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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/880

of 5 March 2021

amending Delegated Regulation (EU) 2020/686 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards the traceability, animal health and certification 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 122(1) and (2), Article 160(1) and (2), Article 162(3) and (4), Article 163(5), Article 164(2), Article 165(3) and Article 279(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 Chapters 1, 2 and 5 of Title I of Part IV of Regulation (EU) 2016/429, as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification 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) Article 11 of Delegated Regulation (EU) 2020/686 lays down the traceability requirements for germinal products of dogs and cats, terrestrial animals other than bovine, porcine, ovine, caprine and equine animals kept at confined establishments, and animals of the families *Camelidae* and *Cervidae*. Establishment where germinal products are collected, produced, processed or stored should be registered or approved by the competent authority and a registration or approval number should be assigned to that establishment. The registration or approval number is a part of the mark on the straws or other packages in which germinal products are placed. Paragraph 1(c) of Article 11 of Delegated Regulation (EU) 2020/686 should be amended to provide a clarity of such requirement.
- (6) Article 13 of Delegated Regulation (EU) 2020/686 lays down a derogation for the movements to other Member States of semen of ovine and caprine animals from the establishments where those animals are kept. Donor animals, regardless of whether the place of collection of semen is a semen collection centre or an establishment, should not be used for natural breeding during the period of at least 30 days prior to the date of first collection and during the period of collection of the semen intended for movement to another Member State. Such a requirement should be included in Article 13 of Delegated Regulation (EU) 2020/686.
- (7) Articles 30 and 39 of Delegated Regulation (EU) 2020/686 provide for a 10-day validity period of an animal health certificate issued for a consignment of germinal products intended to be moved between Member States. As germinal products are not perishable goods, there should not be any limit to the validity period of these animal health certificates.
- (8) Articles 35, 43 and 48 of Delegated Regulation (EU) 2020/686 lay down rules for emergency procedures for the notification of movements of consignments of germinal products between Member States in the event of disturbances caused to the information management system for official controls (IMSOC). Articles 99 and 107 of Commission Delegated Regulation (EU) 2020/688 ⁽³⁾ lay down rules on the same matter for movements between Member States of consignments of certain terrestrial animals. However, the wording of the provisions concerned in both Delegated Regulations differ. For the sake of consistency and clarity of procedures, Articles 35, 43 and 48 of Delegated Regulation (EU) 2020/686 should be amended by aligning their wording with that of Articles 99 and 107 of Delegated Regulation (EU) 2020/688.
- (9) Part IV of Delegated Regulation (EU) 2020/686 lays down certain transitional measures regarding Council Directives 88/407/EEC ⁽⁴⁾, 89/556/EEC ⁽⁵⁾, 90/429/EEC ⁽⁶⁾ and 92/65/EEC ⁽⁷⁾ in relation to the approval of semen collection centres, semen storage centres, embryo collection teams and embryo production teams and the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported. However, in order to enable continuity of the movements between Member States of germinal products fulfilling the requirements laid down in those Directives, which were collected or produced, processed and stored before 21 April 2021, certain additional transitional provisions concerning those movements and the use of animal health certificates issued before 21 April 2021 should be laid down in this Regulation.
- (10) Part 1 of Annex II to Delegated Regulation (EU) 2020/686 lays down additional animal health requirements for bovine donor animals. In accordance with point 1(b)(i) and point 2(a) of Chapter I of Part 1 of that Annex bovine semen donors are to be subjected to an intradermal tuberculin test for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*). However, there is also a gamma-interferon assay listed in point 2 of Part 2 of Annex I to Delegated Regulation (EU) 2020/688 as another diagnostic method for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*). Therefore, Delegated Regulation (EU) 2020/686 should be amended in order to provide for the possibility of using of both diagnostic methods.

⁽³⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

⁽⁴⁾ Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p. 10).

⁽⁵⁾ Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p. 1).

⁽⁶⁾ Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p. 62).

⁽⁷⁾ Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54).

- (11) Points 1 and 2 of Annex IV to Delegated Regulation (EU) 2020/686 lay down information that is to be contained in the animal health certificate for germinal products. The date of dispatch of the consignment has been unintentionally omitted from that information and therefore it should be inserted in those provisions. In addition, point 1(f)(i) of Annex IV to that Delegated Regulation requires the breed of donor animal to be specified in the animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine animals. Such information is unnecessary from an animal health point of view and therefore should be removed from the required information to be contained in the animal health certificate for germinal products of bovine, porcine, ovine, caprine and equine animals.
- (12) After the publication of Delegated Regulation (EU) 2020/686 in the *Official Journal of the European Union*, some clerical errors and unintentional omissions were spotted. In the interest of legal certainty and clarity, those errors and omissions should be corrected.
- (13) Delegated Regulation (EU) 2020/686 should therefore be amended accordingly.
- (14) As Delegated Regulation (EU) 2020/686 applies from 21 April 2021, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

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

- (1) Article 1(9) is amended as follows:
 - (a) point (b) is replaced by the following:

‘(b) the marking of straws and other packages in which semen, oocytes or embryos are placed, stored and transported;’;
 - (b) the following points (c) and (d) are added:

‘(c) the use of animal health certificates issued before 21 April 2021;

(d) the movements between Member States of semen, oocytes and embryos collected, produced, processed and stored before 21 April 2021.’;
- (2) in Article 2, point (28) is replaced by the following:

‘(28) “IMSOC” means an information management system for official controls for the integrated operation of the mechanisms and tools through which data, information and documents concerning official controls and other official activities are managed, handled, and automatically exchanged as referred to in Article 131 of Regulation (EU) 2017/625;’;
- (3) in Article 11(1), point (c) is replaced by the following:

‘(c) one of the following:

 - (i) where the establishment of collection or production, processing and storage of those germinal products was assigned with a unique registration number, the unique registration number which shall include the ISO 3166-1 alpha-2 code of the country in which the establishment is registered;
 - (ii) where the establishment of collection or production, processing and storage of those germinal products is a confined establishment, the unique approval number which shall include the ISO 3166-1 alpha-2 code of the country in which the approval is granted;’;
- (4) Article 13 is amended as follows:
 - (a) point (h) is replaced by the following:

‘(h) ensure that the consignment of semen is transported in accordance with Articles 28 and 29;’;
 - (b) the following point (i) is added:

‘(i) ensure that donor animals were not used for natural breeding during the period of at least 30 days prior to the date of first collection of semen intended for movements between Member States and during the period of collection of that semen.’;

- (5) in Article 17, point (b) is replaced by the following:
- ‘(b) they must not be moved between Member States until the movement restrictions applied to either the semen collection centre or the establishment where the semen, oocytes or embryos were collected have been removed by the competent authorities; and’;
- (6) in Article 20, paragraph 3 is replaced by the following:
- ‘3. By way of derogation from paragraph 1(a)(iii), the team veterinarian may accept a donor animal of oocytes and embryos which came from an establishment which was not free from enzootic bovine leukosis provided that the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years.’;
- (7) in Article 22, point (a) is deleted;
- (8) in Article 27(1), point (b) is replaced by the following:
- ‘(b) the mark on the straws or other packages, applied in accordance with Article 10, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided either in the animal health certificate or in the self-declaration document.’;
- (9) in Article 30, paragraph 3 is deleted;
- (10) Article 32(2) is amended as follows:
- (a) point (e) is replaced by the following:
- ‘(e) the marking of the germinal products, as required by Article 10;’;
- (b) the following points (f), (g) and (h) are added:
- ‘(f) the species of donor animals;
- (g) the number of the seal applied on the transport container;
- (h) the declaration that the consignment fulfils the animal health requirements laid down in Chapter 1.’;
- (11) Article 35 is replaced by the following:

‘Article 35

Emergency procedures for the notification of movements of consignments of germinal products of bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of the IMSOC

In the event of power cuts and other disturbances of the IMSOC, the competent authority of the place of origin of the consignment of germinal products of bovine, porcine, ovine, caprine and equine animals to be moved between Member States shall comply with the contingency arrangements set out in Article 46 of Commission Implementing Regulation (EU) 2019/1715 *.

* Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (“the IMSOC Regulation”) (OJ L 261, 14.10.2019, p. 37).;

- (12) Article 39 is amended as follows:
- (a) in paragraph 1(b), point (ii) is replaced by the following:
- ‘(ii) the mark on the straws or other packages, applied in accordance with Article 11, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided in the animal health certificate.’;
- (b) in paragraph 2(b), point (ii) is replaced by the following:
- ‘(ii) the mark on the straws or other packages, applied in accordance with Article 11, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided in the animal health certificate.’;

(c) in paragraph 3(b), point (ii) is replaced by the following:

‘(ii) the mark on the straws or other packages, applied in accordance with Article 11, and the number of the seal applied on the container in which the straws or other packages are transported, correspond with the mark and the number provided in the animal health certificate;’;

(d) paragraph 5 is deleted;

(13) Article 43 is replaced by the following:

‘Article 43

Emergency procedures for the notification of movements of consignments of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals between Member States in the event of power cuts and other disturbances of the IMSOC

In the event of power cuts and other disturbances of the IMSOC, the competent authority of the place of origin of the consignment of germinal products of kept terrestrial animals other than bovine, porcine, ovine, caprine and equine animals to be moved between Member State shall comply with the contingency arrangements set out in Article 46 of Implementing Regulation (EU) 2019/1715.’;

(14) Article 46(2) is amended as follows:

(a) point (c) is replaced by the following:

‘(c) the date of dispatch of the consignment;’;

(b) point (g) is replaced by the following:

‘(g) available results of the tests referred to in Article 45(2)(b);’;

(c) the following points (h) and (i) are added:

‘(h) the number of the seal applied on the transport container;

(i) the declaration that the consignment fulfils requirements laid down in Article 44 or 45, including that the prior written consent of the competent authority of the Member State of destination to accept the consignment of germinal products has been obtained.’;

(15) Article 48 is replaced by the following:

‘Article 48

Emergency procedures for the notification of movements between Member States of germinal products intended for scientific purposes or for storage in gene banks in the event of power cuts and other disturbances of the IMSOC

In the event of power cuts and other disturbances of the IMSOC, the competent authority of the place of origin of the consignment of germinal products intended for scientific purposes or for storage in gene banks to be moved between Member State shall comply with the contingency arrangements set out in Article 46 of Implementing Regulation (EU) 2019/1715.’;

(16) Article 49 is replaced by the following:

‘Article 49

Transitional measures

1. Semen collection centres, semen storage centres, embryo collection teams and embryo production teams which have been approved before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC referred to in the 6th, 7th, 8th and 12th indents of the first subparagraph of Article 270(2) of Regulation (EU) 2016/429 shall be considered to have been approved in accordance with Article 97 of Regulation (EU) 2016/429 and Article 4 of this Regulation.

