



**Decision of the Executive Director of the European Food Safety Authority
Laying down practical arrangements concerning transparency and confidentiality**

**DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY
LAYING DOWN PRACTICAL ARRANGEMENTS CONCERNING
TRANSPARENCY AND CONFIDENTIALITY**

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 178/2002 of the European Parliament and Council, and in particular Articles 32b(8), 38(3) and 39d(5) thereof,¹
Having regard to Regulation (EC) No 1829/2003 of the European Parliament and Council,²
Having regard to Regulation (EC) No 1831/2003 of the European Parliament and Council,³
Having regard to Regulation (EC) No 2065/2003 of the European Parliament and Council,⁴
Having regard to Regulation (EC) No 1935/2004 of the European Parliament and Council,⁵
Having regard to Regulation (EC) No 1331/2008 of the European Parliament and Council,⁶
Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council⁷ and Commission Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives⁸,
Having regard to Regulation (EC) No 1107/2009 of the European Parliament and Council,⁹
Having regard to Regulation (EU) 2015/2283 of the European Parliament and Council,¹⁰
Having regard to Directive 2001/18/EC of the European Parliament and Council,¹¹
After consulting the European Commission pursuant to Article 39d(5) of Regulation (EC) No 178/2002,

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), as amended by 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.

² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1)

³ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

⁴ Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1).

⁵ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

⁶ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, (OJ L 354, 31.12.2008, p. 16).

⁸ Commission Regulation of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

⁹ 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).

¹⁰ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

¹¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

Whereas,

- (1) The Authority is an independent agency of the European Union responsible for providing scientific advice and scientific and technical support, information and risk communication in matters concerning food safety in order to improve consumer confidence in the food chain;
- (2) 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;
- (3) The Authority is fully committed to carrying out its mission taking as a basis a high level of transparency, while protecting the legitimate interests and rights of business operators;
- (4) 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/EC¹² (hereinafter "the Transparency Regulation") further strengthens the Authority's ability to carry out its risk assessment functions in accordance with a high transparency standards in a proactive manner. In determining the appropriate level of proactive disclosure, the Transparency Regulation has weighed up the relevant rights of the public to transparency in the risk assessment process against the rights of applicants or notifiers, taking into account the objectives of Regulation (EC) No 178/2002 (hereinafter "the General Food Law");
- (5) Accordingly, information, documents and data listed under Article 38(1) of the General Food Law Regulation should be made publicly available by the Authority in a proactive manner in a dedicated section on its website, with the exception of duly justified confidential information. That dedicated section must be publicly available and easily accessible. The information, documents and data to be publicly disclosed pursuant to Article 38(1) of the General Food Law Regulation must be available to be downloaded, printed and searched in an electronic format;
- (6) Article 39 of the General Food Law Regulation sets out specific requirements as to the items of information that may qualify for confidential treatment under certain conditions (hereinafter "closed positive-list"). To address sectoral specificities, this closed positive list is further supplemented by additional items 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. Specific requirements for the protection and confidentiality of personal data are also set out in Article 39e of the General Food Law Regulation. Furthermore, procedural requirements for the submission and processing of confidentiality requests, including their assessment, where a scientific output by the Authority is requested, are laid down in Articles 39a to 39d;
- (7) The provisions on the proactive dissemination laid down in the General Food Law Regulation and the relevant assessment of confidentiality requests should not affect the rights stemming from Regulation (EC) No 1049/2001¹³ 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 (henceforth the "Aarhus Regulation");¹⁴

¹² 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.

¹³ 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.

¹⁴ 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.

- (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 bodies should be subject to higher transparency standards;
- (9) Pursuant to Article 38(3) and Article 39d(5) of the General Food Law Regulation, the Authority should adopt practical arrangements ensuring the implementation of Article 38(1), 1a and (2), taking into account Article 39 to 39g and 41 of that Regulation. In this connection, the Authority should also ensure the implementation of Articles 39, 39a, 39b, 39d and 39e of that Regulation;
- (10) These arrangements should be applicable to all business operators and interested parties contributing to the Authority's calls for data or submitting scientific data, studies and other information, including supplementary information to the Authority in support of applications or notifications, or for evaluation by the Authority pursuant to established procedures under sectoral Union law 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*. Business operators and other interested parties should submit scientific data, studies and other information electronically and comply 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) and 1a;
- (11) Specific user manuals should also be made available on the Authority's website in due time after the entry into force of this Decision to ease the submission of these requests;
- (12) In view of the interconnected nature of proactive public disclosure and confidentiality provisions, 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;
- (13) This document should be complemented, where appropriate, by more specific instructions set out in a practical guidance for applicants submitting confidentiality requests, as well as, where appropriate, in the respective sectorial guidance documents issued by the Authority;
- (14) In making proactively available on its website the information items listed in Article 38(1) of the General Food Law Regulation, and in sectoral laws amended by the Transparency Regulation, the Authority should comply with its Decision on the Linguistic Regime¹⁵ applicable to its operations;
- (15) Applicants and other legal or natural persons submitting confidentiality requests should be provided with a clear, concrete and practical procedure, detailing their rights and obligations, the procedural steps they should follow, the timelines for decisions to be taken by the Authority on their requests, and practical indications concerning the information to be provided in support of their requests in accordance with Articles 39 to 39e, taking into account Article 41 of the General Food Law Regulation;
- (16) Applicants and other legal or natural persons submitting confidentiality requests should be provided with a complete list of the items on which confidentiality requests can be submitted;
- (17) Applicants and other legal or natural persons submitting confidentiality requests should also be provided with information concerning the legal remedies available in order to challenge decisions of the Authority taken pursuant to these practical arrangements. In that respect, effective legal remedies should be made available to applicants affected by the Authority's decisions on confidentiality requests. The possibility to submit a confirmatory application on a confidentiality decision should be deemed to represent a more recent, and more specific,

