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

as amended by Regulation (EC) No 596/2009
as amended in 2019 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 of 6/9/2019, p. 1 – entered into force 26/9/2919, becoming applicable 21/3/2021)

– General Food Law –

highlighted in red

and

Regulation of the European Parliament and of the Council (EU) 2019/1243 of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 178 of 25/7/019, p. 241 – entered into force 26/7/2019)

– "Lisbonisation" –

highlighted in blue

Article 1

Subject matter

1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to smoke flavourings used or intended for use in or on foods, whilst providing the basis for securing a high level of protection for human health and the interests of consumers.

2. To this end, this Regulation lays down:

(a) a Community procedure for the evaluation and authorisation of primary smoke condensates and primary tar fractions for use as such in or on foods or in the production of derived smoke flavourings for use in or on foods;

(b) a Community procedure for the establishment of a list of primary smoke condensates and primary tar fractions authorised to the exclusion of all others in the Community and their conditions of use in or on foods.

Article 2

Scope

This Regulation shall apply to:

1. smoke flavourings used or intended for use in or on foods;

2. source materials for the production of smoke flavourings;

3. the conditions under which smoke flavourings are prepared;

4. foods in or on which smoke flavourings are present.

Article 3

Definitions

For the purposes of this Regulation, the definitions laid down in Directive 88/388/EEC[1] and Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

1. 'primary smoke condensate' shall refer to the purified water-based part of condensed smoke and shall fall within the definition of 'smoke flavourings';

2. 'primary tar fraction' shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of 'smoke flavourings';

3. 'primary products' shall refer to primary smoke condensates and primary tar fractions;

4. 'derived smoke flavourings' shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Article 4

General use and safety requirements

1. The use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that

— it does not present risks to human health,

— it does not mislead consumers.

Each authorisation may be subject to specific conditions of use.

2. No person shall place on the market a smoke flavouring or any food in or on which such a smoke flavouring is present if the smoke flavouring is not a primary product authorised in accordance with Article 6, or if is not derived therefrom, and if the conditions of use laid down in the authorisation in accordance with this Regulation are not adhered to.

Article 5

Conditions of production

1. The wood used for the production of primary products shall not have been treated, whether intentionally or unintentionally, with chemical substances during the six months immediately preceding felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not give rise to potentially toxic substances during combustion.

The person who places on the market primary products must be able to demonstrate by appropriate certification or documentation that the requirements laid down in the first subparagraph have been met.

2. The conditions for the production of primary products are laid down in Annex I. The water-insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.

3. Without prejudice to other Community legislation, primary products may be further processed by appropriate physical processes for the production of derived smoke flavourings. Where opinions differ as to whether a

[1] Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production; repealed by: Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods

particular physical process is appropriate, a decision may be reached in accordance with the procedure referred to in Article 19(2).

Article 6

Community list of authorised primary products

1. A list of the primary products authorised to the exclusion of all others in the Community for use as such in or on foods and/or for the production of derived smoke flavourings shall be established in accordance with the procedure referred to in Article 19(2).

2. In respect of each authorised primary product, the list referred to in paragraph 1 shall give a unique code for that product, the name of the product, the name and address of the authorisation holder, a clear description and characterisation of the product, the conditions of its use in or on specific foods or food categories and the date from which the product is authorised.

3. Following the establishment of the list referred to in paragraph 1, primary products may be added to that list in accordance with the procedure referred to in Article 19(2).

Article 7

Application for authorisation

1. To obtain the inclusion of a primary product in the list referred to in Article 6(1), an application shall be submitted in accordance with the following provisions.

2.

(a) The application shall be sent to the competent authority of a Member State.

(b) The competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the 'Authority'); and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

~~(c) The Authority shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.~~ *Replaced by:*

(c) The Authority shall:

(i) inform without delay the Commission and the other Member States of the application and shall make the application and any supplementary information supplied by the applicant available to them; and

(ii) make public the application, relevant supporting information and any supplementary information supplied by the applicant, in accordance with Articles 14 and 15.

3. The application shall be accompanied by the following:

(a) the name and address of the applicant;

(b) the information listed in Annex II;

(c) a reasoned statement affirming that the product complies with Article 4(1), first indent;

(d) a summary of the dossier.