In all other respects, they shall be subject to the rules provided for in Regulation (EU) 2016/429, and in this Regulation.

2. Semen, oocytes and embryos collected, produced, processed and stored before 21 April 2021 shall be allowed to be moved between Member States, provided they fulfil, as regards the collection, production, processing and storage of germinal products, animal health requirements for donor animals and laboratory and other tests carried out on donor animals and germinal products, the requirements laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC.
 3. Straws and other packages in which semen, oocytes or embryos, whether or not separated into individual doses, are placed, stored and transported, marked before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been marked in accordance with Article 121 of Regulation (EU) 2016/429 and Article 10 of this Regulation.
 4. Animal health certificates issued before 21 April 2021 in accordance with Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC shall be considered to have been issued in accordance with Article 162 of Regulation (EU) 2016/429 and Articles 30 and 31 of this Regulation.’;
- (17) Annexes I to IV to Delegated Regulation (EU) 2020/686 are 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*.

It shall apply from 21 April 2021.

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

Done at Brussels, 5 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

(1) Annex I is amended as follows:

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

‘(v) each straw or other package in which semen is placed is clearly marked in accordance with the requirements laid down in Article 10;’;

(b) in Part 4, point 1(a)(iv) is replaced by the following:

‘(iv) each straw or other package in which semen, oocytes or embryos are placed is clearly marked in accordance with the requirements laid down in Article 10;’;

(c) in Part 5, point 1(a)(iv) is replaced by the following:

‘(iv) each straw or other package in which semen, oocytes or embryos are placed is clearly marked in accordance with the requirements laid down in Article 10;’;

(2) Annex II is amended as follows:

(a) in Chapter I of Part 1, point 1(b)(i) is replaced by the following:

‘(i) for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), a test referred to in Part 2 of Annex I to Delegated Regulation (EU) 2020/688;’;

(b) in Chapter I of Part 1, point 1(b)(iii) is replaced by the following:

‘(iii) for enzootic bovine leukosis, a serological test referred to in point (a) of Part 4 of Annex I to Delegated Regulation (EU) 2020/688, unless the derogation provided for in Article 20(2)(a) of this Regulation applies;’;

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

‘(a) for infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), a test referred to in Part 2 of Annex I to Delegated Regulation (EU) 2020/688;’;

(d) in Chapter I of Part 3, points 1(b), 1(c) and 1(d) are replaced by the following:

‘(b) in the case of ovine animals, they must come from an establishment where, during the period of 60 days prior to their stay in the quarantine accommodation referred to in point (a), they, and any male caprine animal kept with them together, have been subjected with negative results to a serological test for ovine epididymitis (*Brucella ovis*), or any other test for ovine epididymitis (*Brucella ovis*) of an equivalent documented sensitivity and specificity;

(c) the animals have been subjected to the following tests carried out on samples taken within a period of 30 days preceding the commencement of the period of quarantine referred to in point (a), with negative results:

(i) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;

(ii) in the case of ovine animals, and any male caprine animals kept with them together, a serological test for ovine epididymitis (*Brucella ovis*), or any other test for ovine epididymitis (*Brucella ovis*) of an equivalent documented sensitivity and specificity;

(d) the animals have been subjected to the following tests carried out on samples taken during the period of quarantine referred to in point (a), and within a period of at least 21 days from the date of being admitted to the quarantine accommodation, with negative results:

(i) for infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*, a serological test referred to in point 1 of Part 1 of Annex I to Delegated Regulation (EU) 2020/688;

(ii) in the case of ovine animals, and any male caprine animals kept with them together, a serological test for ovine epididymitis (*Brucella ovis*), or any other test for ovine epididymitis (*Brucella ovis*) of an equivalent documented sensitivity and specificity;’;

(e) in Chapter I of Part 3, the introductory phrase of point 2 is replaced by the following:

‘2. All ovine and caprine animals kept at a semen collection centre shall be subjected at least once a year to the following tests (compulsory routine tests), with negative results:’;

(f) in Chapter II of Part 5, point 1(a) is replaced by the following:

‘(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 free from infection with bluetongue virus (serotypes 1-24), where no case of infection with bluetongue virus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animal population.’;

(g) in Chapter II of Part 5, point 2(a) is replaced by the following:

‘(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 free from infection with bluetongue virus (serotypes 1-24), where no case of infection with bluetongue virus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animal population.’;

(3) Annex III is amended as follows:

(a) in Part 1, point 3 is replaced by the following:

‘3. Where necessary, the antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the following antibiotics or their mixtures in each ml of semen, may be added to semen or contained in semen diluents:

(a) a mixture of lincomycin-spectinomycin (1 50/300 µg), penicillin (500 IU) and streptomycin (500 µg); or

(b) a mixture of gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (1 50/300 µg); or

(c) a mixture of amikacin (75 µg) and divexacin (25 µg); or

(d) in the case of semen of ovine and caprine animals, gentamicin (250 µg) or a mixture of penicillin (500 IU) and streptomycin (500 µg).’;

(b) in Part 1, point 4 is replaced by the following:

‘4. In respect of semen of bovine animals, antibiotics or mixtures of antibiotics referred to in point 3(a), (b) and (c) or antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the antibiotics or their mixtures referred to in point 3(a), (b) and (c), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against campylobacters, leptospires and mycoplasmas.’;

(c) in Part 1, point 5 is replaced by the following:

‘5. In respect of semen of porcine animals, antibiotics or mixtures of antibiotics referred to in point 3(a), (b) and (c) or antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the antibiotics or their mixtures referred to in point 3(a), (b) and (c), or semen diluents containing such antibiotics or mixtures of antibiotics, shall be added and be effective in particular against leptospires.’;

(4) Annex IV is amended as follows:

(a) in point 1(f), point (i) is replaced by the following:

‘(i) the species and identification of the donor animals in accordance with the requirements laid down in Title I, II, III or IV of Part III of Delegated Regulation (EU) 2019/2035 from which germinal products were collected.’;

(b) in point 1, point (i) is replaced by the following:

‘(i) the date and place of issue of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment.’;

(c) in point 1, the following point (j) is added:

‘(j) the date of dispatch of the consignment.’;

(d) in point 2, point (i) is replaced by the following:

‘(i) the date and place of issue of the animal health certificate, the name, capacity and signature of the official veterinarian, and the stamp of the competent authority of the place of origin of the consignment;’;

(e) in point 2, the following point (j) is added:

‘(j) the date of dispatch of the consignment.’.

COMMISSION DELEGATED REGULATION (EU) 2021/881**of 23 March 2021****amending Delegated Regulation (EU) 2020/689 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****(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 the introductory phrase and points (a) and (d) of Article 29, the introductory phrase and points (a) and (b) of Article 31(5), the introductory phrase and point (c) of Article 32(2), the introductory phrase and points (a) and (b) of Article 41(3), and Article 42(6) 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 diagnostic methods, rules for Union surveillance programmes and rules for the approval by the Commission of eradication programmes.
- (2) Commission Delegated Regulation (EU) 2020/689 ⁽²⁾ supplements the rules on surveillance, eradication programmes and disease-free status for certain listed diseases and emerging diseases of terrestrial, aquatic and other animals as provided for in Regulation (EU) 2016/429.
- (3) Article 83 of Delegated Regulation (EU) 2020/689 provides for a derogation from the requirement for the Commission to approve certain disease-free statuses for aquatic animal diseases. In order to reduce the administrative burden this derogation should be expanded to include a similar provision for the approval of certain eradication programmes for aquatic animal diseases.
- (4) When a Member State wishes to obtain the approval of an eradication programme for aquatic animal diseases for its entire territory or for a zone or compartment thereof accounting for more than 75 % of its territory, or which is shared with another Member State or third country, it is required to apply to the Commission for approval. In all other cases, a system of self-declaration by the Member State must be followed.
- (5) The system of self-declaration of an eradication programme for aquatic animal diseases for zones and compartments other than those which are approved by the Commission is designed to give transparency to the process and to make it easier and potentially quicker for Member States to have the eradication programme approved. The entire process should be completed electronically unless the Commission or another Member State raises concerns which cannot be resolved satisfactorily. If there are concerns that cannot be resolved satisfactorily, the declaration must be submitted to the Standing Committee on Plants, Animals, Food and Feed.
- (6) Commission Decision 2010/367/EU ⁽³⁾ lays down minimal requirements for surveillance programmes for avian influenza in poultry and in wild birds and sets out technical guidelines in its annexes. Those requirements are now laid down in Annex II to Delegated Regulation (EU) 2020/689. For the sake of clarity and transparency Decision 2010/367/EU should be included in the list of acts to be repealed by Article 86 of Delegated Regulation (EU) 2020/689.
- (7) After publication of Delegated Regulation (EU) 2020/689, incorrect cross-references were noticed in Annex IV to that Regulation. Those cross-references should be corrected.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ 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).

⁽³⁾ Commission Decision 2010/367/EU of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds (OJ L 166, 1.7.2010, p. 22).