¹⁵ Decision of the Executive Director on the Linguistic Regime of EFSA, 20 April 2015, REF. EFSA/LRA/DEC/14046420/2015.

provision derogating from the more general provisions enabling the triggering of an administrative review of the Authority's decisions 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 396/2005¹⁶ or Article 6 of Regulation (EC) No 1367/2006;

- (18) To ensure a high level of transparency, legal certainty and accessibility, the present practical arrangements should take the form of a decision of the Authority's Executive Director;
- (19) Given that this decision implements certain provisions of Regulation (EU) 2019/1381, which applies from 27 March 2021, this decision should apply from the same date;
- (20) 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,

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

1. The objective of these practical arrangements is to give the fullest effect to the principle of transparency in the risk assessment process in the food chain, in particular in the context of the proactive public disclosure of all information supporting any request for a scientific output to be delivered by the Authority, with the exception of duly justified confidential data.
2. This decision outlines the standards and procedure applicable to the obligation of proactive publication of information laid down in Article 38(1) and (2) of Regulation (EC) No 178/2002 (General Food Law Regulation) and to the submission, and assessment, of any accompanying confidentiality requests in accordance with Articles 39, 39a, 39b, 39d and 39e, taking into account Articles 39f and 39g thereof.

Article 2

Scope

1. The present decision shall apply to all scientific data, studies and other information listed in Article 38(1) of the General Food Law Regulation and is without prejudice to any other specific provisions laid down in Union sectoral legislation in the area of the food chain.
2. Chapter III of the present decision shall apply to all confidentiality requests accompanying the submission of scientific data, studies and other information, including supplementary information, the assessment of which is entrusted to the Authority pursuant to the applicable Union provisions.¹⁷ It shall not apply to:

¹⁶ 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.

¹⁷ *E.g.* Regulation (EC) No 178/2002, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 2065/2003, Regulation (EC) No 1935/2004, and, Regulation (EC) No 1924/2006.

- (a) Confidentiality requests submitted to, and assessed by, the national competent authorities, under Article 25 of Directive 2001/18/EC;
- (b) Confidentiality requests submitted in accordance with Article 63 and assessed by the national competent authorities under Article 7 of Regulation (EC) No 1107/2009;
- (c) Confidentiality requests submitted in the context of Regulation (EC) No 1331/2008, where an opinion by the Authority is not required in accordance with Article 3(2) thereof.
- (d) Confidentiality requests submitted in the context of Regulation (EU) 2015/2283 with regard to notifications of traditional foods pursuant to Article 14, as well as applications of novel foods for which the Commission does not request the opinion of the Authority in accordance with Article 10(3) thereof.
- (e) Confidentiality requests submitted in the context of Article 7a of Commission Implementing Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives, where the Authority is not requested to take further steps.

Article 3

Definitions

1. For the purpose of this decision, and without prejudice to any relevant Union law provisions, the following definitions also apply:

(a) "Applicant" means:

- (i) any natural or legal person submitting an application or notification under Union law;
- (ii) any natural or legal person submitting scientific data and information for evaluation to the Authority pursuant to established sectoral Union law procedures;¹⁸
- (iii) where permitted under sectoral Union law procedures and/or in the absence thereof, any natural or legal person submitting information voluntarily to the Authority upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the General Food Law Regulation;
- (iv) any natural or legal person who has produced information supporting a request from the European Parliament, the Commission and the Member States for a scientific output and therefore having a direct interest with respect to the closed list of information items for which confidentiality treatment can be requested as laid down in the Annex.

This definition does not include the European Commission, the European Parliament, other Union Institutions, bodies, offices or agencies, Union Member States, or third countries' public authorities as such.

- (b) "Confirmatory application" means a request submitted in accordance with Article 12 (confirmatory application), asking for the review by the Authority's Executive Director of a decision taken by the Authority pursuant to Article 11 (confidentiality requests).
- (c) "Sanitisation" means the process of masking or unmasking scientific data, studies and other information in accordance with a confidentiality request or with a confidentiality decision, including the masking of personal data in accordance with Article 39e(2) of Regulation (EC) No 178/2002.

¹⁸ E.g. Article 8(4) of Regulation (EC) No 1925/2006 read in conjunction with Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods; Article 32 of Regulation (EC) 1332/2008.

- (d) "Data exclusivity rules" mean any provisions set out in sectoral Union law, which aim to protect the investments made by innovators in gathering the information and data supporting relevant applications for authorisations.

