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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1322

of 3 August 2021

amending Implementing Regulation (EU) 2019/2076 to make administrative changes to the Union authorisation of the biocidal product family ‘Contec IPA Product Family’*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the first subparagraph of Article 44(5) and Article 50(2) thereof,

Whereas:

- (1) On 29 November 2019, Commission Implementing Regulation (EU) 2019/2076 ⁽²⁾ granted a Union authorisation with authorisation number EU-0020460-0000 to Contec Europe for the making available on the market and use of the biocidal product family ‘Contec IPA Product Family’.
- (2) On 5 February 2020, Contec Europe submitted a notification to the European Chemicals Agency (‘the Agency’), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ⁽³⁾, regarding the administrative changes to the Union authorisation for the biocidal product family ‘Contec IPA Product Family’ as referred to in Section 1 of Title 1 of the Annex to that Regulation.
- (3) Contec Europe proposed the revision of the list of product trade names, including the changes in the trade names and the removal of the trade names of the individual products in the meta SPCs 1 and 2, of the summary of the product characteristics for the biocidal product family ‘Contec IPA Product Family’ as set out in Annex II to Implementing Regulation (EU) 2019/2076. The notification was recorded under the case number BC-GC057245-55 in the Register for Biocidal Products.
- (4) On 6 March 2020, the Agency submitted an opinion ⁽⁴⁾ on the proposed changes to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder fall under Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 of that Regulation are still met. On the same date, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2019/2076 of 29 November 2019 granting a Union authorisation for the biocidal product family ‘Contec IPA Product Family’ (OJ L 316, 6.12.2019, p. 19).

⁽³⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

⁽⁴⁾ ECHA opinion of 2 March 2020 on the administrative change of the Union authorisation of the biocidal product family ‘Contec IPA Product Family’, https://echa.europa.eu/documents/10162/22836226/opinion_for_ua_admin_change_bc-gc057245-55_en.pdf/b848e01c-b8bb-41ac-4dff-650cbfd33ff9

- (5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'Contec IPA Product Family'.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Implementing Regulation (EU) 2019/2076 is replaced by the text in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 3 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

ANNEX II

Summary of product characteristics for a biocidal product family

Contec IPA Product Family

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0020460-0000

R4BP asset number: EU-0020460-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Contec IPA Product Family
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1.2. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)
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1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Contec Europe
	Address	ZI Du Prat, Avenue Paul Duplaix, 56000, Vannes, France
Authorisation number	EU-0020460-0000	
R4BP asset number	EU-0020460-0000	
Date of the authorisation	26 December 2019	
Expiry date of the authorisation	30 November 2029	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Contec Inc.
Address of manufacturer	525 Locust Grove, SC 29303 Spartanburg United States
Location of manufacturing sites	525 Locust Grove, SC 29303 Spartanburg United States

Name of manufacturer	Contec Cleanroom Technology (Suzhou) Co., Ltd. China
Address of manufacturer	17 Longyun Road, Suzhou Industrial Park, 215024 Suzhou China
Location of manufacturing sites	17 Longyun Road, Suzhou Industrial Park, 215024 Suzhou China

Name of manufacturer	Contec Cleanroom (UK) Ltd
Address of manufacturer	Unit 6A, Wansbeck Business Park, Rotary Parkway, NE63 8QW Ashington, Northumberland United Kingdom
Location of manufacturing sites	Unit 6A, Wansbeck Business Park, Rotary Parkway, NE63 8QW Ashington, Northumberland United Kingdom

Name of manufacturer	Flexible Medical Packaging
Address of manufacturer	Unit 8 Hightown, White Cross Industrial Estate, LA1 4XS Lancaster, Lancashire United Kingdom
Location of manufacturing sites	Unit 8 Hightown, White Cross Industrial Estate, LA1 4XS Lancaster, Lancashire United Kingdom

1.5. Manufacturer(s) of the active substance(s)

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11, 45131 Essen, Germany
Location of manufacturing sites	Haven 3222, Vondelingenweg 601, 3196 KK Vondelingenplaat Netherlands

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

2.2. Type(s) of formulation

Formulation(s)	AL (any other liquid) – RTU solution/trigger spray AL (any other liquid) – RTU wipe
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PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Contec IPA Liquid Products
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	AL (any other liquid) – RTU solution/trigger spray
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours.

	Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a Poison centre if you feel unwell. If eye irritation persists: Get medical advice. In case of fire: Use alcohol resistant foam to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents/container in accordance with local regulations.
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4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – Professional use

Product type	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Mycobacteria Yeasts
Field(s) of use	Indoor Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications, and in industrial food and feed preparation areas. Acceptable use temperature: room temperature (20 ± 2 °C)
Application method(s)	Spraying and wiping
Application rate(s) and frequency	50 ml product per m² of surface. Wiping: 1 minute contact time for bacteria and mycobacteria 3 minutes contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	High-density polyethylene (HDPE) trigger spray bottle – 0,5 L – 1 L HDPE capped refill bottle – 5 L

4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

Use at room temperature. For visibly soiled surfaces, cleaning prior to disinfection is required.

Wiping: Apply/Spray product to a suitable quality cleanroom wipe. Ensure the wipe is sufficiently and uniformly saturated before wiping the surface to be disinfected.

Ensure the surface is uniformly covered with the product then wipe to dry with a sterile cleanroom wipe.

Contact times: Wiping 1 minute for bacteria and mycobacteria 3 minutes for yeast.

Used wipes must be disposed of in a closed container.

5.2. **Risk mitigation measures**

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes

"For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV"

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Likely direct or indirect adverse effects:

Headache, vertigo, hallucinations, respiratory depression, CNS depression or coma.

Severe irritation of the eyes and or ocular damage.

Nausea, vomiting, diarrhoea and haemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycaemia.

First aid measures:

Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention

Skin contact; wash affected area with plenty of water and soap. No scrubbing.

In case of ingestion: Do NOT induce vomiting and never give anything by mouth to an impaired or unconscious individual; if the individual is unconscious place individual in left sideways (recovery) position with the head lowered and the knees bent.

Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

Take the individual to a healthcare centre and bring packaging or label whenever possible.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

Monitor vital signs and provide symptomatic and supportive treatment.

Evaluate endoscopic procedure in case of ingestion.

Monitor glycaemia and ketones.

Ipecac use is contraindicated.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTRE ☐ [INSERT LOCAL NUMBER HERE].

5.4. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with local regulations.

Do not re-use empty container for any other purpose.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.

Keep away from sources of ignition.

Keep away from direct sunlight.

Keep container tightly closed.

Shelf-life: 2 years

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Contec IPA Contec Sterile IPA				
Authorisation number	EU-0020460-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Contec IPA Wipes
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	AL (any other liquid) – RTU wipe
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Avoid breathing vapours. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear eye protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTRE if you feel unwell. If eye irritation persists: Get medical advice. In case of fire: Use alcohol resistant foam to extinguish. Store in a well-ventilated place. Keep cool. Store locked up.

	Dispose of contents/container in accordance with local regulations.
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4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 2

Use # 1 – Professional use

Product type	PT02 – Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Mycobacteria Yeasts
Field(s) of use	Indoor Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications, and in industrial food and feed preparation areas. Acceptable use temperature: room temperature (20 ± 2 °C)
Application method(s)	Wiping
Application rate(s) and frequency	1 minute contact time for bacteria and mycobacteria 3 minutes contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	Impregnated 100 % polypropylene wipes in: — HDPE canister with HDPE cap – 150 wipes (1,7 L or 2,15 L) — Polyethylene terephthalate (PET)/polyethylene (PE) packet sealed with PET/PE flow wrap – 30, 40 or 50 wipes Impregnated 100 % polyester wipes in: — HDPE canister with HDPE cap – 100 wipes (2,25 L) — PET/PE packet sealed with PET/PE flow wrap – 20 wipes Impregnated 100 % knitted polyester wipes in: — PET/PE packet sealed with PET/PE flow wrap – 8, 10, 20, 30 or 50 wipes Impregnated 55 % cellulose/45 % polyester wipes in: — HDPE canister with HDPE cap – 100 wipes (2,25 L) — PET/PE packet sealed with PET/PE flow wrap – 24, 30, 50 or 75 wipes Impregnated 50 % rayon/50 % polyester wipes in: — HDPE canister with HDPE cap – 700 wipes (11,4 L)

4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. Use-specific risk mitigation measures

See general directions for use

- 4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use

- 4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use

- 4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

5. GENERAL DIRECTIONS FOR USE ^(*) OF THE META SPC 2

5.1. **Instructions for use**

For soiled surfaces, cleaning prior to disinfection is required.

Ensure the surface is uniformly covered with the product, allow to act for a contact time of 1 minute for bactericidal and mycobactericidal action and 3 minutes for yeasticidal action

5.2. **Risk mitigation measures**

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes

"For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV"

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Likely direct or indirect adverse effects:

Headache, vertigo, hallucinations, respiratory depression, CNS depression or coma.

