



Decision of the Executive Director of the European Food Safety Authority
Laying down practical arrangements concerning confidentiality in accordance with
Articles 7(3) and 16 of Regulation (EC) No 1107/2009

**DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY
LAYING DOWN PRACTICAL ARRANGEMENTS CONCERNING CONFIDENTIALITY
IN ACCORDANCE WITH ARTICLES 7(3) and 16 OF REGULATION (EC) No 1107/2009**

The Executive Director of the European Food Safety Authority,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Charter of Fundamental Rights of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and Council and in particular Articles 7(3) and 16 thereof,¹

After considering the comments received in the context of consultations with the Member States held between 22 October and 9 November 2020,

Whereas,

- (1) Regulation (EC) No 1107/2009 sets out the Union provisions concerning the placing of plant protection products on the Union market;
- (2) Regulation (EU) 2019/1381 of the European Parliament and of the Council² (hereinafter "Transparency Regulation") amended, amongst others, Regulation (EC) No 1107/2009. The said Regulation introduced additional provisions relating to confidentiality as well as specific procedural requirements for the submission of confidentiality requests in relation to information submitted by an applicant;
- (3) In particular, under Regulation (EC) No 1107/2009, as amended by the Transparency Regulation, Member States are responsible for the assessment of confidentiality requests pertaining to applications submitted for the approval of a new active substance or the amendment to the conditions of approval of active substances, while the Authority is responsible for the assessment of confidentiality requests pertaining to applications submitted under the procedure for the renewal of the approval of an active substance;
- (4) Pursuant to Articles 7(3) and 16 of Regulation (EC) No 1107/2009, as amended by the Transparency Regulation, the Authority is empowered to lay down practical arrangements to ensure the consistency of those assessments by the Member States and the Authority in the context of applications launched by applicants as part of the approval (or amendment to an approval) process of an active substance and the renewal process of such an approval respectively;
- (5) These Practical Arrangements should be applicable to the rapporteur Member States when assessing confidentiality requests lodged by applicants with regard to scientific data, studies and other information submitted by applicants applying for the approval of a new active substance or the amendment to the conditions of approval of active substances, including supplementary information submitted at the request of the rapporteur Member States;
- (6) In view of the fact that the assessment of confidentiality requests pursuant to Article 16 of Regulation (EC) No 1107/2009, read in conjunction with Commission Implementing Regulation (EU) 2020/1740³ is entrusted to the Authority and is regulated by Articles 39 to 39e of

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

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

³ Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012, OJ L 392, 23.11.2020, p. 20–31.

Regulation (EC) No 178/2002, it is appropriate that such confidentiality assessments are carried out in accordance with the Practical Arrangements concerning Transparency and Confidentiality drawn up by the Authority pursuant to Article 39d(5) of Regulation (EC) No 178/2002, as amended by the Transparency Regulation;⁴

- (7) Confidential treatment that can be requested under Articles 7(3) and 16 of Regulation (EC) No 1107/2009 is an exception to the principle of proactive public disclosure set out in Regulation (EC) No 1107/2009 as amended by the Transparency Regulation. Therefore, it should be applied and interpreted strictly, and confidential treatment should be granted only with respect to the items listed in Article 63 of Regulation (EC) No 1107/2009, and only to the extent the applicant successfully demonstrates that the disclosure of the information potentially harms its interests to a significant degree;
- (8) Documents, information or data falling under the definition of environmental information pursuant to Article 2 of 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 bodies⁵ and Article 2 of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information should be subject to higher transparency standards;
- (9) Applicants should also be provided with concrete and punctual information concerning the legal remedies available to them in order to challenge decisions taken pursuant to these practical arrangements;
- (10) Given the intertwined nature of the confidentiality assessments performed under Regulation (EC) No 1107/2009, where appropriate the Authority may provide support services to Member States. This administrative support may take the form of the provision of IT assistance or of a more comprehensive service package;
- (11) To ensure the highest level of transparency, legal certainty and accessibility, the present practical arrangements should take the form of a decision of the Executive Director of the Authority;
- (12) Given that this decision implements certain provisions of Regulation (EU) 2019/1381, which applies from 27 March 2021, it should apply from the same date;
- (13) These Practical Arrangements should be interpreted so as not to affect the rights stemming from Regulation (EC) No 1049/2001⁶ and, where environmental information is concerned, the rights enshrined in Regulation (EC) No 1367/2006 or in Directive 2003/4/EC⁷.
- (14) It may become appropriate to refine certain elements of this Decision based on the experience gained in the implementation of Regulation (EU) 2019/1381. To this end, the Executive Director should review this decision every five years following its entry into force.