CHAPTER II

PROACTIVE TRANSPARENCY

Article 4

Submission of information, studies, documents and other data to the Authority

1. To ensure compliance with the requirements laid down in Article 38(1), last subparagraph of the General Food Law Regulation, applicants shall submit any information supporting applications or requests for a scientific output, including scientific data and scientific studies and supplementary information, electronically through the available tools and in accordance with applicable Union law requirements.
2. Where Standard Data Formats pursuant to Article 39f of the General Food Law Regulation exist, the information referred to in paragraph 1 should be submitted accordingly.
3. Pending the adoption of Standard Data Formats pursuant to Article 39f(2) of the General Food Law Regulation and in the absence of specific Union law requirements, applicants supplying any such information, are required to do so in the form of structured dossiers, and wherever possible using existing structured templates such as those developed by the OECD – OECD Harmonised Templates (OHTs) – and the Global Harmonised Submission Transport Standard (GHSTS) as transmission protocol, from machine to machine, or as permitted by the IT system made available by the Commission or the Authority for the submission of such dossiers. Where the nature of the information, documents or data is technically not compatible with OHT, semi-structured data may be submitted. The same obligation shall be applicable to all contributors of scientific data accompanying requests from the European Parliament, the Commission and the Member States for a scientific output by the Authority as well as to third parties sharing their datasets with the Authority.
4. Compliance with paragraphs 1 to 3, as applicable, shall be ensured with respect to:
 - (a) Submissions of non-confidential as well as confidential versions of application dossiers, information, documents and data, including supplementary information in accordance with Union law;
 - (b) Submissions of confidentiality requests pursuant to Article 9 of this Decision (Formal and procedural requirements for the submission of confidentiality requests) as well as, where appropriate, the justification supporting them;
5. Non-confidential versions of application dossiers, information, documents and data submitted in the context of this Article shall not contain personal data of any kind, with the exception of the name and address of the applicant, where applicable, and the names of authors of published or publicly available studies. Particular attention should be paid so as to ensure the absence, sanitisation or anonymisation, as appropriate, of information relating to identified or identifiable persons from non-confidential versions of dossiers, information, documents and data.

Article 5

Proactive disclosure of information, documents or data in relation to which confidentiality requests may not be submitted

1. The Authority shall make publicly available on its website the information, documents and data listed in Article 38(1) of the General Food Law Regulation.
2. For the purpose of Article 38(1) of the General Food Law Regulation, the Authority shall make proactively available the following information, documents and data, with no sanitisation by the Authority, according to the timeline indicated below:
 - (a) Agendas and lists of participants of meetings of the Management Board, the Advisory Forum, the Authority's networks, the Scientific Committee, the Scientific Panels and their working groups, and any other ad hoc group meeting on the subject matter shall be made public by the Authority without delay after the end of the relevant meeting.
 - (b) Annual declarations of interest ("ADoIs") made by the members of the Management Board, the Executive Director, members of the Authority's operational management and the members of the Advisory Forum, the Scientific Committee and the Scientific Panels, as well as the members of the working groups, and participants to pesticides peer review meetings shall be made public by the Authority without delay after their validation pursuant to the Authority's Policy on Independence.¹⁹ Additional transparency requirements related to Declarations of Interest ("DoI") screening processes are set out in the Authority's Policy on Independence.
 - (c) Oral DoIs made in relation to items on the agendas of meetings of the Management Board, the Advisory Forum, the Scientific Committee and the Scientific Panels, as well as of the working groups, shall be made public by the Authority without delay together with the disclosure of the minutes of these meetings.
 - (d) Annual reports of the Authority's activities, adopted by its Management Board in accordance with Article 25(8) of the General Food Law Regulation shall be made public by the Authority without delay after their adoption.
 - (e) All documents submitted to the Management Board for discussion or adoption at its open meetings shall be made public by the Authority without delay after the meeting takes place.
 - (f) Summaries of advice provided to potential applicants at the pre-submission phase pursuant to Articles 32a and 32c(1) of the General Food Law Regulation shall be made public by the Authority once an application has been considered admissible or valid.
 - (g) Without prejudice to Commission Implementing Regulation (EU) 2020/1740,²⁰ the comments received from the stakeholders and the public in the framework of public consultations performed in accordance with Article 32c(1) and (2) of the General Food Law shall be made public by the Authority without delay after the closure of the public consultation, except for their identity, in case the submitting entity or person requested non-public disclosure.

¹⁹ EFSA's Policy on Independence.

²⁰ 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.

Article 6

Proactive disclosure of information, studies, documents or data in relation to which confidentiality requests may be submitted