Severe irritation of the eyes and or ocular damage.

Nausea, vomiting, diarrhoea and haemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycaemia.

First aid measures:

Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention

Skin contact; wash affected area with plenty of water and soap, No scrubbing.

In case of ingestion; Do NOT induce vomiting and never give anything by mouth to an impaired or unconscious individual; if the individual is unconscious place individual in left sideways (recovery) position with the head lowered and the knees bent.

Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.

Take the individual to a healthcare centre and bring packaging or label whenever possible.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

Monitor vital signs and provide symptomatic and supportive treatment.

Evaluate endoscopic procedure in case of ingestion.

Monitor glycaemia and ketones.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

Ipecac use is contraindicated.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTRE ☐ [INSERT LOCAL NUMBER HERE].

5.4. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with local regulations.

Do not re-use empty container for any other purpose.

Used wipes must be disposed in a closed container

Dispose of used wipes by dry waste to landfill

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.

Keep away from sources of ignition.

Keep away from direct sunlight.

Keep container tightly closed.

Shelf-life: 2 years

6. OTHER INFORMATION

Polypropylene, polyester, kitted polyester, 55 % cellulose/45 % polyester or 50 % rayon/50 % polyester wipes, 34-240 gsm, containing 5 – 38 ml product (2,75 – 20,9 g propan-2-ol)

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	PROSAT EasyReach PROSAT Sterile EasyReach PROSAT Wipes PROSAT Sterile Wipes SATWipes Wipes SATWipes Sterile Wipes Cleanroom wipes, presaturated Spec-Wipe				
Authorisation number	EU-0020460-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9'

COMMISSION REGULATION (EU) 2021/1323**of 10 August 2021****amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in certain foodstuffs****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 ⁽²⁾ sets maximum levels for cadmium (Cd) in a range of foodstuffs.
- (2) On 30 January 2009, the European Food Safety Authority ('the Authority') adopted an opinion on cadmium in food ⁽³⁾. The Authority concluded that cadmium is primarily toxic to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. In view of the toxic effects of cadmium on the kidneys, the Authority established a tolerable weekly intake for cadmium of 2,5 µg/kg body weight. The Authority further concluded that the mean exposure for adults across the Union is close to, or slightly exceeds, the tolerable weekly intake. It also concluded that subgroups such as vegetarians, children, smokers and people living in highly contaminated areas may exceed the tolerable weekly intake by about 2-fold. Therefore, the CONTAM Panel concluded that the current exposure to cadmium at the population level needs to be reduced. Following that opinion, the Authority issued, on 17 January 2012, a scientific report where it confirmed that children and adults at the 95th percentile exposure could exceed the health-based guidance values ⁽⁴⁾.
- (3) Taking into account the Authority's opinion and scientific report, new maximum levels for baby foods and chocolate/cocoa products were established under Commission Regulation (EU) No 488/2014 ⁽⁵⁾.
- (4) However, the Commission considered that an immediate reduction of the existing MLs was not appropriate at the time. Therefore, it adopted Commission Recommendation 2014/193/EU ⁽⁶⁾, which called on Member States to ensure that the already available mitigation methods were communicated and promoted to farmers and started or continued to be implemented, to regularly monitor the progress of the mitigation measures by collecting occurrence data on cadmium levels in foodstuffs and to report the data, in particular on cadmium levels close to or exceeding the maximum levels, by February 2018.
- (5) An evaluation of the most recent occurrence data gathered after the implementation of the mitigation measures shows that it is now achievable to reduce the presence of cadmium in many foodstuffs. Therefore, it is appropriate to lower the existing maximum levels for cadmium or to establish maximum levels for those foodstuffs.
- (6) Regulation (EC) No 1881/2006 should therefore be amended accordingly.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽³⁾ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific opinion on cadmium in food. *EFSA Journal* 2009(980) 1-139, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.980>.

⁽⁴⁾ Scientific Report of EFSA on Cadmium dietary exposure in the European population. *EFSA Journal* 2012;10(1), 2551 [37 pp.], <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2551>.

⁽⁵⁾ Commission Regulation (EU) No 488/2014 of 12 May 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in foodstuffs (OJ L 138, 13.5.2014, p. 75).

⁽⁶⁾ Commission Recommendation 2014/193/EU of 4 April 2014 on the on the reduction of the presence of cadmium in foodstuffs (OJ L 104, 8.4.2014, p. 80).

- (7) Given that cadmium is an indirect genotoxic carcinogen, and consequently its presence is a higher risk for public health, products containing cadmium, which do not comply with the new maximum levels, and which were placed on the market before the entry into force of this Regulation, should only be allowed to remain on the market for a limited period of time.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Foodstuffs listed in the Annex that were lawfully placed on the market before the entry into force may remain on the market until 28 February 2022.

Article 3

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, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Section 3: Metals of the Annex to Regulation (EC) No 1881/2006, subsection 3.2 (Cadmium) is replaced by the following:

Foodstuffs ⁽¹⁾		Maximum level (mg/kg wet weight)
3.2	Cadmium	
3.2.1	Fruits ⁽²⁷⁾ and tree nuts ⁽²⁷⁾	
3.2.1.1	Citrus fruits, pome fruits, stone fruits, table olives, kiwi fruits, bananas, mangoes, papayas and pineapples	0,020
3.2.1.2	Berries and small fruits, except raspberries	0,030
3.2.1.3	Raspberries	0,040
3.2.1.4	Fruits, except those listed under 3.2.1.1, 3.2.1.2 and 3.2.1.3	0,050
3.2.1.5	Tree nuts (*)	
3.2.1.5.1	Tree nuts, except those listed under 3.2.1.5.2	0,20
3.2.1.5.2	Pine nuts	0,30
3.2.2	Root and tuber vegetables ⁽²⁷⁾	
3.2.2.1	Root and tuber vegetables, except those listed under 3.2.2.2, 3.2.2.3, 3.2.2.4, 3.2.2.5 and 3.2.2.6. For potatoes, the maximum level applies to peeled potatoes.	0,10
3.2.2.2	Radishes	0,020
3.2.2.3	Tropical roots and tubers, parsley roots, turnips	0,050
3.2.2.4	Beetroots	0,060
3.2.2.5	Celeriac	0,15
3.2.2.6	Horseradish, parsnips, salsify	0,20
3.2.3	Bulb vegetables ⁽²⁷⁾	
3.2.3.1	Bulb vegetables, except garlic	0,030
3.2.3.2	Garlic	0,050
3.2.4	Fruiting vegetables ⁽²⁷⁾	
3.2.4.1	Fruiting vegetables, except aubergines	0,020
3.2.4.2	Aubergines	0,030
3.2.5	Brassica vegetables ⁽²⁷⁾	
3.2.5.1	Brassica, other than leafy brassica	0,040
3.2.5.2	Leafy brassica	0,10
3.2.6	Leaf vegetables and herbs ⁽²⁷⁾	
3.2.6.1	Leaf vegetables, except those listed under point 3.2.6.2	0,10
3.2.6.2	Spinaches and similar leaves, mustard seedlings and fresh herbs	0,20
3.2.7	Legume vegetables ⁽²⁷⁾	0,020

3.2.8	Stem vegetables ⁽²⁷⁾	
3.2.8.1	Stem vegetables, other than those listed under point 3.2.8.2 and 3.2.8.3	0,030
3.2.8.2	Leeks	0,040
3.2.8.3	Celeries	0,10
3.2.9	Fungi ⁽²⁷⁾	
3.2.9.1	Cultivated fungi, other than those listed under point 3.2.9.2	0,050
3.2.9.2	<i>Lentinula edodes</i> (Shiitake mushroom) and <i>Pleurotus, ostreatus</i> (Oyster mushroom)	0,15
3.2.9.3	Wild fungi	0,50
3.2.10	Pulses and proteins from pulses	
3.2.10.1	Pulses, except proteins from pulses	0,040
3.2.10.2	Proteins from pulses	0,10
3.2.11	Oilseeds (*)	
3.2.11.1	Oilseeds, except those listed under 3.2.11.2, 3.2.11.3, 3.2.11.4, 3.2.11.5 and 3.2.11.6	0,10
3.2.11.2	Rape seeds	0,15
3.2.11.3	Peanuts and soy beans	0,20
3.2.11.4	Mustard seeds	0,30
3.2.11.5	Linseed and sunflower seed	0,50
3.2.11.6	Poppy seed	1,20
3.2.12	Cereals (**)	
3.2.12.1	Cereals other than those listed under 3.2.12.2, 3.2.12.3, 3.2.12.4 and 3.2.12.5	0,10
3.2.12.2	Rye and barley	0,050
3.2.12.3	Rice, quinoa, wheat bran and wheat gluten	0,15
3.2.12.4	<i>Triticum durum</i> (durum wheat)	0,18
3.2.12.5	Wheat germ	0,20
3.2.13	Specific cocoa and chocolate products as listed below ⁽⁴⁹⁾	
3.2.13.1	— Milk chocolate with < 30 % total dry cocoa solids	0,10
3.2.13.2	— Chocolate with < 50 % total dry cocoa solids; milk chocolate with ≥ 30 % total dry cocoa solids	0,30
3.2.13.3	— Chocolate with ≥ 50 % total dry cocoa solids	0,80
3.2.13.4	— Cocoa powder sold to the final consumer or as an ingredient in sweetened cocoa powder sold to the final consumer (drinking chocolate)	0,60
3.2.14	Products of animal origin – terrestrial animals ⁽⁶⁾	
3.2.14.1	Meat (excluding offal) of bovine animals, sheep, pig and poultry	0,050