- (8) Annex VI to Delegated Regulation (EU) 2020/689 lays down the specific requirements as regards diseases of aquatic animals. They include the general requirements for health visits and sampling for eradication programmes. The general requirements may also be used for demonstrating and maintaining disease-free status.
- (9) Section 5 of Chapter 2 of Part II of Annex VI to Delegated Regulation (EU) 2020/689 lays down the diagnostic and sampling methods for the detection of infection with HPR-deleted infectious salmon anaemia virus. Following the latest available information laid down in the Manual of Diagnostic Test for Aquatic Animals of the World Organisation for Animal Health (OIE) ⁽⁴⁾, the diagnostic and sampling methods should be updated.
- (10) After publication of Delegated Regulation (EU) 2020/689 in the *Official Journal of the European Union*, some mistakes were noticed in Part II of Annex IV and in Part III of Annex VI to that Regulation. Those mistakes should be corrected.
- (11) Delegated Regulation (EU) 2020/689 should therefore be amended accordingly.
- (12) As Delegated Regulation (EU) 2020/689 applies from 21 April 2021, this Regulation should also apply from that date,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/689 is amended as follows:

1. Article 83 is replaced by the following:

‘Article 83

Derogations from approval by the Commission for certain disease-free statuses and certain eradication programmes for aquatic animal diseases

1. By way of derogation from the requirement to submit eradication programmes to the Commission for approval as provided for in Article 31(1)(b) and Article 31(2) of Regulation (EU) 2016/429 or from the requirements to obtain approval by the Commission for disease-free status laid down in Article 36(4) and 37(4) of that Regulation, for aquatic animal diseases, such approval for zones or compartments which cover less than 75 % of the territory of a Member State, and where the water catchment supplying the zone or compartment is not shared with another Member State or third country, shall be gained in accordance with the following procedure:
 - (a) a Member State makes a provisional declaration of freedom or of the establishment of an eradication programme for the zone or compartment, which fulfils the requirements as set out in this Regulation;
 - (b) this provisional declaration is published electronically by the Member State, and the Commission and Member States are alerted to the publication;
 - (c) 60 days after publication, the provisional declaration shall take effect and the zone or compartment referred to in this paragraph shall achieve disease-free status or have the eradication programme approved.
2. Within the 60-day period referred to in point (c) of paragraph 1, the Commission or Member States may seek clarification or additional information in relation to the supporting evidence provided by the Member State making the provisional declaration.
3. Where written comments are made by at least one Member State, or the Commission, within the period referred to in point (c) of paragraph 1 indicating concerns relating to the evidence which supports the declaration, the Commission, the Member State which made the declaration and where relevant, the Member State which has sought clarification or additional information, shall together examine the submitted evidence in order to resolve the concerns.

In such cases, the period referred to in point (c) of paragraph 1 shall be prolonged automatically for 60 days from the date on which the first concerns were raised. There shall be no further prolongation of this period.

⁽⁴⁾ <https://www.oie.int/standard-setting/aquatic-manual/access-online/>

4. Where the process referred to in paragraph 3 fails, the provisions laid down in Articles 31(3), 36(4) and 37(4) of Regulation (EU) 2016/429 shall apply.'
2. In Article 86, the following indent is inserted after the sixth indent:
‘– Decision 2010/367/EU;’
3. Annexes IV and VI to Delegated Regulation (EU) 2020/689 are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 21 April 2021.

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

Done at Brussels, 23 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes IV and VI to Delegated Regulation (EU) 2020/689 are amended as follows:

(1) Annex IV is amended as follows:

(a) in Part II, in Chapter 1, Section 1 is amended as follows:

(i) point 1(c) is replaced by the following

‘(c) since the beginning of the testing or sampling referred to in point (b)(i), all bovine animals introduced into the establishment originate from establishments free from infection with MTBC and:

(i) originate from a Member State or a zone free from infection with MTBC; or

(ii) are bovine animals over 6 weeks of age and have tested negative in an immunological test:

during the 30 days prior to their introduction into the establishment; or

during the 30 days after their introduction provided they have been kept isolated during this period; and’;

(ii) point 2 is replaced by the following:

‘2. By way of derogation from point 1, the status free from infection with MTBC may be granted to an establishment if all bovine animals originate from establishments free from infection with MTBC and:

(a) originate from a Member State or a zone free from infection with MTBC; or

(b) if they are bovine animals over 6 weeks of age, they have tested negative to an immunological test:

(i) during the 30 days prior to their introduction into the establishment; or

(ii) during the 30 days after their introduction provided they have been kept in isolation during this period.’;

(b) in Part VI, Chapter 1 is amended as follows:

(i) in Section 3, point 2(a) is replaced by the following:

‘(a) the requirements laid down in point 1(c) and (d) of Section 1 and point 1(b)(c) and (d) and, if relevant, point 2 of Section 2 are fulfilled.’;

(ii) in Section 4, point 2 is replaced by the following:

‘2. If the status free from BVD has been withdrawn in accordance with point 1(a), it may only be regained if the requirements laid down in point 1(c) and (d) of Section 1 and point 1(b), (c) and (d) and, if relevant, point 2 of Section 2 are fulfilled.’;

(2) Annex VI is amended as follows:

(a) Part II is amended as follows:

(i) in Chapter 1, in Section 1, the introductory phrase is replaced by the following:

‘Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements.’;

(ii) Chapter 2 is amended as follows:

— in Section 1, the introductory phrase is replaced by the following:

‘Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements.’;

— Section 5 is replaced by the following:

Section 5

Diagnostic and sampling methods

1. The organs or tissue material to be sampled and examined must be:

(a) Histology: anterior-kidney, liver, heart, pancreas, intestine, spleen and gill;

- (b) Immunohistochemistry: mid-kidney and heart including valves and *bulbus arteriosus*;
- (c) Conventional RT-PCR and RT-qPCR analysis: mid-kidney and heart;
- (d) Virus culture: mid-kidney, heart and spleen;

Organ pieces from a maximum of five fish may be pooled.

2. The diagnostic method to be used to grant or to maintain the status free from infection with HPR-deleted ISAV in accordance with Sections 2, 3 and 4 must be RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples in accordance with the detailed methods and procedures which must be those approved by the EURL for fish diseases.

In the case of a positive sequencing result for HPR-deleted ISAV, further samples must be tested before the implementation of the initial control measures provided for in Articles 55 to 65.

Those samples must be tested as follows in accordance with the detailed methods and procedures approved by the EURL for fish diseases:

- (a) Screening of the samples by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene of positive samples to verify HPR-deletion; or
 - (b) Detection of ISAV antigen in tissue preparations by means of specific antibodies against ISAV; or
 - (c) Isolation in cell culture and subsequent identification of HPR-deleted ISAV.
3. When a suspicion of infection with HPR-deleted ISAV must be confirmed or ruled out in accordance with Article 55, the following visit, sampling and testing procedure must comply with the following requirements:
 - (a) The suspected establishment must be subject to at least one health visit and one sampling of 10 moribund fish, when clinical signs or post-mortem lesions consistent with infection with HPR-deleted ISAV are observed, or a minimum of 30 fish when clinical signs or *post-mortem* lesions are not observed. Samples shall be tested using one or more of the diagnostic methods set out in point 2 in accordance with the detailed diagnostic methods and procedures approved by the EURL for fish diseases;
 - (b) In the case of a positive result for infection with HPR-deleted ISAV, further samples shall be tested before the implementation of the initial control measures provided in Article 58. A suspected case of infection with HPR-deleted ISAV shall be confirmed in accordance with the following criteria using one or more of the detailed diagnostic methods and procedures approved by the EURL for fish diseases:
 - (i) Detection of ISAV by RT-qPCR, followed by conventional RT-PCR and sequencing of the HE-gene to verify HPR-deletion; or
 - (ii) Detection of ISAV in tissue preparations by means of specific antibodies against ISAV; or
 - (iii) Isolation and identification of ISAV in cell culture from at least one sample from any fish from the establishment;
 - (c) Where the presence of clinical, gross pathological or histopathological findings consistent with infection are observed, the findings must be corroborated using one or more of the diagnostic methods set out in point 3(b), in accordance with the detailed methods and procedures approved by the EURL for fish diseases.

The suspicion of HPR-deleted ISAV may be ruled out, if tests and health visits over a period of 12 months from the date of the suspicion are found to reveal no further evidence of the presence of the virus.;

- (iii) in Chapter 3, in Section 1, the introductory phrase is replaced by the following:

'Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements:';

- (iv) in Chapter 4, in Section 1, the introductory phrase is replaced by the following:
‘Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements.’;
 - (v) in Chapter 5, in Section 1, the introductory phrase is replaced by the following:
‘Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements.’;
 - (vi) in Chapter 6, in Section 1, the introductory phrase is replaced by the following:
‘Health visits and sampling for the surveillance referred to in Article 3(2)(b)(ii) and (iii) must comply with the following requirements.’;
 - (b) Part III is amended as follows:
 - (i) in Chapter 3, in Section 3, in point (b), the introductory phrase is replaced by the following:
‘(b) repopulation occurs using molluscs that originate from establishments which are.’;
 - (ii) in Chapter 4, in Section 3, in point (b), the introductory phrase is replaced by the following:
‘(b) repopulation occurs using molluscs that originate from establishments which are.’;
 - (iii) in Chapter 5, in Section 3, in point (b), the introductory phrase is replaced by the following:
‘(b) repopulation occurs using molluscs that originate from establishments which are.’;
 - (iv) in Chapter 6, in Section 3, in point (b), the introductory phrase is replaced by the following:
‘(b) repopulation occurs using crustaceans that originate from establishments which are.’.
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COMMISSION IMPLEMENTING REGULATION (EU) 2021/882**of 1 June 2021****authorising the placing on the market of dried *Tenebrio molitor* larva as a novel food 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 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 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.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) On 13 February 2018, the company SAS EAP Group ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place dried *Tenebrio molitor* larva (yellow mealworm) on the Union market as a novel food. The application requested for dried *Tenebrio molitor* larva to be used as whole, dried insect in the form of snacks, and as a food ingredient in a number of food products, the target population being the general population. The applicant also made a request to the Commission for the protection of proprietary data submitted in the application.
- (4) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 3 July 2018, asking it to provide a scientific opinion by carrying out an assessment for dried *Tenebrio molitor* larva as a novel food.
- (5) On 24 November 2020, the Authority adopted a scientific opinion on the safety of *Tenebrio molitor* larva as a novel food ⁽³⁾, in accordance with Article 11 of Regulation (EU) 2015/2283.
- (6) In its opinion, the Authority concluded that dried *Tenebrio molitor* larva is safe under the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that dried *Tenebrio molitor* larva under the assessed conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.
- (7) In that opinion, the Authority also concluded on the basis of limited published evidence on food allergy related to insects and in particular from two studies in humans where a total of four suspect allergic reactions were attributed to dried *Tenebrio molitor* larva and one study in animals, that consumption of this novel food may trigger sensitisation to yellow mealworm proteins as well as to tropomyosin from other sources such as crustaceans and mites. The Authority recommended carrying out further research on the allergenicity of dried *Tenebrio molitor* larva. To address the Authority's recommendation the Commission is currently exploring the ways to carry out the necessary research on the allergenicity of *Tenebrio molitor* larvae.