1. For the purpose of Article 38(1) of the General Food Law Regulation, the Authority shall make the information, documents or data listed below available in their non-confidential version according to the timeline indicated below:
 - (a) Minutes of meetings of the Management Board, the Advisory Forum, the Authority networks, the Scientific Committee and the Scientific Panels and their working groups, the Authority's peer review meetings, shall be made public by the Authority without delay after their finalisation.
 - (b) The Authority's scientific outputs, including the opinions of the Scientific Committee and the Scientific Panels, minority opinions as well as the Authority's conclusions on pesticides peer review processes, shall be made public by the Authority without delay after the adoption of the relevant scientific output, taking into account Article 39(4)(b) of the General Food Law Regulation, where applicable.
 - (c) Non-confidential versions – as submitted by applicants – of scientific data, studies and other information part of, or supporting, an application shall be made public by the Authority, without delay, once a valid or admissible application has been received by the Authority. Non confidential versions – as submitted by applicants – of any additional or supplementary information supplied by the latter, at the request of the Authority in relation to a submitted application shall be made public by the Authority, without delay, upon receipt.
 - (d) Results of consultations performed during the risk assessment process shall be made public by the Authority without delay after the adoption of the relevant scientific output.
 - (e) Scientific data and information, documents and data supporting requests from the European Parliament, the Commission and the Member States for a scientific output shall be made public by the Authority without delay once received by the Authority.
 - (f) Information notified pursuant to Article 32b(2) and (3) of the General Food Law Regulation shall be made public by the Authority without delay after a corresponding application has been considered valid or admissible and once a final decision on confidentiality requests becomes applicable.
 - (g) Any justifications provided by applicants pursuant to Article 32b(4) and (5) of the General Food Law Regulation to prove compliance with obligations requiring the notification of studies shall be made public by the Authority once a valid or admissible application has been received by the Authority..
 - (h) Any justifications provided by applicants pursuant to Article 32b(6) of the General Food Law Regulation to motivate the non-submission of certain data of notified studies included in the application shall be made public by the Authority without delay after the Authority concludes that they are valid.
 - (i) Information on which the Authority bases its scientific outputs, including scientific opinions, shall be made public by the Authority without delay after the adoption of the relevant scientific output.
 - (j) Requests from the European Parliament, from the Commission or from a Member State for scientific opinions, which have been refused or modified, and the justifications for the refusal or modification, shall be made public by the Authority without delay after their modification or refusal.

- (k) Scientific studies, including verification studies, commissioned by the Authority via a procurement or grant awarding procedure, shall be made public by the Authority without delay after the adoption of the related Authority's scientific output.
2. Where the information, studies, documents or data referred to in paragraph 1 are the subject of confidentiality requests or require sanitisation due to the rejection of confidentiality requests submitted by applicants, the Authority shall make public the updated version of the relevant document following its sanitisation pursuant to Article 13 (Implementation of the Authority's confidentiality decisions). Information notified to the Authority pursuant to Article 32b of the General Food Law Regulation shall be made available after the implementation of the relevant confidentiality decision pursuant to Article 13.

Article 7

Limitations of the re-use of disclosed data

1. Proactive disclosure by the Authority of information, documents or data referred to in Articles 5 (proactive disclosure of information, documents or data on which confidentiality requests may not be submitted) or 6 (Proactive disclosure of information, studies, documents or data in relation to which confidentiality requests may be submitted) shall not provide permission or licence for their dissemination, re-use, reproduction, or exploitation in breach of rules concerning existing rights, including intellectual property rights, or data exclusivity rules under Union law.
2. The Authority shall not be held responsible for re-use of the disclosed information, documents or data by third parties in breach of any existing rights, including intellectual property rights, or data exclusivity rules under Union law. The Authority is unable to guarantee the completeness, veracity, accuracy or integrity of information, documents or data made publicly available for the purposes of Article 38(1)(d) of the General Food Law. The Authority may not be held liable for errors, inaccuracies or inconsistencies with regard to information, documents or data available on its website and other than the scientific and administrative documents officially adopted, issued or endorsed by its bodies.

Article 8

Personal data protection

1. Without prejudice to Article 39e of the General Food Law Regulation, the processing of personal data by, or on the Authority's behalf, pursuant to this Decision shall be governed by Regulation (EU) 2018/1725.²¹
2. In application of Article 39e(3) of the General Food Law Regulation, personal data made public pursuant to this Decision shall only be used to ensure the transparency of the risk assessment processes managed by the Authority and shall not be further processed in a manner that is incompatible with this purpose, in accordance with point (b) of Article 4(1) of Regulation (EU) 2018/1725.

²¹ 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 (General Data Protection Regulation) (Text with EEA relevance) OJ L 119, 4.5.2016, p. 1–88.

CHAPTER III CONFIDENTIALITY

Article 9

Procedural requirements for the submission of confidentiality requests

1. Where an applicant requests certain parts of the information, documents or data forming part of a file submitted for the attention of the Authority to be treated as confidential in accordance with Articles 39 to 39e of the General Food Law Regulation and/or relevant sectoral Union law provisions, a confidentiality request shall be submitted through the applicable tools indicated by the Authority on its website.
2. No fees are attached to the submission, or processing, of confidentiality requests, although the Authority reserves the right to introduce charges pursuant to Article 43(1) of the General Food Law Regulation for publications, conferences, training and similar activities provided by the Authority concerning this topic.
3. Applicants submitting confidentiality requests may do so in the context of the following procedural steps:
 - (a) submission of scientific data, studies and other information supporting applications under relevant Union law provisions, including supplementary information upon request by the Authority;
 - (b) submission of scientific data and information to Authority for evaluation pursuant to established procedures under Union law;²²
 - (c) where permitted under established sectoral Union law procedures or in the absence thereof, voluntary submission of scientific data and information upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the General Food Law Regulation. This includes submissions made in response to public calls for data, other than those covered by point (b) above;
 - (d) submission of scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, pursuant to Article 38(1)(c) of the General Food Law Regulation;
4. Confidentiality requests may be submitted only with respect to certain parts of the submitted information, including scientific data, studies in support of applications or of requests by the Commission, Member States or the European Parliament for a scientific output, and provided that:
 - (a) they fall within the scope of the information items listed in the Annex; and
 - (b) verifiable justification is provided proving compliance with Article 10 (substantive requirements).
5. Applicants may not modify or complement confidentiality requests submitted to the Authority, unless requested to do so by the Authority. The Authority may request applicants having submitted a confidentiality request to provide clarifications when the information initially provided by them does not allow the Authority to issue a decision pursuant to Articles 11 (first decision) or 12 (confirmatory decision). In case of lack of reaction by the deadline set by the Authority, the confidentiality request shall be rejected.

