



DECISION CONCERNING ACCESS TO DOCUMENTS

Having regard to the Treaty establishing the European Community, and in particular Article 255 thereof,

Having regard to the Declaration (No 17) attached to the Final Act of the Treaty on European Union on the right of access to information, that transparency of the decision-making process strengthens the democratic nature of the institutions and the public's confidence in the administration,

Having regard to Regulation N° 178/2002/EC¹ (hereinafter referred to as 'the Regulation') of the European Parliament and the Council of 28th January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety and in particular Chapter III thereof,

Having regard to Regulation (EC) No 1049/2001² of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 178/2002 as regards the budgetary and financial rules applicable to the European Food Safety Authority and access to the Agency's documents (2002/C 331 E/18)³,

Whereas EFSA has been designed as an independent source of advice, information and communication in order to improve consumer confidence in matters relating to food safety,

Whereas the independence, scientific quality, transparency and efficiency of the Authority are essential to ensure the confidence of EU Institutions, the general public and interested parties.

According to Article 10 of the Regulation, without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the

¹ Official Journal L 31, 1. 2. 2002, p1

² Official Journal L 145, 31.05.2001, p43

³ Official Journal C 331 E/79

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nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

According to Article 38.3 of the Regulation, the Authority shall lay down in its internal rules practical arrangements for implementing transparency requirements for its documents.

According to Article 39.3 of the Regulation, the conclusions of scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

According to Article 39.4 of the Regulation, the Authority shall lay down in its internal rules practical arrangements for implementing confidentiality rules.

According to article 41.2 of the Regulation, the Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents, taking full account of the general principles and conditions governing the right of access to the Community institutions documents.

According to Article 40.2 of the Regulation, the Authority shall ensure that the public and any other interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material to the general public.

According to Article 30 of the Regulation, the Authority shall make public documents clarifying contentious scientific issues as a result of a substantive divergence over scientific issues with Community agencies, Commission's scientific committees or Member States bodies.

The Management Board of the Authority has adopted the following Decision.

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Article 1: Public access

The Authority shall ensure the widest possible access to the documents it holds, that is to say documents drawn up or received by it and in its possession.

Article 2: Definitions

1. “Document” shall mean any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to activities falling within the Authority’s mission and responsibilities.
2. “Third party” shall mean any natural or legal person, or any entity outside EFSA, including the Member States, other Community or non-Community bodies and third countries.

Article 3: Exceptions

1. EFSA shall refuse access to certain documents in application of one of the exceptions mentioned in article 4 of Regulation (EC) No 1049/2001, and in particular where the disclosure would undermine:
 - a) The privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data
 - b) Commercial interests of a natural or legal person, including intellectual property, court proceedings and legal advice and the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure
 - c) The Authority’s decision-making process, internal or preliminary consultations and deliberations, with a view to safeguard the freedom of the scientific debate and guarantee the independence vis-à-vis external influence. This exception may however be waived in specific and well identified cases where EU legislation requires open consultation on a draft opinion or report and/or where specifically agreed by the Executive Director in consultation with the Scientific Committee or a Panel. This exception may also be waived in cases where there is an overriding public interest in disclosure, in particular in matters relating to risks to health.
 - d) The European Union or the Authority’s public interests, international relations or financial interests
2. Decisions of access refusal shall be duly justified on the basis of one of the above exceptions. Each request shall be treated separately.
3. As regards third party documents, the Authority shall consult the third party with a view to assessing whether one of the above exceptions is applicable, unless it is clear that the document shall or shall not be disclosed.

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4. A Member State may request the Authority not to disclose information in a document originating from that Member State without its prior agreement.
5. If only parts of the requested document are covered by any of the exceptions, the remaining part of the document shall be released.

Article 4: Classification of documents

1. All EFSA documents shall be classified in one of the following categories: public, confidential and restricted. Criteria and guidance for the classification of EFSA documents are set out in Annex 1 to this decision.
2. The classification of an EFSA document shall be decided by the Executive Director. When the classification raises questions of principle, and/or when the document relates to the work of the Management Board, the Advisory Form the Scientific Committee and Scientific Panels or their Working Groups, the Executive Director may consult the relevant chairperson before taking his decision.
3. Applications for access to classified documents under the procedure laid down in article 4 shall be handled by the Executive Director, as appropriate in consultation with the chairperson of the relevant EFSA constitutive body.
4. If access to a classified document is to be given, it shall be first declassified by a decision of the Executive Director.

