

Official Journal of the European Union

L 81



English edition

Legislation

Volume 66

21 March 2023

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⁽¹⁾ Text with EEA relevance.

EN

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/647

of 13 January 2023

amending Delegated Regulation (EU) 2020/686 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 160(1) and (2), and Articles 162(4) and 164(2) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of animal diseases which are transmissible to animals or humans, including rules for the registration and approval of germinal product establishments, and for the traceability and animal health requirements for movements of consignments of germinal products within the Union. Regulation (EU) 2016/429 also empowers the Commission to adopt rules to supplement certain non-essential elements of that Regulation by means of delegated acts.
- (2) Commission Delegated Regulation (EU) 2020/686 ⁽²⁾ lays down supplementing rules for the approval of germinal product establishments, record keeping and traceability of germinal products, as well as animal health and certification requirements for movements within the Union of germinal products of certain kept terrestrial animals.
- (3) The rules laid down in this Regulation are required to supplement those laid down in Part IV, Title I, Chapter 5, of Regulation (EU) 2016/429 as regards the traceability and animal health requirements and animal health certification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products.
- (4) These rules are substantively linked and many are intended to be applied in tandem. In the interests of simplicity and transparency, as well as to facilitate their application and to avoid a multiplication of rules, they therefore should be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

- (5) During the implementation of Delegated Regulation (EU) 2020/686 several Member States and stakeholders indicated that following recent developments and specialisations in the germinal product sector, the definition of embryo collection team should also include a team which only collects and handles unfertilised oocytes. That definition and the related requirements should therefore be amended to cover such a team.
- (6) Germinal product establishments of processing may engage in other processes than sex-sorting of semen. In the interest of the traceability of the processed products, the supplementary traceability requirements previously applicable only to sex-sorted semen should be equally extended to all processed products.
- (7) Article 19 of Delegated Regulation (EU) 2020/686 lays down a derogation from the animal health requirements for donor bovine, porcine, ovine, caprine and equine animals moved between semen collection centres. Experience from Member States and stakeholders with the implementation of that Article have indicated legal uncertainty as regards the degree of involvement of official veterinarians. That Article should therefore be clarified.
- (8) Article 36 of Delegated Regulation (EU) 2020/686 lays down animal health requirements for movements within the Union of germinal products of dogs and cats, mainly to mitigate rabies and promote compliance with preventive animal health measures against *Echinococcus multilocularis*. Member States and stakeholders have questioned the relevance and proportionality of these requirements. As the relevant international standards of the World Organisation for Animal Health (WOAH) do not contain comparable requirements, Article 36 of Delegated Regulation (EU) 2020/686 and related wording in requirements concerning official certification and notification of movement of germinal products of dogs and cats between Member States should be deleted.
- (9) Part 2 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements for porcine donor animals. In accordance with Part 2, Chapter I, point 1(c)(iv), of that Annex, animals positive for infection with porcine reproductive and respiratory syndrome virus are to be removed immediately from the quarantine accommodation. Member States and stakeholders have questioned the proportionality of this requirement in the light of practical and scientifically proven difficulties with current diagnostic methods. Therefore, Delegated Regulation (EU) 2020/686 should be amended in order to provide for different possibilities of follow-up when using different types of diagnostic methods to confirm or rule out suspected cases in accordance with Commission Delegated Regulation (EU) 2020/689 ⁽³⁾.
- (10) Part 2 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements, including testing for classical swine fever of porcine animals kept at semen collection centres. However, the relevant international standards of the WOAH do not require testing of such animals in countries where outbreaks of classical swine fever have not been reported and vaccination against this disease has not been practised in the preceding 12 months. Therefore, testing for that disease of porcine animals kept at semen collection centres should be discontinued in those countries which neither have reported classical swine fever, nor have vaccinated against it in the preceding 12 months.
- (11) References to the epizootic haemorrhagic disease virus should be amended to align them with references to that virus in other Union acts and to clarify that all serotypes of that virus are covered by the rules. In addition, requirements related to infection with epizootic haemorrhagic disease virus should more closely follow international standards of the WOAH to provide for the possibility of a vector-free period as an optional and additional risk mitigating measure related to that infection, to ensure safe trade in germinal products of bovine, ovine and caprine animals.

⁽³⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

- (12) Annex III to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements with respect to the addition of antibiotics to semen, including their compulsory addition to semen of bovine and porcine animals. While those requirements are in line with international standards of the WOAH, those international standards are in the process of being amended, towards the voluntary, more flexible and prudent use of antibiotics. In addition, information from scientific literature, Member States and stakeholders indicates similar needs. Therefore, the relevant requirements should be streamlined and made optional.
- (13) After the publication of Delegated Regulation (EU) 2020/686 in the *Official Journal of the European Union*, some substantial errors were spotted. In particular, the wording in relation to the prevention of the entry of unauthorised persons to semen collection centres and germinal product processing establishments created legal uncertainty. Furthermore, an incorrect reference in the text applicable to certain equine animals entering semen collection centres for equine animals unintentionally changed the requirements whose fulfilment centre veterinarians are to ensure. In the interest of legal certainty and clarity, those errors should be corrected.
- (14) Delegated Regulation (EU) 2020/686 should therefore be amended and corrected accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/686 is amended as follows:

- (1) in Article 1(7), point (a) is deleted;
- (2) in Article 2, point (12) is replaced by the following:
- ‘(12) “embryo collection team” means a germinal product establishment comprised of a group of professionals or a structure approved by the competent authority for the collection, processing, storage and transport of oocytes or *in vivo* derived embryos of bovine, porcine, ovine, caprine or equine animals intended for movement to another Member State, as referred to in Article 4;’;
- (3) in Article 3, point (b) is replaced by the following:
- ‘(b) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, processing and storage of oocytes or embryos of bovine, porcine, ovine, caprine or equine animals for approval as an embryo collection team;’;
- (4) in Article 4(1), point (b)(ii) is replaced by the following:
- ‘(ii) Part 2, point 2, of Annex I, in respect of the collection, processing, storage and transport of oocytes or embryos of bovine, porcine, ovine, caprine or equine animals;’;
- (5) in Article 10, paragraph 2 is replaced by the following:
- ‘2. In case of a germinal product processed in a germinal product establishment other than the germinal product establishment of collection, the operator of the germinal product establishment of processing shall supplement the information referred to in paragraph 1 with information which permits the identification of the unique approval number of the establishment of processing of that germinal product.’;
- (6) in Article 19, paragraph 2 is replaced by the following:
- ‘2. Operators shall only move donor animals, as referred to in the introductory phrase of paragraph 1, with the prior consent of the centre veterinarian of the semen collection centre of destination.’;
- (7) Article 36 is deleted;
- (8) Article 39 is amended as follows:
- (a) paragraph 1 is deleted;

(b) paragraph 4 is replaced by the following:

‘4. The official veterinarian shall carry out the checks and examinations as provided for in paragraphs 2 and 3 and issue the animal health certificate within the period of 72 hours preceding the time of dispatch of the consignment of germinal products.’;

(9) Article 40 is replaced by the following:

‘Article 40

Animal health certification requirements for movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine or equine animals between Member States

The animal health certificates for movements between Member States of consignments of germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments and of animals of the family *Camelidae* or *Cervidae*, shall contain at least the information set out in point 2 of Annex IV.’;

(10) Article 41 is replaced by the following:

‘Article 41

Requirement for advance notification by operators of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine or equine animals between Member States

Where consignments of germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments or of animals of the family *Camelidae* or *Cervidae* are moved to another Member State, the operator shall notify the competent authority in the Member State of origin of the consignments in advance of the intended movement of those consignments of germinal products.’.

Article 2

Annexes I to IV to Delegated Regulation (EU) 2020/686 are amended in accordance with Part A of the Annex to this Regulation.

Article 3

Annex I to Delegated Regulation (EU) 2020/686 is corrected in accordance with Part B of the Annex to this Regulation.

Article 4

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

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

Done at Brussels, 13 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

PART A

Annexes I to IV to Delegated Regulation (EU) 2020/686 are amended as follows:

(1) Annex I is amended as follows:

(a) Part 2 is amended as follows:

(i) point 1(a)(v) is replaced by the following:

‘(v) the marking of straws and other packages where oocytes or *in vivo* derived embryos are placed in accordance with the requirements set out in Article 10(1) and (5);’;

(ii) point 2 is replaced by the following:

‘2. The facilities, equipment and operational procedures of the embryo collection team, as referred to in Article 4(1), point (b)(ii), shall comply with the following points (a) and (b):

(a) the embryo collection team must have at its disposal a laboratory where oocytes or *in vivo* derived embryos can be examined, processed and packaged with adequate equipment, and that laboratory must be either:

(i) a permanently located laboratory, which must have the following:

- a room where oocytes or *in vivo* derived embryos can be processed which is physically separated from the area used to handle the donor animals during collection,
- a room or area for cleansing and sterilising instruments used for oocytes or *in vivo* derived embryo collection and processing, except when using only new single-use equipment,
- a room for the storing of oocytes or *in vivo* derived embryos;

or

(ii) a mobile laboratory, which must:

- have a specially equipped part of the vehicle consisting of two separate sections: one section for the examination and processing of oocytes or *in vivo* derived embryos, which must be the clean section; and another section for accommodating equipment and materials used in contact with the donor animals,
- use only new single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of oocytes or *in vivo* derived embryos is carried out at a permanently located laboratory.