⁽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⁾ Safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283; *EFSA Journal* 2021;19(1):6343.

- (8) Until the data generated by the research is assessed by the Authority, and considering that, to date, only the abovementioned few allergic cases have been reported according to data available to the insect industry of dried *Tenebrio molitor* larva ⁽⁴⁾, the Commission considers that no specific labelling requirements concerning the potential of dried *Tenebrio molitor* larva to cause primary sensitization should be included in the Union list of authorised novel foods.
- (9) The Authority in its opinion also considered that the consumption of dried *Tenebrio molitor* larva may cause allergic reactions to persons that are allergic to crustaceans and dust mites. Furthermore, the Authority noted that additional allergens may end up in the novel food, if these allergens are present in the substrate fed to the insects. This may include allergens, listed in the Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽⁵⁾. Therefore, it is appropriate that dried *Tenebrio molitor* larva made available to the consumer as such and foods containing dried *Tenebrio molitor* larva are appropriately labelled following the requirements in accordance with Article 9 of Regulation (EU) 2015/2283 and Regulation (EU) No 1169/2011.
- (10) In its opinion, the Authority noted that its conclusion on the safety of the novel food was based on analyses of contaminants in the novel food ⁽⁶⁾, a detailed description of the drying process ⁽⁷⁾, analytical data on chitin levels ⁽⁸⁾, and data on the oxidative and microbiological status of the novel food during storage ⁽⁹⁾. It also noted that it could not have reached that conclusion without the data from the unpublished reports of the studies contained in the applicant's file.
- (11) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those studies and to clarify their claim to an exclusive right of reference to those studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.
- (12) The applicant declared that they held proprietary and exclusive right of reference to analyses of contaminants in the novel food, the detailed description of the drying process, the analytical data on chitin levels, and the data on the oxidative and microbiological status of the novel food during storage, at the time they submitted the application and that therefore third parties cannot lawfully access, use or refer to those studies.
- (13) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the specific studies on analyses of contaminants in the novel food, the detailed description of the drying process, the analytical data on chitin levels, and the data on the oxidative and microbiological status of the novel food during storage, contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, should not be used for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place dried *Tenebrio molitor* larva on the market within the Union during that period.
- (14) However, restricting the authorisation of dried *Tenebrio molitor* larva and the reference to the studies contained in the applicant's file for the sole use of the applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such authorisation.
- (15) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁴⁾ *Tenebrio molitor* larva is marketed in a number of Member States under the transitional measures laid down in Article 35(2) of Regulation (EU) 2015/2283.

⁽⁵⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

⁽⁶⁾ SAS EAP Group 2016 (unpublished).

⁽⁷⁾ SAS EAP Group 2013 (unpublished).

⁽⁸⁾ SAS EAP Group 2018 (unpublished).

⁽⁹⁾ SAS EAP Group 2020 (unpublished).

HAS ADOPTED THIS REGULATION:

Article 1

1. Dried *Tenebrio molitor* larva, as specified in the Annex to this Regulation, shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation, only the initial applicant:
Company: SAS EAP Group;
Address: 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France,
is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of SAS EAP Group.
3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of SAS EAP Group.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with 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, 1 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

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

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

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
Dried <i>Tenebrio molitor</i> larva (yellow mealworm)	<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 “Dried <i>Tenebrio molitor</i> larva (yellow mealworm)”. - The labelling of the foodstuffs containing dried <i>Tenebrio molitor</i> larva (yellow mealworm) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans and products thereof, and to dust mites. This statement shall appear in close proximity to the list of ingredients.		Authorised on 22 June 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: SAS EAP Group, 35 Boulevard du Libre Échange, 31650 Saint-Orens-de-Gameville, France. During the period of data protection, the novel food is authorised for placing on the market within the Union only by SAS EAP Group, unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283, or with the agreement of SAS EAP Group. End date of the data protection: 22 June 2026.’
	Dried <i>Tenebrio molitor</i> larva, whole or in powder				
	Protein products	10 g/100 g			
	Biscuits	10 g/100 g			
	Legumes-based dishes	10 g/100 g			
	Pasta-based products	10 g/100 g			

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

Authorised Novel Food	Specification
Dried <i>Tenebrio molitor</i> larva (yellow mealworm)	Description/Definition: The novel food is the whole, thermally dried yellow mealworm, either whole (blanched, oven-dried larva) or in the form of a powder (blanched, oven-dried, ground larva). The term “mealworm” refers to the larval form of <i>Tenebrio molitor</i>, an insect species that belongs to the family of <i>Tenebrionidae</i> (darkling beetles). The entire mealworms are meant for human consumption and no parts are removed. A minimum 24 hours fasting period is required before the thermal drying step, to allow the larvae to discard their bowel content. Characteristics/Composition: Ash (% w/w): 3,5 – 4,5 Moisture (% w/w): 1-8 Crude protein (N x 6,25) (% w/w): 56–61 Digestible Carbohydrates (*) (% w/w): 1–6 Fat (% w/w): 25–30 of which saturated (% w/w): 4–9 Peroxide value (Meq O₂/kg fat): ≤ 5 Dietary fibre (% w/w): 4–7 Chitin (% w/w): 4–7 Heavy metals: Lead: ≤ 0,075 mg/kg Cadmium: ≤ 0,1 mg/kg Mycotoxins: Aflatoxins (Sum of B1, B2, G1, G2): ≤ 4 µg/kg Aflatoxin B1: ≤ 2 µg/kg Deoxynivalenol: ≤ 200 µg/kg Ochratoxin A: ≤ 1 µg/kg Microbiological criteria: Total aerobic colony count: ≤ 10⁵ CFU (**)/g Yeasts and moulds: ≤ 100 CFU/g <i>Escherichia coli</i>: ≤ 50 CFU/g

	<i>Salmonella</i> spp.: Not detected in 25 g <i>Listeria monocytogenes</i> : Not detected in 25 g Sulfite-reducing Anaerobes: ≤ 30 CFU/g <i>Bacillus cereus</i> (presumptive): ≤ 100 CFU/g Enterobacteriaceae (presumptive): < 10 CFU/g Coagulase-positive <i>staphylococci</i> : ≤ 100 CFU/g
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(*) Digestible carbohydrates = $100 - (\text{crude protein} + \text{fat} + \text{dietary fibre} + \text{ash} + \text{moisture})$.

(**) CFU: colony forming units.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/883**of 1 June 2021****amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union****(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 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating carrier, and repealing Article 9 of Directive 2004/36/CE ⁽¹⁾, and in particular Article 4(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 474/2006 ⁽²⁾ establishes the list of air carriers, which are subject to an operating ban within the Union.
- (2) Certain Member States and the European Union Aviation Safety Agency ('the Agency') communicated to the Commission, pursuant to Article 4(3) of Regulation (EC) No 2111/2005, information that is relevant for updating that list. Third countries and international organisations also provided relevant information. The information provided contributes to the determination that the list should be updated.
- (3) The Commission informed all air carriers concerned, either directly or through the authorities responsible for their regulatory oversight, about the essential facts and considerations which would form the basis of a decision to impose an operating ban on them within the Union or to modify the conditions of an operating ban imposed on an air carrier, which is included in the list in Annex A or B to Regulation (EC) No 474/2006.
- (4) The Commission gave the air carriers concerned the opportunity to consult all relevant documentation, to submit written comments and to make an oral presentation to the Commission and to the Committee established by Regulation (EC) No 2111/2005 (the 'EU Air Safety Committee').
- (5) The Commission has informed the EU Air Safety Committee about the ongoing joint consultations, within the framework of Regulation (EC) No 2111/2005 and Commission Regulation (EC) No 473/2006 ⁽³⁾, with the competent authorities and air carriers of Armenia, Indonesia, Kazakhstan, Kyrgyzstan, Moldova, Pakistan and Russia. The Commission also informed the EU Air Safety Committee about the aviation safety situation in the Dominican Republic, Equatorial Guinea, Libya, Nepal, and South Sudan.
- (6) The Agency informed the Commission and the EU Air Safety Committee about the technical assessments conducted for the initial evaluation and the continuous monitoring of third country operator ('TCO') authorisations, issued pursuant to Commission Regulation (EU) No 452/2014 ⁽⁴⁾.

⁽¹⁾ OJ L 344, 27.12.2005, p. 15.

⁽²⁾ Commission Regulation (EC) No 474/2006 of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 14).

⁽³⁾ Commission Regulation (EC) No 473/2006 of 22 March 2006 laying down implementing rules for the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 8).

⁽⁴⁾ Commission Regulation (EU) No 452/2014 of 29 April 2014 laying down technical requirements and administrative procedures related to air operations of third country operators pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 133, 6.5.2014, p. 12).