3.2.14.2	Horsemeat, excluding offal	0,20
3.2.14.3	Liver of bovine animals, sheep, pig, poultry and horse	0,50
3.2.14.4	Kidney of bovine animals, sheep, pig, poultry and horse	1,0
3.2.15	Products of animal origin- fish, fish products and any other marine and freshwater food products	
3.2.15.1	Muscle meat of fish ⁽²⁴⁾ ⁽²⁵⁾ , excluding species listed under points 3.2.15.2, 3.2.15.3 and 3.2.15.4	0,050
3.2.15.2	Muscle meat of the following fish ⁽²⁴⁾ ⁽²⁵⁾ : mackerel (<i>Scomber species</i>), tuna (<i>Thunnus species</i> , <i>Katsuwonus pelamis</i> , <i>Euthynnus species</i>), bichique (<i>Sicyopterus lagocephalus</i>)	0,10
3.2.15.3	Muscle meat of the following fish ⁽²⁴⁾ ⁽²⁵⁾ : bullet tuna (<i>Auxis species</i>)	0,15
3.2.15.4	Muscle meat of the following fish ⁽²⁴⁾ ⁽²⁵⁾ : anchovy (<i>Engraulis species</i>), swordfish (<i>Xiphias gladius</i>), sardine (<i>Sardina pilchardus</i>)	0,25
3.2.15.5	Crustaceans ⁽²⁶⁾ : muscle meat from appendages and abdomen ⁽⁴⁴⁾ . In case of crabs and crab-like crustaceans (<i>Brachyura</i> and <i>Anomura</i>) muscle meat from appendages.	0,50
3.2.15.6	Bivalve molluscs ⁽²⁶⁾	1,0
3.2.15.7	Cephalopods (without viscera) ⁽²⁶⁾	1,0
3.2.16	Infant formulae, follow-on formulae and foods for special medical purposes intended for infants and young children ⁽³⁾ ⁽²⁹⁾ and young child formulae ⁽²⁹⁾ ⁽⁵⁷⁾	
3.2.16.1	— marketed as powder and manufactured from cow's milk proteins or from cow's milk protein hydrolysates	0,010
3.2.16.2	— marketed as liquid and manufactured from cow's milk proteins or from cow's milk protein hydrolysates	0,005
3.2.16.3	— marketed as powder and manufactured from soya protein isolates, alone or in a mixture with cow's milk proteins	0,020
3.2.16.4	— marketed as liquid and manufactured from soya protein isolates, alone or in a mixture with cow's milk proteins	0,010
3.2.17	Young child formulae ⁽²⁹⁾ ⁽⁵⁷⁾	
3.2.17.1	— marketed as powder and manufactured from plant protein isolates other than soya protein isolates, alone or in a mixture with cow's milk proteins	0,020
3.2.17.2	— marketed as liquids and manufactured from plant protein isolates other than soya protein isolates, alone or in a mixture with cow's milk proteins	0,010

3.2.18	Processed cereal-based foods and baby foods for infants and young children ⁽³⁾ ⁽²⁹⁾	0,040
3.2.19	Drinks for infants and young children labelled and sold as such, other than those mentioned in 3.2.16 and 3.2.17	
3.2.19.1	Marketed as liquids or to be reconstituted following instructions of the manufacturer including fruit juices ⁽⁴⁾	0,020
3.2.20	Food supplements ⁽³⁹⁾	
3.2.20.1	Food supplements, except food supplements listed in point 3.2.20.2	1,0
3.2.20.2	Food supplements consisting exclusively or mainly of dried seaweed, products derived from seaweed, or of dried bivalve molluscs	3,0
3.2.21	Salt	0,50

(*) The maximum levels do not apply to tree nuts or oilseeds for crushing and oil refining, provided that the remaining pressed tree nuts or oilseeds are not placed on the market as food. In case the remaining pressed tree nuts or oilseeds are placed on the market as food, the maximum levels apply, taking into account Articles 2(1) and 2(2) of this Regulation.

(**) The maximum levels do not apply to cereals used for malt for beer or distillates production, provided that the remaining malt is not placed on the market as food. In case the remaining malt is placed on the market as food, the maximum levels apply, taking into account Articles 2(1) and 2(2) of this Regulation.'

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1324**of 10 August 2021****amending Regulation (EC) No 1597/2002 as regards the format for the submission of national lists of the basic material of forest reproductive material**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material ⁽¹⁾, and in particular Article 10(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1597/2002 ⁽²⁾ lays down a standardised format for Member States to submit to the Commission national lists of basic material of forest reproductive material.
- (2) The Commission has recently developed an information system for the electronic submission of those national lists, called Forest Reproductive Material Information System (FOREMATIS). FOREMATIS allows Member States to publish their national lists on the website of the Commission.
- (3) Due to that technical development, the format of national lists provided for by Regulation (EC) No 1597/2002 should be replaced by that of FOREMATIS.
- (4) Regulation (EC) No 1597/2002 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1597/2002 is amended as follows:

- (1) Article 1 is replaced by the following:

‘Article 1

The national list referred to in Article 10(2) of Directive 1999/105/EC shall be submitted by each Member State through and in accordance with the format of the Forest Reproductive Material Information System of the Commission (*).

(*) <https://ec.europa.eu/forematis/>;

- (2) the Annex is deleted.

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*.

⁽¹⁾ OJ L 11, 15.1.2000, p. 17.

⁽²⁾ Commission Regulation (EC) No 1597/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the format of national lists of the basic material of forest reproductive material (OJ L 240, 7.9.2002, p. 34).

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

Done at Brussels, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1325**of 10 August 2021****amending Implementing Regulation (EU) 2020/977 as regards the period of application of the temporary measures in relation to controls on the production of organic products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 ⁽¹⁾, and in particular Article 28(6), Article 30(2), third subparagraph, and Article 38, points (c), (d) and (e), thereof,

Whereas:

- (1) The COVID-19 pandemic and the extensive movement restrictions put in place in the Member States and in third countries in the form of national measures constitute an exceptional and unprecedented challenge for Member States and operators in relation to performing controls as specified in Regulation (EC) No 834/2007 and Commission Regulations (EC) No 889/2008 ⁽²⁾ and (EC) No 1235/2008 ⁽³⁾.
- (2) In order to address the specific circumstances due to the ongoing crisis related to the COVID-19 pandemic, Commission Implementing Regulation (EU) 2020/977 ⁽⁴⁾ allows Member States to apply temporary measures that derogate from Regulations (EC) No 889/2008 and (EC) No 1235/2008 in relation to the control system on the production of organic products and certain procedures provided for in the Trade Control and Expert System (TRACES).
- (3) In addition, as regards official controls and other official activities within the scope of Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽⁵⁾, Commission Implementing Regulation (EU) 2020/466 ⁽⁶⁾ allows Member States to apply temporary measures to avoid serious health risks for the staff of the competent authorities, in view of the difficulties to perform those controls and activities and to the extent necessary to manage the related serious disruptions of the control systems of the Member States. The period of application of that Regulation was

⁽¹⁾ OJ L 189, 20.7.2007, p. 1.

⁽²⁾ Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1).

⁽³⁾ Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 334, 12.12.2008, p. 25).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/977 of 7 July 2020 derogating from Regulations (EC) No 889/2008 and (EC) No 1235/2008 as regards controls on the production of organic products due to the COVID-19 pandemic (OJ L 217, 8.7.2020, p. 1).

⁽⁵⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/466 of 30 March 2020 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States' control systems due to coronavirus disease (COVID-19) (OJ L 98, 31.3.2020, p. 30).

prolonged until 1 July 2021 by Commission Implementing Regulation (EU) 2021/83 ⁽⁷⁾. Commission Implementing Regulation (EU) 2021/772 ⁽⁸⁾ therefore prolonged the period of application of Implementing Regulation (EU) 2020/977 until 1 July 2021.