²² E.g. Article 8(4) of Regulation (EC) No 1925/2006 read in conjunction with Commission Implementing Regulation (EU) No 307/2012.

Article 10

Substantive requirements (minimum content) for confidentiality requests

Applicants submitting confidentiality requests under Article 9 shall provide at least the following elements:

- (a) a clear identification of the relevant parts of the submitted information that, in their opinion, qualify for confidential treatment, accompanied by a link to and a detailed reference to the exact paragraph, page, line or part thereof as appropriate, where this information is located, in a sufficiently precise manner so as 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 the following cumulative requirements are deemed to be satisfied:
 - (i) the document, information or data for which confidential 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 confidential 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 Authority that the harm that may be caused is of a significance corresponding at least to 5% of the gross annual turnover²³ for legal persons, or the gross annual earnings for natural persons, for the financial year preceding the calendar year of 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 applicant shall provide a specific reason as to why they consider that any 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 confidential status is requested does, or does not, fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation;
 - (vi) the document, information or data for which confidential status is requested has been finalised in the form in which it was submitted to the Authority up to five (5) years prior to the submission of the confidentiality request. If the document, information or data for which confidential status is requested is older than five (5) years, the applicant shall provide (a) specific reason(s) as to why public disclosure of that information would still potentially harm its interests to a significant degree.

²³ 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.

Article 11

Decision on confidentiality requests

1. Confidentiality requests submitted in accordance with Article 39 to 39e of the General Food Law Regulation will be processed by the responsible department within the Authority. Such requests shall be handled on an individual basis pursuant to the Union and the Authority's code of Good Administrative Behaviour and to this decision.
2. Before assessing the merits of the confidentiality request, the department responsible for the processing of these requests shall first examine whether the request is admissible as per Article 9 (Procedural requirements for the submission of confidentiality requests).
3. Each confidentiality decision shall be adopted after assessing compliance of the requests with the requirements set out in Article 10 (Substantive requirements (minimum content) for confidentiality requests), and shall be taken in accordance with the following procedural measures:
 - (a) Where the Authority informs the applicant in writing through the applicable tools of its draft decision pursuant to Articles 11 (Decision on confidentiality request) or 14 (Review of previous confidentiality decisions) and the applicant disagrees with that assessment it can - through the applicable tools - state its views in writing or withdraw the application within two (2) calendar weeks of the notification of the Authority's draft decision.
 - (b) With respect to confidentiality requests received in languages other than English, the Authority shall operate in accordance with its Decision on the Linguistic Regime.
4. The Authority shall issue a decision on confidentiality requests no later than ten (10) calendar weeks from the receipt of a confidentiality request. A confidentiality request shall only be deemed received by the Authority when the application to which it refers has been considered valid or admissible and the Authority has been requested to provide a scientific output, including a scientific opinion.
5. The Authority shall decide upon confidentiality requests concerning additional or supplementary information provided once the submission has been considered complete in a single decision.
6. The Authority shall notify the applicant of its reasoned decision on the confidentiality request. The notification of the reasoned decision on the confidentiality request, or the decision itself, shall inform the applicant of its right to submit a confirmatory application, as per Article 12 (confirmatory application and decision).
7. The Authority shall communicate the reasoned decision on the confidentiality request to the Commission and the Member State's competent authorities or EU Reference Laboratory involved in the risk assessment process, as appropriate.

Article 12

Confirmatory application and resulting confirmatory decision

1. In accordance with Article 39b(2) of the General Food Law Regulation, the applicant may file a confirmatory application asking the Authority to reconsider its decision adopted under Article 11 (Decision on confidentiality requests) or under Article 14 (Review of previous confidentiality decisions).
2. Without prejudice to the possibility to provide clarifications at the Authority's request, the confirmatory application shall be limited to the review of the contested decision and shall not result

in new confidentiality requests, which were not part of the original confidentiality request subject to the confirmatory application.

3. The confirmatory application referred to in paragraph 1 shall be submitted via the relevant tool to the attention of the Authority's Executive Director within two (2) calendar weeks of the notification of the contested decision to the applicant.
4. The Authority shall put on hold the implementation of its confidentiality decisions with respect to which it has received confirmatory applications.
5. Following an examination of the accompanying grounds, the Executive Director shall issue a reasoned decision on the confirmatory application referred to in paragraph 1 and notify the applicant thereof via the relevant tool not later than three (3) calendar weeks from its receipt as per paragraphs 1 to 3 of Article 11.
6. The Authority shall notify the applicant of its reasoned confirmatory decision. The notification of the reasoned confirmatory decision, or the decision itself, shall indicate the possibility for the applicant to withdraw its application as well as the legal remedies available to the applicant, namely the possibility to bring an action challenging the legality of the confirmatory decision under Articles 263 and 278 of the Treaty on the Functioning of the European Union (TFEU).
7. The Authority shall communicate the reasoned confirmatory decision to the Commission and the Member States competent authorities or EU Reference Laboratory involved in the risk assessment process, as appropriate.