~~4. The Authority shall publish detailed guidance concerning the preparation and the submission of the application.~~

4. The Authority shall publish detailed guidance, following the agreement with the Commission, concerning the preparation and the submission of the application, referred to in paragraph 1 of this Article, taking into account standard data formats, where they exist in accordance with Article 39f of Regulation (EC) No 178/2002.

Article 8

Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application as to whether the product and its intended use complies with Article 4(1). The Authority may extend the said period. In such a case it shall provide an explanation for the delay to the applicant, the Commission and the Member States.

2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority which in no event shall exceed 12 months. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that this information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.

3. In order to prepare its opinion, the Authority shall:

(a) verify that the particulars and documents submitted by the applicant are in accordance with Article 7(3) in which case the application shall be regarded as valid;

(b) inform the applicant, the Commission and the Member States if an application is not valid.

4. In the event of an opinion in favour of authorising the evaluated product, the opinion shall include:

(a) any conditions or restrictions which should be attached to the use of the evaluated primary product either as such and/or as derived smoke flavourings in or on specific foods or food categories;

(b) an assessment as to whether the analytical method proposed in accordance with point 4 of Annex II is appropriate for the intended control purposes.

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.

6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 15.

Article 9

Community authorisation

1. Within three months of receiving the opinion of the Authority, the Commission shall prepare a draft of the measure to be taken in respect of the application for inclusion of a primary product in the list referred to in Article 6(1), taking into account the requirements of Article 4(1), Community law and other legitimate factors relevant to the matter under consideration. Where the draft measure is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the reasons for the differences.

The measure referred to in the first subparagraph shall be

(a) a draft regulation amending the list referred to in Article 6(1), by including the primary product on the list of authorised products, in accordance with the requirements under Article 6(2); or

(b) a draft decision, addressed to the applicant, refusing authorisation.

2. The measure shall be adopted in accordance with the procedure referred to in Article 19(2). The Commission shall inform the applicant of its adoption without delay.

3. Without prejudice to Article 11, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for 10 years and shall be renewable in accordance with Article 12.

4. After an authorisation has been issued in accordance with this Regulation, the authorisation holder or any other food business operator using the authorised primary product or derived smoke flavourings shall comply with any condition or restriction attached to such authorisation.

5. The authorisation holder shall inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the authorised primary product or derived smoke flavourings in relation to human health. If necessary, the Authority shall then review the assessment.

6. The granting of an authorisation shall not diminish the general civil and criminal liability of any food business operator in respect of the authorised primary product, derived smoke flavouring or food containing the authorised primary product or derived smoke flavouring.

Article 10

Initial establishment of the Community list of authorised primary products

1. During the 18 months following the entry into force of this Regulation, business operators shall submit an application in accordance with Article 7 with a view to the establishment of an initial Community list of authorised primary products. Without prejudice to Article 9(1), this initial list shall be established after the Authority has issued an opinion on each primary product for which a valid application has been submitted during this period.

Applications for which the Authority could not issue an opinion owing to the applicant's failure to comply with the time limits specified for submission of supplementary information in accordance with Article 8(2) shall be excluded from consideration for inclusion in the initial Community list.

2. Within three months of receiving all the opinions referred to in paragraph 1, the Commission shall prepare a draft regulation for the initial establishment of the list referred to in Article 6(1), having regard to the requirements of Article 6(2).

Article 11

Modification, suspension and revocation of authorisations

1. The authorisation holder may, in accordance with the procedure laid down in Article 7, apply for a modification of the existing authorisation.

2. On its own initiative or following a request from a Member State or the Commission, the Authority shall deliver an opinion on whether an authorisation is still in accordance with this Regulation, following the procedure laid down in Article 8, where applicable.

3. The Commission shall examine the opinion of the Authority without delay and prepare a draft of the decision to be taken.

4. A draft measure modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attaching to that authorisation.

5. The final measure, i.e. the modification, suspension or revocation of the authorisation, shall be adopted in accordance with the procedure referred to in Article 19(2).

6. The Commission shall without delay inform the authorisation holder of the measure taken.

Article 12

Renewal of authorisations

1. Without prejudice to Article 11, authorisations under this Regulation shall be renewable for 10-year periods on application to the Commission by the authorisation holder, at the latest 18 months before the expiry date of the authorisation.

2. The application shall be accompanied by the following particulars and documents:

(a) a reference to the original authorisation;

(b) any available information concerning the points listed in Annex II which supplements the information already provided to the Authority in the course of the previous evaluation(s) and updates this in the light of the most recent scientific and technical developments;

(c) a reasoned statement affirming that the product complies with Article 4(1), first indent.

3. Articles 7 to 9 shall apply *mutatis mutandis*.

4. Where, for reasons beyond the control of the authorisation holder, no decision is taken on the renewal of an authorisation until one month before its expiry date, the period of authorisation of the product shall automatically be extended by six months. The Commission shall inform the authorisation holder and the Member States about the delay.

Article 13

Traceability

1. At the first stage of the placing on the market of an authorised primary product or smoke flavouring derived from the authorised products specified in the list referred to in Article 6(1), food business operators shall ensure that the following information is transmitted to the food business operator receiving the product:

(a) the code of the authorised product as given in the list referred to in Article 6(1);

(b) the conditions of use of the authorised product as set out in the list referred to in Article 6(1);

(c) in the case of a derived smoke flavouring, the quantitative relation to the primary product; this shall be expressed in clear and easily understandable terms so that the receiving food business operator can use the derived smoke flavouring in compliance with the conditions of use set out in the list referred to in Article 6(1).

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, food business operators shall ensure that the information received in accordance with paragraph 1 is transmitted to the food business operators receiving the products.

3. Food business operators shall have in place systems and procedures making it possible to identify the person from whom and to whom the products mentioned in paragraph 1 have been made available.

4. Paragraphs 1 to 3 shall be without prejudice to other specific requirements under Community legislation.

Article 14

Public access

~~1. Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of Regulation (EC) No 178/2002.~~ *Replaced by:*

1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant as well as its scientific opinions, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002.

2. The Authority shall apply the principles of 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 when handling applications for access to documents held by the Authority.

3. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

Article 15 (new)

Confidentiality

~~1. The applicant may indicate which information submitted under Article 7 should be treated as confidential because disclosure may significantly harm his or her competitive position. Verifiable justification must be given in such cases.~~

~~2. Without prejudice to paragraph 3, the Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant and the Authority of its decision.~~

~~3. Without prejudice to Article 39(3) of Regulation (EC) No 178/2002, information relating to the following shall not be considered confidential:~~

~~(a) the name and address of the applicant and the name of the product;~~

~~(b) in the case of an opinion in favour of authorising the evaluated product, the particulars mentioned in Article 6(2);~~

~~(c) information of direct relevance to the assessment of the safety of the product;~~

~~(d) the analytical method referred to in point 4 of Annex II.~~

~~4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and the Member States with all information in its possession.~~

~~5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation except for information which must be made public if circumstances so require in order to protect human health.~~

~~6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of the commercial and industrial information provided, including research and development information as well as information on which the Commission and the applicant disagree as to its confidentiality.~~

Replaced by:

1. In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002: (a) the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification; and (b) the Authority shall assess the confidentiality request submitted by the applicant.

2. This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002.

Article 16

Data protection

The information in the application submitted according to Article 7 may not be used for the benefit of another applicant, unless the other applicant has agreed with the authorisation holder that such information may be used.

Article 17

Inspection and control measures

1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.

2. Where necessary and at the request of the Commission, the Authority shall assist in developing technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1.

3. ~~If necessary, the Commission shall, after requesting scientific and technical assistance from the Authority, adopt quality criteria for validated analytical methods proposed in accordance with point 4 of Annex II, including substances to be measured.~~

~~Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).~~ *Replaced by:*

The Commission is empowered to adopt delegated acts in accordance with Article 18a in order to supplement this Regulation by establishing quality criteria for validated analytical methods referred to in point 4 of Annex II, including substances to be measured. Those delegated acts shall take into account available scientific evidence.

Article 18

Amendments

1. ~~Amendments to the Annexes shall be adopted by the Commission following a request to the Authority for scientific and/or technical assistance. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3).~~ *Replaced by:*

The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the Annexes following a request to the Authority for scientific and/or technical assistance.

2. Amendments to the list referred to in Article 6(1) shall be adopted in accordance with the regulatory procedure referred to in Article 19(2) following a request to the Authority for scientific and/or technical assistance.

Article 18a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 17(3) and Article 18(1) shall be conferred on the Commission for a period of five years from ... [date of entry into force of this amending Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period.

3. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period. The delegation of power referred to in Article 17(3) and Article 18(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.[2]

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 17(3) and Article 18(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 19

Committee procedure

1. The Commission shall be assisted by the Committee referred to in Article 58(1) of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

~~3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.~~

[2] OJ L 123 of 12/5/2016, p. 1–14

Article 20

Transitional measures

Without prejudice to Article 4(2), trade in and use of the following primary products and derived smoke flavourings, as well as foods containing any of those products, already on the market on the date of entry into force of this Regulation, shall be permitted for the following periods:

(a) primary products for which a valid application is submitted in accordance with Article 7 and Article 8(3) before 16 June 2005 and derived smoke flavourings: until the establishment of the list referred to in Article 10(1);

(b) foods containing primary products for which a valid application is submitted in accordance with Article 7 and Article 8(3) before 16 June 2005 and/or containing derived smoke flavourings: until 12 months after the establishment of the list referred to in Article 10(1);

(c) foods containing primary products for which a valid application is not submitted in accordance with Article 7 and Article 8(3) before 16 June 2005 and/or derived smoke flavourings: until 16 June 2006.

Foods that have been lawfully placed on the market before the end of the periods referred to in (b) and (c) may be marketed until stocks are exhausted.

Article 21

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4(2) shall apply from 16 June 2005. Until this date, national provisions in force concerning smoke flavourings and their use in and on foods continue to apply in the Member States.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

Conditions for the production of primary products

1. Smoke is generated from the wood referred to in Article 5(1). Herbs, spices, twigs of juniper and twigs, needles and cones of picea may be added if they are free of residues of intentional or unintentional chemical treatment or if they comply with more specific Community legislation. The source material is subjected to controlled burning, dry distilla- tion or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600 °C.

2. The smoke is condensed. Water and/or, without prejudice to other Community legislation, solvents may be added to achieve phase separation. Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases:

(a) a water-based 'primary smoke condensate' mainly containing carboxylic acids, carbonylic and phenolic compounds, having a maximum content of:

benzo[a]pyrene	10 µg/kg
benz[a] anthracene	20 µg/kg

(b) a water-insoluble high-density tar phase which during the phase separation will precipitate, and which cannot be used as such for the production of smoke flavourings but only after appropriate physical processing to obtain fractions from this water-insoluble tar phase which are low in polycyclic aromatic hydrocarbons, already defined as 'primary tar fractions', having a maximum content of:

benzo[a]pyrene	10 µg/kg
benz[a] anthracene	20 µg/kg

(c) a 'water-insoluble oily phase'.

If no phase separation has occurred during or after the condensation, the smoke condensate obtained must be regarded as a water-insoluble high-density tar phase, and must be processed by appropriate physical processing to obtain primary tar fractions which stay within the specified limits.

ANNEX II

Information necessary for the scientific evaluation of primary products

The information should be compiled in accordance with the guidelines referred to in Article 7(4) and should be submitted as described therein. Without prejudice to Article 8(2), the following information should be included in the application for authorisation referred to in Article 7:

1. the type of wood used for the production of the primary product;

2. detailed information on the production methods of the primary products and the further processing in the production of derived smoke flavourings;

3. the qualitative and quantitative chemical composition of the primary product and the characterisation of the portion which has not been identified. Of major importance are the chemical specifications of the primary product and information on the stability and the degree of variability of the chemical composition. The portions which have not been identified, i.e. the amount of substances whose chemical structure is not known, should be as small as possible and should be characterised by appropriate analytical methods, e.g. chromatographic or spectrometric methods;

4. a validated analytical method for sampling, identification and characterisation of the primary product;

5. information on the intended use levels in or on specific foods or food categories;

6. toxicological data following the advice of the Scientific Committee on Food given in its report on smoke flavourings of 25 June 1993 or its latest update.

([1]) OJ C 262 E, 29.10.2002, p. 523.

([2]) OJ C 85, 8.4.2003, p. 32.

([3]) Opinion of the European Parliament of 5 June 2003 (not yet published in the Official Journal) and the Council Decision of 9 October 2003.

([4]) OJ L 184, 15.7.1988, p. 61; Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

([5]) Reports of the Scientific Committee for Food, 34th series, pp. 1 to 7.

([6]) Council of Europe Publishing, 1992, reprinted 1998, ISBN 92-871-2189-3.

([7]) OJ L 31, 1.2.2002, p. 1.

([8]) OJ L 184, 17.7.1999, p. 23.

([9]) Until publication, applicants shall follow the 'Guidance on submissions for food additive evaluations' by the Scientific Committee on Food, of 11 July 2001 or its latest update: http://europa.eu.int/comm/food/fs/sc/scf/out98_en.pdf

([10]) OJ L 145, 31.5.2001, p. 43.

"Additional recital"

The "Lisbonisation" legislative act provides for a clause that must be read in conjunction with the provisions of the Smoke Flavourings Regulation on delegated acts. It reads:

"In order to achieve the objectives of Regulation (EC) No 2065/2003, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to that Regulation following a request to the Authority for scientific and/or technical assistance and to supplement that Regulation with quality criteria for validated analytical methods. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.[3] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts."

[3] OJ L 123 of 12/5/2016, p. 1–14

Regulation (EC) No 178/2002, as amended (excerpt)

Article 39

Confidentiality

1. By way of derogation from Article 38, the Authority shall not make public any information for which confidential treatment has been requested under the conditions laid down in this Article.

2. Upon the request of an applicant, the Authority may grant confidential treatment only with respect to the following items of information where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:

(a) 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;

(b) commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;

(c) commercial information revealing sourcing, market shares or business strategy of the applicant; and

(d) quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

3. The list of information referred to in paragraph 2 shall be without prejudice to any sectoral Union law.

4. Notwithstanding paragraphs 2 and 3:

(a) where urgent action is essential to protect human health, animal health or the environment, such as in emergency situations, the Authority may disclose the information referred to in paragraphs 2 and 3;

(b) information which forms part of conclusions of scientific outputs, including scientific opinions, delivered by the Authority and which relate to foreseeable effects on human health, animal health or the environment, shall nevertheless be made public.

Article 39a

Confidentiality request

1. When submitting an application, supporting scientific data and other supplementary information in accordance with Union law, the applicant may request certain parts of the information submitted to be treated as confidential in accordance with Article 39(2) and (3). Such request shall be accompanied by verifiable justification that demonstrates how making public the information concerned significantly harms the interests concerned in accordance with Article 39(2) and (3).

2. Where an applicant submits a request for confidentiality, it shall provide a non- confidential version and a confidential version of the information submitted in accordance with standard data formats, where they exist, pursuant to Article 39f. The non-confidential version shall not include the information the applicant deems confidential on the basis of Article 39(2) and (3) and shall indicate the places where such information has been deleted. The confidential version shall contain all information submitted, including information the applicant deems confidential. Information requested to be treated as confidential in the confidential version shall be clearly marked. The applicant shall clearly indicate the grounds on the basis of which confidentiality is requested for the different pieces of information.

Article 39b

Decision on confidentiality

1. The Authority shall:

(a) make public the non-confidential version of the application as submitted by the applicant without delay once that application has been considered valid or admissible;

(b) proceed, without delay, to a concrete and individual examination of the confidentiality request in accordance with this Article;

(c) inform the applicant in writing of its intention to disclose information and the reasons for that, before the Authority formally takes a decision on the confidentiality request. If the applicant disagrees with the assessment of the Authority, the applicant may state its views or withdraw its application within two weeks of the date on which it was notified of the Authority's position;

(d) adopt a reasoned decision on the confidentiality request, taking into account the observations of the applicant, within 10 weeks of the date of receipt of the confidentiality request with respect to applications and without delay in the case of supplementary data and information; notify the applicant of its decision and provide information on the right to submit a confirmatory application in accordance with paragraph 2;, and inform the Commission and the Member States, where appropriate, of its decision; and

(e) make public any additional data and information for which the confidentiality request has not been accepted as justified at the earliest two weeks after the notification of its decision to the applicant has taken place pursuant to
point (d).

2. Within two weeks of the notification of the Authority's decision on the confidentiality request to the applicant pursuant to paragraph 1, the applicant may submit a confirmatory application asking the Authority to reconsider its decision. The confirmatory application shall have suspensive effect. The Authority shall examine the grounds for the confirmatory application and shall adopt a reasoned decision on that confirmatory application. It shall notify the applicant of that decision within three weeks of submitting the confirmatory application and shall include in that notification information on the available remedies, namely an action before the Court of Justice of the European Union (the 'Court of Justice') against the Authority pursuant to paragraph 3. The Authority shall make public any additional data and information for which the confidentiality request has not been accepted by the Authority as justified, at the earliest two weeks after the notification of the Authority's reasoned decision on the confirmatory application to the applicant has taken place pursuant to this paragraph.