- (4) Member States have informed the Commission that, in view of the crisis linked to the COVID-19 pandemic, certain serious disruptions in the functioning of their control systems in the organic sector will persist beyond 1 July 2021.
- (5) Due to the persistence of the crisis and the related disruptions, the period of application of Implementing Regulation (EU) 2020/466 has been prolonged until 1 September 2021 by Commission Implementing Regulation (EU) 2021/984 ⁽⁹⁾.
- (6) However, the control system in the organic sector operates on the basis of a calendar year, in particular as regards inspections and sampling. Therefore, it is necessary to apply Implementing Regulation (EU) 2020/977 beyond 1 September 2021 and to extend its period of application until the end of 2021 in order to ensure the correct implementation of the controls.
- (7) Implementing Regulation (EU) 2020/977 should therefore be amended accordingly.
- (8) There is a need not to disrupt the application of the provisions of Implementing Regulation (EU) 2020/977 that is extended by this Regulation. It is therefore appropriate to provide for a retroactive application of this Regulation from 1 July 2021.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Organic Production,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2020/977 is amended as follows:

- (1) in Article 1(7), the date '1 July 2021' is replaced by '31 December 2021';
- (2) in Article 3, second, third, fourth and fifth paragraphs, the date '1 July 2021' is replaced by '31 December 2021'.

Article 2

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

It shall apply from 1 July 2021.

⁽⁷⁾ Commission Implementing Regulation (EU) 2021/83 of 27 January 2021 amending Implementing Regulation (EU) 2020/466 as regards the performance of official controls and other official activities by specifically authorised natural persons and the period of application of temporary measures (OJ L 29, 28.1.2021, p. 23).

⁽⁸⁾ Commission Implementing Regulation (EU) 2021/772 of 10 May 2021 amending Implementing Regulation (EU) 2020/977 as regards the temporary measures in relation to controls on the production of organic products, in particular the period of application (OJ L 165, 11.5.2021, p. 28).

⁽⁹⁾ Commission Implementing Regulation (EU) 2021/984 of 17 June 2021 amending Implementing Regulation (EU) 2020/466 as regards the period of application of temporary measures (OJ L 216, 18.6.2021, p. 202).

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

Done at Brussels, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1326**of 10 August 2021****authorising the placing on the market of *Schizochytrium* sp. (FCC-3204) oil 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 23 January 2019, the company Fermentalg ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 for an extension of use of the novel food *Schizochytrium* sp. oil. The applicant requested to extend the use of *Schizochytrium* sp. oil to infant formula and follow-on formula intended for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽³⁾. The strain of *Schizochytrium* sp. used by the applicant and concerned by that application is specified as strain FCC-3204.
- (4) On 15 April 2019, the applicant submitted another application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 requesting to change the conditions of use of the novel food *Schizochytrium* sp. oil. The applicant requested to increase the maximum level of *Schizochytrium* sp. oil in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾ for the adult population, excluding pregnant and lactating women. The strain of *Schizochytrium* sp. used by the applicant and concerned by that application is the same strain FCC-3204 as above.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 13 May 2019, requesting it to provide a scientific opinion by carrying out an assessment for an extension of the use of *Schizochytrium* sp. oil as a novel food in infant formula and follow-on formula.
- (6) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the Authority on 10 July 2019, requesting it to provide a scientific opinion by carrying out an assessment for the change of the conditions of use of *Schizochytrium* sp. oil as a novel food in food supplements.

⁽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⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

⁽⁴⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

- (7) On 24 November 2020, the Authority adopted its scientific opinions on the 'Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in infant and follow-on formula as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁵⁾ and 'Safety of oil from *Schizochytrium limacinum* (strain FCC-3204) for use in food supplements as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁶⁾. These opinions are in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (8) In these opinions, the Authority confirmed that the strain FCC-3204 belongs to the species *Schizochytrium limacinum*, which was attributed the qualified presumption of safety ('QPS') status and included in 2020 in the list of QPS-recommended biological agents intentionally added to food or feed ⁽⁷⁾.
- (9) The Authority concluded that *Schizochytrium* sp. oil produced from the strain FCC-3204, belonging to the species *Schizochytrium limacinum*, is safe under the proposed conditions of use in infant formula and in follow-on formula and at the maximum level of 1 g/day in food supplements.
- (10) With regard to the application concerning the food supplements, the Authority considered that the data provided by the applicant were not sufficient to conclude on the safety of the novel food at the proposed uses (3 g DHA/day in food supplements for adults, excluding pregnant and lactating women). However, the Authority in its 2012 scientific opinion on the 'Tolerable Upper Intake Level of eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and docosapentaenoic acid (DPA)' ⁽⁸⁾ concluded that supplemental intakes of DHA alone up to about 1 g/day do not raise safety concerns for the general population. In line with the conclusions made by the Authority, and taking into account the Member States views, the Commission is of the view that this authorisation should concern general population above 3 years of age.
- (11) A labelling requirement should be provided in order to properly inform the consumers that the food supplements containing *Schizochytrium* sp. (FCC-3204) oil should not be consumed by infants and children under 3 years of age.
- (12) Data submitted by the applicant did not allow for a conclusion on the safety of oil produced from other strains of the *Schizochytrium* microalgae genus. Therefore, the opinions of the Authority do not give sufficient grounds to establish that oil produced from other strains of *Schizochytrium* microalgae genus when used in infant formula and follow-on formula and with increased levels in food supplements fulfil the requirements of Article 12(1) of Regulation (EU) 2015/2283.
- (13) Following the Authority's opinions and taking into account that authorised *Schizochytrium* sp. oil for which an extension of use was requested is neither species-specific nor strain-specific, it is therefore necessary to authorise the placing on the market of oil from strain FCC-3204 of *Schizochytrium* sp. under the assessed conditions of use, and not an extension of use of oil from all strains of the *Schizochytrium* genus as requested by the applicant.
- (14) Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. *Schizochytrium* sp. (FCC-3204) oil 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.

⁽⁵⁾ EFSA Journal 2021;19(1):6344.

⁽⁶⁾ EFSA Journal 2021;19(1):6345.

⁽⁷⁾ EFSA BIOHAZ Panel, 2020. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 11: suitability of taxonomic units notified to EFSA until September 2019. EFSA Journal 2020;18(2):5965, 57 pp.

⁽⁸⁾ EFSA Journal 2012;10(7):2815.

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

Article 3

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, 10 August 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:

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	<i>Specified food category</i>	<i>Maximum levels of DHA</i>			
Schizochytrium sp. (FCC-3204) oil	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae <i>Schizochytrium</i> sp.". The labelling of food supplements containing <i>Schizochytrium</i> sp. (FCC-3204) oil shall bear a statement that they should not be consumed by infants and children under 3 years of age.'		
	Food supplements as defined in Directive 2002/46/EC for the general population above 3 years of age	1 g/day			

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

'Authorised Novel Food	Specifications
Schizochytrium sp. (FCC-3204) oil	Description/Definition: The novel food is an oil produced from the strain FCC-3204 of the microalgae <i>Schizochytrium</i> sp. Composition: Acid value: $\leq 0,5$ mg KOH/g Peroxide value (PV): $\leq 5,0$ meq/kg oil Moisture and volatiles: $\leq 0,05$ % Unsaponifiables: $\leq 4,5$ % Trans-fatty acids: $\leq 1,0$ % Docosahexaenoic acid (DHA): $\geq 32,0$ % p-anisidine value: ≤ 10

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1327**of 10 August 2021**

amending Annexes II, IX and XV to Implementing Regulation (EU) 2021/405 as regards the lists of third countries or regions thereof authorised for the entry into the Union of fresh meat of wild solipeds, fishery products from aquaculture, and insects, and correcting Annex XI to that Implementing Regulation as regards the list of third countries and regions thereof authorised for the entry into the Union of frogs' legs and snails

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 127(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2019/625 ⁽²⁾ supplements Regulation (EU) 2017/625 as regards the requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption from third countries or regions thereof, in order to ensure that they comply with the applicable requirements established in the rules on food safety referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent. Those requirements include the identification of the animals and goods intended for human consumption which may only enter the Union from third countries or regions listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625.
- (2) A third country or region thereof can only be included in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625 if it complies with the requirements laid down in Article 127 of Regulation (EU) 2017/625, and with those laid down in Article 4(a) to (f) of Delegated Regulation (EU) 2019/625. The requirement laid down in Article 4(f) of Delegated Regulation (EU) 2019/625 is the existence, implementation and communication of a residues control programme approved by the Commission, when applicable, in accordance with Council Directive 96/23/EC ⁽³⁾.
- (3) Commission Implementing Regulation (EU) 2021/405 ⁽⁴⁾ lays down the lists of third countries and regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625, while Commission Decision 2011/163/EU ⁽⁵⁾ approves the residue monitoring plans submitted by certain third countries concerning specific animals and animal products listed in the Annex to that Decision.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

⁽³⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽⁴⁾ Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