Has adopted the following decision,

⁴ Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality.

⁵ 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.

⁶ 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.

⁷ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC, OJ L 41, 14.2.2003, p. 26–3.

CHAPTER I
SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter, scope and objective

1. These practical arrangements apply to the confidentiality assessments of applications, including any other supplementary information, submitted by applicants to, and carried out by, the rapporteur Member State pursuant to Article 7(3) of Regulation (EC) No 1107/2009 and by the Authority pursuant to Article 16 of the same Regulation. This includes dossiers and updated dossiers.
2. The objective of these practical arrangements is to ensure the consistency of the confidentiality assessments performed under paragraph 1.
3. For the purposes of paragraph 2, this decision lays down the general principles and rules applicable to the assessment of confidentiality requests submitted by applicants and carried out by the rapporteur Member State pursuant to Article 7(3) of Regulation (EC) No 1107/2009 and by the Authority pursuant to Article 16 of the same Regulation.

Article 2

Definitions

1. For the purpose of this decision, the definitions set out in Article 3 of Regulation (EC) No 1107/2009 shall apply.
2. For the purpose of this decision, and without prejudice to applicable Union law, “sanitisation” means the process of masking or unmasking scientific data, studies and other information supporting an application under Regulation (EC) No 1107/2009 in accordance with a confidentiality request or with a confidentiality decision, including the masking or unmasking of personal data in accordance with Article 39e of Regulation (EC) No 178/2002.

CHAPTER II
CONFIDENTIALITY

Article 3

General principles relating to confidentiality

1. Duly justified confidential treatment in accordance with the applicable provisions constitutes an exception to the principle of proactive transparency of the EU risk assessment in the food chain, set out in Regulation (EU) 2019/1381.
2. The rapporteur Member State and the Authority shall interpret and apply the provisions of Regulation (EC) No 1107/2009 on confidentiality as well as the provisions of this Decision strictly, so as not to defeat the application of the principle of proactive transparency referred to in paragraph 1.

Article 4

Confidentiality of information submitted for the renewal of approval of an active substance

1. Confidentiality requests of information submitted for the renewal of approval of an active substance pursuant to Article 16 of Regulation (EC) No 1107/2009, including any supplementary information requested, shall be processed in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002, Commission Implementing Regulation (EU) 2020/1740, as well as with the Practical Arrangements concerning Transparency and Confidentiality laid down by the Authority.
2. For the purpose of paragraph 1, the Rapporteur Member State shall inform the Authority when an application under Article 16 of Regulation (EC) No 1107/2009 is found admissible in accordance with Article 8(5) of Commission Implementing Regulation (EU) 2020/1740.
3. Confidentiality requests on renewal of approval of an active substance, including any supplementary information requested, shall be submitted using the relevant IUCLID functionality pursuant to Article 7(4) of Commission Implementing Regulation (EU) 2020/1740.
4. By way of temporary derogation from Article 13 of the Practical Arrangements concerning Transparency and Confidentiality of the Authority, until the applicable software package used for the submission of applications under Article 16 of Regulation (EC) No 1107/2009 is adapted to permit the direct intervention of the Authority on the dossier submitted by the applicant, implementation of the Authority's decisions pursuant to Article 16 of Regulation (EC) No 1107/2009 shall be performed by the Authority in accordance with the procedure set out in Article 9 of this decision, *mutatis mutandis*.