The laboratories referred to in points (i) and (ii) must be designed and have a layout so as to prevent the cross-contamination of oocytes or *in vivo* derived embryos, and team operations shall be carried out in a manner that prevents such cross-contamination;

(b) the embryo collection team must have at its disposal storage premises which comply with the following conditions:

- (i) they comprise at least one lockable room for the storage of oocytes or *in vivo* derived embryos;
- (ii) they must be easy to cleanse and disinfect;
- (iii) they must have permanent records of all incoming and outgoing oocytes or *in vivo* derived embryos;
- (iv) they must have storage containers for oocytes or *in vivo* derived embryos.’;

(b) in Part 5, point 2(d) is deleted;

(2) Annex II is amended as follows:

(a) in Part 2, Chapter I, point 1(c)(iii) is deleted;

(b) in Part 2, Chapter I, point 1(c)(iv) is replaced by the following:

‘(iv) as regards infection with porcine reproductive and respiratory syndrome virus, a serological test (IPMA, IFA, or ELISA) or a test for virus genome (reverse-transcription polymerase chain reaction (RT-PCR), nested set RT-PCR, real-time RT-PCR).

If any of the animals prove positive in the serological tests for infection with porcine reproductive and respiratory syndrome virus, the competent authority shall classify all animals in the quarantine accommodation as a suspected case in accordance with Article 9(1), point (b), of Delegated Regulation (EU) 2020/689. The operator shall isolate the positive animals immediately from other animals within the quarantine accommodation. The competent authority shall conduct an investigation to confirm or to rule out infection with porcine reproductive and respiratory syndrome virus in accordance with Article 8 of Delegated Regulation (EU) 2020/689.

If any of the animals prove positive in the tests for virus genome for porcine reproductive and respiratory syndrome virus, the competent authority shall classify all animals in the quarantine accommodation as a confirmed case in accordance with Article 9(2), point (b), of Delegated Regulation (EU) 2020/689. The operator shall remove those animals immediately from the quarantine accommodation and follow the instructions of the competent authority.’;

(c) in Part 2, Chapter I, point 2(a)(iii) is replaced by the following:

‘(iii) as regards classical swine fever, an antibody ELISA or serum neutralisation test, in case of animals in a Member State or zone thereof where classical swine fever has been reported or vaccination against this disease has been practiced for the period of the preceding 12 months’;

(d) in Part 5, Chapter III is replaced by the following:

‘CHAPTER III

Requirements for bovine, ovine and caprine animals as regards infection with the epizootic haemorrhagic disease virus

1. The bovine, ovine and caprine animals which are semen donors must fulfil at least one of the following conditions:

- (a) they have been kept for a period of at least 60 days prior to and during collection of the semen in a Member State or zone thereof where infection with epizootic haemorrhagic disease virus has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;
- (b) they have been kept for a period of at least 60 days prior to and during collection of the semen in a Member State or zone thereof seasonally free from infection with epizootic haemorrhagic disease virus;
- (c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the semen;
- (d) they have been subjected to a serological test to detect antibodies to infection with epizootic haemorrhagic disease virus, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days from the date of the final collection of the semen;
- (e) they have been subjected to an agent identification test for infection with epizootic haemorrhagic disease virus, with negative results, on blood samples taken at commencement and final collection of the semen and during collection of the semen at intervals of:
 - (i) at least every 7 days, in the case of virus isolation test; or
 - (ii) at least every 28 days, in the case of PCR.

2. The bovine, ovine and caprine animals which are oocyte donors for the *in vitro* production of embryos and *in vivo* derived embryo donors must fulfil at least one of the following conditions:
 - (a) they have been kept for a period of at least 60 days prior to and during collection of the oocytes or embryos in a Member State or zone thereof where infection with epizootic haemorrhagic disease virus has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;
 - (b) they have been kept for a period of at least 60 days prior to and during collection of the oocytes or embryos in a Member State or zone thereof seasonally free from infection with epizootic haemorrhagic disease virus;
 - (c) they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection of the oocytes or embryos;
 - (d) they have been subjected to a serological test to detect antibodies to infection with epizootic haemorrhagic disease virus, with negative results, on a blood sample taken between 28 and 60 days from the date of collection of the oocytes or embryos;
 - (e) they have been subjected to an agent identification test for infection with epizootic haemorrhagic disease virus, with negative results, on a blood sample taken on the date of collection of the oocytes or embryos.
 3. The semen used to fertilise the oocytes must be collected from animals which comply with the requirements set out in point 1.;
- (3) Annex III is amended as follows:
- (a) in Part 1, point 3 is replaced by the following:

‘3. Where necessary, antibiotics or mixtures of antibiotics may be added to semen or contained in semen diluents.’;
 - (b) in Part 1, points 4 and 5 are deleted;
- (4) in Annex IV, in point 2, the introductory wording is replaced by the following:
- ‘The animal health certificate for the germinal products of terrestrial animals other than bovine, porcine, ovine, caprine or equine animals kept at confined establishments and of animals of the family *Camelidae* or *Cervidae* moved between Member States, referred to in Article 40, shall contain at least the following information.’.

PART B

Annex I to Delegated Regulation (EU) 2020/686 is corrected as follows:

- (1) in Part 1, point 1(a)(iii) is replaced by the following:

‘(iii) the entry of unauthorised persons is effectively prevented.’;
 - (2) in Part 1, point 1(e) is replaced by the following:

‘(e) the centre veterinarian of a semen collection centre for equine animals, located within the perimeters of a registered establishment which also hosts an artificial insemination or service centre, shall ensure that equine animals entering the establishment meet the requirements of Article 23(1), point (a), and may decide that where direct contact of donor male equine animals with female equine animals or castrated male equine animals for teasing or with uncastrated male equine animals used on the establishment outside the semen collection centre for natural service cannot be excluded, those female and male equine animals must meet all the requirements of Article 23(1).’;
 - (3) in Part 4, point 1(a)(ii) is replaced by the following:

‘(ii) the entry of unauthorised persons is effectively prevented.’.
-

COMMISSION REGULATION (EU) 2023/648**of 20 March 2023****authorising a health claim made on foods and referring to the reduction of disease risk****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 17(3) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and are included in the list of permitted health claims.
- (2) Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims are to be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority ('the Authority').
- (3) Following the receipt of an application, the Authority is to inform without delay the other Member States and the Commission, and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Laboratoire Lescuyer ('the applicant'), submitted pursuant to Article 14(1), point (a), of Regulation (EC) No 1924/2006 and including a request for the protection of proprietary data, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate (contained in applicant's product Limicol®) and the reduction of blood LDL-cholesterol concentrations ⁽²⁾. The claim proposed by the applicant was worded as follows: 'Limicol® has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease'.
- (6) On 26 July 2013, the Commission and the Member States received the scientific opinion ⁽³⁾ on that application from the Authority which concluded that on the basis of the data presented, a cause and effect relationship had been established between the consumption of the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in the food subject to the claim and a reduction in blood LDL-cholesterol concentrations. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted health claims.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ Question No EFSA-Q-2012-00968.

⁽³⁾ EFSA Journal 2013;11(7):3327.

- (7) The Authority indicated in its opinion that it could not have reached its conclusions without three human intervention studies (*), which are claimed as proprietary by the applicant.
- (8) Following the receipt of the Authority's opinion, the Commission requested the applicant to further clarify the justifications provided with regard to their proprietary claim over the three human intervention studies, and their claim to an exclusive right of reference to those studies in accordance with Article 21(1) of Regulation (EC) No 1924/2006.
- (9) The applicant has declared that, at the time the application was submitted, it held proprietary right as well as an exclusiveright of reference to those studies and that therefore third parties could not lawfully access or use those studies. The Commission assessed all the justifiable information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 for the studies claimed as proprietary.
- (10) Accordingly, the scientific data and other information included in those three studies should not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. As a consequence, the use of the health claim authorised by this Regulation should be restricted to the applicant for a period of 5 years.
- (11) However, restricting the authorisation of this claim and the reference to the studies contained in the applicant's file to the sole use by them, does not prevent other applicants from applying for an authorisation to use the same claim provided that their application is based on legally obtained information supporting the authorisation under this Regulation.
- (12) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that their wording and the presentation are taken into account in that respect. Therefore, where the wording of a claim used by an applicant has the same meaning for consumers as that of this authorised health claim, because it demonstrates that the same relationship exists between a food category, a food or one of its constituents and health, that claim should be subject to the same conditions of use as those authorised by this Regulation.
- (13) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should therefore be updated.