3. Decisions taken by the Authority pursuant to this Article may be subject to an action before the Court of Justice, under the conditions laid down in Articles 263 and 278 of the Treaty on the Functioning of the European Union (TFEU) respectively.

Article 39c

Review of confidentiality

Before the Authority issues its scientific outputs, including scientific opinions, it shall review whether information that has been previously accepted as confidential may nevertheless be made public in accordance with point (b) of Article 39(4). Should that be the case, the Authority shall follow the procedure laid down in Article 39b, which shall apply mutatis mutandis.

Article 39d

Obligations with regard to confidentiality

1. The Authority shall make available, upon request, to the Commission and the Member States all information in its possession relating to an application or to a request by the European Parliament, by the Commission or by the Member States for a scientific output, including a scientific opinion, unless otherwise indicated in Union law.

2. The Commission and the Member States shall take the necessary measures so that information received by them under Union law for which confidential treatment has been requested is not made public until a decision on the confidentiality request has been taken by the Authority and has become final. The Commission and the Member States shall also take the necessary measures so that information for which confidential treatment has been accepted by the Authority is not made public.

3. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of information as granted by the Authority in accordance with Articles 39 to 39e. The application shall be considered withdrawn as of the moment the written request to that effect is received by the competent body that had received the original application. Where the withdrawal of the application takes place before a final decision on the confidentiality request has been adopted by the Authority pursuant to, where appropriate, Article 39b(1) or (2), the Commission, the Member States and the Authority, shall not make public the information for which confidentiality has been requested.

4. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of the obligation of professional secrecy pursuant to Article 339 TFEU.

5. The Authority shall lay down in consultation with the Commission the practical arrangements for implementing the confidentiality rules laid down in Articles 39, 39a, 39b, 39e and in this Article, including arrangements concerning the submission and treatment of confidentiality requests with respect to information to be made public under Article 38, and taking into account Articles 39f and 39g. As regards Article 39b(2), the Authority shall ensure that appropriate separation of tasks is applied for the assessment of confirmatory applications.

Article 39e

Protection of personal data

1. With respect to requests for scientific outputs, including scientific opinions under Union law, the Authority shall always make public:

(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.

2. Notwithstanding paragraph 1, disclosure of names and addresses of natural persons involved in testing on vertebrate animals or in obtaining toxicological information shall be deemed to significantly harm the privacy and the integrity of those natural persons and shall not be made publicly available unless otherwise specified in Regulations (EU) 2016/679 and (EU) 2018/1725 of the European Parliament and of the Council.

3. Regulations (EU) 2016/679 and (EU) 2018/1725 shall apply to the processing of personal data carried out pursuant to this Regulation. Any personal data made public pursuant to Article 38 of this Regulation and this Article shall only be used to ensure the transparency of the risk assessment under this Regulation and shall not be further processed in a manner that is incompatible with these purposes, in accordance with point (b) of Article 5(1) of Regulation (EU) 2016/679 and point (b) of Article 4(1) of Regulation (EU) 2018/1725, as the case may be.

Article 39f

Standard data formats

1. For the purposes of point (c) of Article 38(1) and in order to ensure the efficient processing of requests to the Authority for a scientific output, standard data formats shall be adopted in accordance with paragraph 2 of this Article to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. Those standard data formats shall:

(a) not be based on proprietary standards;

(b) ensure interoperability with existing data submission approaches to the extent possible;

(c) be user-friendly and adapted for the use by small and medium-sized enterprises.

2. For the adoption of standard data formats referred to in paragraph 1, the following procedure shall be followed:

(a) the Authority shall draw up draft standard data formats for the purposes of the different authorisation procedures and relevant requests for a scientific output by the European Parliament, by the Commission and by the Member States;

(b) the Commission shall, taking into account the applicable requirements in the different authorisation procedures and other legal frameworks and following any necessary adaptations, adopt, by means of implementing acts, standard data formats. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2);

(c) the Authority shall make the standard data formats, as adopted, available on its website;

(d) where standard data formats have been adopted pursuant to this Article, applications as well as requests for a scientific output, including a scientific opinion by the European Parliament, by the Commission and by the Member States, shall only be submitted in accordance with those standard data formats.