- (7) The Agency also informed the Commission and the EU Air Safety Committee about the results of the analysis of ramp inspections carried out under the Safety Assessment of Foreign Aircraft programme ('SAFA'), in accordance with Commission Regulation (EU) No 965/2012 ⁽⁵⁾.
- (8) In addition, the Agency informed the Commission and the EU Air Safety Committee about the technical assistance projects carried out in third countries affected by an operating ban under Regulation (EC) No 474/2006. Furthermore, the Agency provided information on the plans and requests for further technical assistance and cooperation to improve the administrative and technical capability of civil aviation authorities in third countries with a view to helping them resolve non-compliance with applicable international civil aviation safety standards. Member States were invited to respond to such requests on a bilateral basis in coordination with the Commission and the Agency. In that regard, the Commission reiterated the usefulness of providing information to the international aviation community, particularly through the International Civil Aviation Organisation's ('ICAO') Aviation Safety Implementation Assistance Partnership tool, on technical assistance to third countries provided by the Union and Member States to improve aviation safety around the world.
- (9) Eurocontrol provided the Commission and the EU Air Safety Committee with an update on the status of the SAFA and TCO alarming functions, including statistics about alert messages for banned air carriers.

Union air carriers

- (10) Following the Agency's analysis of information resulting from ramp inspections carried out on the aircraft of Union air carriers, as well as standardisation inspections carried out by the Agency, complemented also with information stemming from specific inspections and audits carried out by national aviation authorities, several Member States have taken certain enforcement measures and informed the Commission and the EU Air Safety Committee about those measures.
- (11) Member States reiterated their readiness to act as necessary in the event that the relevant safety information indicates imminent safety risks resulting from non-compliance by Union air carriers with the relevant safety standards.

Air carriers from Armenia

- (12) In June 2020, air carriers from Armenia were included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2020/736 ⁽⁶⁾.
- (13) On 15 April 2021, the Commission, the Agency, Member States and representatives of the Civil Aviation Committee of Armenia ('CAC') held a technical meeting, during which the CAC provided information on its oversight activities and on the progress of the corrective action plan developed in July 2020. The CAC provided also an overview of challenges encountered during the last year, information about the overall situation of the aviation environment in Armenia and the gaps identified in different areas of responsibility of the CAC requiring attention.
- (14) Additionally, during that meeting, the CAC provided a detailed presentation on the status of the implementation of the corrective actions to the observations raised during the Union on-site assessment visit from February 2020 and an overview regarding the CAC's risk management process.
- (15) In this context, the CAC informed the Commission that the Air Operator Certificates ('AOC') of the air carriers *Atlantis European Airways* and *Mars Avia* have been revoked, and that the new air carriers *Fly Armenia Airways* (AOC No 070), *Novair* (AOC No 071) and *Shirak Avia* (AOC No 072) have been certified. Since the CAC has not demonstrated a sufficient ability to implement and enforce the relevant safety standards, the issuance of AOCs to those new air carriers does not guarantee sufficient compliance with international safety standards.

⁽⁵⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/736 of 2 June 2020 amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union (OJ L 172, 3.6.2020, p. 7).

- (16) The Commission takes note of the progress made by the CAC in addressing the aviation safety concerns that in June 2020 led to the inclusion of Armenian certified carriers in Annex A to Regulation (EC) No 474/2006. However, currently there is not enough evidence to justify lifting the operational restrictions on air carriers from Armenia. The Commission will continue its monitoring and assessment of how the situation develops further.
- (17) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Armenia, the list of air carriers which are subject to an operating ban within the Union should be amended to include *Fly Armenia Airways*, *Novair* and *Shirak Avia* in Annex A to Regulation (EC) No 474/2006, and to remove *Atlantis European Airways* and *Mars Avia* from that Annex.
- (18) Member States should continue verifying the effective compliance of air carriers certified in Armenia with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from Indonesia

- (19) In June 2018, all carriers from Indonesia were removed from Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2018/871 ⁽⁷⁾.
- (20) On 26 February 2021, the Directorate-General of Civil Aviation of Indonesia ('DGCA Indonesia') provided information and an update on the safety oversight activities for the period from September 2020 to February 2021. In addition to the update on the corrective action plan developed on the basis of the Union on-site assessment visit in March 2018, the information provided by DGCA Indonesia also included updates with respect to the list of AOC holders, registered aircraft, accidents, serious incidents, and aviation occurrences and enforcement measures taken by DGCA Indonesia.
- (21) The Commission, having examined the information and documentation received, considers that all remaining open observations, stemming from the March 2018 on-site assessment visit, have been successfully addressed and can be closed. In view of the progress made, the Commission considers it sufficient that DGCA Indonesia should send an update once a year instead of the two it has done so far.
- (22) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Indonesia, there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (23) Member States should continue verifying the effective compliance of air carriers certified in Indonesia with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (24) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Kazakhstan

- (25) In December 2016, air carriers from Kazakhstan were removed from Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2016/2214 ⁽⁸⁾.
- (26) In February 2020, as part of the continuous monitoring of the safety oversight system in Kazakhstan, formal consultations were opened with the competent authorities of Kazakhstan. In that context, at the occasion of its meetings in May and November 2020, the EU Air Safety Committee was provided with an overview of the safety oversight situation in Kazakhstan.

⁽⁷⁾ Commission Implementing Regulation (EU) 2018/871 of 14 June 2018 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are subject to an operating ban within the Union (OJ L 152, 15.6.2018, p. 5).

⁽⁸⁾ Commission Implementing Regulation (EU) 2016/2214 of 8 December 2016 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are subject to an operating ban within the Union (OJ L 334, 9.12.2016, p. 6).

- (27) As a follow up to the November 2020 EU Air Safety Committee deliberations, the Commission and the Agency have maintained a continuous contact with the Aviation Administration of Kazakhstan Joint Stock Company ('AAK'). In that context, a video conference call took place on 26 March 2021 between the Commission, the Agency, Member States and representatives from both the Civil Aviation Committee of Kazakhstan and the AAK. During that technical meeting, the AAK provided a comprehensive presentation of the measures taken to improve the safety oversight in Kazakhstan, including an overview of its surveillance activities, its plans as regards the recruitment and training of technical personnel, and the enforcement actions taken towards some of the air carriers certified in Kazakhstan. In addition, the AAK emphasized its commitment to further pursuing its policy of continuous improvement, including its essential work on safety oversight development.
- (28) Furthermore, the AAK presented its strategy for 2021-2025, including adoption of the new aviation law and the consequential amendments to the Kazakh national legislative framework.
- (29) Based on the information currently available, it can be concluded that substantial efforts and consequential developments have been made to address the safety situation in Kazakhstan. Whilst acknowledging the progress made to date, the Commission should continue its monitoring and assessment of how the situation develops further. In this context, the Commission intends to carry out, with the assistance of the Agency and Member States, a Union on-site assessment visit to Kazakhstan.
- (30) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Kazakhstan, there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (31) Member States should continue verifying the effective compliance of air carriers certified in Kazakhstan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (32) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Kyrgyzstan

- (33) In October 2006, air carriers from Kyrgyzstan were included in Annex A to Regulation (EC) No 474/2006, by Commission Regulation (EC) No 1543/2006 ⁽⁹⁾.
- (34) On 25 November 2020, at Kyrgyzstan's request and as part of continuous monitoring activities, the Commission, the Agency and representatives of the Civil Aviation Agency of the Kyrgyz Republic ('CAA KG') held a technical meeting, during which the CAA KG provided a comprehensive presentation of its organisation and functions, including the basic principles of its conduct of safety oversight. Other information provided by the CAA KG included the staffing challenges it is encountering, an overview of the Kyrgyz legislative framework, and its strategic approach to technical development within the context of aviation safety capacity building. It also provided an update with respect to the list of AOC holders and registered aircraft.
- (35) Furthermore, on 14 December 2020, as a follow-up to the 25 November 2020 technical meeting, CAA KG informed the Commission that the air carriers *Heli Sky* (AOC No 47), *Valor Air* (AOC No 07), *AeroStan* (AOC No 08), *KAP.KG Aircompany* (AOC No 52) and *FlySky Airlines* (AOC No 53) hold an active AOC. Since the CAA KG has not demonstrated that it has a sufficient ability to implement and enforce the relevant safety standards, the issuance of AOCs to those new air carriers does not guarantee sufficient compliance with international safety standards.

⁽⁹⁾ Commission Regulation (EC) No 1543/2006 of 12 October 2006 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council and as amended by Regulation (EC) No 910/2006 (OJ L 283, 14.10.2006, p. 27).

- (36) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that the list of air carriers from Kyrgyzstan, which are subject to an operating ban within the Union, should be amended to include *AeroStan*, *FlySky Airlines*, *Heli Sky*, *KAP.KG Aircompany* and *Valor Air* in Annex A to Regulation (EC) No 474/2006.
- (37) Member States should continue verifying the effective compliance of air carriers certified in Kyrgyzstan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from Moldova

- (38) In April 2019, all air carriers from Moldova, except for *Air Moldova*, *Fly One* and *Aerotranscargo*, were included in Annex A to Regulation (EC) No 474/2006 by Commission Implementing Regulation (EU) 2019/618 ⁽¹⁰⁾.
- (39) By letter of 2 March 2021, the Civil Aviation Authority of Moldova ('CAAM') provided information and a comprehensive update on the corrective action plan addressing the observations and recommendations resulting from the Union on-site assessment visit in February 2019.
- (40) The Commission, having examined the information and documentation received, considers that the explanations given on the corrective action plan are well-structured and adequate.
- (41) On 25 March 2021, at Moldova's request and as part of continuous monitoring activities, the Commission, the Agency, Member States and representatives of the CAAM held a technical meeting, during which the CAAM provided a comprehensive overview of its organisation and functions, including the basic principles of its conduct of safety oversight. Other information provided by the CAAM included an updated overview of developments and state-of-play of their corrective action plan addressing the observations and recommendations resulting from the Union on-site assessment visit in February 2019. The CAAM stated that the vast majority of the observations of the corrective action plan were closed, with only four observations still open.
- (42) During that meeting, the CAAM informed the Commission that all Moldovan air carriers were recertified according to the new operational regulation, which transposed in Moldova's legislation Commission Regulation (EU) No 965/2012 ⁽¹¹⁾. At present, there are 11 AOC holders in Moldova. The majority of the eight AOC holders that are not holding a TCO authorisation are performing operations from bases outside of Moldova. According to the CAAM, the surveillance of these out-bases is being performed in accordance with the international safety standards.
- (43) Furthermore, the CAAM informed the Commission that the new air carrier *HiSky* (AOC No MD 025) has been certified. Since the CAAM has not demonstrated that it has a sufficient ability to implement and enforce the relevant safety standards, the issuance of an AOC to this new air carrier does not guarantee sufficient compliance with international safety standards.
- (44) Based on the information currently available, it seems that the CAAM has made substantial efforts in the implementation of international safety standards. However, currently there is not enough evidence to justify lifting the operational restrictions on air carriers from Moldova. The information provided about the improvements should be further verified during a Union on-site assessment visit to Moldova.
- (45) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Moldova the list of air carriers, which are subject to an operating ban within the Union, should be amended to include *HiSky* in Annex A to Regulation (EC) No 474/2006.