Article 5: Requests for access

1. Applications for access to EFSA documents which are not publicly available shall be made in written form, including electronic form, to the Executive Director and in a sufficiently precise manner to enable the EFSA to identify the document(s).
2. If an application is not sufficiently precise, EFSA shall ask the applicant to clarify his request and shall assist the applicant in doing so, for example by providing information on the use of public registers of documents.
3. An application for access to a document shall be handled promptly. An acknowledgement of receipt shall be sent to the applicant. Within one month from registration of the application, the Authority shall either grant access to the document requested or state in writing the reasons for a total or partial refusal of access.
4. In exceptional circumstances, for example in the event of an application for long documents or for a large number of documents, the time-limit may be extended by 15 working days.
5. Failure to reply within the prescribed time-limit shall entitle the applicant to make a confirmatory application, to be made and handled under the conditions set out in paragraphs 1 to 3. Failure by the Authority to reply to a confirmatory

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application within the prescribed time-limit shall be considered as a negative reply and entitle the applicant to lodge a complaint to the European Ombudsman or institute Court proceedings against the Authority, under Article 195 or 230 of the EC Treaty, respectively.

6. Where access is refused, the decision shall specify which of the exceptions mentioned in Article 3 of this decision it is based on and the reasons for it. It shall also indicate the means of redress available, namely making a complaint to the European Ombudsman or the institution of Court proceedings against the Authority, under Article 195 or 230 of the EC Treaty, respectively.

Article 6: Consultation following application

1. Applicants shall have access to documents either by consulting them on EFSA premises or by receiving a copy, whether in paper or electronic form according to the applicant's preference.
2. Consultation on EFSA premises, copies of less than 20 pages or direct access in electronic form shall be free of charge. As regards documents of more than 20 pages, the charge shall not exceed the real cost of producing and sending the copies.

Article 7: Register of documents

1. To make citizen's rights under this decision effective, the Authority shall provide, within six months from the entry into force of this decision, public access to an electronic register of documents available in particular through the Authority's Internet site. References to documents shall be recorded in the register without delay.
2. The register shall contain the title of the document, an identifier, the subject matter and/or a short description of the document and the date on which it was received or drawn up and recorded in the register.
3. Guidance for EFSA staff on the type of documents to be recorded in the register is set out in Annex II.

Article 8: 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, in particular statistics on the number of requests for access to EFSA documents, the number of refusals, and the reasons for such refusals.

Article 9: Entry into force

1. The present Decision shall enter into force on 1 March 2004. It shall be made public on the EFSA Internet site.

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2. The Management Board may review these rules whenever deemed necessary and adopt any modifications needed.
3. The European Ombudsman shall be informed of this decision and subsequent revisions.

Done at Brussels, 16 September 2003

Dr Stuart Slorach
The Chair

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ANNEX I
**CRITERIA AND GUIDANCE FOR THE CLASSIFICATION OF EFSA
DOCUMENTS**

This Annex sets out the EFSA rules on classification of documents and provides indications on the types of documents covered by the different levels of classification. It takes into account Annex 2 of Decision 2001/844 of the European Commission modifying its internal rules of procedure⁴, and its practical classification guide.

EFSA documents shall be classified as follows:

1. Public documents

EFSA documents not classified as Restricted or Confidential are accessible by the public. Without prejudice to the rules concerning confidentiality and the exceptions to the right of access to documents, these include:

Management Board

- Agendas and minutes of meetings
- Draft decisions concerning management issues (e.g. budgets, work programmes)
- Final decisions or documents adopted

Scientific Committee and Panels

- Agendas and minutes of plenary meetings
- Final opinions immediately after adoption, minority opinions always being included. Final published opinions include comprehensive information on which the opinion is based, including the question or the issue raised, the author of the question, the background to the request, the information considered, the scientific reasoning leading to the final opinion of the Scientific Committee or Panel.

Advisory Forum

- Final agendas and minutes of meetings

Declaration of interests

- Annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels
- Declarations of interest made in relation to items on the agendas of plenary meetings will be published as part of meeting minutes

⁴ JO L 317 of 03/12/2001.

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Other

- Scientific questions referred to the Authority by the European Commission, the European Parliament, the Member States or the Authority itself under Article 29 of the Regulation;
- 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 modification (Art. 38g);
- Results of scientific studies conducted by EFSA under Article 32 of the Regulation
- EFSA reports clarifying contentious issues as a result of a substantive divergence over scientific issues with Community agencies, Commission's scientific committees or Member States bodies (Art. 30).
- All other information which must be made public if circumstances so require, in order to protect public health, and in particular information concerning risks to health.