Article 5

Procedural requirements applicable to confidentiality requests submitted pursuant to Article 7(3) of Regulation (EC) No 1107/2009

1. The rapporteur Member States shall ensure that applicant(s) may submit a confidentiality request to the rapporteur Member State with respect to certain parts of the information submitted in the context of an application for the approval of an active substance or for an amendment to the conditions of an approval, including any supplementary information requested by the rapporteur Member State. Confidentiality requests shall be made in written form and submitted in accordance with the relevant process of the rapporteur Member State for that purpose.
2. The rapporteur Member States shall ensure that confidentiality requests may be submitted only with respect to certain parts of the information submitted in the context of an application for the approval of an active substance or for an amendment to the conditions of an approval, including any supplementary information requested by the latter and provided that:
 - (a) they fall within the scope of the information items listed in Article 63(2) of Regulation 1107/2009; and,
 - (b) verifiable justification is provided proving compliance with Article 6 (substantive requirements).
3. The confidentiality request shall be accompanied by a confidential and a non-confidential version of the information submitted through the applicable software package used for the submission of applications under Article 7(3) of Regulation (EC) No 1107/2009.

4. The rapporteur Member State shall ensure that applicants submitting confidentiality requests may not modify or complement confidentiality requests submitted to the rapporteur Member State, unless requested to do so by the latter. The rapporteur Member State may request applicants to clarify their confidentiality requests when the information initially provided by the applicant(s) does not allow the rapporteur Member State to issue a decision pursuant to Article 7 of this decision (assessment of confidentiality requests). If the applicant does not respond within the timeline set by the rapporteur Member State, the confidentiality request shall be considered unjustified and consequently shall be rejected by default.
5. Upon receipt of an admissible application, the rapporteur Member State shall forward the confidentiality requests submitted by the applicant(s) to the other Member States, the Commission and the Authority for the purpose of complying with Article 7(5) of this decision.

Article 6

Substantive requirements for confidentiality requests submitted pursuant to Article 7(3) of Regulation 1107/2009

1. The rapporteur Member State shall ensure that a confidentiality request shall pertain to an admissible application and shall specify at least the following elements:
 - (a) a clear identification of the relevant parts of the submitted information that the applicant considers eligible for confidential treatment on the basis of Article 63(1) and (2) of Regulation (EC) No 1107/2009 accompanied by a link and a detailed reference to the exact paragraph, page and line where this information is located, sufficiently precise to exclude any information that is not subject to the confidentiality request;
 - (b) a text explaining comprehensively and in plain language the reason(s) why the information should be granted confidential status. This shall include at least an explanation or justification as to why each and every of the following requirements are deemed to be satisfied:
 - (i) 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;
 - (ii) 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;
 - (iii) explanation or evidence demonstrating to the satisfaction of the rapporteur Member State that the harm that may be caused is of a significance corresponding at least to 5% of the total gross annual turnover⁸ for legal persons, or the gross annual earnings for natural persons, for the financial year preceding the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the rapporteur Member State shall ensure that the applicant provides specific reasons as to why they considered that public disclosure would potentially harm their interests to a significant degree;
 - (iv) the document, information or data for which confidential treatment is requested is eligible for legal protection and has not been acquired in an unlawful manner;
 - (v) the document, information or data for which confidentiality status is requested has been finalised in the form submitted to the rapporteur Member State up to five years

⁸ For a definition of net turnover, refer to Article 2(5) of Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC, OJ L 182, 29.6.2013, p. 19–76.

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 rapporteur Member State shall ensure that the applicant provides specific reason on why public disclosure of that information would still potentially harm its interests to a significant degree.