(*) Barrat E, Zaïr Y, Chauveau P, Maudet C, Housez B, Derbord E, Lescuyer JF, Bard JM, Cazaubiel M and Peltier SL, 2012, unpublished; Effect on LDL-cholesterol of a large dose of a dietary portfolio supplement in subjects with untreated moderate hypercholesterolaemia: a double-blind, placebo-controlled study, *published as*: Barrat E, Zaïr Y, Sirvent P, Chauveau P, Maudet C, Housez B, Derbord E, Lescuyer JF, Bard JM, Cazaubiel M and Peltier SL, 2012; Effect on LDL-cholesterol of a large dose of a dietary supplement with plant extracts in subjects with untreated moderate hypercholesterolaemia: a randomised, double-blind, placebo-controlled study, *European Journal of Nutrition*, Dec 25. [Epub ahead of print]; Barrat E, Zaïr Y, Ogier N, Housez B, Vergara C, Maudet C, Lescuyer JF, Bard JM, Carpentier YA, Cazaubiel M and Peltier SL, 2012, unpublished; A dietary portfolio supplement substantially lowers LDL-cholesterol in subjects with moderate untreated hypercholesterolaemia: a randomised controlled study, *published as*: Barrat E, Zaïr Y, Ogier N, Housez B, Vergara C, Maudet C, Lescuyer JF, Bard JM, Carpentier YA, Cazaubiel M and Peltier SL, 2013; A combined natural supplement lowers LDL cholesterol in subjects with moderate untreated hypercholesterolemia: a randomized placebo-controlled trial. *International Journal of Food Sciences and Nutrition*, Jul 2. [Epub ahead of print]; Ogier N, Amiot MJ, Georges S, Maillot M, Mallmann C, Maraninchi M, Morange S, Lescuyer JF, Peltier SL and Cardinault N, 2013; LDL-cholesterol-lowering effect of a dietary supplement with plant extracts in subjects with moderate hypercholesterolemia, *European Journal of Nutrition*, 52, p. 547.

- (14) The Commission has considered the comments received from the applicant pursuant to Article 16(6) of Regulation (EC) No 1924/2006 when adopting this Regulation.
- (15) The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 14(1) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff. Concerning specifically monacolins from red yeast rice, Commission Regulation (EU) 2022/860 ⁽⁵⁾ regulated its use by amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽⁶⁾ to add the substance to the list of 'Restricted substances' and thus to permit the use of monacolins from red yeast rice only under certain conditions. Regulation (EU) 2022/860 also provides for appropriate labelling requirements for all foods containing monacolins from red yeast rice.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim set out in the Annex to this Regulation shall be included in the Union list of permitted health claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006 and may be made on foods in compliance with the conditions laid down in the Annex to this Regulation.

Article 2

Only Laboratoire Lescuyer ⁽⁷⁾ is authorised to use the health claim set out in the Annex, for a period of 5 years from the date into force of this Regulation in accordance with Article 4 of this Regulation, unless a subsequent applicant obtains an authorisation to use the same claim without reference to the scientific data protected pursuant to Article 3, or with the agreement of Laboratoire Lescuyer. After the expiry of that period, that health claim may be used, in conformity with the conditions applying to it, by any food business operator.

Article 3

The scientific data of the studies included in the application, on the basis of which the health claim referred to in Article 1 has been assessed by the Authority, and fulfilling the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006, shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the prior agreement of Laboratoire Lescuyer.

Article 4

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

⁽⁵⁾ Commission Regulation (EU) 2022/860 of 1 June 2022 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice. OJ L 151, 2.6.2022, p. 37.

⁽⁶⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26.

⁽⁷⁾ Address: ZAC de Belle Aire Nord, 15 rue le Corbusier, 17440 Aytré, France.

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

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Permitted health claim

Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Laboratoire Lescuyer, ZAC de Belle Aire Nord, 15 rue le Corbusier, 17440 Aytré, France	A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate	A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate reduces blood LDL-cholesterol concentrations. High LDL-cholesterol is a risk factor in the development of coronary heart disease ⁽¹⁾ .	The claim may be used only for food supplements which provide 600 mg artichoke leaf dry extract with 30-36 mg caffeoylquinic acids, 500 mg red yeast rice with 2 mg monacolin K, 10 mg sugar-cane derived policosanols, 20 mg French maritime pine bark extract with 18 mg procyanidolic oligomers, 30 mg garlic dry extract with 0,25 mg allicin, 30 mg α -tocopherol equivalents, 5 mg riboflavin and 9 mg inositol hexanicotinate divided in three daily doses to be consumed with the major meals.		Q-2012-00968

⁽¹⁾ Authorised on 10 April 2023 and restricted to the use by Laboratoire Lescuyer, ZAC de Belle Aire Nord, 15 rue le Corbusier, 17440 Aytré, France, for a period of 5 years.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/649**of 20 March 2023****concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ⁽²⁾ that, under the proposed conditions of use, L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 does not have an adverse effect on consumer safety or the environment, or on animal health when supplemented in appropriate amounts to the diet according to the nutritional needs of the target species and when nutritional imbalances caused by the simultaneous administration of L-arginine via water for drinking and feed are prevented.
- (5) The Authority further concluded that exposure of users by inhalation is possible. The applicant provided the safety data sheet required in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾ which demonstrates that the additive may cause eyes and skin irritation.
- (6) The Authority concluded that the additive has the potential to be efficacious for all animal species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2022;20(7):7427.

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feed with a moisture content of 12 %			
3c365	L-arginine	<i>Additive composition</i> ≥ 98,5 % L-arginine (on a dry matter basis) and ≤ 1 % of water Solid form	All species	—	—	—	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. The label of the additive and premixture shall indicate the following: 'The supplementation with L-arginine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection.	11.4.2033
		<i>Characterisation of the active substance</i> L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by <i>Corynebacterium glutamicum</i> CGMCC 20516 Chemical formula: C ₆ H ₁₄ N ₄ O ₂ CAS number: 74–79-3						
		<i>Analytical method</i> ⁽¹⁾ For the identification of L-arginine in the feed additive: — Food Chemical Codex 'L-arginine monograph'. For the determination of arginine in the feed additive and water: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS). For the determination of arginine in premixtures and complete feed: — Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/650**of 20 March 2023****concerning the authorisation of a preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and minor poultry species reared for breeding (holder of authorisation: Biomin GmbH)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for all poultry species, to be classified in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives'. As the preparation was already authorised for the same holder of authorisation by Commission Implementing Regulation (EU) 2020/996 ⁽²⁾ as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species reared for laying, the request for authorisation in accordance with Article 4 of Regulation (EC) No 1831/2003 is considered only for the species not covered by the previous authorisation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ⁽³⁾ that, under the proposed conditions of use, the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol does not have an adverse effect on consumer safety or the environment and that the aforementioned preparation is safe for poultry species for fattening or reared for laying or breeding. In the absence of adequate data, it could not conclude on the safety of the said preparation for laying or breeding birds. The Authority also concluded that an exposure of users by inhalation is unlikely and that the conclusions of the previous opinion regarding the safety for the users apply also to the present assessment. In the context of the previous opinion on this additive, adopted on 15 May 2019 ⁽⁴⁾, the safety data sheet required by Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁵⁾ described skin irritation, eye irritation and allergic skin reaction. In addition, the Authority

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2020/996 of 9 July 2020 concerning the authorisation of the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species reared for laying (holder of authorisation Biomin GmbH) (OJ L 221, 10.7.2020, p. 87).

⁽³⁾ EFSA Journal 2022; 20(9):7429.

⁽⁴⁾ EFSA Journal 2019;17(6):5724.

⁽⁵⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

concluded that the additive has the potential to be efficacious in chickens for fattening. This conclusion could be extrapolated to turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and minor poultry species reared for breeding. In the absence of sufficient data, it could not conclude on the efficacy for laying hens or for other poultry species for laying or breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and minor poultry species reared for breeding. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of that additive.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d20	Biomin GmbH	Preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol	<i>Additive composition</i> Preparation of: — carvacrol (120-160 mg/g) — thymol (1-3 mg/g) — D-carvone (3-6 mg/g) — methyl salicylate (10-35 mg/g) — L-menthol (30-55 mg/g) — amorphous silica (maximum 100 mg/g) — hydrogenated vegetable oil (maximum 700 mg/g) Solid encapsulated form <i>Characterisation of the active substance</i> Carvacrol (CAS number: 499-75-2) Thymol (CAS number: 89-83-8) D-Carvone (CAS number: 2244-16-8) Methyl salicylate (CAS number: 119-36-8) - L-Menthol (CAS number: 2216-51-8) <i>Analytical method</i> ⁽¹⁾ For the quantification of the active substances: Gas chromatography coupled with flame ionisation detection (GC-FID).	Turkeys for fattening Turkeys reared for breeding Minor poultry species for fattening Minor poultry species reared for breeding	—	65	105	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall not be used with other sources of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and eye protection.	11.4.2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2023/651**of 20 March 2023****concerning the authorisation of riboflavin (vitamin B₂) produced by *Bacillus subtilis* KCCM 10445 and a preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of riboflavin 98 % (vitamin B₂) produced by *Bacillus subtilis* KCCM 10445 and of a preparation of riboflavin 80 % produced by *Bacillus subtilis* KCCM 10445. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of riboflavin produced by *Bacillus subtilis* KCCM 10445 and of a preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 as feed additives for all animal species, to be classified in the category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 5 May 2021 ⁽²⁾ and of 27 September 2022 ⁽³⁾ that, under the proposed conditions of use, riboflavin (98 %) produced by *Bacillus subtilis* KCCM 10445 and the preparation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM 10445 do not have adverse effects on animal health, consumer safety or the environment. It further concluded that the preparation of riboflavin is not hazardous by inhalation. In the absence of data, no conclusions on the possible risk by inhalation of riboflavin produced by *Bacillus subtilis* KCCM 10445 can be reached. Neither riboflavin nor the preparation of riboflavin are irritant to skin or eyes. In addition, in the absence of data, no conclusions on the skin sensitisation potential of riboflavin produced by *Bacillus subtilis* KCCM 10445 and of the preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 can be reached.
- (5) The Authority concluded that riboflavin produced by *Bacillus subtilis* KCCM 10445 and the preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 are an effective source in covering the nutritional needs of animals when administered via feed and/or water for drinking. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) An authorisation of riboflavin with a purity of minimum 80 % produced by *Bacillus subtilis* KCCM 10445 was previously denied and existing stocks of that additive and feed containing it were to be withdrawn from the market as laid down by Commission Implementing Regulation (EU) 2018/1254 ⁽⁴⁾, due to the presence in the additive of viable cells and recombinant DNA from the genetically modified production strain *Bacillus subtilis* KCCM 10445,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(6):6629.