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2019/618 of 15 April 2019 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are banned from operating or are subject to operational restrictions within the Union (OJ L 106, 17.4.2019, p. 1).

⁽¹¹⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1)

- (46) Member States should continue verifying the effective compliance of air carriers certified in Moldova with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (47) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Pakistan

- (48) In March 2007, *Pakistan International Airlines* was included in Annex B to Regulation (EC) No 474/2006 by Commission Regulation (EC) No 235/2007 ⁽¹²⁾ and subsequently removed in November 2007 by Commission Regulation (EC) No 1400/2007 ⁽¹³⁾.
- (49) On 24 June 2020, a statement from the Pakistan Federal Minister for Aviation revealed that a high number of pilot licenses, issued by the Pakistan Civil Aviation Authority ('PCAA'), were obtained by fraudulent means.
- (50) This event, and the apparent lack of effective safety oversight by the PCAA, has led the Agency to suspend the TCO authorisations of *Pakistan International Airlines* and *Vision Air* with effect from 1 July 2020.
- (51) On 1 July 2020, the Commission opened consultations with the PCAA pursuant to Article 3(2) of Regulation (EC) No 473/2006, and requested the PCAA to provide information about its response to the Federal Minister's statement. In particular, the Commission requested information about the oversight of Pakistan-certified air carriers, including their Safety Management Systems, as well as evidence that a similar situation is not prevalent in other domains also subject to the PCAA safety oversight, such as cabin crew certification, the licensing of maintenance engineers, or the certification of air carriers.
- (52) In 2020, the Commission organised two technical meetings with the PCAA, on 9 July and 25 September.
- (53) In preparation for the May 2021 EU Air Safety Committee meeting and considering the Agency's procedural requirements related to the TCO suspensions of *Pakistan International Airlines* and *Vision Air*, the Commission organised a technical meeting on 15 and 16 March 2021 to ensure coordination between the Commission and the Agency with respect to their respective obligations. Member States' representatives attended those meetings.
- (54) During those meetings various issues were discussed, in particular crew licensing, air operations, airworthiness, occurrence reporting, and the PCAA's responses to the safety recommendations and their follow-up.
- (55) The PCAA has provided relevant evidence and information that has been assessed by the Commission and the Agency experts. Whereas it has been found that the PCAA has a sufficient number of competent and knowledgeable staff, some organisational issues of concern have been identified. Those include quality management deficiencies of the documented procedures, lack of guidance for the inspectors, non-compliant Airline Transport Pilot License qualification process, little or no tracking of corrective actions as a result of findings, and lack of proper root-cause analysis capabilities.
- (56) Furthermore, the PCAA could not provide evidence that Pakistan has notified ICAO of its substantial derogations from the applicable international safety standards of ICAO Annex 1 as stipulated in the section 'Personnel Licensing'.
- (57) Based on the assessment of available evidence and information, the Commission acknowledges the PCAA's efforts to adopt corrective actions to address the identified safety deficiencies. The Commission, however, should continue monitoring the situation in Pakistan, including through a Union on-site assessment visit to Pakistan.

⁽¹²⁾ Commission Regulation (EC) No 235/2007 of 5 March 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 66, 6.3.2007, p. 3).

⁽¹³⁾ Commission Regulation (EC) No 1400/2007 of 28 November 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 311, 29.11.2007, p. 12)

- (58) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Pakistan, there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (59) Member States should continue verifying the effective compliance of air carriers certified in Pakistan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (60) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Russia

- (61) The Commission, the Agency and the competent authorities of the Member States have continued to closely monitor the safety performance of air carriers certified in Russia and operating within the Union, including through prioritisation of the ramp inspections carried out on certain Russian air carriers, pursuant to Regulation (EU) No 965/2012.
- (62) On 14 April 2021, representatives from the Commission, the Agency and the Member States met with representatives from the Russian Federal Air Transport Agency ('FATA') to review the safety performance of air carriers certified in Russia on the basis of ramp inspection reports carried out in the period from 15 October 2020 to 14 April 2021, and to identify in which cases FATA should strengthen its oversight activities.
- (63) The review of the SAFA ramp inspections of air carriers certified in Russia did not reveal any significant or recurrent safety deficiency.
- (64) Based on available information, including information provided by FATA at the 14 April 2021 meeting, the Commission considers that at this stage FATA has the necessary ability and willingness to address safety deficiencies when identified. On those grounds, a hearing of the Russian aviation authorities or of any air carriers certified in Russia before the EU Air Safety Committee was not deemed necessary.
- (65) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union by including air carriers from Russia.
- (66) Member States should keep verifying effective compliance with the relevant international safety standards by the air carriers from Russia, through the conduct of ramp inspections in accordance with Regulation (EU) No 965/2012.
- (67) Where those inspections detect an imminent safety risk resulting from non-compliance with international safety standards, the Commission can impose an operating ban on the Russian-certified air carriers concerned and include them in Annex A or Annex B to Regulation (EC) No 474/2006.
- (68) Regulation (EC) No 474/2006 should therefore be amended accordingly.
- (69) Articles 5 and 6 of Regulation (EC) No 2111/2005 recognise the need for decisions to be taken swiftly and, where appropriate, urgently, given the safety implications. It is therefore essential, for the protection of sensitive information and the traveling public, that any decisions in the context of updating the list of air carriers which are subject to an operating ban or restriction within the Union, are published and enter into force immediately after their adoption.
- (70) The measures provided for in this Regulation are in accordance with the opinion of the EU Air Safety Committee established by Regulation (EC) No 2111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 474/2006 is amended as follows:

- (1) Annex A is replaced by the text in Annex I to this Regulation;
- (2) Annex B is replaced by the text in Annex II to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 1 June 2021.

*For the Commission,
On behalf of the President,
Adina VĂLEAN
Member of the Commission*

ANNEX I

ANNEX A

LIST OF AIR CARRIERS WHICH ARE BANNED FROM OPERATING WITHIN THE UNION, WITH EXCEPTIONS ⁽¹⁾

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number or Operating Licence Number	ICAO three letter designator	State of the Operator
AVIOR AIRLINES	ROI-RNR-011	ROI	Venezuela
BLUE WING AIRLINES	SRBWA-01/2002	BWI	Suriname
IRAN ASEMAN AIRLINES	FS-102	IRC	Iran
IRAQI AIRWAYS	001	IAW	Iraq
MED-VIEW AIRLINE	MVA/AOC/10-12/05	MEV	Nigeria
AIR ZIMBABWE (PVT)	177/04	AZW	Zimbabwe
All air carriers certified by the authorities with responsibility for regulatory oversight of Afghanistan, including			Afghanistan
ARIANA AFGHAN AIRLINES	AOC 009	AFG	Afghanistan
KAM AIR	AOC 001	KMF	Afghanistan
All air carriers certified by the authorities with responsibility for regulatory oversight of Angola, with the exception of TAAG Angola Airlines and Heli Malongo, including			Angola
AEROJET	AO-008/11-07/17 TEJ	TEJ	Angola
GUICANGO	AO-009/11-06/17 YYY	Unknown	Angola
AIR JET	AO-006/11-08/18 MBC	MBC	Angola
BESTFLYA AIRCRAFT MANAGEMENT	AO-015/15-06/17YYY	Unknown	Angola
HELIANG	AO 007/11-08/18 YYY	Unknown	Angola
SJL	AO-014/13-08/18YYY	Unknown	Angola
SONAIR	AO-002/11-08/17 SOR	SOR	Angola
All air carriers certified by the authorities with responsibility for regulatory oversight of Armenia, including			Armenia
AIRCOMPANY ARMENIA	AM AOC 065	NGT	Armenia
ARMENIA AIRWAYS	AM AOC 063	AMW	Armenia
ARMENIAN HELICOPTERS	AM AOC 067	KAV	Armenia