Article 13

Implementation of the Authority's confidentiality decisions

1. The Authority shall implement decisions taken under Articles 11 (Decision on confidentiality requests), 12 (Confirmatory application and resulting confirmatory decision) or 14 (Review of previous confidentiality decisions) without delay after the finalisation of such decisions, and shall aim at notifying the sanitised documents together with the confidentiality decisions, in accordance with the timeline foreseen for their adoption.
2. The Authority shall comply with paragraph 1 by revising the public (non-confidential) version of the information, document or data submitted by the applicant pursuant to Article 4 (Submission of scientific data, studies and other information to the Authority) in accordance with the Authority's decision taken under Articles 11 (Decision on confidentiality requests), 12 (Confirmatory application and resulting confirmatory decision), or 14 (Review of previous confidentiality decisions) and by submitting the revised version for dissemination by the timeline referred to in paragraph 1. The Authority shall carry out the sanitisation of the documents it develops, adopts or otherwise produces by ensuring the blackening of all information, documents or data to which it grants confidential status.
3. For the purpose of complying with paragraph 1, the Authority may share with the applicant the documents sanitised pursuant to this Article with a view to further verifying the consistency between the confidentiality decisions and the way in which they have been implemented by the Authority. This additional and optional verification shall not serve the purpose, or otherwise allow, the applicant to introduce new confidentiality requests, or reopen the decision making process concluded as per Articles 11 (Decision on confidentiality request), 12 (Confirmatory application and resulting confirmatory decision) or 14 (Review of previous confidentiality decisions).
4. After the steps mentioned in the previous paragraphs, the Authority shall publish the sanitised documents on its website in accordance with Article 6 (Proactive disclosure of

information, studies, documents or data in relation to which confidentiality requests may be submitted).

Article 14

Review of previous confidentiality decisions

1. Upon adoption by the Authority of a scientific output (i) containing information relating to foreseeable effects on human health, animal health or the environment, and (ii) when these effects relate to items that have been granted confidential status pursuant to a decision adopted under Articles 11 (Decision on confidentiality request) or 12 (Confirmatory application and resulting confirmatory decision), the Authority shall review this decision.
2. If the conditions set out in paragraph 1 are met, the Authority shall adopt a new reasoned decision concluding that the elements previously considered confidential must be made publicly available pursuant to Article 39c of the General Food Law Regulation. In the review of its previous decisions, the Authority shall follow the procedure set out in Articles 11 (Decision on confidentiality request). The decision shall be adopted within twenty (20) working days of the adoption of the concerned scientific output.
3. Article 12 (Confirmatory application and resulting confirmatory decision) shall be applicable to decisions adopted pursuant to paragraph 2. A reasoned confirmatory decision shall be adopted within ten (10) working days of the receipt of a confirmatory application.

Article 15

Withdrawal of applications and the impact on confidentiality decision making process

1. In cases whereby an applicant withdraws its application prior to the adoption of a corresponding confidentiality decision or, where relevant, prior to the issuing of a corresponding confirmatory decision, by submitting a withdrawal notification, the Member States, the Commission and the Authority shall not make public the information for which confidentiality had been requested pursuant to Article 9 (Procedural requirements for submission of confidentiality requests).
2. In cases whereby an applicant withdraws its application prior to the implementation of a corresponding confidentiality decision or, where relevant, prior to the implementation of a corresponding confirmatory decision, by submitting a withdrawal notification before a sanitised version of the relevant application dossier is made publicly available, the Member States, the Commission and the Authority shall not make public the information for which confidentiality had been requested pursuant to Article 9 (Procedural requirements for submission of confidentiality requests).
3. In cases whereby an applicant withdraws its application after the adoption and the implementation of a corresponding confidentiality decision or, where relevant, a corresponding confirmatory decision, including where relevant a corresponding review of a previous confidentiality decision, the Member States, the Commission and the Authority shall not make public information that has been granted confidential status.
4. In cases whereby an applicant withdraws its application in the context of the adoption of a decision under Article 14 (review of previous confidentiality decisions), the Member States, the Commission and the Authority shall likewise not make public the information that has been granted confidential status pursuant to the decision under review or for which confidentiality was requested .

5. Upon receipt of a withdrawal notice from the applicant, the Authority shall delete from its website without delay all information made publicly available pursuant to Article 6 (Proactive disclosure of information, studies, documents or data in relation to which confidentiality requests may be submitted) and in accordance with Article 13 (Implementation of the Authority's confidentiality decisions). The Authority shall store one copy of the withdrawn information, documents or data in its archives for auditing purposes in accordance with its internal rules on archiving. This Article is without prejudice to Regulation (EC) No 1049/2001, or Regulation (EC) No 1367/2006.