⁽⁵⁾ Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

- (4) Commission Implementing Decision (EU) 2021/653 ⁽⁹⁾ amended Decision 2011/163/EU and approved the residue monitoring plans of certain third countries, which comply with the requirement laid down in Article 4(f) of Delegated Regulation (EU) 2019/625. Some of these third countries had already submitted appropriate evidence and guarantees that the animals and goods concerned comply with the requirements laid down in Article 4(a) to (e) of Delegated Regulation (EU) 2019/625. These countries should be accordingly included in the lists laid down in Implementing Regulation (EU) 2021/405.
- (5) Implementing Decision (EU) 2021/653 removed or restricted the approval of the residue monitoring plans of certain third countries, which are currently included in the lists laid down in Implementing Regulation (EU) 2021/405. The lists laid down in Implementing Regulation (EU) 2021/405 should be amended accordingly so as to remove or restrict the authorisation of these countries.
- (6) Implementing Decision (EU) 2021/653 approved the residue monitoring plan of Namibia for wild game. Since Namibia provided sufficient evidence and guarantees that it fulfils the requirements of Union legislation for the entry into the Union of consignments of fresh meat, excluding offal and minced meat, and of meat preparations of wild solipeds, this country should be added to the list of third countries authorised for the entry into the Union of meat of wild solipeds laid down in Annex II to Implementing Regulation (EU) 2021/405, with the remark 'only wild game'.
- (7) Implementing Decision (EU) 2021/653 approved the residue monitoring plan of Nigeria for aquaculture with the remark 'excluding finfish'. Since Nigeria has provided sufficient evidence and guarantees that it fulfils the requirements of Union legislation for the entry into the Union of consignments of fishery products from aquaculture, the entry of Nigeria in the list laid down in Annex IX to Implementing Regulation (EU) 2021/405 should be amended so as to authorise the country for entry into the Union of consignments of fishery products from aquaculture with the exception of finfish.
- (8) Implementing Decision (EU) 2021/653 approved the residue monitoring plan of Oman for aquaculture with the remark 'excluding crustaceans'. Since Oman has provided sufficient evidence and guarantees that it fulfils the requirements of Union legislation for the entry into the Union of consignments of fishery products from aquaculture, the entry of Oman in the list laid down in Annex IX to Implementing Regulation (EU) 2021/405 should be amended so as to authorise the country for the entry into the Union of consignments of fishery products from aquaculture with the exception of crustaceans.
- (9) Implementing Decision (EU) 2021/653 added the remark 'excluding crustaceans' to the approval of the residue monitoring plans for aquaculture of the Falklands Islands, Montenegro, Morocco and Ukraine. Therefore, these countries should not be authorised for the entry into the Union of crustaceans from aquaculture. Annex IX to Implementing Regulation (EU) 2021/405 should therefore be amended accordingly.
- (10) Implementing Decision (EU) 2021/653 added the remark 'excluding finfish' to the approval of the residue monitoring plans for aquaculture of Guatemala, Mozambique, Nicaragua, and Tanzania. Therefore, these countries should not be authorised for the entry into the Union of finfish from aquaculture. Annex IX to Implementing Regulation (EU) 2021/405 should therefore be amended accordingly.
- (11) Implementing Decision (EU) 2021/653 amended the footnotes applying to aquaculture products. 'Only crustaceans' and 'only finfish' were replaced by 'excluding finfish' and 'excluding crustaceans', respectively. For consistency reasons, it is necessary to align the wording of the remarks in Annex IX to Implementing Regulation (EU) 2021/405 to that in Implementing Decision (EU) 2021/653.
- (12) On 12 March 2021, the competent authority of the United Kingdom submitted to the Commission the relevant questionnaire for the evaluation of the entry of insects intended for human consumption into the Union. The competent authority of the United Kingdom responded satisfactorily to all questions, and therefore provided sufficient evidence and guarantees to the Commission that requirements equivalent to Article 126(1) of Regulation (EU) 2017/625 were complied with. The United Kingdom should therefore be included in the list of third countries

⁽⁹⁾ Commission Implementing Decision (EU) 2021/653 of 20 April 2021 amending Decision 2011/163/EU on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 138, 22.4.2021, p. 1).

authorised for the entry into the Union of consignments of insects laid down in Annex XV to Implementing Regulation (EU) 2021/405, without prejudice to the application of Union law to and in the United Kingdom in respect of Northern Ireland in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community in conjunction with Annex 2 to that Protocol.

- (13) Annexes II, IX and XV to Implementing Regulation (EU) 2021/405 should therefore be amended accordingly.
- (14) Annex XI to Implementing Regulation (EU) 2021/405 contains errors concerning Armenia and Azerbaijan in terms of omission and product authorisation. Those errors alter the meaning of the text.
- (15) Annex XI to Implementing Regulation (EU) 2021/405 should therefore be corrected 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,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, IX, XI and XV to Implementing Regulation (EU) 2021/405 are replaced by the text set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

ANNEX II

List of third countries authorised for the entry into the Union of consignments of fresh meat, excluding offal and minced meat, and of meat preparations of wild solipeds, as referred to in Article 5 and Article 19(2)

COUNTRY ISO CODE	THIRD COUNTRY	REMARKS
NA	Namibia	Only wild game
ZA	South Africa	Only wild game

ANNEX IX

List of third countries or regions thereof authorised for the entry into the Union of consignments of certain fishery products, as referred to in Article 13, Articles 18(3), 19(4), and 20(3), and Articles 22(b) and 25(d)

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	REMARKS
AE	United Arab Emirates	Aquaculture: Only raw material either from Member States or from other third countries approved for imports of such raw material into the Union
AG	Antigua and Barbuda	Only live lobsters from wild catch
AL	Albania	Excluding crustaceans from aquaculture
AM	Armenia	Only live wild crayfish, heat processed non-farmed crayfish and frozen non-farmed crayfish
AO	Angola	Only wild catch
AR	Argentina	
AU	Australia	
AZ	Azerbaijan	Only caviar from wild catch
BA	Bosnia and Herzegovina	Excluding crustaceans from aquaculture
BD	Bangladesh	
BJ	Benin	Only wild catch
BN	Brunei	Only aquaculture products
BQ	Bonaire, Sint Eustatius, Saba	Only wild catch
BR	Brazil	
BS	Bahamas	Only wild catch
BY	Belarus	
BZ	Belize	Only wild catch
CA	Canada	
CG	Congo	Only wild catch. Only fishery products caught, frozen and packed in their final packaging at sea

CH	Switzerland ⁽¹⁾	
CI	Cote d'Ivoire	Only wild catch
CL	Chile	
CN	China	
CO	Colombia	
CR	Costa Rica	
CU	Cuba	
CV	Cape Verde	Only wild catch
CW	Curaçao	Only wild catch
DZ	Algeria	Only wild catch
EC	Ecuador	
EG	Egypt	Only wild catch
ER	Eritrea	Only wild catch
FJ	Fiji	Only wild catch
FK	Falkland Islands	Excluding crustaceans from aquaculture
GA	Gabon	Only wild catch
GB	United Kingdom ⁽²⁾	
GD	Grenada	Only wild catch
GE	Georgia	Only wild catch
GG	Guernsey	Only wild catch
GH	Ghana	Only wild catch
GL	Greenland	Only wild catch
GM	Gambia	Only wild catch
GN	Guinea	Only wild catch. Only fish that has not undergone any preparation or processing operation other than heading, gutting, chilling or freezing.
GT	Guatemala	Excluding finfish from aquaculture
GY	Guyana	Only wild catch
HK	Hong Kong	Only wild catch
HN	Honduras	
ID	Indonesia	
IL	Israel ⁽³⁾	
IM	Isle of Man	
IN	India	
IR	Iran	Excluding finfish from aquaculture
JE	Jersey	Only wild catch
JM	Jamaica	Only wild catch

JP	Japan	
KE	Kenya	
KI	Kiribati	Only wild catch
KR	South Korea	
KZ	Kazakhstan	Only wild catch
LK	Sri Lanka	
MA	Morocco	Excluding crustaceans from aquaculture
MD	Moldova	Only caviar
ME	Montenegro	Excluding crustaceans from aquaculture
MG	Madagascar	
MK	North Macedonia	
MM	Myanmar/Burma	
MR	Mauritania	Only wild catch
MU	Mauritius	
MV	Maldives	Only wild catch
MX	Mexico	
MY	Malaysia	
MZ	Mozambique	Excluding finfish from aquaculture
NA	Namibia	Only wild catch
NC	New Caledonia	Excluding finfish from aquaculture
NG	Nigeria	Excluding finfish from aquaculture
NI	Nicaragua	Excluding finfish from aquaculture
NZ	New Zealand	
OM	Oman	Excluding crustaceans from aquaculture
PA	Panama	
PE	Peru	
PF	French Polynesia	Only wild catch
PG	Papua New Guinea	Only wild catch
PH	Philippines	
PM	Saint Pierre and Miquelon	Only wild catch
PK	Pakistan	Only wild catch
RS	Serbia	
RU	Russia	Only wild catch
SA	Saudi Arabia	
SB	Solomon Islands	Only wild catch
SC	Seychelles	Only wild catch
SG	Singapore	

SH	Saint Helena (Not including the islands of Tristan da Cunha and Ascension)	Only wild catch
	Tristan da Cunha (Not including the islands of Saint Helena and Ascension)	Only lobsters (fresh or frozen) from wild catch
SN	Senegal	Only wild catch
SR	Suriname	Only wild catch
SV	El Salvador	Only wild catch
SX	Sint Maarten	Only wild catch
TH	Thailand	
TN	Tunisia	Excluding crustaceans from aquaculture
TR	Turkey	
TW	Taiwan	
TZ	Tanzania	Excluding finfish from aquaculture
UA	Ukraine	Excluding crustaceans from aquaculture
UG	Uganda	
US	United States	
UY	Uruguay	
VE	Venezuela	
VN	Vietnam	
YE	Yemen	Only wild catch
ZA	South Africa	Only wild catch
ZW	Zimbabwe	Only wild catch

(¹) In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

(²) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.