2. Protected documents

The general principle of widest possible access to EFSA documents is subject to certain exceptions which are required to protect various interests. These exceptions should be clearly defined and individual documents classified according to objective criteria.

It should be noted that under Article 39.2 of the Regulation, members of the Management Board, the Executive Director, members of the Scientific Committee and Panels, external experts participating in the working groups, members of the Advisory Forum and members of EFSA staff are bound by an obligation of professional secrecy, even after their duties have ceased.

2.1 Confidential documents

This classification shall be applied to information and material the unauthorized disclosure of which could harm the essential interests of the European Union Institutions, the Member States, the Authority and its constitutive bodies, their members and experts and, in particular, would be likely to:

- Cause financial loss or facilitate improper gain or advantage for individuals or companies;
- Breach undertakings to maintain the confidence of information provided by third parties;
- Breach statutory restrictions on disclosure of information;
- Impede or undermine the effective management or operations of EFSA.

Documents classified as confidential include:

- All Scientific Committee, Panel and Working Group meeting documents contributing to the formation of scientific opinion (correspondence,

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presentations, draft contributions from members, informal notes, working papers).

- Except for minority opinions published with the final opinion, all documents stating personal opinions of the members of the Committee, a Panel, a Working Group or an expert, and relating to a question which has not yet been subject to a scientific opinion.
- Correspondence and minutes of meetings between and with members of Committee or Panels, experts, stakeholder representatives, petitioners and undertakings.
- Documents given by third parties concerning sensitive industrial and commercial matters, and/or for which confidentiality has been requested and agreed. This includes petitions and evaluation tables for a given substance.
- Background scientific references not yet published.
- All documents drawn up by EFSA for internal use or received by it, relating to matters on which it has not yet taken a decision.

2.2 *Restricted*

Restricted documents are typically characterized by the fact that their disclosure might be prejudicial to the interests of EFSA, including relations with EU Institutions, the Member States, third countries, petitioners and undertakings. These include:

- Agendas and minutes of the meetings of Working Groups created by the Advisory Forum, the Scientific Committee or a Scientific Panel
- Draft opinions from the Scientific Committee or a Scientific Panel. These may however be released totally or partially for public consultation where EU legislation so requires and/or where a technical hearing has been expressly authorized by the Scientific Committee or a Panel.
- Draft scientific reports from EFSA.
- Any press release or public announcement prior to the lifting of any embargo

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ANNEX II

**GUIDANCE ON TYPE OF DOCUMENTS TO BE RECORDED IN THE
EFSA REGISTER OF DOCUMENTS**

Article 7 of the Management Board decision on access to EFSA documents states:

- 1. To make citizen's rights under this decision effective, the Authority shall provide, within six months from the entry into force of this decision, public access to a register of documents through its Internet site. References to documents shall be recorded in this register without delay.*
- 2. The register shall contain the title of the document, an identifier, the subject matter and/or a short description of the document and the date on which it was received or drawn up and recorded in the register.*

In order to adequately exercise its right of access, the public needs to be informed through the register of all relevant documents produced or received by EFSA. The register should therefore provide a record of all of those relevant documents, irrespective of their classification (public, restricted, confidential). It follows that some documents that are classified as confidential or restricted must also be recorded in the register. The classification rules set out in Annex I to this Decision will govern separately the procedure for handling requests for access.

The EFSA is keen to meet its legal obligations whilst keeping the workload within reason in view of its limited resources. Therefore documents to be recorded in the register will be limited to key business documents bearing legal or financial implications for EFSA and dealing with significant issues pertaining to the mission and responsibilities of EFSA. E-mails of significant business importance will be also recorded in the register.

Documents to be recorded in the register includes

- All official correspondence and communications with stakeholders, institutional partners as part of the normal conduct of EFSA activities.
- Agendas and minutes of Panels and Scientific Committee
- Final terms of reference for requests of scientific opinions
- All EFSA scientific opinions formulated by the Committee or a Panel

The following documents should not be recorded in the register:

- Documents dealing with factual or organisational issues (e.g. invitation to meetings, flight, hotel and meeting rooms bookings)
- Documents pertaining to internal management of EFSA (staffing, budget execution, internal meeting notes)
- Preparatory documents, i.e. documents that may at some stage be recorded when final but that are under preparation.