Article 7

Assessment of the confidentiality requests

and decisions by the rapporteur Member State under Article 7(3) of Regulation 1107/2009

1. Upon receipt of a confidentiality request relating to information submitted by the applicant(s) in the context of an admissible application under Article 7(3) of Regulation (EC) No 1107/2009, the competent authority of the rapporteur Member State responsible for the processing of these requests shall handle each instance pursuant to Article 41 of the Charter of Fundamental Rights of the European Union (CFREU) and to the criteria laid down in these Practical Arrangements.
2. The competent authority of the rapporteur Member States shall assess and decide upon confidentiality requests submitted as part of additional or supplementary information provided after the application has been found admissible by grouping them in a single decision.
3. The competent authority in the rapporteur Member State shall take an explicit and written decision ruling on confidentiality requests.
4. Each confidentiality decision shall be adopted by assessing compliance of the requests with the procedural and substantive requirements set out in Articles 5 (procedural requirements) and 6 (substantive requirements), respectively, as well as with applicable Union law and case law. The rapporteur Member State shall only grant confidential treatment to the information listed in Article 5(2) (procedural requirements) where disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree. The decision shall be taken in accordance with the following principles:
 - (a) The right of the applicant to provide its comments prior to the decision being taken by having the opportunity of commenting on a draft negative decision;
 - (b) The impartiality and independence of the competent authority responsible for the confidentiality assessment pursuant to Article 11 (impartiality and independence);
 - (c) The duty to state reasons, which requires that the statement of reasons in the decision must be appropriate to the measure taken and must disclose in a clear and unequivocal fashion the reasoning followed by the rapporteur Member State, in such a way as to enable the applicant concerned to ascertain the reasons and to enable the competent court or tribunal to exercise its power of review.
5. The rapporteur Member State, as well as other national authorities involved in the peer review process, the Commission and the Authority shall ensure that items on which confidentiality requests have been submitted are not disclosed to unauthorised third parties pending the adoption by the rapporteur Member State of a confidentiality decision pursuant to this Article, unless this is necessary for the purposes of protecting human health, animal health or the environment pursuant to Article 63(2b)(e)(i) of Regulation (EC) No 1107/2009.
6. A confidentiality request shall be deemed received by the rapporteur Member State at the moment the application is found admissible by the rapporteur Member State. No later than four (4) calendar weeks after receipt of a complete confidentiality request under Article 7(3) of Regulation (EC) No 1107/2009, and prior to finalising its confidentiality decision, the rapporteur

Member State shall consult with the Authority by sharing the draft decision in an electronic format and via the tool indicated by the Authority for this purpose.

7. The Authority shall provide its comments on the draft confidentiality decision not later than ten (10) working days from its receipt by making them available to the rapporteur Member State via the appropriate tool. The Authority shall comment on the draft decision by verifying its compliance with the present Practical Arrangements and applicable Union law and case law.
8. After taking into account the comments received from the Authority, the rapporteur Member State shall inform the applicant in writing of its intention to disclose information and the reasons for that, before formally taking a decision on the confidentiality request. If the applicant disagrees with the assessment of the rapporteur Member State, the applicant may state its views or withdraw its application within one (1) calendar week of the date on which it was notified of the rapporteur Member State's position. The rapporteur Member State shall issue a decision on confidentiality requests, taking into account the observations of the applicant, within four (4) calendar weeks from the receipt of the Authority's comments.
9. Once a confidentiality decision has been issued by the rapporteur Member State, it shall notify the applicant of its decision and indicate the legal remedies available to the applicant under the applicable national law.
10. The rapporteur Member State shall forward to the Authority, the Commission and the other Member States without delay the decision notified to the applicant and shall keep the Authority informed of its entry into force or of the receipt of a judicial relief suspending its applicability or validity, in order to allow the Authority to make publicly available the documents subject of the decision.

Article 8

Judicial review of the rapporteur Member State's confidentiality decisions

1. The decisions adopted by the rapporteur Member State under Article 7(3) of Regulation 1107/2009 and pursuant to Article 7 of this Decision (assessment of confidentiality requests) shall be subject to judicial review by the courts or tribunals having jurisdiction under the applicable national law in order to ensure the applicant's right to an effective remedy before a tribunal in accordance with Article 47 of the Charter of Fundamental Rights of the European Union.
2. The national rules governing actions intended to ensure the protection of the applicant's rights conferred by Regulation (EC) No 1107/2009 shall not be less favourable than those governing similar domestic actions and shall not render the exercise of the applicant's rights under this arrangement practically impossible or excessively difficult.

Article 9

Implementation of confidentiality decisions by the rapporteur Member State

1. The rapporteur Member State shall implement its decisions taken under Article 7(3) of Regulation 1107/2009 and pursuant to Article 7 of this Decision (assessment of confidentiality requests) without delay and in any event no later than one (1) calendar month from the notification of the decision.

2. By way of temporary derogation from paragraph 1, and until the moment the applicable software package used for the submission of the applications under Article 7(3) of Regulation 1107/2009 permits the direct intervention of the rapporteur Member State on the submitted dossier, the rapporteur Member State shall ensure that the applicant implements the decisions taken under Article 7 of this Decision (assessment of confidentiality requests) within the time limit set out in paragraph 1.
3. The rapporteur Member State shall take the necessary measures to ensure that the applicant complies with paragraph 2 by revising the public version of the scientific data, studies and other information submitted during the approval procedure in accordance with the rapporteur Member State's decision taken under Article 7 of this Decision (assessment of confidentiality requests).
4. Until the applicable software package used for the submission of the applications under Article 7(3) of Regulation 1107/2009 permits the direct intervention of the rapporteur Member State on the submitted dossier, once the confidential information has been sanitised to the satisfaction of the rapporteur Member State, the rapporteur Member State shall forward the sanitised documents to the Authority, which shall make the documents available to the public.

CHAPTER III COMMON PROVISIONS

Article 10

Provision of services by the Authority

1. For the exercise of their competences under Article 7(3) of Regulation (EC) No 1107/2009, and without prejudice of the advice to be provided by law under Article 7(7) above, the competent authority of the rapporteur Member States may receive support services from the Authority on a voluntary basis.
2. The Authority may recover the costs associated with the provision of support to the rapporteur Member State as per paragraph 1, by means of financial contributions as per Article 20(2) point *a* of Commission Delegated Regulation (EU) 2019/715⁹ to be specified in a Service Level Agreement. The Authority shall establish the financial contribution in a transparent manner and to a degree not exceeding the actual costs of the services provided by the Authority to the rapporteur Member State.

Article 11

Impartiality and independence

1. Pursuant to Article 41 of the CFREU, the administrative action of the European Union, including that of its Member States when implementing Union law, shall be based *inter alia* on the principle of impartiality and independence. The rapporteur Member State shall ensure that the assessment of a confidentiality request under Article 7 (assessment of confidentiality requests) is performed by officials, agents or professionals devoid of any bias or perception thereof.

⁹ Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, OJ L 122, 10.5.2019, p. 1–38.

2. For the purpose of ensuring compliance with paragraph 1, the rapporteur Member State shall ensure that staff involved in the handling of confidentiality requests are devoid of conflicts of interest.
3. The rapporteur Member State shall document compliance with the requirements set out in paragraphs 1 and 2.

Article 12

Personal data protection

1. Article 39e of Regulation (EC) No 178/2002 shall apply *mutatis mutandis* to the assessment of confidentiality requests by the competent authority of the rapporteur Member State under Regulation (EC) No 1107/2009 and these Practical Arrangements.
2. The processing of personal data by the rapporteur Member State is regulated by Regulation (EU) No 2016/679 (*General Data Protection Regulation*)¹⁰.

Article 13

Entry into force

This Decision shall enter into force on the day following its signature and shall apply from 27 March 2021.

Bernhard Url

Executive Director of the European Food Safety Authority

¹⁰ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119, 4.5.2016, p. 1–88.