(³) Hereinafter understood as the State of Israel, excluding the territories under Israeli administration since June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.

ANNEX XI

List of third countries or regions thereof authorised for the entry into the Union of consignments of frogs' legs and of snails, as referred to in Article 17

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	REMARKS
AL	Albania	
AM	Armenia	Only snails
AU	Australia	

AZ	Azerbaijan	
BA	Bosnia and Herzegovina	Only snails
BR	Brazil	Only frogs' legs
BY	Belarus	Only snails
CA	Canada	Only snails
CH	Switzerland ⁽¹⁾	
CI	Côte d'Ivoire	Only snails
CL	Chile	Only snails
CN	China	
DZ	Algeria	Only snails
EG	Egypt	Only frogs' legs
GB	United Kingdom ⁽²⁾	
GG	Guernsey	
GH	Ghana	Only snails
ID	Indonesia	
IM	Isle of Man	
IN	India	Only frogs' legs
JE	Jersey	
MA	Morocco	Only snails
MD	Moldova	Only snails
MK	North Macedonia	Only snails
NG	Nigeria	Only snails
NZ	New Zealand	Only snails
PE	Peru	Only snails
RS	Serbia	Only snails
TH	Thailand	Only snails
TN	Tunisia	Only snails
TR	Turkey	
UA	Ukraine	Only snails
US	United States	Only snails
VN	Vietnam	
ZA	South Africa	Only snails

⁽¹⁾ In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (OJ L 114, 30.4.2002, p. 132).

⁽²⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.

ANNEX XV

List of third countries authorised for the entry into the Union of consignments of insects as referred to in Article 24

COUNTRY ISO CODE	THIRD COUNTRY OR REGIONS THEREOF	REMARKS
CA	Canada	
CH	Switzerland	
GB	United Kingdom ⁽¹⁾	
KR	South Korea	
TH	Thailand	
VN	Vietnam'	

(¹) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1328**of 10 August 2021****specifying the infrastructure requirements applicable to certain categories of dual-use infrastructure actions pursuant to Regulation (EU) 2021/1153 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/1153 of the European Parliament and of the Council of 7 July 2021 establishing the Connecting Europe Facility and repealing Regulations (EU) No 1316/2013 and (EU) No 283/2014 ⁽¹⁾ and in particular Article 12(2) thereof,

Whereas:

- (1) One of the specific objectives of the Connecting Europe Facility is to adapt parts of the trans-European transport network for a dual-use of the transport infrastructure in view of improving both civilian and military mobility. Actions or specific activities within an action, supporting parts, new or existing of the trans-European transport network suitable for military transport, in order to adapt it to dual-use transport infrastructure requirements, are eligible to receive Union financial assistance under Regulation (EU) 2021/1153 under certain conditions.
- (2) The transport infrastructure requirements applicable to certain categories of dual-use infrastructure actions should be specified. The dual-use transport infrastructure requirements should be based on the information contained in the updated military requirements ⁽²⁾ and the gap analysis ⁽³⁾, and the results of consultations with the representatives of European and international transport associations should be taken into account.
- (3) The dual-use requirements should represent generic technical values and standards for transport infrastructure projects, to be taken into account with regard to the actions under Regulation (EU) 2021/1153, contributing to the adaptation of the TEN-T core or comprehensive networks with the purpose of enabling a civilian-defence dual use of the infrastructure.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Connecting Europe Facility Coordination Committee, established by Regulation (EU) 2021/1153,

HAS ADOPTED THIS REGULATION:

Article 1

The transport infrastructure requirements provided for in Article 12(2) of Regulation (EU) 2021/1153 shall be as set out in the Annex.

Article 2

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

⁽¹⁾ OJ L 249, 14.7.2021, p. 38.

⁽²⁾ Military Requirements for Military Mobility within and beyond the EU (ST 11373/19; 19.7.2019)

⁽³⁾ 'Military requirements and trans-European transport network: gap analysis (SWD(2019) 175 final)' as well as 'the updated gap analysis between military requirements and trans-European transport network requirements' (SWD(2020) 144 final).

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

Done at Brussels, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Table 1

Airports and air traffic management

No	Dual-use requirement	Dual-use value	Remark
1	Operating Periods	Construction or expansion of infrastructure and connections to multimodal transport and equipment allowing capability for 24/7 operations/Day/Night/All Weather operations.	Includes rail and pipeline connections for fuel (conditional to fuel for both military and civilian aircraft to be delivered).
2	Base Service Operations 24/7	Capability for Day/Night/All Weather operations.	
3	Air Traffic Control	Air Traffic Control infrastructure with sufficient capacity to manage airfield day and night operations.	To be understood according to ICAO and EU Regulations as well as Eurocontrol CUMA Guidelines.
4	Air Assets per day	Infrastructure capacity of handling: Aircraft per day: Minimum 6 per day. Assumption for Wide-Body Aircraft: 4 concurrent maximum on ground parking on the apron.	
5	Runway Length	Minimum Requirement: 3 000 m. Recommended: 3 500 m. To be determined in each Member State where a 2 800 m runway length could be sufficient.	Suitable for Aircraft Category Strategic Transportation as well as A330/A400M/IL76/B747/An225/C5/C17 aircraft.
6	Runway Width	45 m up to 60 m. To be determined by Member States where the 60 m width is necessary.	Suitable for Aircraft Category Strategic Transportation as well as A330/A400M/IL76/B747/An225/C5/C17 aircraft.
7	Runway Surface	May be rigid or flexible type. To be determined in each Member State where the 150m at the end of the runway should be rigid to combat the effects of jet engine efflux.	
8	Taxiway	Width: 22,5 m, may be rigid or flexible type.	
9	Runway Pavement Strength	Sufficient for Strategic Wide Body Aircraft	This requirement can be delivered in accordance with ICAO and EU regulations.
10	Apron – Length	Minimum of 190 m.	
11	Apron Width	Minimum of 350 m.	

12	Apron Capacity	66 500 m ² .	
13	Apron Pavement Classification Number (PCN) ⁽¹⁾	Driven by Aircraft Classification Number (ACN) ⁽²⁾ deriving from the subgrade type.	The ACR is a single unit rating expressing the related effect of an aircraft on a basement for a specific subgrade strength indicating a particular basement thickness (measured by its PCR). This requirement can be delivered in accordance with ICAO and EU regulations. The relation between ACR/PCR is an updated methodology of the Aircraft Classification Number (ACN) and Pavement Classification Number (PCN) methodology. As of November 2024, the methodology for the assessment and reporting of airfield pavement bearing capacity will be expressed as a relation between the Aircraft Classification Rating and Pavement Classification Rating (ACR/PCR), instead of the relation between the Aircraft Classification Number and Pavement Classification Number (ACN/PCN). The method has been approved by the ICAO Airport Design & Operations Panel (ADOP) and is since July 2020 the new ICAO Pavement Rating System. Adaptations of national documentations and design specificities will take place during a transition period between 2020 and 2024.
14	Runway Snow and Ice Equipment and De-Icing products	Storage enclosed area of 180 m ² .	
15	Crash Fire Rescue (Category)	Steel Frame or Masonry construction facility with storage (minimum 200 m ² with internal bay space of 98 m ²) to store both crash and fire rescue vehicles.	

⁽¹⁾ The Pavement Classification Rating (PCR) has replaced the Pavement Classification Number (PCN) methodology. PCN remains valid during the transition phase until 2024.

⁽²⁾ The Aircraft Classification Rating (ACR) has replaced the Aircraft Classification Number (ACN) methodology. ACN remains valid during the transition phase until 2024.