⁽³⁾ EFSA Journal 2022;20(10):7607.

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/1254 of 19 September 2018 concerning the denial of authorisation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 as a feed additive belonging to the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect (OJ L 237, 20.9.2018, p. 5).

carrying antimicrobial resistance genes and posing a risk for the target species, consumers, users and the environment. The riboflavin for which authorisation was denied as well as the present riboflavin (98 %) produced by *Bacillus subtilis* KCCM 10445 and the preparation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM 10445 are produced by the same production strain (*Bacillus subtilis* KCCM 10445). However, the purity of riboflavin has been improved, by increasing from 80 % in the authorisation that was denied to 98 % in this authorisation. In its above-mentioned opinions, the Authority stated that viable cells and recombinant DNA from *Bacillus subtilis* KCCM 10445 were not detected in the riboflavin and in the preparation of riboflavin subject to this application and that therefore, those additives do not pose any safety concern associated with the genetic modification of the production strain.

- (7) The assessment of riboflavin produced by *Bacillus subtilis* KCCM 10445 and of the preparation of riboflavin produced by *Bacillus subtilis* KCCM 10445 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the substance and of the preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of those additives.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance and the preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825 iii	'Riboflavin' or 'Vitamin B ₂ '	<i>Additive composition</i> Riboflavin with a maximum of 1,5 % of water Solid form <i>Characterisation of active substance</i> Chemical formula: C ₁₇ H ₂₀ N ₄ O ₆ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with <i>Bacillus subtilis</i> KCCM 10445 <i>Analytical method</i> ⁽¹⁾ For the determination of riboflavin in the feed additive: — European Pharmacopoeia Ph. Eur 01/2008:0292 For the determination of riboflavin in premixtures: — High Performance Liquid Chromatography with UV detection (HPLC-UV) — VDLUFA Bd. III, 13.9.1 For the determination of riboflavin (as total vitamin B2) in compound feed and water: — High Performance Liquid Chromatography with Fluorescence detection (HPLCFLD) — EN 14152	All animal species	—	—	—	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin and breathing protection.	11.4.2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825 _{IV}	'Riboflavin' or 'Vitamin B ₂ '	<i>Additive composition</i> Preparation containing a minimum of 80 % of riboflavin and a maximum of 3 % of water Solid form <i>Characterisation of active substance</i> Chemical formula: C ₁₇ H ₂₀ N ₄ O ₆ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with <i>Bacillus subtilis</i> KCCM 10445 <i>Analytical method</i> ⁽¹⁾ For the determination of riboflavin in the feed additive: European Pharmacopoeia Ph. Eur. monograph:0292 For the determination of riboflavin in premixtures: — High Performance Liquid Chromatography with UV detection (HPLC-UV) — VDLUFA Bd. III, 13.9.1 For the determination of riboflavin (as total vitamin B2) in compound feed and water: — High Performance Liquid Chromatography with Fluorescence detection (HPLCFLD) — EN 14152.	All animal species	—	—	—	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organizational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin protection.	11.4.2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2023/652**of 20 March 2023****authorising the placing on the market of roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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 and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 15(4) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union. On the basis of the definition set out in Article 3(2)(c) of Regulation (EU) 2015/2283, traditional food from a third country is considered a novel food.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ has established a Union list of novel foods.
- (3) On 8 October 2021, the company Zenko Superfoods Pte. Ltd ('the applicant') submitted a notification to the Commission of their intention to place roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) on the Union market as a traditional food from a third country in accordance with Article 14 of Regulation (EU) 2015/2283. The applicant requested that the roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) be used as such as snacks by the general population.
- (4) Pursuant to Article 7(3) of Commission Implementing Regulation (EU) 2017/2468 ⁽³⁾, the Commission requested additional information from the applicant as regards the requirements for validity of the notification. The requested information was submitted on 9 February 2022.
- (5) The notification complies with the requirements laid down in Article 14 of Regulation (EU) 2015/2283. The data presented by the applicant demonstrate that roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) consumed as such as snacks have a history of safe food use in India.
- (6) Pursuant to Article 15(1) of Regulation (EU) 2015/2283, on 22 March 2022, the Commission forwarded the valid notification to the Member States and to the European Food Safety Authority ('the Authority').
- (7) No duly reasoned safety objections to the placing on the market within the Union of roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) were submitted to the Commission by the Member States or the Authority within the four-month period laid down in Article 15(2) of Regulation (EU) 2015/2283.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 55).

- (8) On 5 September 2022, the Authority published its ‘Technical Report on the notification of roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283’⁽⁴⁾. The Authority concluded that the available data on the composition and the history of use of the roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) do not raise safety concerns.
- (9) The Commission should therefore authorise the placing on the market within the Union of roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) as such as a snack and update the Union list of authorised novel foods accordingly.
- (10) Roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) should be included as a traditional food from a third country in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

1. The roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) are authorised to be placed on the market within the Union.

The roasted and popped kernels from the seeds of *Euryale ferox* Salisb. (makhana) shall be included as a traditional food from a third country in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ EFSA Journal 2022;19(9):EN-7538. <https://doi.org/10.2903/sp.efsa.2022.EN-7538>.

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following entry is inserted in Table 1 (Authorised novel foods):

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Roasted and popped kernels from the seeds of <i>Euryale ferox</i> Salisb. (makhana) (Traditional food from a third country)	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “roasted seeds of <i>Euryale ferox</i> ” or “makhana (<i>Euryale ferox</i>) roasted seeds”	
	Processed nuts			

(2) the following entry is inserted in Table 2 (Specifications):

Authorised Novel Food	Specifications
'Roasted and popped kernels from the seeds of <i>Euryale ferox</i> Salisb. (makhana) (Traditional food from a third country)	Description/Definition The traditional food consists of the roasted and popped kernels of the seeds of the fresh plants of <i>Euryale ferox</i> Salisb. (family: Nymphaeaceae, commonly referred to also as prickly water lily) to be consumed as a snack. The traditional food is produced via a series of steps involving the collection, washing, and drying of the seeds, a first roasting in oil, tempering at ambient temperatures, a subsequent second roasting in oil to pop the kernels, followed by hitting of the hot seeds to release the popped kernels. The traditional food is also known as makhana or fox nuts. Typical nutritional components: Fat: 13,0 g/100 g Carbohydrates: 75,0 g/100 g Fibre: 2,5 g/100 g Protein: 7 g/100 g Moisture (% w/w): < 5,0 Ash: < 0,5 g/100 g Microbiological criteria: Total plate count: < 10³ CFU/g Total yeast and mould count: < 100 CFU/g Total Enterobacteriaceae: < 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g <i>Listeria monocytogenes</i>: Absence in 25 g Heavy metals: Selenium: ≤ 0,8 mg/kg Copper: ≤ 30,0 mg/kg Lead: ≤ 0,1 mg/kg Arsenic: ≤ 0,1 mg/kg Cadmium: ≤ 0,1 mg/kg

	Tin: ≤ 3,5 mg/kg Mercury: ≤ 0,025 mg/kg Mycotoxins: Aflatoxin B1: ≤ 2,0 µg/kg Sum of aflatoxins B1, B2, G1, and G2: ≤ 4,0 µg/kg Ochratoxin A: ≤ 1,0 µg/kg Citrinin: ≤ 20,0 µg/kg Cyanotoxins: Microcystins: ≤ 0,0015 mg/kg Pesticides: Pesticides: ≤ 0,01 mg/kg Process contaminants: Acrylamide: ≤ 40,0 µg/kg Sum of PAHs: ≤ 10,0 µg/kg Sum of dioxin-like PCBs: ≤ 0,35 pg/g 3-MCPD: ≤ 20,0 µg/kg Glycidyl fatty acid esters (expressed as glycidol): ≤ 500,0 µg/kg Sum of 3-MCPD and 3-MCPD fatty acid esters: ≤ 750,0 µg/kg CFU: Colony Forming Units; PAHs: Polycyclic Aromatic Hydrocarbons; PCBs: Polychlorinated Biphenyls; 3-MCPD: 3-MonoChloroPropane Diol.'
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DECISIONS