Article 16

Handling of items in relation to which confidentiality requests have been submitted or which have been granted "confidential status"

1. The Authority shall ensure that items for which a decision concerning confidentiality is still pending, or which have been awarded confidential status, are made available upon request, to the Commission and the Member States, unless otherwise specified in Union law. Internally, the Authority shall make available these items only to the individuals who need to have access to them in order to perform the tasks assigned to them in the context of their operational responsibilities.
2. For the purposes of paragraph 1, the Authority also shall communicate to the intended recipients the relevant confidentiality requests, and shall identify items for which confidential status has been awarded pursuant to Articles 11 (Decision on confidentiality requests), 12 (Confirmatory application and resulting confirmatory decision) or 14 (Review of previous confidentiality decisions).
3. The Authority, the Commission and the Member States shall ensure that items they receive and for which confidentiality requests have been submitted pursuant to Article 4 (Submission of scientific data, studies and other information to the Authority), or which have been awarded confidential status pursuant to Articles 11 (Decision on confidentiality requests), 12 (Confirmatory application and resulting confirmatory decision) or 14 (Review of previous confidentiality decisions), are not disclosed to unauthorised third parties, unless this becomes necessary where urgent action is essential for the purposes of protecting human health, animal health or the environment, pursuant to Article 39(4)(a) of the General Food Law Regulation.
4. In order to ensure the protection of items awarded confidential status pursuant to Articles 11 (Decision on confidentiality requests), 12 (Confirmatory application and resulting confirmatory decision) or 14 (Review of previous confidentiality decisions), the Authority, the Commission and the Member States shall put in place IT and physical solutions ensuring the appropriate degree of IT and physical security in accordance with Article 39g of the General Food Law Regulation.

CHAPTER IV COMMON PROVISIONS

Article 17

Individuals' obligation of professional secrecy

1. Members of the Management Board, the Executive Director, the Scientific Committee and Scientific Panels, Working Groups, peer review meetings and any other meeting on a subject matter dealt with by the aforementioned scientific bodies, as well as members of the Advisory Forum and networks, shall sign a written declaration that they undertake to comply with the obligation of professional secrecy pursuant to Article 339 TFEU.
2. Individuals referred to in paragraph 1 shall be bound not to disclose information of the kind covered by the obligation of professional secrecy, including the obligation to protect items granted confidential status by the Authority in accordance with Articles 11 (Decision on confidentiality requests), 12 (Confirmatory application and resulting confirmatory decision) or 14 (Review of previous confidentiality decisions), or claimed confidential by the persons submitting a confidentiality request, pending a confidentiality decision thereon.
3. Members of the Authority's staff shall be subject to the obligation of professional secrecy set out in Article 339 of TFEU. They are bound not to disclose information of the kind covered by the obligation of professional secrecy and shall refrain from any unauthorised disclosure of information received in the line of duty as per Article 17 of the Staff Regulations of officials and the Conditions of Employment of other servants of the European Union,²⁴ unless that information has already been made public or is accessible to the public.
4. The obligations set out in paragraphs 1 to 3 shall last during the term of office, service or appointment and shall continue after their duties have ceased with respect to the information and knowledge acquired during the term of office, service or appointment. The Authority shall ensure that individuals handling or processing confidentiality requests and decisions dispose of the necessary professional background and expertise and shall develop, also by the means of training, a corporate culture of regulatory awareness conducive to the adoption of legally sound and well-reasoned decisions.

Article 18

Individuals' obligation of impartiality

1. The Authority attaches high value to the importance of ensuring the neutrality of the processes it is responsible for and the impartiality of the professionals involved therein. In order to ensure that the assessment of a confirmatory application under Article 12 (confirmatory application) or of a confirmatory application submitted with regard to a confidentiality decision adopted under Article 14 (review) is evaluated by officials or agents devoid of any actual or reasonably perceivable bias, the confirmatory application shall be assigned to individuals not involved in the preparation or adoption of the respective contested decision.
2. The Authority shall ensure that staff involved in the handling of confidentiality requests are devoid of conflicts of interest pursuant to its Policy on independence²⁵ and are in a position to fulfil their duties impartially.

²⁴ OJ 45, 14.6.1962, p. 1385.

²⁵ EFSA, mb170621-a2, EFSA's policy on independence – ADOPTED.

3. The Authority shall document and monitor compliance with the requirements set out in this Article by setting up and maintaining a roster of staff involved in the handling of each confidentiality request.

Article 19

Entry into force

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

Done on

Bernhard Url

Executive Director of the European Food Safety Authority

Annex –Items for which confidentiality requests may be submitted

a. When submitting supporting scientific data and other supplementary information in accordance with Union law unless falling under one of the sectoral legal acts listed in letters b to h below.	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Article 39(2)(a) of Regulation (EC) No 178/2002	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
Article 39(2)(b) of Regulation (EC) No 178/2002	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
Article 39(2)(c) of Regulation (EC) No 178/2002	commercial information revealing sourcing, market shares or business strategy of the applicant;
Article 39(2)(d) of Regulation (EC) No 178/2002	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;
Article 39e(1) of Regulation (EC) No 178/2002	any personal data except for (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.
Article 39e(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information.
b. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 1829/2003	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Article 30(2)(a) of Regulation (EC) No 1829/2003	DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and