Table 2

Seaports

No	Dual-use requirement	Dual-use value	Remark
1	Sea port operating period	Construction or expansion of infrastructure to multimodal transport network access, and equipment that allows operations 24/7 in all-weather conditions.	Includes icebreaking capacity and equipment to remove snow in a port. Buildings, storage and warehouse facilities, cranes, conveyors, and other devices for moving freight, and mobile assets such as locomotives shall not be included. Actions shall not provide selective advantage to a particular operator or group of operators and shall be accessible on a non-discriminatory basis.
2	Number of Berths	3.	The berths have to be within a port as defined in the geographic data of the military requirements. The berths do not necessarily have to be situated next to each other.
3	Beam	32 m.	Entrance to seaport.
4	Vessel acceptance draught	Minimum 12 m at mean low water.	Entrance to seaport.
5	Port depth	Minimum 12 m, recommended 14 m to allow 2 m draught clearance. To be determined in each Member State where a 12 m port depth could be sufficient. 1 m draught clearance could be sufficient in ports without tide effect.	Entrance to seaport.
6	Berth length	Minimum 310 m and up to 340 m per vessel.	
7	Port berth beam	Minimum 32 m	For large/medium ships category at berth.
8	Port berth type	Should accommodate the following types of ships: Barge, break-bulk, container, passengers, RoRo, tanker.	
9	Berth draught	Minimum 12 m, recommended 14 m. To be determined in each Member State where a 12 m berth draught depth would be sufficient.	Needed for large ships category and very large RoRo.
10	Offloading capabilities	2 ships simultaneously.	
11	Number of rail spurs/heads	3.	Number of railheads needed.

Table 3

Railways

No	Dual-use requirement	Dual-use value	Remark
1	Railhead service operating period	Construction or expansion of infrastructure to multimodal transport network access, and equipment that allows operations 24/7 in all-weather conditions.	
2	Railway passengers assets	Infrastructure capable of handling railway passenger's carriage cars (capable of moving passengers), including double-deckers, for loading minimum 80 PAX on each; minimum number of carriages per day: 6 pieces.	
3	Railway stations	Platform infrastructure capable of managing 3-4 trains (10 x double-decker carriages or equivalent) per station per day (5k PAX per day per station).	
4	Railhead operations	Infrastructure capable of handling at least 3 freight trains simultaneously in terminal locations.	Equipment traveling by rail will be subjected to careful load and journey planning to ensure compliance with available MS rail gauge, infrastructure, routes and tunnels.
5	Electrification system availability	Permanent with back-up system regardless of the energy source.	Concerns back-up systems for stations or multimodal handling facilities.
6	Bi-polarization	Yes for access.	Pertains to safety systems and track circuits to detect trains on the tracks, and if the railhead allows one or more tracks on a multiple track railway to be operated in either direction, whether for regular or emergency use.
7	Lighting availability	24/7 lighting capability in stations and terminals.	
8	Track gauge	1 435 mm. Ideal for standard continuous rail network pan-Europe and highly desirable for military mobility. In instances where there is a clear benefit for both the civilian and military sectors, 1 520 /1 524 mm and 1 668 mm railway gauges can be accepted.	
9	Loading gauge	GC standard recommended. To be determined in each Member State where a different loading gauge enveloping P-400 and that is in line with the rail TSIs would be sufficient.	Large container loading gauge. GC fits the UIC P-400 standard.

10	Max cargo height	4,5 m.	The figure includes the safety margin.
11	Max cargo width	3,15 m in normal circumstances. Up to 3,75 m in exceptional cases, where there is a clear civilian benefit and the TSIs are respected.	Desirable width would be up to 4,5 m for military movement.
12	Max cargo length	18,75 m.	
13	Rail axle load in tonnes	Minimum 22.5 t/axle on the core TEN-T; recommended 25 t/axle.	The axle load requirement for the TEN-T core rail network including bridges is minimum 22,5 t/axle. Of note, upgrades of axle weight to minimum 25 t/axle could be beneficial for civilian and military movements. Currently military movement is at the limit of existing gross weight.
14	Max train length	Minimum 740 m.	Regulation (EU) No 1315/2013 of the European Parliament and of the Council ⁽¹⁾ requires the capacity to operate at least 740 m long trains. The length of a moving train varies (e.g. when breaking or accelerating). The dual-use requirement is therefore congruent with the military requirement.
15	Siding spurs	Minimum 3, each minimum ≥ 300 m.	Can either be in the vicinity of or within terminal locations.

⁽¹⁾ Regulation (EU) No 1315/2013 of the European Parliament and of the Council of 11 December 2013 on Union guidelines for the development of the trans-European transport network and repealing Decision No 661/2010/EU (OJ L 348, 20.12.2013, p. 1).

Table 4

Roads

No	Dual-use requirement	Dual-use value	Remark
1	Road classification	Single lane: 3,5 m – 5,5 m Single flow 5,5 m – 7,3 m Double flow $\geq 7,3$ m.	Single flow – isolated vehicles pass or travel in the opposite direction at set points/areas. Double flow – 2 columns of vehicles travel concurrently and at least 2 lanes wide (ideally no narrower than 8,2 m). Projects related to using hard shoulders as additional lanes are excluded.
2	Route types	Type X – all-weather well maintained route, usable all year to maximum capacity.	Type X is preferred for military movement, with waterproof surfaces generally unaffected by precipitation or temperature changes.

3	Road gross weights	130 t.	130 t does not refer to the free circulation of vehicles with a gross weight of 130 t. This dual-use requirement refers to the capacity of road surfaces to withstand movements or transport of the overweight military assets on an occasional basis. The civilian limitation 44 t (as indicated in Council Directive 96/53/EC ⁽¹⁾) should therefore allow for occasional movements of overweight transport assets of up to 130 t with a maximum axle load of 12,23 t/axle. Such occasional movements (both military and civilian) do most likely require special permits or waivers and appropriate mitigation measures, which are exceptionally determined by the MS.
4	Bridge gross weights	130 t.	130 t does not refer to the free circulation of vehicles with a gross weight of 130 t. This dual-use requirement refers to bridges' capacity to withstand movements or transport of the overweight military assets on an occasional basis. Such occasional movements (both military and civilian) do most likely require special permits or waivers and appropriate mitigation measures, which are exceptionally determined by the Member States. Bridges shall be capable of allowing a gross weight of 130 t with a maximum axle load of 12,23 t/axle (Directive 96/53/EC allows up to 11,5 t/axle with the exception of France, where the allowed load is 13 t/axle). In circumstances where a single vehicle weighs 130 t, it will be necessary to ensure that appropriate mitigation measures such as speed, distance to other vehicles have been applied and, if necessary, single traffic flow are imposed for bridge use. Road bridges are designed to withstand fully loaded vehicles across their entire length on each lane. Therefore, if a bridge can support multiple trucks weighing 44 t simultaneously, it should also be able to support an occasional total gross weight of 130 t, if the appropriate mitigation measures such as speed, distance between vehicles and distance between the vehicles' axles are ensured.

5	Maximum cargo height	4.5 m. Tunnel restrictions need consideration in route planning particularly for flatbed vehicles, trailers and dangerous goods. To be determined in each country if and where 4.5 m shall be applicable.	This includes the combination of the height of the vehicle cargo-deck, plus the cargo height and an overhead safety clearance margin. Directive 96/53/EC allows up to 4 m vehicle height. Upon receiving an exceptional transport permit, 4.5 m height is possible (4.35 m transport height + 0.15 m for suspension and vehicle movements).
6	Maximum cargo width	4.5 m.	As indicated in Directive 96/53/EC, the maximum vehicle width of an authorized vehicle is 2,55 m. Typically, wheeled vehicles require 3.5 m and tracked vehicles 4.5 m for military transport. Such occasional movements (both military and civilian) do most likely require special permits or waivers and appropriate mitigation measures, which are exceptionally determined by the Member States.
7	Maximum cargo length	18,75 m up to 27,5 m	Maximum vehicle length is 18,75 m with an extension up to 25,03 m where infrastructure development allows. Longer vehicles may be allowed to circulate upon receiving an exceptional transport permit. Cargo weighing over 130 t will generally require an 8-tyre x 4-axle tractor + an 8-axle trailer combination. In most cases, a traditional 8-axle semi-trailer suffices for dual-use purposes. However, when for practical reasons (e.g. bridge clearance height) a low-bed trailer is required, this will necessarily be a 3-bed-5 semi-trailer, whose length is around 22,5 m. Coupled to an 8-tyre x 4-axle tractor unit, the total length of the combined vehicle will be around 27 m. The use of low-bed trailers brings benefits when it comes to extra bridges and flyover height clearances, as axle loads of a longer vehicle will be distributed on a larger area, thus reducing the point loadings on bridges and overpasses. Most Member States already accept 27,5 m vehicles as part of the exceptional transport permits they issue.
8	Turning radius for heavy equipment transport	12,5 m up to 15,5 m. To be determined in each Member State.	The requirement in Directive 96/53/EC is that road vehicles must be able to turn within an outer radius of 12,5 m.

(¹) Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorized dimensions in national and international traffic and the maximum authorized weights in international traffic (OJ L 235, 17.9.1996, p. 59).

Table 5

Inland waterways

No	Dual-use requirement	Dual-use value	Remark
1	Locks	In accordance with the UNECE 'Blue Book' Standards ⁽¹⁾	
2	Draught	In accordance with the UNECE 'Blue Book' Standards ⁽²⁾	
3	Berth	2	Number of berths.
4	Offloading Capabilities	2 barges simultaneously	
5	Bridge clearance	3,5 m	In line with Regulation (EU) No 1315/2013.