⁽¹⁾ Air carriers listed in Annex A could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number or Operating Licence Number	ICAO three letter designator	State of the Operator
ATLANTIS ARMENIAN AIRLINES	AM AOC 068	AEU	Armenia
FLY ARMENIA AIRWAYS	AM AOC 070	FBB	Armenia
NOVAIR	AM AOC 071	NAI	Armenia
SHIRAK AVIA	AM AOC 072	SHS	Armenia
SKYBALL	AM AOC 073	N/A	Armenia
All air carriers certified by the authorities with responsibility for regulatory oversight of Congo (Brazzaville), including			Congo (Brazzaville)
CANADIAN AIRWAYS CONGO	CG-CTA 006	TWC	Congo (Brazzaville)
EQUAFLIGHT SERVICES	CG-CTA 002	EKA	Congo (Brazzaville)
EQUAJET	RAC06-007	EKJ	Congo (Brazzaville)
TRANS AIR CONGO	CG-CTA 001	TSG	Congo (Brazzaville)
SOCIETE NOUVELLE AIR CONGO	CG-CTA 004	Unknown	Congo (Brazzaville)
All air carriers certified by the authorities with responsibility for regulatory oversight of Democratic Republic of Congo (DRC), including			Democratic Republic of Congo (DRC)
AIR FAST CONGO	AAC/DG/OPS-09/03	Unknown	Democratic Republic of Congo (DRC)
AIR KATANGA	AAC/DG/OPS-09/08	Unknown	Democratic Republic of Congo (DRC)
BUSY BEE CONGO	AAC/DG/OPS-09/04	Unknown	Democratic Republic of Congo (DRC)
COMPAGNIE AFRICAINE D'AVIATION (CAA)	AAC/DG/OPS-09/02	Unknown	Democratic Republic of Congo (DRC)
CONGO AIRWAYS	AAC/DG/OPS-09/01	Unknown	Democratic Republic of Congo (DRC)
KIN AVIA	AAC/DG/OPS-09/10	Unknown	Democratic Republic of Congo (DRC)
MALU AVIATION	AAC/DG/OPS-09/05	Unknown	Democratic Republic of Congo (DRC)

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number or Operating Licence Number	ICAO three letter designator	State of the Operator
SERVE AIR CARGO	AAC/DG/OPS-09/07	Unknown	Democratic Republic of Congo (DRC)
SWALA AVIATION	AAC/DG/OPS-09/06	Unknown	Democratic Republic of Congo (DRC)
MWANT JET	AAC/DG/OPS-09/09	Unknown	Democratic Republic of Congo (RDC)
All air carriers certified by the authorities with responsibility for regulatory oversight of Djibouti, including			Djibouti
DAALLO AIRLINES	Unknown	DAO	Djibouti
All air carriers certified by the authorities with responsibility for regulatory oversight of Equatorial Guinea, including			Equatorial Guinea
CEIBA INTERCONTINENTAL	2011/0001/MTTCT/DGAC/SOPS	CEL	Equatorial Guinea
CRONOS AIRLINES	2011/0004/MTTCT/DGAC/SOPS	Unknown	Equatorial Guinea
All air carriers certified by the authorities with responsibility for regulatory oversight of Eritrea, including			Eritrea
ERITREAN AIRLINES	AOC No 004	ERT	Eritrea
NASAIR ERITREA	AOC No 005	NAS	Eritrea
All air carriers certified by the authorities with responsibility for regulatory oversight of Kyrgyzstan, including			Kyrgyzstan
AEROSTAN	08	BSC	Kyrgyzstan
AIR COMPANY AIR KG	50	Unknown	Kyrgyzstan
AIR MANAS	17	MBB	Kyrgyzstan
AVIA TRAFFIC COMPANY	23	AVJ	Kyrgyzstan
FLYSKY AIRLINES	53	FSQ	Kyrgyzstan
HELI SKY	47	HAC	Kyrgyzstan
KAP.KG AIRCOMPANY	52	KGS	Kyrgyzstan
SKY KG AIRLINES	41	KGK	Kyrgyzstan

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number or Operating Licence Number	ICAO three letter designator	State of the Operator
TEZ JET	46	TEZ	Kyrgyzstan
VALOR AIR	07	VAC	Kyrgyzstan
All air carriers certified by the authorities with responsibility for regulatory oversight of Liberia.			Liberia
All air carriers certified by the authorities with responsibility for regulatory oversight of Libya, including			Libya
AFRIQYAH AIRWAYS	007/01	AAW	Libya
AIR LIBYA	004/01	TLR	Libya
AL MAHA AVIATION	030/18	Unknown	Libya
BURAQ AIR	002/01	BRQ	Libya
GLOBAL AVIATION AND SERVICES	008/05	GAK	Libya
LIBYAN AIRLINES	001/01	LAA	Libya
LIBYAN WINGS AIRLINES	029/15	LWA	Libya
PETRO AIR	025/08	PEO	Libya
All air carriers certified by the authorities with responsibility for regulatory oversight of Moldova with the exception of Air Moldova, Fly One and Aerotranscargo, including			Moldova
Î.M "VALAN ICC" SRL	MD009	VLN	Moldova
CA "AIM AIR" SRL	MD015	AAM	Moldova
CA "AIR STORK" SRL	MD018	MSB	Moldova
CA "HISKY" SRL	MD025	HYM	Moldova
Î M "MEGAVIATION" SRL	MD019	ARM	Moldova
CA "PECOTOX-AIR" SRL	MD020	PXA	Moldova
CA "TERRA AVIA" SRL	MD022	TVR	Moldova
CA "FLY PRO" SRL	MD023	PVV	Moldova
All air carriers certified by the authorities with responsibility for regulatory oversight of Nepal, including			Nepal
AIR DYNASTY HELI. S.	035/2001	Unknown	Nepal

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number or Operating Licence Number	ICAO three letter designator	State of the Operator
ALTITUDE AIR	085/2016	Unknown	Nepal
BUDDHA AIR	014/1996	BHA	Nepal
FISHTAIL AIR	017/2001	Unknown	Nepal
SUMMIT AIR	064/2010	Unknown	Nepal
HELI EVEREST	086/2016	Unknown	Nepal
HIMALAYA AIRLINES	084/2015	HIM	Nepal
KAILASH HELICOPTER SERVICES	087/2018	Unknown	Nepal
MAKALU AIR	057A/2009	Unknown	Nepal
MANANG AIR PVT	082/2014	Unknown	Nepal
MOUNTAIN HELICOPTERS	055/2009	Unknown	Nepal
PRABHU HELICOPTERS	081/2013	Unknown	Nepal
NEPAL AIRLINES CORPORATION	003/2000	RNA	Nepal
SAURYA AIRLINES	083/2014	Unknown	Nepal
SHREE AIRLINES	030/2002	SHA	Nepal
SIMRIK AIR	034/2000	Unknown	Nepal
SIMRIK AIRLINES	052/2009	RMK	Nepal
SITA AIR	033/2000	Unknown	Nepal
TARA AIR	053/2009	Unknown	Nepal
YETI AIRLINES	037/2004	NYT	Nepal
All air carriers certified by the authorities with responsibility for regulatory oversight of Sao Tome and Principe, including			Sao Tome and Principe
AFRICA'S CONNECTION	10/AOC/2008	ACH	Sao Tome and Principe
STP AIRWAYS	03/AOC/2006	STP	Sao Tome and Principe
All air carriers certified by the authorities with responsibility for regulatory oversight of Sierra Leone			Sierra Leone
All air carriers certified by the authorities with responsibility for regulatory oversight of Sudan, including			Sudan

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number or Operating Licence Number	ICAO three letter designator	State of the Operator
ALFA AIRLINES SD	54	AAJ	Sudan
BADR AIRLINES	35	BDR	Sudan
BLUE BIRD AVIATION	11	BLB	Sudan
ELDINDER AVIATION	8	DND	Sudan
GREEN FLAG AVIATION	17	GNF	Sudan
HELEJETIC AIR	57	HJT	Sudan
KATA AIR TRANSPORT	9	KTV	Sudan
KUSH AVIATION CO.	60	KUH	Sudan
NOVA AIRWAYS	46	NOV	Sudan
SUDAN AIRWAYS CO.	1	SUD	Sudan
SUN AIR	51	SNR	Sudan
TARCO AIR	56	TRQ	Sudan'

ANNEX II

ANNEX B

LIST OF AIR CARRIERS WHICH ARE SUBJECT TO OPERATIONAL RESTRICTIONS WITHIN THE UNION ⁽¹⁾

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number	ICAO three letter designator	State of the Operator	Aircraft type restricted	Registration mark(s) and, when available, construction serial number(s) of restricted aircraft	State of registry
AIR SERVICE COMORES	06-819/TA-15/DGACM	KMD	Comoros	All fleet with the exception of: LET 410 UVP.	All fleet with the exception of: D6-CAM (851336).	Comoros
IRAN AIR	FS100	IRA	Iran	All aircraft of type Fokker F100 and of type Boeing B747	Aircraft of type Fokker F100 as mentioned on the AOC; aircraft of type Boeing B747 as mentioned on the AOC	Iran
AIR KORYO	GAC-AOC/KOR-01	KOR	North Korea	All fleet with the exception of: 2 aircraft of type TU-204.	All fleet with the exception of: P-632, P-633.	North Korea'

⁽¹⁾ Air carriers listed in Annex B could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2021/884

of 8 March 2021

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards the validity period of an exemption for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽¹⁾, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications which are specific to medical devices and monitoring and control instruments and are listed in Annex IV to that Directive.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Mercury is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) By Delegated Directive (EU) 2015/574 ⁽²⁾, the Commission granted an exemption for the use of mercury in intravascular ultrasound imaging systems ('the exemption'), by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 30 June 2019, in accordance with the third subparagraph of Article 5(2) of that Directive.
- (5) The Commission received an application for renewal of the exemption ('the renewal request') on 6 October 2017 that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.
- (6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU. The comments received during these consultations were made publicly available on a dedicated website.
- (7) Mercury is used in electric rotating connectors of intravascular ultrasound imaging systems which provide the electrical conduction path between the rotating transducer and stationary electronic equipment. The use of mercury enables, inter alia, higher frequency operation which allows obtaining higher resolution imaging beneficial for patients.
- (8) Due to the lack of alternatives, a substitution or elimination of mercury in the applications concerned is currently scientifically and technically impracticable. The exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾ and thus does not weaken the environmental and health protection afforded by it.

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

⁽²⁾ Commission Delegated Directive (EU) 2015/574 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems (OJ L 94, 10.4.2015, p. 6).

⁽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) and 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).

- (9) It is, therefore, appropriate to grant the renewal of the exemption.
- (10) The exemption should be renewed for the maximum duration of 7 years until 30 June 2026, in accordance with Article 4(3) and the third subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (11) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 June 2022 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 July 2022.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In entry 42 of Annex IV to Directive 2011/65/EU, the second paragraph is replaced by the following:

‘Expires on 30 June 2026.’