COUNCIL DECISION (CFSP) 2023/653

of 20 March 2023

amending Decision (CFSP) 2020/472 on the European Union military operation in the Mediterranean (EUNAVFOR MED IRINI)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 42(4) and 43(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 31 March 2020, the Council adopted Decision (CFSP) 2020/472 ⁽¹⁾, which established a European Union military operation in the Mediterranean (EUNAVFOR MED IRINI).
- (2) On 26 March 2021, following a Strategic Review of the operation, the Council adopted Decision (CFSP) 2021/542 ⁽²⁾, which *inter alia* extended EUNAVFOR MED IRINI until 31 March 2023.
- (3) In the context of the Strategic Review of the operation, the Political and Security Committee agreed that EUNAVFOR MED IRINI should be extended until 31 March 2025.
- (4) The disposal of arms and related materiel seized by EUNAVFOR MED IRINI should be further facilitated.
- (5) Decision (CFSP) 2020/472 should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2020/472 is amended as follows:

- (1) in Article 2, paragraph 5, the third subparagraph is replaced by the following:

‘A Member State assisting EUNAVFOR MED IRINI in the disposal of seized arms and related materiel shall undertake, upon communication by EUNAVFOR MED IRINI of a certificate of seizure, to complete as swiftly as possible the procedures required to allow for the disposal of the seized items, within the framework of the applicable law and procedures. EUNAVFOR MED IRINI shall provide that Member State with a disposal certificate.’;

- (2) in Article 13, the following paragraph is added:

‘4. For the period from 1 April 2023 until 31 March 2025, the reference amount for the common costs of EUNAVFOR MED IRINI shall be EUR 16 921 000. The percentage of the reference amount referred to in Article 51(2) of Decision (CFSP) 2021/509 shall be 10 % for commitments and 5 % for payments.’;

⁽¹⁾ Council Decision (CFSP) 2020/472 of 31 March 2020 on a European Union military operation in the Mediterranean (EUNAVFOR MED IRINI) (OJ L 101, 1.4.2020, p.4).

⁽²⁾ Council Decision (CFSP) 2021/542 of 26 March 2021 amending Decision (CFSP) 2020/472 on the European Union military operation in the Mediterranean (EUNAVFOR MED IRINI) (OJ L 108, 29.3.2021, p. 57).

(3) in Article 15, paragraph 2 is replaced by the following:

‘2. EUNAVFOR MED IRINI shall end on 31 March 2025.’.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 20 March 2023.

For the Council

The President

J. BORRELL FONTELLES

COUNCIL DECISION (CFSP) 2023/654**of 20 March 2023****in support of the implementation of United Nations Security Council Resolution 1540 (2004) on the non-proliferation of weapons of mass destruction and their means of delivery**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 31(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 12 December 2003, the European Council adopted the EU strategy against the proliferation of weapons of mass destruction, Chapter III of which contains a list of measures which need to be taken both within the Union and in third countries to combat such proliferation.
- (2) On 28 April 2004, the United Nations (UN) Security Council adopted Resolution 1540 (2004) (UNSCR 1540 (2004)), which was the first international instrument to deal in an integrated and comprehensive manner with weapons of mass destruction, their means of delivery and related materials. UNSCR 1540 (2004) established binding obligations for all States, which aimed to prevent and deter non-State actors from obtaining access to such weapons and weapons-related material. It also called upon States to present the Committee of the Security Council established by UNSCR 1540 (2004) (the '1540 Committee') with a report on steps which they have taken or intend to take to implement UNSCR 1540 (2004).
- (3) On 27 April 2006, the UN Security Council adopted Resolution 1673 (2006), and decided that the 1540 Committee was to intensify its efforts to promote the full implementation of UNSCR 1540 (2004) through programmes of work, outreach, assistance, dialogue and cooperation. It also invited the 1540 Committee to explore with States and international, regional and sub-regional organisations the possibility of sharing experience and lessons learned, and the availability of programmes which might facilitate the implementation of UNSCR 1540 (2004).
- (4) On 20 April 2011, the UN Security Council adopted Resolution 1977 (2011) and decided to extend the mandate of the 1540 Committee for a period of 10 years until 25 April 2021. It also decided that the 1540 Committee was to continue to intensify its efforts to promote the full implementation by all States of UNSCR 1540 (2004), to engage actively in matching offers and requests for assistance, through such means as visits at the invitation of the State concerned, assistance templates, action plans or other information submitted to the 1540 Committee, and to conduct a comprehensive review on the status of implementation of UNSCR 1540 (2004) before December 2016.
- (5) On 15 December 2016, the UN Security Council unanimously adopted Resolution 2325 (2016) and thereby endorsed the outcome of the comprehensive review process of UNSCR 1540 (2004) conducted during 2016. It called on all States to strengthen national measures in implementing UNSCR 1540 (2004) and called for greater assistance for building State capability in that regard, including through voluntary contributions, as well as for greater cooperation among stakeholders, civil society and academia.
- (6) On 30 November 2022, the UN Security Council adopted Resolution 2663 (2022), and decided to extend the mandate of the 1540 Committee for a period of 10 years until 30 November 2032.

- (7) Union support to the implementation of UNSCR 1540 (2004), that has since 2006 been channelled through the implementation of Council Joint Actions 2006/419/CFSP ⁽¹⁾ and 2008/368/CFSP ⁽²⁾ and Council Decisions 2013/391/CFSP ⁽³⁾ and (CFSP) 2017/809 ⁽⁴⁾, has contributed to diminishing significantly the number of non-reporting States and the number of States which did not submit additional information required by the 1540 Committee following their submission of incomplete reports.
- (8) There is a need for continued Union support to the implementation of UNSCR 1540 (2004).
- (9) The Union should therefore adopt this Decision in order to provide the necessary support.
- (10) The UN Office for Disarmament Affairs (UNODA), which is responsible for providing the 1540 Committee and its Group of Experts with substantive and logistical support, should be entrusted with the technical implementation of the activities to be carried out under this Decision.
- (11) This Decision is guided by the principle of making best use of the experience gained through previous Joint Actions and Council Decisions in support of the implementation of UNSCR 1540 (2004). It takes into account specific needs expressed by States and tailored approaches in support of those needs and encourages national and regional ownership of the activities in order to ensure their long-term sustainability. This Decision is based on the principle of building partnerships between the Union and third parties in the framework of UNSCR 1540 (2004) to ensure synergies and complementarities and focuses on those activities that have brought concrete results in terms of strengthening national implementation, enhanced assistance, awareness raising and engagement on UNSCR 1540 (2004).
- (12) This Decision should be implemented in accordance with the Financial and Administrative Framework Agreement concluded by the Commission with the UN concerning the management of financial contributions by the Union to programmes or projects administered by the UN,

HAS ADOPTED THIS DECISION:

Article 1

The Union shall support the following activities corresponding to measures of the EU strategy against the proliferation of weapons of mass destruction:

- (a) thematic capacity-building workshops and trainings for up to five assistance requests from States;
- (b) Regional Points of Contact Training;
- (c) support the development of National Action Plans and provide tailored support;
- (d) Virtual Regional Assistance Conference on UNSCR 1540 (2004) implementation;
- (e) Regional Outreach Conferences;
- (f) Knowledge Generation and Dissemination.

A detailed description of those activities is set out in the Annex to this Decision.

⁽¹⁾ Council Joint Action 2006/419/CFSP of 12 June 2006 in support of the implementation of the United Nations Security Council Resolution 1540 (2004) and in the framework of the implementation of the EU Strategy against the Proliferation of Weapons of Mass Destruction (OJ L 165, 17.6.2006, p. 30).

⁽²⁾ Council Joint Action 2008/368/CFSP of 14 May 2008 in support of the implementation of United Nations Security Council Resolution 1540 (2004) and in the framework of the implementation of the EU strategy against the proliferation of weapons of mass destruction (OJ L 127, 15.5.2008, p. 78).

⁽³⁾ Council Decision 2013/391/CFSP of 22 July 2013 in support of the practical implementation of United Nations Security Council Resolution 1540 (2004) on non-proliferation of weapons of mass destruction and their means of delivery (OJ L 198, 23.7.2013, p. 40).

⁽⁴⁾ Council Decision (CFSP) 2017/809 of 11 May 2017 in support of the implementation of United Nations Security Council Resolution 1540 (2004) on the non-proliferation of weapons of mass destruction and their means of delivery (OJ L 121, 12.5.2017, p. 39).

Article 2

1. The High Representative of the Union for Foreign Affairs and Security Policy (HR) shall be responsible for the implementation of this Decision.
2. The technical implementation of the activities referred to in Article 1 shall be entrusted to UNODA. It shall perform that task under the responsibility of the HR. For that purpose, the HR shall enter into the necessary arrangements with UNODA.

Article 3

1. The financial reference amount for the implementation of the activities referred to in Article 1 shall be EUR 2 368 769,46.
2. The expenditure financed by the amount set out in paragraph 1 shall be managed in accordance with the procedures and rules applicable to the general budget of the Union.
3. The Commission shall supervise the proper management of the expenditure referred to in paragraph 1. For that purpose, it shall conclude the necessary agreement with UNODA. The agreement shall stipulate that UNODA is to ensure visibility of the Union contribution appropriate to its size.
4. The Commission shall endeavour to conclude the agreement referred to in paragraph 3 as soon as possible after the entry into force of this Decision. It shall inform the Council of any difficulties in that process and of the date of conclusion of that agreement.