⁽¹⁾ Inventory of main standards and parameters of the E waterway network 'Blue Book' (ECE/TRANS/SC.3/144/Rev.3.), by the United Nations Economic Commission for Europe. The dual-use requirement should be read in conjunction with this document.

⁽²⁾ Ibid.

Table 6

Multimodal equipment handling (road, rail, maritime and inland waterways)

No	Dual-use requirement	Dual-use value	Remark
1	Node connection	Required at seaport/airport/inland waterway/railway head/main roads where applicable including cross-decking loading points across multi-modal transport means	
2	Loading ramps and handling equipment/ Parking capacity	Sufficient number of loading ramps (fixed) capable of supporting 100 t cargo and vehicles up to 120 t including Main Battle Tanks with a maximum axle load of 12,23 t/axle (road) and minimum 22,5 t/axle (rail). Handling equipment particular for cross-connection to multimodal nodes (rail, air, seaport (LoLo/RoRo) and inland waterways). Parking capacity capable for temporary hold rolling stock and general cargo. Actions relating to fixed infrastructure supporting the movement of road, rail, maritime and inland waterways assets in multimodal equipment handling facilities.	Suitable for freight containers meeting the definition of the ISO 1496-1:2013 Series 1 standard. Road ramps should have ability to handle containers, heavy equipment and general cargo. Buildings, storage and warehouse facilities, cranes, conveyors, and other devices for moving freight, and mobile assets such as locomotives are excluded. Actions shall not provide selective advantage to a particular operator or group of operators and shall be accessible on a non-discriminatory basis.

Table 7

Cybersecurity

No	Dual-use requirement	Dual-use value	Remark
1	Cybersecurity	Cybersecurity equipment, solutions and systems directly related to project proposals linked to the resilience of dual-use infrastructure, where it is appropriate.	

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1329**of 10 August 2021****amending Implementing Regulations (EU) 2020/2235, (EU) 2020/2236, (EU) 2021/403 and (EU) 2021/404 as regards extending the transitional period for the use of animal health certificates, animal health/official certificates and official certificates required for the entry into the Union of certain consignments****(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 Articles 213(2), 224(4), 230(1), 238(3) and 239(3) thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽²⁾, and in particular Article 90 and Article 126(3) thereof,

Whereas:

- (1) Commission Implementing Regulations (EU) 2020/2235 ⁽³⁾, (EU) 2020/2236 ⁽⁴⁾ and (EU) 2021/403 ⁽⁵⁾ lay down, inter alia, models of animal health certificates, animal health/official certificates and official certificates required to accompany consignments of animals and goods for the entry into the Union of those consignments. Those Implementing Regulations were adopted within the framework of Regulations (EU) 2016/429 and (EU) 2017/625. Regulation (EU) 2016/429 and those three Implementing Regulations apply from 21 April 2021.
- (2) Implementing Regulations (EU) 2020/2235, (EU) 2020/2236 and (EU) 2021/403 provide for a transitional period for the entry into the Union of consignments of animals and goods accompanied by the appropriate certificates required for the entry into the Union of those consignments, issued in accordance with the relevant model

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1.).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008 (OJ L 442, 30.12.2020, p. 410).

⁽⁵⁾ Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU (OJ L 113, 31.3.2021, p. 1).

certificates laid down in Union legislation in force before 21 April 2021, provided that they are duly signed before 21 August 2021. Those certificates are required to be read in accordance with the transitional provisions laid down in those Implementing Regulations, as regards any acts that have ceased to apply referred to in those certificates. That transitional period ends on 20 October 2021.

- (3) In addition, Commission Implementing Regulation (EU) 2021/404 ⁽⁶⁾ lays down, inter alia, rules concerning the model animal health certificates to be used for the entry into the Union of certain consignments of animals, germinal products and products of animal origin from third countries, territories or zones thereof. That Implementing Regulation provides for transitional provisions as regards the entry into the Union of consignments of animals, germinal products and products of animal origin from third countries, territories or zones thereof accompanied by the appropriate certificates issued in accordance with Union legislation in force before 21 April 2021, provided that the certificates are duly signed before 21 August 2021. Those certificates are required to be read in accordance with the transitional provisions laid down in that Implementing Regulation, as regards any acts that have ceased to apply referred to in those certificates. That transitional period also ends on 20 October 2021.
- (4) The transitional period currently provided for in Implementing Regulations (EU) 2020/2235, (EU) 2020/2236, (EU) 2021/403 and (EU) 2021/404, does not give sufficient time to put in place the necessary measures in third countries and territories for the issuance of new certificates in accordance with Union legislation applicable since 21 April 2021. Accordingly, the transitional period laid down in those Implementing Regulations should be extended to 15 March 2022 by which time the necessary measures should be in place and operational. That extension should assist the transition to the use of the new certificates provided for in those four Implementing Regulations and prevent any unnecessary disruption to trade concerning the entry into the Union of consignments falling within the scope of those Implementing Regulations.
- (5) It is therefore necessary to extend the transitional period laid down in Implementing Regulations (EU) 2020/2235, (EU) 2020/2236, (EU) 2021/403 and (EU) 2021/404 in order to provide sufficient time for the third countries and territories to put in place the necessary measures for the new certification requirements applicable since 21 April 2021, for a period until 15 March 2022, provided that the relevant certificate is signed before 15 January 2022 by the person authorised to sign it, in order to avoid any unnecessary disruptions in trade.
- (6) Implementing Regulations (EU) 2020/2235, (EU) 2020/2236, (EU) 2021/403 and (EU) 2021/404 should therefore be amended accordingly.
- (7) In the interest of legal certainty, the amendments to be made to Implementing Regulations (EU) 2020/2235, (EU) 2020/2236, (EU) 2021/403 and (EU) 2021/404 by this Regulation should take effect as a matter of urgency.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) 2020/2235

In Article 35 of Implementing Regulation (EU) 2020/2235, paragraph 1 is replaced by the following:

‘1. Consignments of products of animal origin, composite products, sprouts intended for human consumption and seeds intended for the production of sprouts for human consumption accompanied by the appropriate certificate issued in accordance with the models laid down in Regulation (EU) No 28/2012 and Implementing Regulation (EU) 2019/628 shall be accepted for entry into the Union until 15 March 2022 provided that the certificate was signed by the person authorised to sign the certificate in accordance with that Regulation and Implementing Regulation before 15 January 2022.’

⁽⁶⁾ Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).

*Article 2***Amendment to Implementing Regulation (EU) 2020/2236**

In Article 10 of Implementing Regulation (EU) 2020/2236, paragraph 1 is replaced by the following:

‘1. Consignments of aquatic animals and products of animal origin from aquatic animals accompanied by the appropriate animal health certificate issued in accordance with the model laid down in Regulation (EC) No 1251/2008 shall be accepted for entry into the Union until 15 March 2022 provided that the animal health certificate was signed by an official inspector before 15 January 2022.’

*Article 3***Amendment to Implementing Regulation (EU) 2021/403**

In Article 27 of Implementing Regulation (EU) 2021/403, paragraph 1 is replaced by the following:

‘1. Consignments of terrestrial animals and germinal products thereof accompanied by the appropriate certificate issued in accordance with the models laid down in Regulations (EC) No 798/2008 and (EU) No 206/2010, Implementing Regulations (EU) No 139/2013 and (EU) 2018/659, Decisions 2006/168/EC and 2010/472/EU, as well as in accordance with Implementing Decisions 2011/630/EU, 2012/137/EU and (EU) 2019/294, shall be accepted for entry into the Union until 15 March 2022 provided that the certificate was signed by the person authorised to sign the certificate in accordance with those Regulations, Implementing Regulations, Decisions and Implementing Decisions before 15 January 2022.’

*Article 4***Amendment to Implementing Regulation (EU) 2021/404**

In Article 6 of Implementing Regulation (EU) 2021/404, paragraph 1 is replaced by the following:

‘1. Consignments of animals, germinal products and products of animal origin from third countries, territories or parts thereof authorised for entry into the Union in accordance with the following acts and, accompanied by the appropriate certificate issued in accordance with those acts, shall be permitted for entry into the Union until 15 March 2022, provided that the certificate was signed by the person authorised to sign the certificate in accordance with those acts before 15 January 2022:

- Regulation (EC) No 798/2008,
- Regulation (EC) No 1251/2008,
- Regulation (EU) No 206/2010,
- Regulation (EU) No 605/2010,
- Implementing Regulation (EU) No 139/2013,
- Implementing Regulation (EU) 2016/759,
- Implementing Regulation (EU) 2018/659,
- Decision 2006/168/EC,
- Decision 2007/777/EC,
- Decision 2008/636/EC,
- Decision 2010/472/EU,
- Decision 2011/630/EU,
- Implementing Decision 2012/137/EU,
- Implementing Decision (EU) 2019/294.’

*Article 5***Entry into force**

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, 10 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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