DECISIONS

DECISION (EU) 2021/885 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 May 2021

on the mobilisation of the European Union Solidarity Fund to provide assistance to Greece and France in relation to natural disasters and to Albania, Austria, Belgium, Croatia, Czechia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Montenegro, Portugal, Romania, Serbia, Spain in relation to a public health emergency

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund ⁽¹⁾, and in particular Article 4(3) thereof,

Having regard to the Interinstitutional Agreement of 16 December 2020 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management, as well as on new own resources, including a roadmap towards the introduction of new own resources ⁽²⁾, and in particular point 10 thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The European Union Solidarity Fund ('the Fund') aims to enable the Union to respond in a rapid, efficient and flexible manner to emergency situations in order to show solidarity with the population of regions struck by major or regional natural disasters or major public health emergency.
- (2) The Fund is not to exceed the ceilings as laid down in Article 9 of Council Regulation (EU, Euratom) 2020/2093 ⁽³⁾. In accordance with Article 9(2) and 9(4) of that Regulation, the maximum amount that can be mobilised by the Fund from the 2021 allocation until 1 September 2021 is EUR 477 543 750. In accordance with Article 4a(4) of Regulation (EC) No 2012/2002, the amount of EUR 50 000 000 has already been inscribed in the general budget for the financial year 2021 (in commitments and payments) for the payment of advances. In addition, an amount of EUR 47 981 598 of the 2020 allocation was not used until the end of that year and is carried over to 2021. Therefore, the maximum amount available under the EUSF at this point in 2021 is EUR 525 525 348, which is enough to cover the needs under this Decision.
- (3) On 29 October 2020, Greece submitted an application to mobilise the Fund, following the floods in August 2020 in Sterea Ellada.
- (4) On 9 December 2020, Greece submitted an application to mobilise the Fund, following the damages caused by the cyclone Ianos in September 2020 that affected the Regions of Ionia Nisia, Sterea Ellada, Ditiki Ellada, Thessalia and Peloponnisos.
- (5) On 22 January 2021, Greece submitted an application to mobilise the Fund, following the earthquake in October 2020 that affected the islands of Samos, Ikaria and Chios.
- (6) On 21 December 2020, France submitted an application to mobilise the Fund, following the damages caused by Storm Alex in Provence-Alpes-Côtes d'Azur region in October 2020.

⁽¹⁾ OJ L 311, 14.11.2002, p. 3.

⁽²⁾ OJ L 433I, 22.12.2020, p. 28.

⁽³⁾ Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433I, 22.12.2020, p. 11).

- (7) By 24 June 2020, Albania, Austria, Belgium, Croatia, Czechia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Montenegro, Portugal, Romania, Serbia and Spain submitted applications to mobilise the Fund in relation to the major public health emergency caused by the COVID-19 pandemic in early 2020.
- (8) The applications by those States meet the conditions for providing a financial contribution from the Fund, as laid down in Article 4 of Regulation (EC) No 2012/2002.
- (9) The Fund should therefore be mobilised in order to provide a financial contribution to Greece and France in relation to the natural disasters and to Albania, Austria, Belgium, Czechia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Montenegro, Portugal, Romania, Serbia, Spain in relation to the major public health emergency.
- (10) In the case of Croatia, since the advance already paid exceeds the final aid amount, no further amount needs to be mobilised and the unduly paid advance will be recovered in accordance with Article 4a of Regulation (EC) No 2012/2002.
- (11) In order to minimise the time taken to mobilise the Fund, this Decision should apply from the date of its adoption,

HAVE ADOPTED THIS DECISION:

Article 1

For the general budget of the Union for the financial year 2021, the European Union Solidarity Fund shall be mobilised as follows in commitment and payment appropriations in relation to natural disasters:

- (a) the amount of EUR 3 300 100 shall be provided to Greece in relation to the floods in Sterea Ellada, including the amount of EUR 330 010 as advance payment;
- (b) the amount of EUR 21 588 519 shall be provided to Greece in relation to cyclone Ianos, including the amount of EUR 2 158 852 as advance payment;
- (c) the amount of EUR 2 531 301 shall be provided to Greece in relation to the earthquake in the islands of Samos, Chios and Ikaria, including the amount of EUR 253 131 as advance payment;
- (d) the amount of EUR 59 325 000 shall be provided to France in relation to the storm Alex, including the amount of EUR 5 932 500 as advance payment.

Article 2

For the general budget of the Union for the financial year 2021, the European Union Solidarity Fund shall be mobilised as follows in commitment and payment appropriations in relation to a major public health emergency:

- (a) the amount of EUR 905 271 shall be provided to Albania;
- (b) the amount of EUR 31 755 580 shall be provided to Austria;
- (c) the amount of EUR 37 298 777 shall be provided to Belgium;
- (d) the amount of EUR 17 373 205 shall be provided to Czechia;
- (e) the amount of EUR 3 588 755 shall be provided to Estonia;
- (f) the amount of EUR 91 365 053 shall be provided to France;
- (g) the amount of EUR 13 648 386 shall be provided to Germany;
- (h) the amount of EUR 3 994 022 shall be provided to Greece;
- (i) the amount of EUR 13 136 857 shall be provided to Hungary;
- (j) the amount of EUR 20 480 330 shall be provided to Ireland;
- (k) the amount of EUR 76 271 930 shall be provided to Italy;
- (l) the amount of EUR 1 177 677 shall be provided to Latvia;

- (m) the amount of EUR 2 828 291 shall be provided to Lithuania;
- (n) the amount of EUR 2 857 025 shall be provided to Luxembourg;
- (o) the amount of EUR 199 505 shall be provided to Montenegro;
- (p) the amount of EUR 18 039 670 shall be provided to Portugal;
- (q) the amount of EUR 13 926 870 shall be provided to Romania;
- (r) the amount of EUR 11 968 276 shall be provided to Serbia;
- (s) the amount of EUR 36 639 441 shall be provided to Spain.

Article 3

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

It shall apply from 20 May 2021.

Done at Brussels, 20 May 2021.

For the European Parliament
The President
D. M. SASSOLI

For the Council
The President
A. P. ZACARIAS

DECISION (EU) 2021/886 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 20 May 2021****on the mobilisation of the European Globalisation Adjustment Fund following an application from Estonia – EGF/2020/002 EE/Estonia Tourism**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Regulation (EU) No 1309/2013 of the European Parliament and of the Council of 17 December 2013 on the European Globalisation Adjustment Fund (2014-2020) and repealing Regulation (EC) No 1927/2006 ⁽¹⁾, and in particular Article 15(4) thereof,

Having regard to the Interinstitutional Agreement of 16 December 2020 between the European Parliament, the Council of the European Union and the European Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management, as well as on new own resources, including a roadmap towards the introduction of new own resources ⁽²⁾, and in particular point 9 thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The European Globalisation Adjustment Fund (EGF) aims to provide support for workers made redundant and self-employed persons whose activity has ceased as a result of major structural changes in world trade patterns due to globalisation, as a result of a continuation of the global financial and economic crisis, or as a result of a new global financial and economic crisis, and to assist them with their reintegration into the labour market.
- (2) The EGF is not to exceed a maximum annual amount of EUR 186 million (2018 prices), as laid down in Article 8(1) of Council Regulation (EU, Euratom) 2020/2093 ⁽³⁾.
- (3) On 12 November 2020 Estonia submitted an application to mobilise the EGF, in respect of redundancies and cessations of activities (hereafter referred to as 'redundancies') in the tourism industry, defined by the economic sectors classified under the Statistical classification of economic activities in the European Community ('NACE') Revision 2 Division 45 (Wholesale and retail trade and repair of motor vehicles and motorcycles), 49 (Land transport and transport via pipelines), 50 (Water transport), 51 (Air transport), 52 (Warehousing and support activities for transportation), 55 (Accommodation), 56 (Food and beverage service activities), 74 (Other professional, scientific and technical activities), 77 (Rental and leasing activities), 79 (Travel agency, tour operator and other reservation service and related activities), 90 (Creative, arts and entertainment activities), 91 (Libraries, archives, museums and other cultural activities), 92 (Gambling and betting activities), 93 (Sports activities and amusement and recreation activities), in Estonia. The Republic of Estonia is one unit in the Nomenclature of Territorial Units for Statistics ('NUTS') ⁽⁴⁾ level 2 regions. The application was supplemented by additional information provided in accordance with Article 8(3) of Regulation (EU) No 1309/2013. It complies with the requirements for determining a financial contribution from the EGF as laid down in Article 13 of Regulation (EU) No 1309/2013.
- (4) In accordance with Article 4(2) of Regulation (EU) No 1309/2013, the application from Estonia is considered admissible since the redundancies have a serious impact on employment and the national economy.
- (5) The EGF should, therefore, be mobilised in order to provide a financial contribution of EUR 4 474 480 in respect of the application submitted by Estonia.

⁽¹⁾ OJ L 347, 20.12.2013, p. 855.

⁽²⁾ OJ L 433I, 22.12.2020, p. 29.

⁽³⁾ Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021-2027 (OJ L 433I, 22.12.2020, p. 11).

⁽⁴⁾ Commission Regulation (EU) No 1046/2012 of 8 November 2012 implementing Regulation (EC) No 1059/2003 of the European Parliament and of the Council on the establishment of a common classification of territorial units for statistics (NUTS) as regards the transmission of the time series for the new regional breakdown (OJ L 310, 9.11.2012, p. 34).

(6) In order to minimise the time taken to mobilise the EGF, this decision should apply from the date of its adoption,

HAVE ADOPTED THIS DECISION:

Article 1

For the general budget of the Union for the financial year 2021, the European Globalisation Adjustment Fund shall be mobilised to provide the amount of EUR 4 474 480 in commitment and payment appropriations.

Article 2

This decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 20 May 2021.

Done at Brussels, 20 May 2021.

For the European Parliament
The President
D. M. SASSOLI

For the Council
The President
A. P. ZACARIAS

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