Article 4

The HR shall report to the Council on the implementation of this Decision on the basis of regular reports prepared by UNODA. Those reports shall form the basis for the evaluation carried out by the Council. The Commission shall provide information on the financial aspects of the activities referred to in Article 1.

Article 5

1. This Decision shall enter into force on the date of its adoption.
2. This Decision shall expire 36 months after the date of conclusion of the agreement referred to in Article 3(3), or on 21 September 2023 if that agreement has not been concluded by that date.

Done at Brussels, 20 March 2023.

For the Council

The President

J. BORRELL FONTELLES

ANNEX

PROJECT DOCUMENT

RELATED TO EU COUNCIL DECISION IN SUPPORT OF THE IMPLEMENTATION OF UNITED NATIONS SECURITY COUNCIL RESOLUTION 1540 (2004) ON THE NON-PROLIFERATION OF WEAPONS OF MASS DESTRUCTION AND THEIR MEANS OF DELIVERY

HR(2023) 37

1. BACKGROUND

In accordance with the European Union (EU) strategy against the proliferation of weapons of mass destruction adopted on 12 December 2003, which sets the objective of fostering the role of the United Nations Security Council and of enhancing its expertise in addressing the challenges of proliferation, the EU has further supported the implementation of UN Security Council Resolution 1540 (2004) ('UNSCR 1540 (2004)') and its subsequent resolutions.

The implementation of Council Joint Action in support of the implementation of UNSCR 1540 (2004) has been delivered by the United Nations Office for Disarmament Affairs (UNODA) through the technical implementation of previous projects, as the Office has been mandated to provide the 1540 Committee and its experts with substantive and logistical support.

2. GENERAL FRAMEWORK

This Council Decision is designed to strengthen the implementation of UNSCR 1540 (2004) and its subsequent resolutions. As applicable, the Council Decision will build upon achievements of EU CD 2017/809 and previous Joint Actions and Council Decisions ⁽¹⁾ in support of the implementation of UNSCR 1540 (2004) being implemented by UNODA, in close cooperation with the Organization for Security and Co-operation in Europe (OSCE).

The implementation of the EU Council Decision will be guided by the following principles:

- (a) Making best use of the experience gained through previous Joint Actions and Council Decisions in support of implementation of UNSCR 1540 (2004);
- (b) Taking into account specific needs expressed by States and tailored approaches in support;
- (c) Encouraging national and regional ownership of the projects in order to ensure their long-term sustainability;
- (d) Building partnerships between the EU and third parties in the framework of UNSCR 1540 (2004) to ensure synergies and complementarities; and
- (e) Focusing on those activities that have shown to bring concrete results in terms of strengthening national implementation, enhanced assistance, awareness raising and engagement on UNSCR 1540 (2004).

3. OBJECTIVES

Taking advantage of the progress made through previous Council Decisions and the 2022 Comprehensive Review on the Status of Implementation of UNSCR 1540 (2004), UNODA seeks, to continue to promote the implementation of UNSCR 1540 (2004) and its subsequent resolutions through specific measures with the following aims: to enhance the relevant national and regional efforts and capabilities primarily through capacity-building; strengthened capacity and cooperation between Points of Contact; the facilitation of technical thematic assistance with support through international cooperation; and raising public awareness.

Overall objective (expected impact)

The overall objective of the Project is to contribute to international peace and security and to the implementation of the EU strategy against the proliferation of weapons of mass destruction by contributing to better implementation by States of UNSCR 1540 (2004).

⁽¹⁾ Joint Actions 2006/419/CFSP and 2008/368/CFSP and Council Decisions 2013/391/CFSP and 2017/809/CFSP.

Specific objectives

The specific objectives are:

- To enhance the relevant national and regional efforts and capabilities to implement UNSCR 1540, primarily through training, capacity-building and assistance facilitation.
- To strengthen the capacity of Points of Contact (PoC), cooperation and interaction between States and the UNSCR 1540 Committee, as well as among PoC, to assist in the implementation of the resolution.
- To improve the implementation of voluntary UNSCR 1540 (2004) national implementation action plans by supporting their development upon States' request and subsequent access to support in addressing their needs.
- To enhance sub-regional, regional and international cooperation, contributing to achieving greater synergies in the implementation of UNSCR 1540 (2004).
- To enhance awareness of relevant stakeholders, including civil society on the implementation of UNSCR 1540 (2004).
- To enhance the involvement of relevant stakeholders in international, regional and national UNSCR 1540 (2004) implementation efforts.
- To enhance the practical implementation of specific recommendations of the 2009, 2016 and 2022 Comprehensive Reviews on the status of implementation of UNSCR 1540 (2004).

Expected results

This project aims to achieve the following results:

1. Strengthened capacity of government officials, including Points of Contact, to implement the obligations of Resolution 1540 (2004).
2. Effective and realistic national action plans or road maps for the implementation of the key requirements of UNSCR 1540 (2004) developed and the related effective practice and lessons learnt shared.
3. Awareness of governments and civil society on the importance of fully implementing UNSCR 1540 (2004) promoted.

4. ACTIVITIES

Activity 1A: Thematic Capacity Building Workshops and Trainings

Description: Thematic capacity building workshops and trainings for up to five assistance requests from States will be organised, giving priority to States from Latin America and the Caribbean, Africa, and Asia regions. Such assistance will complement the matchmaking function of the 1540 Committee and will be designed to enable States to take additional, practical steps to implement the obligations of UNSCR 1540 (2004) at a national level.

The activity will increase the capacity of government officials and strengthen inter-agency cooperation, contributing to the enhanced implementation of UNSCR 1540 (2004) by States. International organisations and partners will also be invited to provide training, present existing legislative tools and related assistance.

Contingent on national requests and contexts, the objectives of the workshops will be to:

- Raise awareness among participants of resolution 1540;
- Overview the national legislative framework and enforcement measures to identify remaining gaps and prioritise action on enhancing national legislative framework(s) towards fulfilling obligations under resolution 1540 (2004);
- Address the identified gaps and determine the national entities concerned and action required by each; and
- Provide assistance tailored to the needs of States, necessary to build its national capacity.

Activity 1B: Regional PoC Training

Description: Points of Contact act as a link between the Committee and their Government officials. Some PoC also fulfil the role of national coordinator on issues related to the resolution. The implementation of training programmes for 1540 PoC is a critical contribution to enhancing the understanding of the resolution, its implementation challenges, and building the requisite capacities. Support will therefore be provided for two regional/sub-regional training courses for national points of contact nominated by States.

PoC will be provided with an in-depth knowledge of the resolution, strengthening cooperation and communication between States, the Committee and among the PoC. The training courses will provide the opportunity to exchange experiences and approaches among States in the respective regions.

The objective of the training course will be to:

- Impart detailed knowledge of:
- The risks related to the proliferation of weapons of mass destruction and their means of delivery by non-State actors;
- How resolution 1540 interrelates with international and regional legally binding instruments on disarmament and the non-proliferation of weapons of mass destruction and other related regimes and organisations;
- Resolution 1540 and its follow-up resolutions and the role of a national Point of Contact;
- How the 1540 Committee functions, including its assistance mechanism and the importance and methods of reporting.
- To promote and enhance cooperation between Points of Contact at a regional level.

Activity 2A: Support development of NAPs and provide tailored support

Description: Action plans are considered an important tool in the toolkit to support implementation of resolution 1540. They can help States evaluate gaps, prioritise implementation measures, map national stakeholders, and assess required resources and assistance needs. Action plans can thus enable States to follow a tailored and phased approach towards the full and effective implementation of the resolution.

At least two States will be supported in the development of voluntary national action plans or road maps, including the identification and mapping of assistance needs. Such thematic support will enhance capacity for implementation, evaluating gaps, prioritising implementation measures, and assessing required assistance needs. It will also include tailored support for drafting assistance requests, or analysis of existing national legal framework, as applicable, towards fulfilling obligations under resolution 1540 (2004).

The activity will assist the States to have in place voluntary national action plans or road maps with clear targets, timelines and division of labour, including the identification of capacity gaps to inform the drafting of assistance requests and to establish effective partnerships between States and assistance providers. Tailored assistance will be provided on aspects related to UNSCR 1540, including enforcement, national coordination, and analysis of existing national legal framework conducted to identify potential gaps that can be addressed through drafting new or additional legislation and/or regulations towards fulfilling obligations under resolution 1540 (2004).

Activity 2B: Virtual Regional Assistance Conference on UNSCR 1540 (2004) implementation

Description: A virtual conference bringing together States and relevant international, regional and sub-regional organisations will be convened to promote the sharing of experiences in developing national action plans, identify opportunities, lessons learned and effective practices in the areas covered by resolution 1540 (2004), including raising awareness of non-reporting States and training on the development of reports.

The activity will support the engagement by States on experiences in developing national action plans, taking stock of progress made in the implementation of action plans and resolution 1540, sharing accomplishments, recommendations, identifying effective practices and lessons learned as elements for new iterations of action plans, and dialogues initiated towards report submission as applicable. The Conference will be designed in a manner that allows participants to analyse and capture lessons learned at all stages, including formulation, execution, and review of action plans and reports as applicable. The Conference will aim to cover aspects regarding the scope and structure of plans, prioritisation and phasing, stakeholder engagement and buy-in, interagency coordination, resourcing action plans, and international assistance.

