decision and shall draw their attention to the remedies available to them to oppose disclosure.
5. In the absence of consultation, when it is clear that the document shall or shall not be disclosed, EFSA shall make every effort to inform third parties and Member States of the release of documents originating from them.

Article 8 – Exceptions

1. When processing an application for access to documents, EFSA shall verify whether one or more of the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001 apply. These exceptions shall be applied strictly as they deviate from the overarching principle of the widest possible access to documents. If only parts of the requested document are covered by any of the exceptions, the remaining parts of the document shall be released.

2. EFSA shall take into account decisions on confidentiality requests taken by the European Commission, European Union Member States or EFSA under Union law.
3. Should EFSA decide that any of the exceptions to disclosure outlined in Article 4(2) and (3) of Regulation (EC) No 1049/2001 are applicable, EFSA shall ascertain whether there is any overriding public interest justifying disclosure, notwithstanding the fact that the interests in question would thereby be undermined. In this respect, EFSA shall balance the particular interest to be protected against any public interest in disclosure.

Article 9 – Applications for access to environmental information

1. In case of applications for access to environmental information, the Aarhus Regulation shall apply in conjunction with Regulation (EC) No 1049/2001.
2. When assessing the applicability of the exceptions of Article 4 of Regulation (EC) No 1049/2001, EFSA shall interpret these in accordance with Article 6 of the Aarhus Regulation. The first sentence of Article 6(1) of Regulation (EC) No 1367/2006 establishes a legal presumption that, within the meaning of Article 4(2), first and third indents of Regulation (EC) No 1049/2001, with the exception of information relating to investigations, i.e. the commercial interests of a particular natural or legal person, inspections or audits, an overriding public interest in disclosure shall be deemed to exist where the information requested constitutes 'information which relates to emissions into the environment'. The notion of 'information which relates to emissions into the environment' shall apply as interpreted by Union Courts taking into account the latest case law developments.
3. Where EFSA receives an application for access to environmental information and where this information is not held by EFSA, pursuant to Article 7 of the Aarhus Regulation, the Authority shall inform the applicant within 15 working days at the latest of the Union institution, agency or body or the Member State public authority which it believes may hold the information requested. Alternatively, EFSA may transfer the application to the relevant Union institution, agency or body or the Member State public authority and inform the applicant accordingly.

Article 10 – Measures facilitating transparency

1. To ensure that the fullest possible effect is given by EFSA to the right of public access to documents, as envisioned in Articles 11 and 12 of Regulation (EC) No 1049/2001, EFSA shall register documents online in electronic form⁶.
2. EFSA shall draw up practical guidance for applicants to inform the public of their rights under Regulation (EC) No 1049/2001. The guidance shall be published on EFSA's website.

Article 11 – Reproduction and reuse of documents released to requesters

1. This Decision shall be without prejudice to any existing rules on copyright which may limit a third party's right to reproduce, distribute, adapt, translate or communicate to the public documents released following an application for access to documents.

⁶ Further information may be found in the practical arrangements concerning transparency and confidentiality in accordance with Articles 38(1) and 39(5) of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381.

2. Applicants shall be informed of the existence of data exclusivity rules set out in EU legislation limiting the reuse of certain documents for regulatory purposes.

Article 12 - Report

The Management Board, acting on a proposal from the Executive Director, shall publish annually, as part of the annual activity report, information concerning the implementation of this Decision for the preceding year including the number of applications in response to which the Authority refused to grant access to documents, and the reasons for such refusals.

Article 13 – Application measures

1. The Decision of the Management Board of EFSA of 16 September 2003 concerning access to documents is repealed.
2. The present Decision shall take effect on the day of its adoption.

Adopted by written procedure on 27 March 2020

For EFSA's Management Board

[ADOPTED]

Jaana Husu-Kallio

Chair of the Management Board