Article 30(2)(b) of Regulation (EC) No 1829/2003	breeding patterns and strategies;
Article 30 of Regulation 1829/2003 (making reference to Article 39 of Regulation (EC) No 178/2002)	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant;
Article 30 of Regulation 1829/2003 (making reference to Article 39e(1) of Regulation (EC) No 178/2002)	any other personal data except for <ul style="list-style-type: none"> (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.
Article 30 of Regulation 1829/2003 (making reference to Article 39e(2) of Regulation (EC) No 178/2002)	personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies or in obtaining toxicological information.

c. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 1831/2003	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Article 18(3)(a) of Regulation (EC) No 1831/2003	the study plan for studies demonstrating the efficacy of a feed additive in terms of the aims of its intended use as defined in Article 6(1) of, and Annex I to Regulation (EC) No 1831/2003;
Article 18(3)(b) of Regulation (EC) No 1831/2003	specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment;
Article 18(3) of Regulation (EC) No 1831/2003 (making reference to Article 39 of Regulation (EC) No 178/2002)	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant;
	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;

<p>Article 39e(1) of Regulation (EC) No 178/2002</p>	<p>any other personal data except for</p> <ul style="list-style-type: none"> (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.
<p>Article 39e(2) of Regulation (EC) No 178/2002</p>	<p>personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies or in obtaining toxicological information.</p>

<p>d. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 2065/2003</p>	
<p>Legal basis under which the request may be submitted</p>	<p>Items that may be claimed confidential</p>
<p>Article 15(1) of Regulation (EC) No 2065/2003 (making reference to Article 39 of Regulation (EC) No 178/2002)</p>	<p>the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;</p> <p>commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;</p> <p>commercial information revealing sourcing, market shares or business strategy of the applicant;</p> <p>quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;</p>
<p>Article 15(1) of Regulation (EC) No 2065/2003 making reference to Article 39e(1) of Regulation (EC) No 178/2002</p>	<p>any other personal data except for</p> <ul style="list-style-type: none"> (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.
<p>Article 39e(2) of Regulation (EC) No 178/2002</p>	<p>personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies or in obtaining toxicological information.</p>

e. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 1935/2004	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Article 20(2)(a) of Regulation (EC) No 1935/2004	any information provided in detailed descriptions of starting substances and mixtures used to manufacture the substance subject to the authorisation, the composition of mixtures, materials or articles in which the applicant intends to use that substance, the manufacturing methods of those mixtures, materials or articles, impurities, and migration testing results, except for information which is relevant to the assessment of safety;
Article 20(2)(b) of Regulation (EC) No 1935/2004	the trademark under which the substance shall be marketed as well as the trade name of the mixtures, material or articles in which it shall be used, where applicable;
Article 20(2)(c) of Regulation (EC) No 1935/2004	any other information deemed confidential within the specific procedural rules referred to in point (n) of Article 5(1) of Regulation (EC) No 1935/2004;
Article 20(2) of Regulation (EC) No 1935/2004 (making reference to Article 39 of Regulation (EC) No 178/2002)	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant
Article 20(2) of Regulation (EC) No 1935/2004 (making reference to Article 39 of Regulation (EC) No 178/2002)	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;
	any other personal data except for
	(a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.
Article 39e(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies or in obtaining toxicological information.

f. When submitting supporting scientific data and other supplementary information with the procedure set out in Regulation (EC) No 1331/2008	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Article 12(3)(a) of Regulation (EC) No 1331/2008	Where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety;

Article 12(3)(b) of Regulation (EC) No 1331/2008	where applicable, detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety;
Article 12(3) of Regulation (EC) No 1331/2008 (making reference to Article 39 of Regulation (EC) No 178/2002)	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant;
	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;
Article 12(2) of Regulation (EC) No 1331/2008 (making reference to Article 39e(1) of Regulation (EC) No 178/2002)	any other personal data except for (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.
Article 39e(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies or in obtaining toxicological information.

g. When submitting supporting scientific data and other supplementary information under Regulation (EC) No 1107/2009	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of Regulation (EC) No 178/2002)	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant;
	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;

Article 63(2)(b) of Regulation (EC) No 1107/2009	the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities;
Article 63(2)(c) of Regulation (EC) No 1107/2009	results of production batches of the active substance including impurities;
Article 63(2)(d) of Regulation (EC) No 1107/2009	information on the complete composition of a plant protection product;
Article 39(e)(1) of Regulation (EC) No 178/2002	any other personal data except for (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and 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.
Article 39(e)(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information.

h. When submitting supporting scientific data and other supplementary information under Regulation (EU) 2015/2283	
Legal basis under which the request may be submitted	Items that may be claimed confidential
Articles 23(1) and 23(4) of Regulation (EU) 2015/2283 (making reference to Article 39(2) of Regulation (EC) No 178/2002)	the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
	commercial information revealing sourcing, market shares or business strategy of the applicant;
	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety;
Article 23(4)(a) of Regulation (EU) 2015/2283	where applicable, information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the assessment of safety;
Article 23(4)(b) of Regulation (EU) 2015/2283	where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety;
Article 39(e)(1) of Regulation (EC) No 178/2002	any other personal data except for (a) the name and address of the applicant; (b) the names of authors of published or publicly available studies supporting such requests; and (c) 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.

Article 39(e)(2) of Regulation (EC) No 178/2002	personal data (names and addresses) of individuals involved in testing on vertebrate studies or in obtaining toxicological information.
---	---