Activity 3A: Regional Outreach Conferences

Description: Outreach and awareness raising remain essential in enhancing knowledge on and building commitment towards 1540 implementation. Two regional outreach conferences will be organised to raise awareness amongst policy-makers, and representatives of civil society regarding the importance of the implementation of UNSCR 1540 (2004), including supporting women to be more systematically and deeply involved, ensuring their meaningful participation in the implementation of UNSCR 1540 (2004).

The activity will increase awareness by policy makers, strengthen the role of civil society and contribute towards addressing key issues, providing diverse perspectives, operationalising women's meaningful participation in implementing UNSCR 1540 (2004), and enhanced sub-regional and regional cooperation regarding the implementation of UNSCR 1540 (2004).

Activity 3B: Knowledge Generation and Dissemination

Description: Two knowledge generating outputs will be produced, including publications and thematic webinars to explore the topic of 1540. Recognising the importance of compiling experiences and effective practices, staying informed about relevant advances and providing a better understanding of the interplay between UNSCR 1540 (2004) and areas that may require further research, dialogue, and policy action.

The activity will enhance knowledge among stakeholders on how best to the implement obligations under UNSCR 1540 (2004) and address relevant potential and emerging threats, as well as sharing effective practices which will benefit the work of the Committee.

The themes of the knowledge products will be informed by observed implementation trends, gaps and needs, including those captured in the 2022 Comprehensive Review. These include among others, intangible technology transfers, reporting, and legislative approaches.

5. COORDINATION MECHANISM AND ROLES

UNODA will serve as the implementing organisation that would link the project to the 1540 Committee and its Group of Experts while taking the lead in making use of the UN's convening power to organise activities. As the implementing organisation, UNODA will streamline communications with the donor, organise coordination meetings, compile regular donor reports, and provide political and organisational support to its implementing partners. The project funds will be disbursed and managed in accordance with the rules and regulations of the United Nations.

UNODA will partner with the Organization for Security and Co-operation in Europe (OSCE) on projects implemented in its Participating States, maximising synergies from the participating organisations' strong presence and deep relationships with its Participating States, technical expertise and experience of delivering assistance in the region.

The operational capabilities of UNODA and the OSCE are complementary and UNODA will coordinate regular reporting that will be presented in an annual report on the financial and narrative progress of the project. The reports will be complemented by informal updates via email, videoconference calls and additional ad-hoc meetings as needed.

UNODA will liaise and coordinate with the implementing entities of other relevant programmes and projects funded by the European Union, notably the EU CBRN Centres of Excellence Initiative and the P2P Export Control Programme for Dual-Use Goods of the European Commission as well as projects under the following Council Decisions:

- Council Decision (CFSP) 2019/97 of 21 January 2019 in support of the Biological and Toxin Weapons Convention;
- Council Decision (CFSP) 2019/1296 of 31 July 2019 in support of strengthening biological safety and security in Ukraine in line with the implementation of United Nations Security Council Resolution 1540 (2004) on non-proliferation of weapons of mass destruction and their means of delivery;
- Council Decision (CFSP) 2019/2108 of 9 December 2019 in support of strengthening biological safety and security in Latin America in line with the implementation of United Nations Security Council Resolution 1540 (2004) on non-proliferation of weapons of mass destruction and their means of delivery;

- Council Decision (CFSP) 2020/732 of 2 June 2020 in support of the UN Secretary-General's Mechanism for investigation of alleged use of chemical and biological or toxin weapons;
- Council Decision (CFSP) 2021/2072 of 25 November 2021 in support of building resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention.

Through resolution 1977 (2011), the UN Security Council urged the 1540 Committee to continue to engage actively with States and relevant international, regional and sub-regional organisations to promote the sharing of experiences, lessons learned and effective practices, in the area covered by resolution 1540 (2004). In this regard, UNODA has maintained a strong relationship with its regional centres and other international and regional organisations to ensure Member States receive adequate support in their efforts to fully implement the obligations under the resolution.

To further strengthen this effort, UNODA has placed 1540 regional coordinators in Addis Ababa and Bangkok. The regional coordinators focus is on strengthening UNODA's efforts to provide and facilitate assistance to States and foster closer cooperation with regional organisations in the respective regions. Additionally, close coordination between UNODA, its regional centres and partner organisations will ensure that collective efforts avoid duplication and maximise opportunities for synergies.

6. STAFFING

The implementation of this Council Decision will require staffing presence to ensure the coordinated and streamlined implementation of all activities. The following roles are therefore suggested:

- **One Political Affairs Officer based in New York City:** UNODA's 1540 Support Unit, under the Weapons of Mass Destruction Branch, will play the lead implementation role for the project. The Political Affairs Officer of the Unit will be responsible for providing programmatic oversight, project implementation, including coordination with OSCE, project monitoring and evaluation, reporting, and coordinating communications with the donor.
- **One Regional Coordinator based in Addis Ababa, Ethiopia:** the officer (a staff member of UNODA) will be responsible for further heightening awareness amongst African States about UNSCR 1540 (2004) requirements and the means to organise interagency efforts to address them at a national level; improved understanding amongst states with existing implementation capacity and familiarity with UNSCR 1540 (2004) about how to address national implementation gaps. In order to avoid duplications, the Regional Coordinator will work in close coordination notably with the BTWC Africa Coordinator based in Addis Ababa.
- UNODA will strive to secure gender equity in the hiring process to assist beneficiary countries of the project, and will encourage beneficiary countries to meaningfully engage women at all stages of the project. A special effort is always made to incorporate a gender perspective and to position women at the centre of the topics under discussion.

7. DURATION

The total estimated duration of the Projects' implementation is 36 months.

8. EU VISIBILITY

UNODA will take all appropriate measures to publicise the fact that the activities conducted have been funded by the Union. Such measures will be carried out in accordance with the Commission Communication and Visibility Manual for EU External Actions laid down and published by the European Commission. UNODA will thus ensure the visibility of the Union contribution with appropriate branding and publicity, highlighting the role of the Union, ensuring the transparency of its actions, and raising awareness of the reasons for this Decision as well as awareness of Union support for this Decision and the results of that support. Material produced in the context of the implementation of activities under this Decision will prominently display the Union flag in accordance with Union guidelines for the accurate use and reproduction of the flag.

9. BENEFICIARIES

The beneficiaries of the Project will be UN Member States.

COMMISSION IMPLEMENTING DECISION (EU) 2023/655**of 10 March 2023****fixing the definitive allocation of Union aid to Member States for school fruit and vegetables and for school milk for the period from 1 August 2023 to 31 July 2024 and amending Implementing Decision (EU) 2022/493***(notified under document C(2023) 1532)*

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EU) No 1370/2013 of 16 December 2013 determining measures on fixing certain aids and refunds related to the common organisations of the markets in agricultural products ⁽¹⁾, and in particular Article 5(6) thereof,

Whereas:

- (1) Pursuant to Article 3 of Commission Implementing Regulation (EU) 2017/39 ⁽²⁾, Member States wishing to participate in the Union aid scheme for the supply of fruit and vegetables, bananas and milk in educational establishments (the school scheme) are to submit to the Commission by 31 January each year their request for Union aid relating to the next school year and, if applicable, update the request for Union aid relating to the ongoing school year.
- (2) In order to ensure the effective implementation of the school scheme, the allocation of Union aid for school fruit and vegetables and for school milk among participating Member States should be fixed on the basis of the amounts indicated in the request for Union aid by those Member States and taking into account the transfers between Member State's indicative allocations referred to in Article 23a(4), point (a), of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽³⁾.
- (3) All Member States notified the Commission of their request for Union aid for the period from 1 August 2023 to 31 July 2024, specifying the amount of aid requested for school fruit and vegetables or for school milk, or for both parts of the scheme. In the case of Belgium, France, the Netherlands and Sweden, the amounts requested took account of the transfers between the indicative allocations.
- (4) In order to maximise the full potential of available funds, the unrequested Union aid should be reallocated to Member States participating in the school scheme that indicate, in their request for Union aid, their willingness to use more than their indicative allocation, should additional resources be available.
- (5) In their request for Union aid for the period from 1 August 2023 to 31 July 2024, Sweden sought less than the indicative allocation for school fruit and vegetables. Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Spain, Croatia, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, the Netherlands, Austria, Poland, Slovenia and Slovakia notified their willingness to use more than the indicative allocation for school fruit and vegetables. No Member State sought less than the indicative allocation for school milk.

⁽¹⁾ OJ L 346, 20.12.2013, p. 12.

⁽²⁾ Commission Implementing Regulation (EU) 2017/39 of 3 November 2016 on rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to Union aid for the supply of fruit and vegetables, bananas and milk in educational establishments (OJ L 5, 10.1.2017, p. 1).

⁽³⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

- (6) On the basis of the notified information by Member States, the definitive allocation of Union aid for school fruit and vegetables and for school milk for the period from 1 August 2023 to 31 July 2024 should be fixed.
- (7) Commission Implementing Decision (EU) 2022/493 ⁽⁴⁾ fixed the definitive allocation of Union aid for school fruit and vegetables and for school milk among Member States wishing to participate in the school scheme for the period from 1 August 2022 to 31 July 2023. Commission Implementing Decision (EU) 2022/1187 ⁽⁵⁾ amended Implementing Decision (EU) 2022/493 as regards the definitive allocation of Union aid to Member States for school fruit and vegetables and for school milk for the period from 1 August 2022 to 31 July 2023 to take into account the exceptional second requests for Union aid submitted by Member States pursuant to Commission Implementing Regulation (EU) 2022/861 ⁽⁶⁾ for that same period.
- (8) In the notifications submitted by 31 January 2023 pursuant to Article 3 of Implementing Regulation (EU) 2017/39, some Member States updated their request for Union aid relating to the school year 2022/2023. Germany, Spain, the Netherlands, Austria and Finland notified transfers between the definitive allocation for school fruit and vegetables and the definitive allocation for school milk. Germany and the Netherlands sought less than the definitive allocation for school milk. Czechia, Denmark, Estonia, Ireland, Latvia, Lithuania, Luxembourg, Hungary, Malta, Slovakia and Sweden notified their willingness to use more than the definitive allocation for school milk.
- (9) Implementing Decision (EU) 2022/493 should therefore be amended accordingly.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS DECISION:

Article 1

The definitive allocation of Union aid for school fruit and vegetables and for school milk among Member States participating in the school scheme for the period from 1 August 2023 to 31 July 2024 is set out in Annex I.

Article 2

Annex I to Implementing Decision (EU) 2022/493 is replaced by the text set out in Annex II to this Decision.

Article 3

This Decision is addressed to the Member States.

⁽⁴⁾ Commission Implementing Decision (EU) 2022/493 of 21 March 2022 fixing the definitive allocation of Union aid to Member States for school fruit and vegetables and for school milk for the period from 1 August 2022 to 31 July 2023 and amending Implementing Decision (EU) 2021/462 (OJ L 100, 28.3.2022, p. 55).

⁽⁵⁾ Commission Implementing Decision (EU) 2022/1187 of 7 July 2022 amending Implementing Decision (EU) 2022/493 as regards the definitive allocation of Union aid to Member States for school fruit and vegetables and for school milk for the period from 1 August 2022 to 31 July 2023 (OJ L 184, 11.7.2022, p. 56).

⁽⁶⁾ Commission Implementing Regulation (EU) 2022/861 of 1 June 2022 laying down exceptional rules for the Member States' second requests for Union aid for school fruit and vegetables and for school milk and derogating from Implementing Regulation (EU) 2017/39 as regards the reallocation of Union aid, for the period from 1 August 2022 to 31 July 2023 (OJ L 151, 2.6.2022, p. 42).

Done at Brussels, 10 March 2023.

For the Commission
Janusz WOJCIECHOWSKI
Member of the Commission

ANNEX I

School year 2023/2024

Member State	Definitive allocation for school fruit and vegetables in EUR	Definitive allocation for school milk in EUR
Belgium	3 815 785	1 433 417
Bulgaria	2 185 256	1 800 090
Czechia	3 473 993	3 048 057
Denmark	1 739 147	1 632 431
Germany	21 196 752	8 910 720
Estonia	412 360	754 955
Ireland	1 966 159	826 537
Greece	3 149 503	1 464 086
Spain	13 922 472	6 023 462
France	18 176 401	14 523 309
Croatia	1 322 043	610 533
Italy	15 293 816	6 910 347
Cyprus	300 828	252 652
Latvia	671 180	868 581
Lithuania	923 603	1 236 781
Luxembourg	297 570	193 000
Hungary	2 994 731	2 970 122
Malta	290 000	193 000
Netherlands	5 722 702	1 632 699
Austria	2 414 539	1 015 027
Poland	12 565 488	12 791 591
Portugal	2 804 412	1 301 261
Romania	6 178 236	11 303 390
Slovenia	689 729	305 638
Slovakia	1 915 162	1 659 402
Finland	1 672 943	2 731 455
Sweden	0	8 316 782
Total	126 094 810	94 709 325

ANNEX II

'ANNEX I

School year 2022/2023

Member State	Definitive allocation for school fruit and vegetables in EUR	Definitive allocation for school milk in EUR
Belgium	3 405 460	1 613 199
Bulgaria	2 145 826	1 030 342
Czechia	3 515 512	2 000 127
Denmark	1 855 060	1 578 658
Germany	20 867 400	9 614 058
Estonia	520 903	779 265
Ireland	1 811 303	1 033 661
Greece	3 221 670	1 550 685
Spain	13 442 293	6 152 902
France	16 271 478	16 146 588
Croatia	1 390 541	800 354
Italy	17 117 780	8 003 535
Cyprus	390 044	400 177
Latvia	658 180	748 041
Lithuania	966 451	1 135 641
Luxembourg	295 111	205 725
Hungary	3 122 448	1 945 693
Malta	293 504	201 724
Netherlands	6 006 511	642 270
Austria	2 401 768	944 680
Poland	12 494 071	10 739 507
Portugal	3 283 397	2 220 981
Romania	6 900 318	10 455 944
Slovenia	570 823	311 770
Slovakia	1 872 965	1 070 557
Finland	1 799 047	3 624 689
Sweden	0	9 233 498
Total	126 619 864	941 842 711

DECISION (EU) 2023/656 OF THE EUROPEAN CENTRAL BANK
of 28 February 2023
on the total amount of annual supervisory fees for 2022 (ECB/2023/2)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

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

Having regard to Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions ⁽¹⁾, and in particular Article 30 thereof,

Whereas:

- (1) In accordance with Article 12(1) of Regulation (EU) No 1163/2014 of the European Central Bank (ECB/2014/41) ⁽²⁾, a fee notice is to be issued annually by the European Central Bank (ECB) to each fee debtor within six months after the start of the following fee period.
- (2) Under Article 5(1) and (2) of Regulation (EU) No 1163/2014 (ECB/2014/41) the annual supervisory fees to be levied on the supervised entities are calculated on the basis of the annual costs of the ECB. The amount of the annual costs is determined on the basis of the amount of the annual expenditure consisting of any expenses incurred by the ECB in the relevant fee period that are directly or indirectly related to its supervisory tasks.
- (3) In accordance with Article 8 of Regulation (EU) No 1163/2014 (ECB/2014/41), in order to calculate the annual supervisory fees payable in respect of significant supervised entities and significant supervised groups, and less significant supervised entities and less significant supervised groups, the annual costs should be split on the basis of the costs allocated to the relevant functions that perform the direct supervision of significant supervised entities and significant supervised groups and the indirect supervision of less significant supervised entities and less significant groups.
- (4) In accordance with Article 5(3) of Regulation (EU) No 1163/2014 (ECB/2014/41), fee amounts related to previous fee periods that were not collectible, interest payments received in accordance with Article 14 and certain other amounts received or refunded in accordance with Article 7(3) of that Regulation, if any, should also be taken into account when determining the annual costs.
- (5) In accordance with Article 5(4) of Regulation (EU) No 1163/2014 (ECB/2014/41), within four months after the end of each fee period, the total amount of the annual supervisory fees for each category of supervised entities and supervised groups for that fee period should be published on the ECB's website,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision, the definitions contained in Regulation (EU) No 468/2014 of the European Central Bank (ECB/2014/17) ⁽³⁾ and Regulation (EU) No 1163/2014 (ECB/2014/41) shall apply.

⁽¹⁾ OJ L 287, 29.10.2013, p. 63.

⁽²⁾ Regulation (EU) No 1163/2014 of the European Central Bank of 22 October 2014 on supervisory fees (ECB/2014/41) (OJ L 311, 31.10.2014, p. 23).

⁽³⁾ Regulation (EU) No 468/2014 of the European Central Bank of 16 April 2014 establishing the framework for cooperation within the Single Supervisory Mechanism between the European Central Bank and national competent authorities and with national designated authorities (SSM Framework Regulation) (ECB/2014/17) (OJ L 141, 14.5.2014, p. 1).

*Article 2***Total amount of annual supervisory fees for 2022**

1. The total amount of annual supervisory fees for 2022 shall be EUR 593 709 671, calculated as shown in the Annex.
2. Each category of supervised entities and supervised groups shall pay the following total amount of annual supervisory fees:
 - (a) significant supervised entities and significant supervised groups: EUR 566 725 313;
 - (b) less significant supervised entities and less significant supervised groups: EUR 26 984 358.

*Article 3***Entry into force**

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

Done at Frankfurt am Main, 28 February 2023.

The President of the ECB
Christine LAGARDE

ANNEX

Calculation of the total amount of annual supervisory fees for 2022

(EUR)

	Significant supervised entities and significant supervised groups	Less significant supervised entities and less significant supervised groups	Total
Actual annual costs for 2022	566 839 250	26 966 687	593 805 937
Amounts to be taken into account in accordance with Article 5(3) of Regulation (EU) No 1163/2014 (ECB/2014/41)			
<i>Fee amounts related to previous fee periods that were not collectible</i>			
<i>Interest payments received in accordance with Article 14 of the above Regulation</i>	– 113 936	– 20 019	– 133 955
<i>Amounts received or refunded in accordance with Article 7(3) of the above Regulation</i>		37 690	37 690
TOTAL	566 725 313	26 984 358	593 709 671
Totals may not add up due to rounding			

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN