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Legislation

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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

([1]) Text with EEA relevance.

Corrigenda

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2023/…

of 21 June 2023

correcting certain language versions of Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC ([1]), and in particular Article 48 thereof,

Whereas:

(1) The Danish, Hungarian, Italian, Lithuanian and Polish language versions of Annex I to Regulation (EC) No 1221/2009 contain an error in point 2, first paragraph as regards the obligation to determine the relevant needs and expectations of the interested parties that changes the substance of the provision. The Polish language version of that Annex contains also an error in point 4.2, third paragraph that narrows the scope of the obligation laid down in that provision. Both errors were introduced by Commission Regulation (EU) 2017/1505 ([2]).

(2) The Danish, Hungarian, Italian, Lithuanian and Polish language versions of Annex I to Regulation (EC) No 1221/2009 should therefore be corrected accordingly. The other language versions are not affected.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 49 of Regulation (EC) No 1221/2009, delivered on 22 December 2016,

([1]) OJ L 342, 22.12.2009, p. 1.

([2]) Commission Regulation (EU) 2017/1505 of 28 August 2017 amending Annexes I, II and III to Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) (OJ L 222, 29.8.2017, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

(Does not concern the English language.)

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, 21 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1200

of 21 June 2023

granting a Union authorisation for the biocidal product family 'Airedale PAA product family' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 26 September 2017, Rigest Trading (Ireland) Limited submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for a Union authorisation of a biocidal product family named 'Airedale PAA product family' of product-types 2, 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under case number BC-EW057176-14 in the Register for Biocidal Products.

(2) 'Airedale PAA product family' contains peracetic acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2, 3 and 4.

(3) On 16 December 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.

(4) On 5 July 2022, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'Airedale PAA product family' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Airedale PAA product family' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(6) On 20 July 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Airedale PAA product family'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) ECHA opinion of 16 June 2022 on the Union authorisation of 'Airedale PAA product family' (ECHA/BPC/347/2022), https://echa.europa.eu/de/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0028970-0000 is hereby granted to Rigest Trading (Ireland) Limited for the making available on the market and use of the biocidal product family 'Airedale PAA product family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 12 July 2023 to 30 June 2033.

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, 21 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Airedale PAA product family

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

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0028970-0000

R4BP asset number: EU-0028970-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	Airedale PAA product family

1.2. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Rigest Trading (Ireland) Limited
	Address	Mullingar Heifer Beef, Nolagh, N91W896 Ballinalack Ireland
Authorisation number	EU-0028970-0000	
R4BP asset number	EU-0028970-0000	
Date of the authorisation	12 July 2023	
Expiry date of the authorisation	30 June 2033	

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

Name of manufacturer	Airedale Chemical Company Ltd
Address of manufacturer	Airedale Mills, Skipton Road, Cross Hills, BD20 7BX Keighley United Kingdom

Location of manufacturing sites	Airedale Mills, Skipton Road, Cross Hills, BD20 7BX Keighley United Kingdom

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

Active substance	Peracetic acid
Name of manufacturer	Airedale Chemical Company Ltd
Address of manufacturer	Airedale Mills, Skipton Road, Cross Hills, BD20 7BX Keighley United Kingdom
Location of manufacturing sites	Airedale Mills, Skipton Road, Cross Hills, BD20 7BX Keighley United Kingdom

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
Peracetic acid		Active Substance	79-21-0	201-186-8	1,74	15,9
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99	1,2
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	8,1	25,97
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	7,7	15,9

2.2. **Type(s) of formulation**

Formulation(s)	SL - Soluble concentrate

PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Peracetic Acid 2%

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **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)

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
Peracetic acid		Active Substance	79-21-0	201-186-8	1,74	2,36
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99	1,2
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	8,1	9,9
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	14,1	15,9

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

Formulation(s)	SL - Soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	May intensify fire; oxidiser May be corrosive to metals. Causes severe skin burns and eye damage. Harmful if swallowed. Toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Keep only in original packaging. Do not breathe vapours.

	Do not breathe spray. Wash exposed skin thoroughly after handling. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing. Rinse skin with water. IF ON SKIN (or hair):Take off immediately all contaminated clothing. Rinse skin with shower. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Wash contaminated clothing before reuse. Collect spillage. Store in a well-ventilated place.Keep container tightly closed. Dispose of contents to a licensed hazardous-waste collection point. Dispose of container to a licensed hazardous-waste collection point.

4. **AUTHORISED USE(S) OF THE META SPC 1**

4.1. **Use description**

Table 1

Use # 1 – Cleaning in Place (CIP) including pharmaceutical and cosmetic industry

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -

Field(s) of use	Indoor General (including pharmaceutical and cosmetic industry) Disinfection of hard, non-porous surfaces by CIP procedures (with circulation of the product solution in the production system)
Application method(s)	Method: CIP - Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment to be disinfected by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria and yeasts: 0,02% PAA (e.g. 1% product with 2% PAA, that is 10 ml product/litre) — Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 5% product with 2% PAA, that is 50 ml product/litre) — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of peracetic acid (PAA). Dilution (%): 2-7,5 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	High-density polyethylene (HDPE) bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with polypropylene (PP) bung: 200 litre HDPE intermediate bulk container (IBC) with HDPE screw cap: 1 000 litre

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

4.2. **Use description**

Table 2

Use # 2 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) including in pharmaceutical and cosmetic industries

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by spraying or pouring

Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product must be placed in and sprayed with trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogeneous distribution).
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 7,5 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.2.1. *Use-specific instructions for use*

See general directions for use

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

4.2.3. *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

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

See general directions for use

4.2.5. *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

4.3. **Use description**

Table 3

Use # 3 – Disinfection of inner surfaces (e.g. tanks, pipes, vessels, filling machines) by CIP in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of hard and non-porous surfaces by CIP procedures (with circulation).
Application method(s)	Method: Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment to be disinfected by manual or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. For all industries, final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.

Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria and yeasts: 0,02% PAA (e.g. 1% product with 2% PAA, that is 10 ml product/litre) — Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 5% product with 2% PAA, that is 50 ml product/litre) — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 1-7,5 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.3.1. *Use-specific instructions for use*

See general directions for use

4.3.2. *Use-specific risk mitigation measures*

See general directions for use

4.3.3. *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

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

See general directions for use

4.3.5. *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

4.4. **Use description**

Table 4

Use # 4 – Surface disinfection by spraying or by pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard and non-porous surfaces by spraying or pouring
Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogenous distribution). For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 7,5% product with 2% PAA, that is 75 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 7,5 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.4.1. *Use-specific instructions for use*

See general directions for use

4.4.2. *Use-specific risk mitigation measures*

See general directions for use

4.4.3. *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

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

See general directions for use

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

See section 5.5 for meta-SPC 1 in this document

4.5. **Use description**

Table 5

Use # 5 – Disinfection by dipping in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -

Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard and non-porous surfaces) by dipping
Application method(s)	Method: Dipping Detailed description: The equipment to be disinfected shall be placed in a dipping bath. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (7,5% product with 2% PAA, that is 75 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 7,5 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.5.1. *Use-specific instructions for use*

See general directions for use

4.5.2. *Use-specific risk mitigation measures*

See general directions for use

4.5.3. *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

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

See general directions for use

4.5.5. *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**

Disinfection cycle (for surface disinfection ONLY):

— the surfaces to be disinfected must be cleaned before the disinfection procedure, and the user must thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected;

— products must be diluted in potable water before use.

Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

Disinfection procedures by CIP:

— final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

Disinfection procedures by dipping:

— the solution shall not be re-used.

Use only once a day after production and replace it with a fresh solution daily.

Disinfection procedures by spraying:

— wet the surface completely

(application rate > 20 ml/m^2 but maximum 100 ml/m^2) in order to keep the surface wet during the required contact time.

— do not use equipment until product is completely absorbed to the surface or air dried.

5.2. **Risk mitigation measures**

— Wear chemical goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under European Standard EN 374 or equivalent. Goggles, protective clothing and glove material (preferably butyl rubber) to be specified by the authorisation holder within the product information. This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full titles of the EN standards and legislation.

— Use with adequate ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels shall be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10 air changes/hour is required in the rooms where the application takes place.

— When respiratory protection is required (that is when the concentration of PAA and/or hydrogen peroxide are above their respective Acute Exposure Concentration (AEC)inhalation (0,5 mg/m3 and 1,25 mg/m3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.

— Do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.

[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.

— Keep out of reach of children and non-target animals and pets.

— Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AEC inhalation (respectively 0,5 mg/m³ for PAA & 1,25 mg/m³ for hydrogen peroxide)

— No bystanders are allowed in treated area during the application phase.

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

— IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

— IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE

— IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

— IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.

— If symptoms: Call 112/ambulance for medical assistance.

— If no symptoms: Call a POISON CENTRE or a doctor.

— Information to healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

— This biocidal product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste in accordance with Directive 2008/98/EC of the European Parliament and of the Council. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.

— Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

— Store between 0°C and 30°C

— Store in dark conditions

— Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.

— Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.

— Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.

— Shelf-life: Meta-SPC 1 (2% PAA): 6 months

6. **OTHER INFORMATION**

With respect to the "Category (ies) of users" note:

Professionals (including industrial users) means trained professionals if this is required by national legislation.

Full titles of EN standards and legislation referred to in section 5.2:

EN 16321– Eye and face protection for occupational users – Part 1: general requirements.

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, (OJ L 312, 22.11.2008, p. 3).

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11.

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)	Peracetic Acid 2% Foamy		Market area: EU		
	PAA Foam 2,4%		Market area: EU		
	Primuzon PE foam		Market area: EU		
	FC 4001		Market area: EU		
	iMClean Pxs		Market area: EU		
	Sterilfoam		Market area: EU		
Authorisation number	EU-0028970-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	2,0
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	9,105
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	14,421

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

Trade name(s)	Peracetic Acid 2%		Market area: EU		
	Talogen 2		Market area: EU		
	iMClean Px		Market area: EU		
Authorisation number	EU-0028970-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	2,0
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	1,2
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	9,105
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	14,421

META SPC 2

1. **META SPC 2 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 2 identifier**

Identifier	Peracetic Acid 5%

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)

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
Peracetic acid		Active Substance	79-21-0	201-186-8	4,5	5,5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99	0,99
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	21,62	24,38
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	7,7	9,4

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

Formulation(s)	SL - Soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	Heating may cause a fire. May be corrosive to metals. Harmful if swallowed.Harmful in contact with skin.Harmful if inhaled. Causes severe skin burns and eye damage. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep only in original packaging. Do not breathe vapours. Do not breathe spray. Wash exposed skin thoroughly after handling. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Wash contaminated clothing before reuse. Collect spillage. Store in a well-ventilated place.Keep container tightly closed. Store at temperatures not exceeding 30 °C/86 °F. Dispose of contents to a licensed hazardous-waste collection point. Dispose of container to a licensed hazardous-waste collection point.

4. **AUTHORISED USE(S) OF THE META SPC 2**

4.1. **Use description**

Table 6

Use # 1 – CIP including in pharmaceutical and cosmetic industry

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by CIP procedures (with circulation)
Application method(s)	Method: CIP - Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria and yeasts 0,02% PAA (e.g. 0,4% product with 5% PAA, that is 4 ml product/litre) — Active against bacteria, yeasts and fungi : 0,1% PAA (e.g. 2% product with 5% PAA, that is 20 ml product/litre) — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 3% product with 5% PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 0,4-3 % Number and timing of application: 1-2 applications per day

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

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

4.2. **Use description**

Table 7

Use # 2 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) including in pharmaceutical and cosmetic industries

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by spraying or pouring

Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogenous distribution).
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 3% product with 5% PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 3 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.2.1. *Use-specific instructions for use*

See general directions for use

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

4.2.3. *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

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

See general directions for use

4.2.5. *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

4.3. **Use description**

Table 8

Use # 3 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) for veterinary hygiene

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor WITH prior cleaning By spraying: On hard and non-porous and porous surfaces By pouring: ONLY on hard/non-porous surfaces
Application method(s)	Method: Spraying or pouring (followed by wiping for homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for homogenous distribution). Cleaning of the surface prior to disinfection is mandatory. Do not use equipment and surfaces, or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.
Application rate(s) and frequency	Application Rate: at +10°C for 5 minutes contact time — Active against bacteria, yeasts and viruses: 0,2% PAA (e.g. 4% product with 5% PAA, that is 40 ml product/litre). The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 4 % Number and timing of application: Disinfection of animal housing takes place once animals have been moved out and the building has been cleaned and cleared of objects not to be disinfected, maximum 1-2 times per day.

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.3.1. *Use-specific instructions for use*

See general directions for use

4.3.2. *Use-specific risk mitigation measures*

See general directions for use

4.3.3. *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

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

See general directions for use

4.3.5. *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

4.4. **Use description**

Table 9

Use # 4 – Disinfection by dipping for veterinary hygiene

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor Disinfection of equipment (hard and non-porous and porous surfaces by dipping), WITH prior cleaning

Application method(s)	Method: Dipping Detailed description: The equipment to be disinfected must be placed in a dipping bath. Cleaning prior to use is mandatory.
Application rate(s) and frequency	Application Rate: at +10°C for 5 min contact time — Active against bacteria, yeasts and viruses: 0,2% PAA (e.g. 4% product with 5% PAA, that is 40 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 4 % Number and timing of application: 1-2 applications per day maximum
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.4.1. *Use-specific instructions for use*

See general directions for use

4.4.2. *Use-specific risk mitigation measures*

See general directions for use

4.4.3. *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

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

See general directions for use

4.4.5. *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

4.5. **Use description**

Table 10

Use # 5 – Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard and non-porous surfaces by CIP procedures (with circulation)
Application method(s)	Method: Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. For all industries, final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria and yeasts: 0,02% PAA (e.g. 0,4% product with 5% PAA, that is 4 ml product/litre) — Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 2% product with 5% PAA, that is 20 ml product/litre) — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 3% product with 5% PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 0,4-3 % Number and timing of application: 1-2 applications per day

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.5.1. *Use-specific instructions for use*

See general directions for use

4.5.2. *Use-specific risk mitigation measures*

See general directions for use

4.5.3. *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

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

See general directions for use

4.5.5. *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

4.6. **Use description**

Table 11

Use # 6 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of hard and non-porous surfaces by spraying or pouring

Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogenous distribution). For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 3% product with 5% PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 3 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.6.1. *Use-specific instructions for use*

See general directions for use

4.6.2. *Use-specific risk mitigation measures*

See general directions for use

4.6.3. *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

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

See general directions for use

4.6.5. *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

4.7. **Use description**

Table 12

Use # 7 – Disinfection by dipping in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood) Disinfection of equipment (hard and non-porous surfaces) by dipping
Application method(s)	Method: Dipping Detailed description: The equipment to be disinfected shall be placed in a dipping bath. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 3% product with 5% PAA, that is 30 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 3 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.7.1. *Use-specific instructions for use*

See general directions for use

4.7.2. *Use-specific risk mitigation measures*

See general directions for use

4.7.3. *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

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

See general directions for use

4.7.5. *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** [2] **OF THE META SPC 2**

5.1. **Instructions for use**

Disinfection cycle (for surface disinfection ONLY):

— the surfaces to be disinfected must be cleaned before the disinfection procedure, and the user must thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected;

— products must be diluted in potable water before use.

Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

Disinfection procedures by CIP:

— final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

Disinfection procedures by dipping:

— the solution shall not be re-used.

Use only once a day after production and replace it with a fresh solution daily.

Disinfection procedures by spraying:

— wet the surface completely

(application rate > 20 ml/m^2 but maximum 100ml/m^2) in order to keep the surface wet during the required contact time.

— do not use equipment until product is completely absorbed to the surface or air dried.

For PT3 uses:

— do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.

— the products shall not be used for the disinfection of animal transport vehicles.

5.2. **Risk mitigation measures**

— Wear chemical goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under European Standard EN 374 or equivalent. Goggles, protective clothing and glove material (preferably butyl rubber) to be specified

[2] 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.

by the authorisation holder within the product information. This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full titles of the EN standards and legislation.

— Use with adequate ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels shall be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10 air changes/hour is required in the rooms where the application takes place.

— When respiratory protection is required (that is when the concentration of PAA and/or hydrogen peroxide are above their respective Acute Exposure Concentration (AEC)inhalation (0,5 mg/m3 and 1,25 mg/m3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.

— Do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.

— Keep out of reach of children and non-target animals and pets.

— Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AEC inhalation (respectively 0,5 mg/m3 for PAA & 1,25 mg/m3 for hydrogen peroxide)

— No bystanders are allowed in treated area during the application phase.

— Animals shall be removed before treatment takes place.

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

— IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

— IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE

— IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

— IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.

— If symptoms: Call 112/ambulance for medical assistance.

— If no symptoms: Call a POISON CENTRE or a doctor.

— Information to healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

— This biocidal product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste in accordance with Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.

— Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

— Store between 0°C and 30°C

— Store in dark conditions

— Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.

— Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.

— Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.

— Shelf-life: Meta-SPC 2 (5% PAA): 6 months

6. **OTHER INFORMATION**

With respect to the "Category (ies) of users" note:

Professionals (including industrial users) means trained professionals, if this is required by national legislation.

Full titles of EN standards and legislation referred to in section 5.2:

EN 16321– Eye and face protection for occupational users – Part 1: general requirements.

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, (OJ L 312, 22.11.2008, p. 3).

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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)	Airocide PAAD	Market area: EU
	DOSAR HPPA	Market area: EU
	EXCEL-CLEANSE	Market area: EU
	Perafoam 5%	Market area: EU
	Tennacide 5 PAAD	Market area: EU
	Abbey PeraD	Market area: EU
	Peraguard Plus	Market area: EU
	Perapro	Market area: EU
Authorisation number	EU-0028970-0003 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	5,0
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	23,513
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	8,453

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

Trade name(s)	Peracetic Acid 5%	Market area: EU
	PERSAN S5	Market area: EU
	Perasan	Market area: EU
	Clusterflush	Market area: EU
	Cleanline Clusterflush	Market area: EU
	Pro-Dis CIP	Market area: EU
	Acidic Sanitiser	Market area: EU
	Virodox	Market area: EU
	Perosan 5	Market area: EU
	PERACLEANSE	Market area: EU
	Oxysan 5	Market area: EU
	Percid 5	Market area: EU
	Peraguard	Market area: EU
	QC 5% Peracetic Acid	Market area: EU
	Crystel QUARTZ	Market area: EU
	AGRI-PER 5%	Market area: EU
	Talogen 5	Market area: EU
	Tomahawk	Market area: EU
	ASL-Multikill 5	Market area: EU
	nu-Peracid 5	Market area: EU
	Thunderbird	Market area: EU
Authorisation number	EU-0028970-0004 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	5,0
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	23,513
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	8,453

META SPC 3

1. **META SPC 3 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 3 identifier**

Identifier	Peracetic Acid 15%

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (Disinfectants)

2. **META SPC 3 COMPOSITION**

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid		Active Substance	79-21-0	201-186-8	14,1	15,9
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99	0,99

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	23,0	25,97
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	14,1	15,9

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation(s)	SL - Soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3**

Hazard statements	Heating may cause a fire. May be corrosive to metals. Harmful if swallowed. Toxic in contact with skin. Toxic if inhaled. Causes severe skin burns and eye damage. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep only in original packaging. Do not breathe vapours. Do not breathe spray. Wash exposed skin thoroughly after handling. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower. 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. Take off immediately all contaminated clothing.And wash it before reuse. Immediately call a doctor. Immediately call a POISON CENTER. Collect spillage. Store in a well-ventilated place.Keep container tightly closed. Store at temperatures not exceeding 30 °C/86 °F. Dispose of contents to a licensed hazardous-waste collection point. Dispose of container to a licensed hazardous-waste collection point.

4. **AUTHORISED USE(S) OF THE META SPC 3**

4.1. **Use description**

Table 13

Use # 1 – CIP, including in pharmaceutical and cosmetic industry

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by CIP procedures (with circulation)
Application method(s)	Method: CIP - Manual or automated dosing Detailed description: The diluted product shall be transferred to equipment by manual dosing or automated dosing. Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces must be rinsed with water and the water must be drained into the sewer system.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria and yeasts: 0,02% PAA (e.g. 0,135% product with 15% PAA, that is 1,35 ml product/litre) — Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 0,675 % product with 15% PAA, that is 6,75 ml product/litre) — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 1% product with 15% PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 0,135-1 % Number and timing of application: 1-2 applications per day

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

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

4.2. **Use description**

Table 14

Use # 2 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution), including in pharmaceutical and cosmetic industries

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor General (including pharmaceutical and cosmetic industry) Disinfection of hard and non-porous surfaces by spraying or pouring

Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogenous distribution).
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 1% product with 15% PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 1 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.2.1. *Use-specific instructions for use*

See general directions for use

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

4.2.3. *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

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

See general directions for use

4.2.5. *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

4.3. **Use description**

Table 15

Use # 3 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) for veterinary hygiene

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor Disinfection of hard and non-porous and porous surfaces by spraying or pouring WITH prior cleaning
Application method(s)	Method: Spraying or pouring (followed by wiping for homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for homogenous distribution). Cleaning prior to use is mandatory.
Application rate(s) and frequency	Application Rate: at +10°C for 5 minutes contact time — Active against bacteria, yeasts and viruses: 0,2% PAA (e.g. approximately 1,33% product with 15% PAA, that is 13,3 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 1,33 % Number and timing of application: Disinfection of animal housing takes place once animals have been moved out and the building has been cleaned and cleared of objects not to be disinfected, maximum 1-2 times per day.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.3.1. *Use-specific instructions for use*

See general directions for use

4.3.2. *Use-specific risk mitigation measures*

See general directions for use

4.3.3. *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

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

See general directions for use

4.3.5. *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

4.4. **Use description**

Table 16

Use # 4 – Disinfection by dipping for veterinary hygiene

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor Disinfection of equipment (hard and non-porous and porous surfaces) by dipping, WITH prior cleaning
Application method(s)	Method: Dipping Detailed description: The equipment to be disinfected must be placed in a dipping bath. Cleaning prior to use is mandatory.
Application rate(s) and frequency	Application Rate: at +10°C in 5 minutes contact time: — Active against bacteria, yeasts and viruses: 0,2% PAA (e.g. approximately 1,33% product with 15% PAA, that is 13,3 ml product/litre)

	The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 1,33 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.4.1. *Use-specific instructions for use*

See general directions for use

4.4.2. *Use-specific risk mitigation measures*

See general directions for use

4.4.3. *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

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

See general directions for use

4.4.5. *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

4.5. **Use description**

Table 17

Use # 5 – Disinfection of inner surfaces (e.g. tanks, pipes, vessels, filling machines) by CIP in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -

Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of hard and non-porous surfaces by CIP procedures (with circulation).
Application method(s)	Method: CIP - Manual or automated dosing Detailed description: The diluted product must be transferred to equipment by manual dosing or automated dosing. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. For all industries, final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria and yeasts: 0,02% PAA (e.g. 0,135% product with 15% PAA, that is 1,35 ml product/litre) — Active against bacteria, yeasts and fungi: 0,1% PAA (e.g. 0,675 % product with 15% PAA, that is 6,75 ml product/litre) — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 1% product with 15% PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 0,135-1 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.5.1. *Use-specific instructions for use*

See general directions for use

4.5.2. *Use-specific risk mitigation measures*

See general directions for use

4.5.3. *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

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

See general directions for use

4.5.5. *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

4.6. **Use description**

Table 18

Use # 6 – Surface disinfection by spraying or pouring (followed by wiping for a homogenous distribution) in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -
Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of hard and non-porous surfaces by spraying or pouring.
Application method(s)	Method: Spraying or pouring (followed by wiping for a homogenous distribution) Detailed description: The diluted product shall be placed in and sprayed with a trigger spray bottle or poured onto the equipment or surface to be disinfected (followed by wiping for a homogenous distribution). For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 1% product with 15% PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA.

	Dilution (%): 1 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.6.1. *Use-specific instructions for use*

See general directions for use

4.6.2. *Use-specific risk mitigation measures*

See general directions for use

4.6.3. *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

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

See general directions for use

4.6.5. *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

4.7. **Use description**

Table 19

Use # 7 – Disinfection by dipping in food and feed industry

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: - Common name: Bacteria Development stage: - Scientific name: - Common name: Yeasts Development stage: - Scientific name: - Common name: Fungi Development stage: - Scientific name: - Common name: Viruses Development stage: -

Field(s) of use	Indoor In food/feed industry including dairies, breweries, beverage and soft drinks industry, food processing and meat industries (except in slaughterhouses and other processes with blood). Disinfection of equipment (hard and non-porous surfaces) by dipping.
Application method(s)	Method: Dipping Detailed description: The equipment to be disinfected must be placed in a dipping bath. For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory.
Application rate(s) and frequency	Application Rate: at room temperature, for 15 minutes contact time — Active against bacteria, yeasts, fungi and viruses: 0,15% PAA (e.g. 1% product with 15% PAA, that is 10 ml product/litre) The dilution instructions in brackets must be adapted when using a product with a different concentration of PAA. Dilution (%): 1 % Number and timing of application: 1-2 applications per day
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE bottle/pail with HDPE screw cap: 5 litre, 25 litre, 30 litre HDPE drum with PP bung: 200 litre HDPE IBC with HDPE screw cap: 1 000 litre

4.7.1. *Use-specific instructions for use*

See general directions for use

4.7.2. *Use-specific risk mitigation measures*

See general directions for use

4.7.3. *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

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

See general directions for use

4.7.5. *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** [3] **OF THE META SPC 3**

5.1. **Instructions for use**

Disinfection cycle (for surface disinfection ONLY):

— the surfaces to be disinfected must be cleaned before the disinfection procedure, and the user must thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected;

— products must be diluted in potable water before use.

Dilution rate and contact time depends on the use considered. Please refer to the description of application method related to each use.

Disinfection procedures by CIP:

— final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

Disinfection procedures by dipping:

— the solution shall not be re-used.

Use only once a day after production and replace it with a fresh solution daily.

Disinfection procedures by spraying:

— wet the surface completely (application rate > 20 ml/m^2 but maximum 100 ml/m^2) in order to keep the surface wet during the required contact time.

— do not use equipment until product is completely absorbed to the surface or air dried.

For PT3 uses:

— do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.

— the products shall not be used for the disinfection of animal transport vehicles.

5.2. **Risk mitigation measures**

— Wear chemical goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under European Standard EN 374 or equivalent. Goggles, protective clothing and glove material (preferably butyl rubber) to be specified by the authorisation holder within the product information. This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full titles of the EN standards and legislation.

— Use with adequate ventilation: Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels shall be maintained below the exposure guideline. For all wiping and spraying application, a ventilation rate of at least 10 air changes/hour is required in the rooms where the application takes place.

— When respiratory protection is required (that is when the concentration of PAA and/or hydrogen peroxide are above their respective Acute Exposure Concentration (AEC)inhalation (0,5 mg/m3 and 1,25 mg/m3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.

— Do not use equipment and surfaces or allow animals/poultry to enter the treated area until product is completely absorbed to the surface or air dried.

— Keep out of reach of children and non-target animals and pets.

— Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AEC inhalation (respectively 0,5 mg/m3 for PAA & 1,25 mg/m3 for hydrogen peroxide)

[3] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

— No bystanders are allowed in treated area during the application phase.

— Animals shall be removed before treatment takes place.

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

— IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

— IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. After washing the skin: Call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE

— IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

— IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance.

— Information to healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.

— If symptoms: Call 112/ambulance for medical assistance.

— If no symptoms: Call a POISON CENTRE or a doctor.

— Information to healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

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

— This biocidal product, when being disposed of in its unused and uncontaminated state, should be treated as a hazardous waste in accordance with Directive 2008/98/EC. Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste. Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment. High-temperature incineration is an acceptable practice.

— Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

— Store between 0°C and 30°C

— Store in dark conditions

— Keep in a well-ventilated place. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent, where fitted.

— Do not store in and avoid contact with aluminium, carbon steel, copper, mild steel, iron.

— Avoid contact with amines, ammonia, strong acids, strong bases, strong oxidizers.

— Shelf-life: Meta-SPC 3 (15% PAA): 12 months

6. **OTHER INFORMATION**

With respect to the "Category (ies) of users" note:

Professionals (including industrial users) means trained professionals, if this is required by national legislation.

Full titles of EN standards and legislation referred to in section 5.2:

EN 16321 – Eye and face protection for occupational users – Part 1: general requirements.

EN 374 – Protective gloves against dangerous chemicals and micro-organisms. Part 1: terminology and performance requirements for chemical risks.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, (OJ L 312, 22.11.2008, p. 3).

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

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

Trade name(s)	Peracetic Acid 15%		Market area: EU		
	PERSAN S15		Market area: EU		
	Kilco Peroxtif 15%		Market area: EU		
	Perosan 15		Market area: EU		
	Oxysan 15		Market area: EU		
	Percid 15		Market area: EU		
	AGRI-PER 15%		Market area: EU		
	Primuzon PE 15		Market area: EU		
	Talogen 15		Market area: EU		
	DSC Forte Des Oxy		Market area: EU		
	ASL-Multikill 15		Market area: EU		
	nu-Peracid 15		Market area: EU		
	DI 1011		Market area: EU		
	Sterilforte		Market area: EU		
Authorisation number	EU-0028970-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	15,0
HEDP	etidronic acid	Non-active substance	2809-21-4	220-552-8	0,99
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	25,109
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	15,07

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1201

of 21 June 2023

on detailed arrangements for the conduct of certain proceedings by the Commission pursuant to Regulation (EU) 2022/2065 of the European Parliament and of the Council ('Digital Services Act')

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act) ([1]), and, in particular, Article 83, first paragraph, points (a), (b) and (c) thereof,

After inviting all interested parties to submit their comments,

After consulting the Digital Services Committee,

Whereas:

(1) Regulation (EU) 2022/2065 empowers the Commission to adopt implementing acts concerning the practical arrangements in respect of certain aspects of proceedings under that Regulation. In compliance with the principle of good administration and the principle of legal certainty, it is necessary to lay down rules concerning the powers of the Commission to conduct inspections pursuant to Article 69 of Regulation (EU) 2022/2065 and to take the necessary monitoring actions pursuant to Article 72 of that Regulation. It is also necessary to lay down rules concerning the exercise of the right to be heard by the addressees of the Commission's preliminary findings and access to the Commission's file provided by Article 79 of Regulation (EU) 2022/2065.

(2) In the context of inspections, Article 69(2)(f) and (g) of Regulation (EU) 2022/2065 empowers Commission officials and other accompanying persons authorised by the Commission to conduct an inspection, to ask any representative or member of staff of the provider of very large online platform or of very large online search engine concerned or, where applicable, of the other persons concerned referred to in Article 67(1) of that Regulation for explanations on facts or documents relating to the subject-matter and purpose of the inspection and to record the answers. In the same context of inspections, Article 69(2)(g) of Regulation (EU) 2022/2065 empowers Commission officials and other accompanying persons authorised by the Commission to address questions to any such representative or member of staff relating to the subject-matter and purpose of the inspection and to record the answers. Pursuant to Article 74(2)(c) of Regulation (EU) 2022/2065 fines may be imposed on such providers or such persons where they fail to rectify within the time period set by the Commission an incorrect, incomplete or misleading answer given by a representative or member of their staff to questions in the course of an inspection. It is therefore necessary to provide such providers and such persons with a record of any explanations given and to establish a procedure enabling them to rectify, amend or supplement explanations given, including by a representative or member of staff who has given such explanations but was not authorised to do so. Explanations given by a representative or a member of staff should remain in the Commission's file as recorded during the inspection.

(3) Pursuant to Article 72 of Regulation (EU) 2022/2065, the Commission may take the necessary actions to monitor the effective implementation of and compliance with that Regulation. To this end, the Commission should be able to order providers of very large online platforms and of very large online search engines to provide access to and explanations of their databases and algorithms, where this is necessary to ensure effective compliance with Regulation (EU) 2022/2065. Access to such databases may consist of enabling the Commission to search such databases through the use of queries, as needed to monitor the effective implementation and compliance with Regulation (EU) 2022/2065. For the purposes of this regulation, the term database should be interpreted as referring to any relevant data assets available to the provider of very large online platform or of very large online search engine concerned, regardless of whether these are accessible in a single database. When ordering such access for purposes of monitoring, the Commission should also be able to specify technical interfaces that can facilitate

([1]) OJ L 277, 27.10.2022, p. 1.

access to databases and algorithms, such as Application Programmable Interfaces (APIs) or other means of technical access, including real time access and/or means of accessing high volumes of data. In this context, the Commission should also be able to require such providers to retain necessary documents, under the terms determined by the Commission. To ensure that the Commission possesses the necessary knowledge and expertise in carrying out its tasks under Regulation (EU) 2022/2065, the Commission should be able to appoint external experts and auditors to assist it in the exercise of its supervisory tasks. Such experts and auditors should be independent from the provider concerned and possess the necessary expertise and knowledge to assist the Commission. To this end, it is necessary to lay down requirements on the independence and expertise of such experts and auditors.

(4) Article 79(1) of Regulation (EU) 2022/2065 requires the Commission, before adopting a decision pursuant to Articles 73(1), 74 or 76 of that Regulation, to give a provider of very large online platform or of a very large online search engine or another person referred to in Article 67(1) of Regulation (EU) 2022/2065 to whom it has notified preliminary findings the opportunity of being heard on those findings and on measures that the Commission may intend to take in view of those findings. Such providers and such persons should present their views in writing, within a time period set by the Commission, with a view to reconciling the efficiency and effectiveness of the proceedings, on one hand, and the possibility to exercise the right to be heard, on the other. The addressee of the preliminary findings should have the right to set out succinctly the relevant facts and provide supporting evidence. In order to ensure fair and efficient proceedings, the effective and full enforcement of Regulation (EU) 2022/2065, and legal certainty for all persons concerned, it is necessary to set out rules as regards the format and maximum length of written observations and the use of languages.

(5) Article 79(4) of Regulation (EU) 2022/2065 requires the Commission to grant access to its file to the parties concerned by its proceedings. While the addressee of the preliminary findings should always obtain from the Commission the non-confidential versions of all documents mentioned in the preliminary findings, the Commission should be able to decide on a case-by-case basis on the appropriate procedure for access to further information in the file. When granting access to the file, the Commission should ensure the protection of business secrets and other confidential information. The Commission should be able to request persons that submit or have submitted information or documents in the course of proceedings to identify business secrets or other confidential information. The Commission should, before making this information available to the addressee of its preliminary findings, assess for each individual document whether, with view to an effective exercise of the right to be heard, the need to disclose is greater than the harm to the person who submitted the information or documents which might result from disclosure,

HAS ADOPTED THIS REGULATION:

CHAPTER I

SCOPE

Article 1

Subject matter and scope

This Regulation lays down rules concerning practical arrangements for:

(a) inspections conducted pursuant to Article 69 Regulation (EU) 2022/2065 and monitoring actions adopted pursuant to Article 72 of that Regulation;

(b) the exercise of the right to be heard and the terms of disclosure provided for in Article 79 of Regulation (EU) 2022/2065.

CHAPTER II

INSPECTIONS AND MONITORING ACTIONS BY THE COMMISSION

Article 2

Explanations provided during inspections

1. Explanations requested by the Commission or accompanying persons pursuant to Article 69(2), points (f) and (g), of Regulation (EU) 2022/2065 shall be given only by authorised representatives or members of staff of a provider of very large online platform, provider of very large online search engine, or, where applicable, of other persons referred to in Article 67(1) of that Regulation. The explanations given may be recorded by Commission's officials or accompanying persons in any form.

2. After the inspection, a copy of any recording made pursuant to paragraph 1 shall be made available to the provider of very large online platform, the provider of very large online search engine or to other person referred to in Article 67(1) of Regulation (EU) 2022/2065 concerned by that inspection.

3. In cases where a representative or a member of staff referred to in paragraph 1 has been asked for and given explanations, but that representative or that member of staff was not authorised to provide explanations on behalf of the provider or of the person concerned, the Commission shall set a time limit within which the provider or person concerned may communicate to the Commission any rectification, amendment or supplement to the explanations given by that representative or that member of staff. The rectification, amendment or supplement shall be added to the explanations recorded pursuant to paragraph 1 of this Article.

4. The possibility for the provider of very large online platform, provider of very large online search engine, or, where applicable, or other persons referred to in Article 67(1) of Regulation (EU) 2022/2065 to communicate to the Commission rectifications, amendments or supplementary information to explanations given pursuant to paragraph 3 shall be without prejudice to the power of the Commission to impose fines and periodic penalty payments in accordance with Articles 74 and 76 of Regulation (EU) 2022/2065 respectively.

Article 3

Monitoring actions

1. Where the Commission orders a provider of very large online platforms or of very large online search engine to grant it access to that provider's databases or algorithmic systems pursuant to Article 72(1) of Regulation (EU) 2022/2065, the Commission may specify the technical means or the interfaces through which providers of very large online platforms or of very large online search engines shall provide such access.

2. Providers of very large online platforms or of very large online search engine ordered to provide access pursuant to Article 72(1) of Regulation (EU) 2022/2065 shall do so in a timely and effective manner, enabling the Commission to access all information in the databases concerned and all information in relation to the algorithm concerned which are necessary for the assessment of the implementation of and compliance by the provider concerned with Regulation (EU) 2022/2065.

3. Providers of very large online platforms or of very large online search engine ordered to provide access pursuant to Article 72(1) of Regulation (EU) 2022/2065 shall comply with the requirements laid down in Article 7 of this Regulation.

4. Where the Commission imposes an obligation on a provider of very large online platforms or of very large online search engine to retain all documents necessary to assess the implementation of and compliance with Regulation (EU) 2022/2065 pursuant to Article 72(1) of that regulation, the Commission shall define the terms of retention, including the period and scope of documents to be retained for which the obligation applies. That period may be prolonged, where necessary, to assess the implementation of and compliance with Regulation (EU) 2022/2065.

5. Where the Commission appoints external experts or auditors to assist it in monitoring the effective implementation of and compliance with Regulation (EU) 2022/2065 by providers of very large online platforms and of very large online search engines pursuant to Article 72(2) of that regulation, the Commission shall ensure that those experts and auditors are independent from the provider concerned and that they have proven expertise and knowledge in the matter on which they assist the Commission.

6. To ensure independence in accordance with paragraph 5, the Commission, when appointing experts or auditors pursuant to that paragraph, shall take into account the existence of shared ownership, governance, management, personnel, or resources of the external experts or auditors concerned and the existence of contractual relationships with the provider of very large online platform or of very large online search engine concerned over the 24 months prior to procedure carried out by the Commission. The appointed expert or auditor shall remain independent throughout the period of appointment.

7. To ensure that the experts and auditors possess the necessary expertise and knowledge in accordance with paragraph 5, the Commission, when appointing an expert or an auditor pursuant to that paragraph, shall take into account the expert's proven expertise in the matter on which they assist the Commission or the auditor's proven technical competence to perform audits on the matter on which they assist the Commission.

CHAPTER III

RIGHT TO BE HEARD AND ACCESS TO THE FILE

Article 4

Written observations on preliminary findings

1. The addressee of preliminary findings communicated pursuant to Articles 73(2), 74(3) and 76 of Regulation (EU) 2022/2065 may, within a time limit set by the Commission, succinctly and in accordance with the format and length requirements for documents set out in the Annex to this Regulation, inform the Commission of its views in writing on those findings and on measures the Commission may intend to take in view of those findings and submit evidence in support thereof. The Commission shall not be obliged to take account of written observations received after the expiry of that time-limit.

2. Information submitted to the Commission pursuant to paragraph 1 shall be correct, complete and not misleading. It shall be presented in a clear, well-structured and intelligible manner.

3. The written observations referred to in paragraph 1 shall be in one of the official languages of the Union. Supporting documents shall be submitted in their original language and, where their original language is not one of the official languages of the Union, they shall be accompanied by a faithful translation into an official language of the Union.

4. The written observations referred to in paragraph 1 shall comply with the format and page limits set out in the Annex to this Regulation. The Commission may, upon reasoned request, authorise an addressee of preliminary findings to exceed those page limits where and to the extent that addressee substantiates that it is objectively impossible or exceedingly difficult to deal with particularly complex legal or factual issues within the maximum page limits.

5. Documents, databases or any other information shall be submitted to the Commission in accordance with Article 7 of this Regulation.

6. Information submitted to the Commission pursuant to paragraph 1 shall be accompanied by written proof that the persons submitting that information are authorised to act on behalf of the addressee of the preliminary findings concerned.

7. The Commission shall acknowledge, without delay and in writing, to the addressee of the preliminary findings concerned or to its representatives receipt of information submitted pursuant to paragraph 1.

Article 5

Access to the file

1. Upon request, the Commission shall grant access to the file to the addressee of the preliminary findings communicated pursuant to Articles 73(2), 74(3) or 76 of Regulation (EU) 2022/2065 ('the addressee'). Access to the file shall not be granted before the notification of the preliminary findings.

2. When providing access to file, the Commission shall provide the addressee with all documents mentioned in the preliminary findings, subject to redactions that have been made by pursuant to Article 6 to protect business secrets or other confidential information.

3. Without prejudice to paragraph 4, the Commission shall also provide access to all documents on its file, without any redactions, under terms of disclosure to be set out in a Commission decision. The terms of disclosure shall be determined in accordance with the following:

(a) Access to documents shall only be granted to a limited number of specified external legal and economic counsel and external technical experts engaged by the addressee and whose names shall be communicated to the Commission in advance.

(b) The specified external legal and economic counsel and external technical experts must be undertakings, employees of undertakings or in a situation comparable to that of employees of undertakings. All of them shall be bound by the terms of disclosure.

(c) Persons listed as specified external legal and economic counsel and technical experts shall not, at the date of the Commission decision setting out the terms of disclosure, be in an employment relationship with the addressee or in a situation comparable to that of an employee of the addressee. Should the specified external legal or economic counsel or external technical experts subsequently enter into such a relationship with the addressee or with other undertakings active on the same markets as the addressee during the investigation or during the three years following the end of the Commission's investigation, the specified external legal or economic counsel or external technical expert and the addressee shall promptly inform the Commission about the terms of such relationship. The specified external legal or economic counsel or external technical expert in question shall also provide the Commission with an assurance that they no longer have access to the information or documents on the file to which they were given access according to point (a) and which were not made available to the addressee by the Commission. They shall also provide assurances to the Commission that they will continue to comply with the requirements referred to in point (d) of this paragraph.

(d) Specified external legal and economic counsel and external technical experts shall not disclose any of the documents provided or their content to any natural or legal person that is not a signatory to the terms of disclosure and shall not use any of the documents provided or their content other than for the purposes referred to in Article 5(9) below.

(e) The Commission shall specify, in the terms of disclosure, the technical means of the disclosure and its duration. Disclosure may be made by electronic means or (for some or all documents) at the Commission's premises.

4. In exceptional circumstances, the Commission may decide not grant access to certain documents or to grant access to partly redacted documents under the terms of disclosure referred to in paragraph 3 if it determines that the harm that the party that submitted the documents in question would likely suffer from disclosure under those terms would, on balance, outweigh the importance of the disclosure of the full document for the exercise of the right to be heard.

5. Pursuant to Article 79(4) of Regulation (EU) 2022/2065, the right of access to the file of the Commission shall not extend to internal documents of the Commission or the competent authorities of the Member States. Correspondence between the Commission and other public authorities, including other institutions of the EU or of non-member countries, and other types of sensitive documents may also be subject to similar protections.

6. The specified external legal and economic counsel and external technical experts referred to in paragraph 3 may, within one week of receiving access under the terms of disclosure, make a reasoned request to the Commission for access to a non-confidential version of any document on the Commission's file not already provided to the addressee under paragraph 2, with a view to making such non-confidential version available to the addressee, or for an extension of the terms of disclosure to additional specified external legal and economic counsel or external technical experts. Such additional access may only be granted exceptionally and provided that it is indispensable for the proper exercise of the addressee's right to be heard.

7. For the purpose of applying paragraphs 4 to 6, the Commission may require the party that submitted the documents in question to provide a non-confidential version thereof, pursuant to Article 6.

8. Where the Commission considers a request under paragraph 6 to be well-founded in view of ensuring that the addressee is in a position to exercise its right to be heard effectively, the Commission shall request the party that submitted the documents in question either to agree to making a non-confidential version available to the addressee or to agree to the extension of the terms of disclosure to specified individuals or undertakings for the documents in question only.

9. In the event that the party that submitted the documents in question does not agree, the Commission shall adopt a decision setting out the terms of disclosure for the documents in question.

10. Documents obtained through access to the file provided pursuant to this Article shall only be used for the purposes of the relevant proceedings within which access to those documents was given or of judicial or administrative proceedings concerning the application of Regulation (EU) 2022/2065 that are related to those proceedings.

11. At any time during the procedure, the Commission may instead of or in combination with the method of granting access to file pursuant to paragraph 3 above, give access to some or all documents redacted pursuant to Article 6(3) in order to avoid a disproportionate delay or administrative burden.

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 6

Identification and protection of confidential information

1. Unless otherwise provided for in Regulation (EU) 2022/2065 or Article 5 of this Regulation, information or documents collected or obtained by the Commission shall not be disclosed or made accessible by the Commission in so far as they contain business secrets or other confidential information of any natural or legal person.

2. When seizing documents or receiving voluntary access to documents during inspections pursuant to Article 69 of Regulation (EU) 2022/2065, or otherwise receiving documents or access to information pursuant to Article 72 of Regulation (EU) 2022/2065, the Commission shall inform the very large online platforms or of very large online search engines concerned or, where applicable, other natural or legal person concerned referred to in Article 67(1) of Regulation (EU) 2022/2065, that access to that information may be granted pursuant to Article 5 of this Regulation. In any event, when very large online platforms or very large online search engines or, where applicable, other natural or legal person concerned voluntarily provide information to the Commission under Regulation (EU) 2022/2065 or this Regulation they agree that access to that information may be granted pursuant to Article 5 of this Regulation.

3. Without prejudice to paragraph 2, the Commission may require very large online platforms or very large online search engines or, where applicable, other natural or legal person concerned who are the originators of documents in its file to identify the documents, statements or parts thereof which they consider to contain business secrets or other confidential information and to identify the natural and legal persons in relation to whom that information is considered

to be confidential. The Commission may also set a time-limit for the very large online platforms or of very large online search engines concerned or, where applicable, other natural or legal person concerned referred to in Article 67(1) of Regulation (EU) 2022/2065 to identify any part of a Commission decision which in their view contains business secrets or other confidential information.

4. The Commission may set a time limit for the provider of very large online platforms and of very large online search engines concerned or, where applicable, for the natural or legal person concerned referred to in Article 67(1) of Regulation (EU) 2022/2065, to:

(a) substantiate their claims for business secrets and other confidential information for each individual document and database or part of document and database;

(b) provide the Commission with a non-confidential version of the documents and database in which the business secrets and other confidential information are redacted in a clear and intelligible manner;

(c) provide a concise, non-confidential, description of each piece of redacted information.

5. If providers of very large online platforms or of very large online search engines or, where applicable, natural or legal person concerned referred to in Article 67(1) of Regulation (EU) 2022/2065, fail to comply with paragraphs 2 and 3, the Commission may consider that the information concerned do not contain business secrets or other confidential information.

6. If the Commission determines that certain information that is claimed to be confidential by providers of very large online platforms or of very large online search engines or, where applicable, natural or legal person concerned referred to in Article 67(1) of Regulation (EU) 2022/2065, may be disclosed, either because this information does not constitute a business secret or other confidential information, or because there is an overriding interest in its disclosure, it shall inform the concerned providers or natural or legal person, that it intends to disclose such information unless it receives objections within one week. Should the providers or natural or legal person in question object, the Commission may adopt a reasoned decision specifying the date after which the information will be disclosed. This date shall not be less than one week from the date of notification. The decision shall be notified to the concerned providers or natural or legal person.

Article 7

Transmission and receipt of documents

1. Transmission of documents, databases or any other information to and from the Commission pursuant to Articles 2, 3 and 4 of this Regulation shall take place by digital means. Technical specifications regarding the means of transmission and signature may be issued or published and regularly updated by the Commission.

2. Documents transmitted by digital means shall be signed using at least one Qualified Electronic Signature complying with the requirements set out in Regulation (EU) No 910/2014 of the European Parliament and of the Council [2].

3. Documents transmitted to the Commission by digital means shall be deemed to have been received on the day when an acknowledgement of receipt is sent by the Commission.

4. For real-time or near-real-time information shared for example through application programming interfaces or any other equivalent means the Commission shall define the method and the duration of such sharing of information.

5. Documents, databases and any other information transmitted to the Commission by digital means, shall be deemed not to have been received if one of the following circumstances occurs:

(a) the document or parts thereof is inoperable or unusable;

[2] Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

(b) the document contains viruses, malware or other threats;

(c) the document contains an electronic signature the validity of which cannot be verified by the Commission.

6. The Commission shall inform the sender without delay if one the circumstances referred to in paragraph 5 occurs and shall give it the possibility to express its views and rectify the situation within a reasonable time limit.

7. By way of derogation from paragraph 1, under exceptional circumstances which make transmission by digital means impossible or exceedingly difficult, documents may be transmitted to the Commission by registered mail. Those documents shall be deemed to have been received by the Commission on the day of their delivery at the address of the responsible Commission service as published by the Commission on its website.

8. By way of derogation from paragraph 1, under exceptional circumstances which make transmission by digital means and registered mail impossible or exceedingly difficult, documents may be transmitted to the Commission by means of hand delivery. Those documents shall be deemed to have been received on the day of their delivery at the address of the responsible Commission service as published by the Commission on its website. The delivery shall be confirmed in an acknowledgement of receipt by the Commission.

Article 8

Entry into force

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, 21 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Format and length of observations submitted pursuant to Article 4

Written observations submitted to the Commission pursuant to Article 4 of this Regulation shall be submitted in a format allowing the Commission to process them electronically and, in particular, enabling their digitisation and character recognition.

For this purpose, the following requirements shall be complied with:

(a) the text, in A4 format, shall be easily legible and appear on one side of the page only;

(b) documents produced in paper format shall be assembled in such a way as to be easily separable (not bound together or permanently attached by other means, such as glue or staples);

(c) the text shall be in a commonly-used font (such as Times New Roman, Courier or Arial) in at least 12 point in the body of the text and at least 10 point in the footnotes, with single line spacing, and upper, lower, left and right margins of at least 2,5 cm (maximum 4 700 characters per page);

(d) the pages and paragraphs of each document shall be numbered consecutively.

Written observations submitted to the Commission pursuant to Article 4 of this Regulation shall not exceed 50 pages in length. Any annexes accompanying those observations shall not count towards the applicable page limits, provided those annexes have a purely evidential and instrumental function and are proportionate in number and length.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1202

of 21 June 2023

amending Implementing Regulation (EU) 2021/2325 as regards the recognition of certain control authorities and control bodies for the purpose of importing organic products into the Union

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 ([1]), and in particular Article 48(3) and Article 57(2) thereof,

Whereas:

(1) Annex I to Commission Implementing Regulation (EU) 2021/2325 ([2]) sets out the list of third countries whose systems of production and control measures for organic production of agricultural products are recognised as equivalent to those laid down in Council Regulation (EC) No 834/2007 ([3]).

(2) India has informed the Commission that its competent authority has withdrawn the accreditation of the control bodies 'APOF Organic Certification Agency' (AOCA- IN-ORG-002), 'Bhumaatha Organic Certification Bureau' (BOCB-IN-ORG-034), 'Karnataka State Organic Certification Agency' (IN-ORG-027), and has suspended the accreditation of the control body 'Faircert Certification Services Pvt Ltd' (IN-ORG-023).

(3) Japan has informed the Commission that its competent authority has withdrawn the accreditation of the control bodies 'Japan Grain Inspection Association' (JP-BIO-039) and 'OCIA Japan' (JP-BIO-008).

(4) Japan has informed the Commission that its competent authority has recognised the control body 'Japan Association for Inspection and Investigation of Food Including Fats and Oils' (JP-BIO-042).

(5) The Republic of Korea has asked the Commission to recognise, in addition to the Ministry of Agriculture, Food and Rural Affairs, the National Agricultural Products Quality Management Service as competent authority.

(6) Annex II to Implementing Regulation (EU) 2021/2325 sets out the list of control authorities and control bodies recognised for the purpose of equivalence and competent to carry out controls and issue certificates in third countries. In the light of new information and requests received by the Commission since the adoption of Implementing Regulation (EU) 2021/2325, certain changes should be made to that list.

(7) The Commission has received a request by 'Albinspekt bio.inspecta' to withdraw its recognition for all the third countries it is recognised for, due to its merger with 'Bio.inspecta AG'.

([1]) OJ L 150, 14.6.2018, p. 1.

([2]) Commission Implementing Regulation (EU) 2021/2325 of 16 December 2021 establishing, pursuant to Regulation (EU) 2018/848 of the European Parliament and of the Council, the list of third countries and the list of control authorities and control bodies that have been recognised under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for the purpose of importing organic products into the Union (OJ L 465, 29.12.2021, p. 8).

([3]) 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 (OJ L 189, 20.7.2007, p. 1).

(8) A number of consignments of products imported from India and Egypt certified as organic by Biocert International Pvt Ltd', have been contaminated with products and substances not allowed in organic production and/or conventional production in the Union, including ethylene oxide (ETO), which is carcinogenic, mutagenic and toxic for reproduction. This has resulted in a number of notifications in the Organic Farming Information System (OFIS). The levels of contamination found in the consignments have usually exceeded the maximum residue levels for ETO established by Regulation (EC) No 396/2005 ([4]) of the European Parliament and of the Council.

(9) Moreover, 'Biocert International Pvt Ltd' has failed to demonstrate that organic products imported under its control have been produced in accordance with production rules and subject to control arrangements equivalent to those laid down in Regulation (EC) No 834/2007 and in Commission Regulations (EC) No 889/2008 ([5]) and (EC) No 1235/2008 ([6]).

(10) Biocert has also failed to demonstrate that all operators controlled by 'Biocert International Pvt Ltd' have been subject to control measures of equivalent effectiveness and that such control measures have been permanently and effectively applied in accordance with Article 33(1), point (b), of Regulation (EC) No 834/2007.

(11) In addition, 'Biocert International Pvt Ltd' has failed to take adequate corrective measures in response to the irregularities and infringements observed.

(12) Finally, the accreditation body IOAS has informed the Commission about the withdrawal of its ISO/IEC 17065 accreditation of 'Biocert International Pvt Ltd' for all product categories and in all third countries for which it was accredited due to failure to comply with previous sanctions, to take the specified required actions and to resolve non-conformities.

(13) For each of the reasons set out in recitals (8)-(12) above, and in accordance with Article 4(1), points (d)(v) and (vii) of Commission Delegated Regulation (EU) 2021/1342 ([7]), 'Biocert International Pvt Ltd' should be withdrawn from the list of control authorities and control bodies set out in Annex II to Implementing Regulation (EU) 2021/2325.

(14) 'Ecogruppo Italia' has informed the Commission of the change of its address.

(15) The Commission has received a request by 'Indocert' to withdraw its recognition for Cambodia.

(16) The Commission has received a request by 'Kiwa BCS Öko-Garantie GmbH' to withdraw its recognition for Albania, Bangladesh, Belarus, Bhutan, Cuba, Ethiopia, Guinea-Bissau, India, Iran, Kosovo, Mongolia, Nepal and Pakistan. In addition, 'Kiwa BCS Öko-Garantie GmbH' has informed the Commission of the change of its internet address.

(17) 'Organic Standard' has informed the Commission of the change of its internet address.

(18) Implementing Regulation (EU) 2021/2325 should therefore be amended accordingly.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Organic Production Committee,

([4]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([5]) 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).

([6]) 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).

([7]) Commission Delegated Regulation (EU) 2021/1342 of 27 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the information to be sent by third countries and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for imported organic products and the measures to be taken in the exercise of that supervision (OJ L 292, 16.8.2021, p. 20).

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2021/2325 is amended as follows:

(1) Annex I is amended in accordance with Annex I to this Regulation;

(2) Annex II is amended in accordance with Annex II 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, 21 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex I to Implementing Regulation (EU) 2021/2325 is amended as follows:

(1) in the table in point 5 of the entry for '**INDIA**', the rows for code numbers IN-ORG-002, IN-ORG-023, IN-ORG-027 and IN-ORG-034 are deleted;

(2) in the entry for '**JAPAN**', the table in point 5 is amended as follows:

(a) the rows for code numbers JP-BIO-008 and JP-BIO-039 are deleted;

(b) the following row is added:

'JP-BIO-042	Japan Association for Inspection and Investigation of Food Including Fats and Oils	www.syken.or.jp'

(3) in the entry for '**REPUBLIC OF KOREA**', point 4 is replaced by the following:

'4. Competent authorities: Ministry of Agriculture, Food and Rural Affairs, www.enviagro.go.kr/portal/en/main.do and National Agricultural Products Quality Management Service (NAQS), www.naqs.go.kr/eng/main/main.do'.

ANNEX II

Annex II to Implementing Regulation (EU) 2021/2325 is amended as follows:

(1) the entry for **'Albinspekt bio.inspecta'** is deleted;

(2) the entry for '**Biocert International Pvt Ltd'** is deleted;

(3) in the entry for **'Ecogruppo Italia'**, point 1 is replaced by the following:

'1. Address: Via Siracusa on the corner of Via Merano 95037 – San Giovanni La Punta/Catania-Italy';

(4) in the table in point 3 of the entry for '**Indocert**', the row for Cambodia is deleted;

(5) the entry for '**Kiwa BCS Öko-Garantie GmbH**' is amended as follows:

(a) point 2 is replaced by the following:

'2. Internet address: www.kiwa.de/bio';

(b) in the table in point 3, the rows for Albania, Bangladesh, Belarus, Bhutan, Cuba, Ethiopia, Guinea-Bissau, India, Iran, Kosovo, Mongolia, Nepal and Pakistan are deleted;

(6) in the entry for '**Organic Standard**', point 2 is replaced by the following:

'2. Internet address: http://www.organicstandard.ua'.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1203

of 21 June 2023

amending Implementing Regulations (EU) 2018/2019 and (EU) 2020/1213 as regards certain plants for planting of *Malus domestica* originating in the United Kingdom

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ([1]), and in particular Article 42(4), third subparagraph thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2018/2019 ([2]) establishes, on the basis of a preliminary risk assessment, a list of high risk plants, plant products and other objects.

(2) Following a preliminary assessment, 34 genera and one species of plants for planting originating from third countries were provisionally listed in Implementing Regulation (EU) 2018/2019 as high risk plants. One of the listed genera is *Malus* Mill.

(3) Commission Implementing Regulation (EU) 2020/1213 ([3]) sets out the phytosanitary measures for the introduction into the Union territory of certain plants, plant products and other objects, which have been removed from the Annex to Implementing Regulation (EU) 2018/2019, but for which phytosanitary risks are not yet fully assessed. This is because one or more pests hosted by those plants are not yet included in the list of Union quarantine pests of Commission Implementing Regulation (EU) 2019/2072 ([4]), but they may fulfil the conditions to be included following a further complete risk assessment.

(4) On 17 September 2021, the United Kingdom ([5]) submitted to the Commission a request for export to the Union of the following: up to one-year-old free of leaves graftwood and budwood of *Malus domestica*; up to seven-year-old dormant, bare rooted free of leaves plants for planting of *Malus domestica*; and up to seven-year-old plants for planting of *Malus domestica* in growing medium ('the relevant plants'). That request was supported by the relevant technical dossier.

([1]) OJ L 317, 23.11.2016, p. 4.

([2]) Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation (OJ L 323, 19.12.2018, p. 10).

([3]) Commission Implementing Regulation (EU) 2020/1213 of 21 August 2020 concerning the phytosanitary measures for the introduction into the Union of certain plants, plant products and other objects which have been removed from the Annex to Implementing Regulation (EU) 2018/2019 (OJ L 275, 24.8.2020, p. 5).

([4]) Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

([5]) 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 act, references to the United Kingdom do not include Northern Ireland.

(5) On 29 March 2023, the European Food Safety Authority ('the Authority') adopted a scientific opinion as regards the risk assessment of the relevant plants originating in the United Kingdom ([6]). The Authority identified *Colletotrichum aenigma, Meloidogyne mali, Eulecanium excrescens, Takahashia japonica,* Tobacco ringspot virus, Tomato ringspot virus and *Erwinia amylovora* as pests relevant for these plants.

(6) The Authority evaluated the risk mitigation measures described in the dossier for *Colletotrichum aenigma, Meloidogyne mali, Eulecanium excrescens, Takahashia japonica,* Tobacco ringspot virus and Tomato ringspot virus and estimated the likelihood of the freedom of "the relevant plants" from those pests. It concluded that the likelihood that "the relevant plants" would be free from those pests is high. Concerning *Erwinia amylovora*, the Authority evaluated whether the special requirements for the introduction into, and movement within the specified protected zones, listed in point 9 of Annex X to Implementing Regulation (EU) 2019/2072, of plants of *Malus* Mill., other than fruits and seeds, are fulfilled. It concluded that the United Kingdom fulfils those special requirements.

(7) On the basis of that opinion, the phytosanitary risk from the introduction into the Union territory of the relevant plants is considered to be reduced to an acceptable level, provided that appropriate measures are applied to address the risk of pests related to those plants.

(8) The measures described by the United Kingdom in the technical dossier are considered sufficient to reduce the risk from the introduction into the Union territory of the relevant plants to an acceptable level. Those measures should therefore be adopted as phytosanitary import requirements to ensure the phytosanitary protection of the Union territory from introduction of the relevant plants into it.

(9) Consequently, the relevant plants should no longer be considered high risk plants.

(10) Implementing Regulation (EU) 2018/2019 should therefore be amended accordingly.

(11) *Erwinia amylovora* is listed as a protected zone quarantine pest, for certain protected zones, and as a Union regulated non-quarantine pest for the rest of the Union territory, in Annexes III and IV to Implementing Regulation (EU) 2019/2072 respectively. Special requirements are in place in point 9 of Annex X to that Regulation, to prevent the entry and spread of the pest within the specified protected zones. Tobacco ringspot virus and Tomato ringspot virus are listed as Union quarantine pests in Annex II to Implementing Regulation (EU) 2019/2072.

(12) *Colletotrichum aenigma, Eulecanium excrescens, Takahashia japonica* are not yet included in the list of Union quarantine pests of Implementing Regulation (EU) 2019/2072. A complete risk assessment on those pests needs to become available, in order to determine whether the pests fulfil the conditions to be listed in Annex II to Implementing Regulation (EU) 2019/2072, and the relevant plants, originating in the United Kingdom, to be listed in Annex VII to that Regulation, together with the respective measures.

(13) Implementing Regulation (EU) 2020/1213 should therefore be amended accordingly.

(14) *Meloidogyne mali* is not included in the list of Union quarantine pests. A pest risk analysis for that pest was published by the European and Mediterranean Plant Protection Organization (EPPO) in September 2017 ([7]). Based on discussions with the Member States, it was concluded that the pest should not be regulated as a Union quarantine pest nor as a Union regulated non-quarantine pest, because although the pest has been present in certain Member States for long time without official control measures, its impact in those Member States is considered low. For that reason, no import requirements are necessary with respect to that pest.

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

([6]) EFSA PLH Panel (EFSA Panel on Plant Health), 2022. Scientific Opinion on the commodity risk assessment of *Malus domestica* plants from United Kingdom. EFSA Journal 2023;21 (5):8002.

([7]) EPPO (2017) Pest risk analysis for Meloidogyne mali. EPPO, Paris. Available at http://www.eppo.int/QUARANTINE/Pest_Risk_Analysis/PRA_intro.htm and https://gd.eppo.int/taxon/MELGMA.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2018/2019 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2020/1213 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the third 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, 21 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

In the Annex to Implementing Regulation (EU) 2018/2019, in the table of point 1, in the second column 'Description', the entry for '*Malus* Mill.', is replaced by the following:

'*Malus* Mill., other than:

— one- to two-year-old bare rooted, dormant, free of leaves, grafted plants for planting of *Malus domestica* originating in Serbia;

— up to three-year-old bare-rooted, dormant, free of leaves, grafted plants for planting of *Malus domestica* originating in Moldova;

— up to three-year old bare-rooted, dormant, free of leaves, rootstocks of *Malus domestica* originating in Ukraine;

— up to three-year old bare-rooted, dormant, free of leaves, grafted plants for planting of *Malus domestica* originating in Ukraine;

— up to one-year-old free of leaves, cuttings of *Malus domestica* originating in the United Kingdom; and

— up to seven-year-old plants for planting of *Malus domestica* originating in the United Kingdom'.

ANNEX II

In the table in the Annex to Implementing Regulation (EU) 2020/1213, the following entry is inserted after '*Ligustrum delavayanum* and *Ligustrum japonicum*, up to 20-year old plants for planting in growing medium, with a maximum diameter of 18 cm at the base of the stem.':

Plants, plant products or other objects	CN Code	Third countries of origin	Measures
'*Malus domestica*: — up to 1-year old cuttings; and — up to 7-year old plants for planting.	ex 0602 10 90 ex 0602 20 20 ex 0602 20 80	United Kingdom	(a) Official statement that: (i) the plants are free from *Colletotrichum aenigma*, *Eulecanium excrescens* and *Takahashia japonica*; (ii) the site of production has been found free from *Colletotrichum aenigma*, *Eulecanium excrescens*, and *Takahashia japonica* during official inspections carried out at appropriate times, since the beginning of the last growing season; (iii) a system has been put in place to ensure that tools and machinery have been cleaned to be free from soil and plant debris, and disinfected to be free from *Colletotrichum aenigma*, before they have been introduced into the site of production; and (iv) immediately prior to export, consignments of the plants have been subjected to an official inspection for the presence of *Eulecanium excrescens*, and *Takahashia japonica*, with such a sample size as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %; and to an official inspection for the presence of *Colletotrichum aenigma* including random sampling and testing of the plants; (b) the phytosanitary certificates for those plants include under the heading 'Additional Declaration': (i) the following statement: 'The consignment complies with Commission Implementing Regulation (EU) 2020/1213'; and (ii) the specification of the registered sites of production.'

DECISIONS

COUNCIL DECISION (EU) 2023/1204

of 20 June 2023

appointing a member, proposed by the Italian Republic, of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to Council Decision (EU) 2019/853 of 21 May 2019 determining the composition of the European Economic and Social Committee ([1]),

Having regard to the proposal of the Italian Government,

After consulting the European Commission,

Whereas:

(1) Pursuant to Article 300(2) of the Treaty, the Economic and Social Committee is to consist of representatives of organisations of employers, of the employed, and of other parties representative of civil society, notably in socioeconomic, civic, professional and cultural areas.

(2) On 2 October 2020, the Council adopted Decision (EU) 2020/1392 ([2]), appointing the members of the European Economic and Social Committee for the period from 21 September 2020 to 20 September 2025.

(3) A member's seat on the European Economic and Social Committee has become vacant following the resignation of Mr Maurizio CASASCO.

(4) The Italian Government has proposed Mr Amedeo BONOMI, *Vice Presidente della Confederazione italiana della piccola e media industria privata (Confapi) di Brescia* (Vice President of the Italian Confederation of Small and Medium Enterprises (Confapi) of Brescia), as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2025,

HAS ADOPTED THIS DECISION:

Article 1

Mr Amedeo BONOMI, *Vice Presidente della Confederazione italiana della piccola e media industria privata (Confapi) di Brescia* (Vice President of the Italian Confederation of Small and Medium Enterprises (Confapi) of Brescia), is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2025.

Article 2

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

([1]) OJ L 139, 27.5.2019, p. 15.

([2]) Council Decision (EU) 2020/1392 of 2 October 2020 appointing the members of the European Economic and Social Committee for the period from 21 September 2020 to 20 September 2025, and repealing and replacing the Council Decision appointing the members of the European Economic and Social Committee for the period 21 September 2020 to 20 September 2025 adopted on 18 September 2020 (OJ L 322, 5.10.2020, p. 1).

Done at Luxembourg, 20 June 2023.

For the Council
The President
R. POURMOKHTARI

COUNCIL DECISION (EU) 2023/1205

of 20 June 2023

appointing a member and five alternate members, proposed by the Kingdom of Sweden, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ([1]),

Having regard to the proposals of the Swedish Government,

Whereas:

(1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.

(2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 ([2]), appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.

(3) A member's seat on the Committee of the Regions has become vacant following the resignation of Ms Karin WANNGÅRD.

(4) Four alternate members' seats on the Committee of the Regions have become vacant following the resignations of Ms Linda ALLANSSON WESTER, Ms Suzanne FRANK, Ms Sara HELGE VIKMÅNG and Ms Charlotte NORDSTRÖM.

(5) An alternate member's seat will become vacant following the appointment of Ms Åsa ÅGREN WIKSTRÖM as a member of the Committee of the Regions.

(6) The Swedish Government has proposed Ms Åsa ÅGREN WIKSTRÖM, representative of a regional body who holds a regional authority electoral mandate, *Ledamot i regionfullmäktige, Region Västerbotten* (Regional Councillor, Region of Västerbotten), as a member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

(7) The Swedish Government has proposed the following representatives of regional or local bodies who hold a regional or local authority electoral mandate as alternate members of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025: Mr William ELOFSSON, *Ledamot i kommunfullmäktige, Gävle kommun* (Municipal Councillor, Municipality of Gävle), Mr Anders JOSEFSSON, *Ledamot i regionfullmäktige, Region Norrbotten* (Regional Councillor, Region of Norrbotten), Ms Elisabet LANN, *Ledamot i kommunfullmäktige, Göteborgs kommun* (Municipal Councillor, Municipality of Gothenburg), Mr Michael ROSENBERG, *Ledamot i kommunfullmäktige, Helsingborgs kommun* (Municipal Councillor, Municipality of Helsingborg), and Ms Anna-Karin SKATT, *Ledamot i regionfullmäktige, Västra Götalandsregionen* (Regional Councillor, Region of Västra Götaland),

([1]) OJ L 139, 27.5.2019, p. 13.

([2]) Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).

HAS ADOPTED THIS DECISION:

Article 1

The following representatives of regional or local bodies who hold an electoral mandate are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025:

(a) as a member:

— Ms Åsa ÅGREN WIKSTRÖM, *Ledamot i regionfullmäktige, Region Västerbotten* (Regional Councillor, Region of Västerbotten),

and

(b) as alternate members:

— Mr William ELOFSSON, *Ledamot i kommunfullmäktige, Gävle kommun* (Municipal Councillor, Municipality of Gävle),

— Mr Anders JOSEFSSON, *Ledamot i regionfullmäktige, Region Norrbotten* (Regional Councillor, Region of Norrbotten),

— Ms Elisabet LANN, *Ledamot i kommunfullmäktige, Göteborgs kommun* (Municipal Councillor, Municipality of Gothenburg),

— Mr Michael ROSENBERG, *Ledamot i kommunfullmäktige, Helsingborgs kommun* (Municipal Councillor, Municipality of Helsingborg),

— Ms Anna-Karin SKATT, *Ledamot i regionfullmäktige, Västra Götalandsregionen* (Regional Councillor, Region of Västra Götaland).

Article 2

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

Done at Luxembourg, 20 June 2023.

For the Council
The President
R. POURMOKHTARI

COUNCIL DECISION (EU) 2023/1206

of 20 June 2023

appointing an alternate member, proposed by the Republic of Estonia, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ([1]),

Having regard to the proposal of the Estonian Government,

Whereas:

(1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.

(2) On 2 March 2023, the Council adopted Decision (EU) 2023/508 ([2]), appointing an alternate member, proposed by the Republic of Estonia, of the Committee of the Regions.

(3) An alternate member's seat on the Committee of the Regions has become vacant following the end of the national mandate on the basis of which Mr Tiit TERIK was proposed for appointment.

(4) The Estonian Government has proposed Mr Tiit TERIK, representative of a local body who is politically accountable to an elected assembly, *Tallinna Linnavalitsuse liige* (Member of Tallinn City Government), as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025,

HAS ADOPTED THIS DECISION:

Article 1

Mr Tiit TERIK, representative of a local body who is politically accountable to an elected assembly, *Tallinna Linnavalitsuse liige* (Member of Tallinn City Government), (change of mandate) is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

Article 2

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

Done at Luxembourg, 20 June 2023.

For the Council
The President
R. POURMOKHTARI

([1]) OJ L 139, 27.5.2019, p. 13.
([2]) Council Decision (EU) 2023/508 of 2 March 2023 appointing an alternate member, proposed by the Republic of Estonia, of the Committee of the Regions (OJ L 70, 8.3.2023, p. 49).

COMMISSION IMPLEMENTING DECISION (EU) 2023/1207

of 21 June 2023

renewing the authorisation for placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87701 × MON 89788 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 3935)

(Only the text in Dutch is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Implementing Decision 2012/347/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87701 × MON 89788. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified soybean MON 87701 × MON 89788, for the same uses as any other soybean, with the exception of cultivation.

(2) On 18 December 2020, Bayer Agriculture BV, based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation.

(3) On 19 December 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified soybean MON 87701 × MON 89788, adopted by the Authority in 2012 ([4]).

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Implementing Decision 2012/347/EU of 28 June 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 × MON 89788 (MON-877Ø1-2 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 171, 30.6.2012, p. 13).

([3]) EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel), 2022. Scientific Opinion on Assessment of genetically modified soybean MON 87701 × MON 89788 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-022). EFSA Journal 2022;20(12):7684, 11 pp. https://doi.org/10.2903/j.efsa.2022.7684.

([4]) EFSA GMO Panel, 2012. Scientific Opinion on application (EFSA-GMO-NL-2009-73) for the placing on the market of insect-resistant and herbicide tolerant genetically modified soybean MON 87701 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012; 10(2):2560, 34 pp. https://doi.org/10.2903/j.efsa.2012.2560.

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87701 × MON 89788 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.

(7) A unique identifier has been assigned to genetically modified soybean MON 87701 × MON 89788, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Implementing Decision 2012/347/EU. That unique identifier should continue to be used.

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([6]), appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified soybean MON 87701 × MON 89788 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([7]).

(10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified soybean MON 87701 × MON 89788, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([8]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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([5]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([6]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([7]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([8]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) MON 87701 × MON 89788, as specified in the Annex, is assigned the unique identifier MON-877Ø1-2 × MON-89788-1, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

The authorisation for placing on the market of the following products is renewed as regards:

(a) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-877Ø1-2 × MON-89788-1;

(b) feed containing, consisting of or produced from genetically modified soybean MON-877Ø1-2 × MON-89788-1;

(c) products containing or consisting of genetically modified soybean MON-877Ø1-2 × MON-89788-1, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean MON-877Ø1-2 × MON-89788-1 as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean MON-877Ø1-2 × MON-89788-1.

Article 5

Monitoring plan for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States,

represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-877Ø1-2 × MON-89788-1;

(2) feed containing, consisting of or produced from genetically modified soybean MON-877Ø1-2 × MON-89788-1;

(3) products containing or consisting of genetically modified soybean MON-877Ø1-2 × MON-89788-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-877Ø1-2 × MON-89788-1 expresses the *cry1Ac* gene, which confers resistance to certain lepidopteran pests, and the *CP4 epsps* gene, which confers tolerance to glyphosate-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified soybean MON-877Ø1-2 × MON-89788-1, with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified soybean events MON-877Ø1-2 and MON-89788-1 and further verified on soybean stack MON-877Ø1-2 × MON-89788-1;

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx;

(3) Reference Material: AOCS 0809-A (for MON-877Ø1-2), AOCS 0906-B (for MON-89788-1) AOCS 0906-A2 (for the non-GM counterpart) are accessible via the American Oil Chemists Society (AOCS) at https://www.aocs.org/crm.

(e) **Unique identifier:**

MON-877Ø1-2 × MON-89788-1

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ([1]).

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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

COMMISSION IMPLEMENTING DECISION (EU) 2023/1208

of 21 June 2023

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 95379 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 3936)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 30 November 2020, Bayer Agriculture BV, based in Belgium, submitted, on behalf of Bayer CropScience LP, based in the United States, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 95379, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 95379 for uses other than food and feed, with the exception of cultivation.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.

(3) On 15 November 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). The Authority concluded that genetically modified maize MON 95379, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified maize reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of genetically modified maize MON 95379 does not represent any nutritional concern.

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

([1]) OJ L 268, 18.10.2003, p. 1.

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

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on assessment of genetically modified maize MON 95379 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-170). EFSA Journal 2022; 2022; 20(11):7588, https://doi.org/10.2903/j.efsa.2022.7588.

(5) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

(6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 95379 should be authorised for the uses listed in the application.

(7) A unique identifier should be assigned to genetically modified maize MON 95379 in accordance with Commission Regulation (EC) No 65/2004 ([4]).

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([5]), appear to be necessary. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize MON 95379, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([6]).

(10) The opinion of the Authority does not justify the imposition of other specific conditions or restrictions for the placing on the market, for the use and handling or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([7]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([5]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([6]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([7]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 95379, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-95379-3, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified maize MON-95379-3;

(b) feed containing, consisting of or produced from genetically modified maize MON-95379-3;

(c) products containing or consisting of genetically modified maize MON-95379-3 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize MON-95379-3 as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize MON-95379-3.

Article 5

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, United States, represented in the Union by Bayer Agriculture BV.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder:**

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States

represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-95379-3;

(2) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-95379-3;

(3) products containing or consisting of genetically modified maize (*Zea mays* L.) MON-95379-3 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-95379-3 expresses *cry1B.868* and *cry1Da_7* genes, which confer protection against lepidopteran pests.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified maize MON-95379-3, with the exception of products referred to in point (b)(1) of this Annex.

(d) **Method for detection:**

(1) Event specific real-time PCR based method for the quantification of genetically modified maize MON-95379-3.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

(3) Reference Material: AOCS 0521-A accessible via the American Oil Chemists Society at https://www.aocs.org/crm

(e) **Unique identifier:**

MON-95379-3

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2023/1209

of 21 June 2023

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9 and its sub-combinations DAS-40278-9 x DP4114 x MON 87411, MON 89034 x DP4114 x MON 87411, MON 89034 x DAS-40278-9 x MON 87411, MON 89034 x DAS-40278-9 x DP4114, DP4114 x MON 87411, DAS-40278-9 x MON 87411, DAS-40278-9 x DP4114, MON 89034 x DP4114, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 3937)

(Only the texts in French and Dutch are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 9 December 2020, Pioneer Overseas Corporation, based in Belgium, submitted, on behalf of Pioneer Hi-Bred International, Inc., based in the United States, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9 for uses other than food and feed, with the exception of cultivation.

(2) In addition, the application covered the placing on the market of products containing, consisting of or produced from ten sub-combinations of the single transformation events constituting genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9. Two sub-combinations included in the application, MON 89034 x MON 87411 and MON 89034 x DAS-40278-9, have already been authorised by, respectively, Commission Implementing Decisions (EU) 2021/65 ([2]) and (EU) 2019/2086 ([3]).

(3) This Decision covers maize DP4114 x MON89034 x MON87411 x DAS-40278-9 and all the non-authorised sub-combinations of the single transformation events constituting this maize: DAS-40278-9 x DP4114 x MON 87411, MON 89034 x DP4114 x MON 87411, MON 89034 x DAS-40278-9 x MON 87411, MON 89034 x DAS-40278-9 x DP4114, DP4114 x MON 87411, DAS-40278-9 x MON 87411, DAS-40278-9 x DP4114, MON 89034 x DP4114.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Implementing Decision (EU) 2021/65 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 26, 26.1.2021, p. 37).

([3]) Commission Implementing Decision (EU) 2019/2086 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 316, 6.12.2019, p. 87).

(4) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([4]). It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.

(5) On 9 November 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([5]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. The Authority concluded that genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9 and its sub-combinations, as described in the application, are as safe as their conventional counterpart and the tested non-genetically modified maize reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9 and its sub-combinations does not represent any nutritional concern.

(6) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(7) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

(8) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9 and the sub-combinations DAS-40278-9 x DP4114 x MON 87411, MON 89034 x DP4114 x MON 87411, MON 89034 x DAS-40278-9 x MON 87411, MON 89034 x DAS-40278-9 x DP4114, DP4114 x MON 87411, DAS-40278-9 x MON 87411, DAS-40278-9 x DP4114, MON 89034 x DP4114 should be authorised for the uses listed in the application.

(9) By a letter dated 24 January 2022, Pioneer Hi-Bred International, Inc. requested that the Commission transfers the rights and obligations of Pioneer Hi-Bred International, Inc. pertaining to all pending applications for genetically modified products, to Corteva Agriscience LLC, based in the United States. Corteva Agriscience LLC confirmed their agreement to the change of authorisation holder proposed by Pioneer Hi-Bred International, Inc.. Corteva Agriscience LLC is represented in the Union by Corteva Agriscience Belgium B.V., based in Belgium.

(10) A unique identifier should be assigned to genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9 and to each of its sub-combinations DAS-40278-9 x DP4114 x MON 87411, MON 89034 x DP4114 x MON 87411, MON 89034 x DAS-40278-9 x MON 87411, MON 89034 x DAS-40278-9 x DP4114, DP4114 x MON 87411, DAS-40278-9 x MON 87411, DAS-40278-9 x DP4114, MON 89034 x DP4114, in accordance with Commission Regulation (EC) No 65/2004 ([6]).

(11) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([7]), appear to be necessary. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of those products, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

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

([5]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on assessment of genetically modified maize DP4114 × MON 89034 × MON 87411 × DAS-40278-9 and sub-combinations for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-171). EFSA Journal 2022; 20(11):7619, https://doi.org/10.2903/j.efsa.2022.7619

([6]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([7]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

(12) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([8]).

(13) The opinion of the Authority does not justify the imposition of other specific conditions or restrictions for the placing on the market, for the use and handling or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(14) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(15) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([9]).

(16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifiers

Genetically modified maize (*Zea mays* L.), as specified in point (b) of the Annex to this Decision, is assigned the following unique identifiers, in accordance with Regulation (EC) No 65/2004:

(a) the unique identifier DP-ØØ4114-3 x MON-89Ø34-3 x MON-87411-9 x DAS-4Ø278-9 for genetically modified maize DP4114 x MON89034 x MON87411 x DAS-40278-9;

(b) the unique identifier DAS-4Ø278-9 x DP-ØØ4114-3 x MON-87411-9 for genetically modified maize DAS-40278-9 x DP4114 x MON 87411;

(c) the unique identifier MON-89Ø34-3 x DP-ØØ4114-3 x MON-87411-9 for genetically modified maize MON 89034 x DP4114 x MON 87411;

(d) the unique identifier MON-89Ø34-3 x DAS-4Ø278-9 x MON-87411-9 for genetically modified maize MON 89034 x DAS-40278-9 x MON 87411;

(e) the unique identifier MON-89Ø34-3 x DAS-4Ø278-9 x DP-ØØ4114-3 for genetically modified maize MON 89034 x DAS-40278-9 x DP4114;

(f) the unique identifier DP-ØØ4114-3 x MON-87411-9 for genetically modified maize DP4114 x MON 87411;

(g) the unique identifier DAS-4Ø278-9 x MON-87411-9 for genetically modified maize DAS-40278-9 x MON 87411;

(h) the unique identifier DAS-4Ø278-9 x DP-ØØ4114-3 for genetically modified maize DAS-40278-9 x DP4114;

(i) the unique identifier MON-89Ø34-3 x DP-ØØ4114-3 for genetically modified maize MON 89034 x DP4114.

([8]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([9]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified maize and its sub-combinations as referred to in Article 1;

(b) feed containing, consisting of or produced from genetically modified maize and its sub-combinations as referred to in Article 1;

(c) products containing or consisting of genetically modified maize and its sub-combinations as referred to in Article 1 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize and its sub-combinations as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize and its sub-combinations as referred to in Article 1.

Article 5

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Corteva Agriscience LLC, represented in the Union by Corteva Agriscience Belgium B.V.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana, 46268-1054, United States, represented in the Union by Corteva Agriscience Belgium B.V., Rue Montoyer 25, 1000 Brussels, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name:	Corteva Agriscience LLC
Address:	9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States

Represented in the Union by Corteva Agriscience Belgium BV, Rue Montoyer 25, 1000 Brussels, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified maize as referred to in point (e);

(2) feed containing, consisting of or produced from genetically modified maize as referred to in point (e);

(3) products containing or consisting of genetically modified maize as referred to in point (e); for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize DP-ØØ4114-3 expresses the *cry1F*, *cry34Ab1* and *cry35Ab1* genes, which confer protection against certain lepidopteran and coleopteran pests and the *pat* gene, which confers tolerance to glufosinate ammonium-based herbicides.

The genetically modified maize MON-89Ø34-3 expresses the *cry1A.105* and *cry2Ab2* genes, which confer protection against certain lepidopteran pests.

The genetically modified maize MON-87411-9 expresses the *dvSnf7 dsRNA* gene, which confers protection against western corn rootworm, *cry3Bb1* gene, which confers protection against certain coleopteran pests and CP4 EPSPS protein, which confers tolerance to glyphosate herbicides.

The genetically modified maize DAS-4Ø278-9 expresses the *aad-1* gene, which confers tolerance to 2, 4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize referred to in point (e), with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events DP-ØØ4114-3, MON-89Ø34-3, MON-87411-9, DAS-4Ø278-9 and further verified on maize DP-ØØ4114-3 x MON-89Ø34-3 x MON-87411-9 x DAS-4Ø278-9;

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx;

(3) Reference Material: AOCS 0906-E2 (for MON-89Ø34-3) and AOCS 0215-B (for MON-87411-9) are accessible via the American Oil Chemist Society at https://www.aocs.org/crm#maize; ERM®-BF439 a-e (for DP-ØØ4114-3) and ERM®-BF433 a-d (for DAS-4Ø278-9) are accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

(e) **Unique identifier:**

DP-ØØ4114-3 x MON-89Ø34-3 x MON-87411-9 x DAS-4Ø278-9;

DAS-4Ø278-9 x DP-ØØ4114-3 x MON-87411-9;

MON-89Ø34-3 x DP-ØØ4114-3 x MON-87411-9;

MON-89Ø34-3 x DAS-4Ø278-9 x MON-87411-9;

MON-89Ø34-3 x DAS-4Ø278-9 x DP-ØØ4114-3;

DP-ØØ4114-3 x MON-87411-9;

DAS-4Ø278-9 x MON-87411-9;

DAS-4Ø278-9 x DP-ØØ4114-3;

MON-89Ø34-3 x DP-ØØ4114-3.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2023/1210

of 21 June 2023

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton 281-24-236 × 3006-210-23 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 3940)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Decision 2011/891/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified cotton 281-24-236 × 3006-210-23. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified cotton 281-24-236 × 3006-210-23, for the same uses as any other cotton, with the exception of cultivation.

(2) On 16 November 2020, Dow AgroSciences Distribution S.A.S., based in France, submitted on behalf of Dow AgroSciences LLC, based in the United States, an application to the Commission for the renewal of that authorisation, in accordance with Article 11(2) and Article 23(2) of Regulation (EC) No 1829/2003.

(3) By letter of 22 March 2021, Corteva Agriscience LLC, based in the United States, informed the Commission that Dow AgroSciences LLC had changed its name to Corteva Agriscience LLC as of 1 January 2021. By that letter, Corteva Agriscience LLC informed the Commission that its representative in the Union was Corteva Agriscience Belgium BV, based in Belgium, as of 22 March 2021.

(4) On 10 November 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified cotton 281-24-236 × 3006-210-23, adopted by the Authority in 2010 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Decision 2011/891/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5x DAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 51).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on the assessment on genetically modified cotton 281-24-236 × 3006-210-23 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-019). *EFSA Journal* 2022;20(11):7587, 12 pp.; https://doi.org/10.2903/j.efsa.2022.7587.

([4]) EFSA GMO Panel, 2010. Scientific Opinion on application (EFSA-GMO-NL-2005-16) for the placing on the market of insect resistant genetically modified cotton (*Gossypium hirsutum* L.) 281-24-236 × 3006-210-23 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Dow AgroSciences. *EFSA Journal* 2010; 8(6):1644, 32 pp.; https://doi.org/10.2903/j.efsa.2010.1644.

(5) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(6) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

(7) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified cotton 281-24-236 × 3006-210-23 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.

(8) A unique identifier has been assigned to genetically modified cotton 281-24-236 × 3006-210-23, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Decision 2011/891/EU. That unique identifier should continue to be used.

(9) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([6]), appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified cotton 281-24-236 × 3006-210-23 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.

(10) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([7]).

(11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified cotton 281-24-236 × 3006-210-23, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(12) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([8]).

(14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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([5]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([6]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([7]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([8]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum* L.) 281-24-236 × 3006-210-23, as specified in the Annex to this Decision, is assigned the unique identifier DAS-24236-5 × DAS-21Ø23-5 in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified cotton DAS-24236-5 × DAS-21Ø23-5;

(b) feed containing, consisting of or produced from genetically modified cotton DAS-24236-5 × DAS-21Ø23-5;

(c) products containing or consisting of genetically modified cotton DAS-24236-5 × DAS-21Ø23-5, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'cotton'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified cotton as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The methods set out in point (d) of the Annex shall apply for the detection of genetically modified cotton DAS-24236-5 × DAS-21Ø23-5.

Article 5

Monitoring plan for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Corteva Agriscience LLC, United States, represented in the Union by Corteva Agriscience Belgium BV, Belgium.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States, represented in the Union by Corteva Agriscience Belgium BV, Rue Montoyer 25, 1000 Brussels, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Corteva Agriscience LLC

Address: 9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States

represented in the Union by: Corteva Agriscience Belgium BV, Rue Montoyer 25, 1000 Brussels, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified cotton DAS-24236-5 × DAS-21Ø23-5;

(2) feed containing, consisting of or produced from genetically modified cotton DAS-24236-5 × DAS-21Ø23-5;

(3) products containing or consisting of genetically modified cotton DAS-24236-5 × DAS-21Ø23-5 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified cotton DAS-24236-5 × DAS-21Ø23-5 expresses the *cry1F and cry1Ac* genes, which confer resistance to certain lepidopteran pests, and the *pat* gene, used as a selectable marker, which confers tolerance to glufosinate-ammonium-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'cotton'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified cotton DAS-24236-5 × DAS-21Ø23-5, with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event-specific method for the quantification of genetically modified cotton DAS-24236-5 × DAS-21Ø23-5 using real-time PCR.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx.

(3) Reference Material: ERM-BF422 is accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

(e) **Unique identifier:**

DAS-24236-5 × DAS-21Ø23-5.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ([1]).

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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

COMMISSION IMPLEMENTING DECISION (EU) 2023/1211

of 21 June 2023

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87429 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 3941)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 27 September 2019, Bayer Agriculture BV, based in Belgium, submitted, on behalf of Bayer CropScience LP, based in the United States, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 87429, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 87429 for uses other than food and feed, with the exception of cultivation.

(2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ([2]). It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.

(3) On 18 November 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. The Authority concluded that genetically modified maize MON 87429, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified maize reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of genetically modified maize MON 87429 does not represent any nutritional concern.

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

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

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on assessment of genetically modified maize MON 87429 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-161). EFSA Journal 2022; 20(11):7589, https://doi.org/10.2903/j.efsa.2022.7589.

(6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87429 should be authorised for the uses listed in the application.

(7) A unique identifier should be assigned to genetically modified maize MON 87429, in accordance with Commission Regulation (EC) No 65/2004 ([4]).

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([5]), appear to be necessary. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified maize MON 87429, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environment effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([6]).

(10) The opinion of the Authority does not justify the imposition of other specific conditions or restrictions for the placing on the market, for the use and handling or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([7]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 87429, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87429-9, in accordance with Regulation (EC) No 65/2004.

([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([5]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([6]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([7]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified maize MON-87429-9;

(b) feed containing, consisting of or produced from genetically modified maize MON-87429-9;

(c) products containing or consisting of genetically modified maize MON-87429-9 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize MON-87429-9 as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize MON-87429-9.

Article 5

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, United States, represented in the Union by Bayer Agriculture BV.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder:**

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States

represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-87429-9;

(2) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-87429-9;

(3) products containing or consisting of genetically modified maize (*Zea mays* L.) MON-87429-9 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-87429-9 expresses the PAT protein, which confers tolerance to glufosinate herbicide, the DMO protein, which confers tolerance to dicamba herbicide and the FT_T protein, which confers tolerance to quizalofop and 2, 4-D herbicides. In addition, maize MON-87429-9 expresses the CP4-EPSPS protein and utilises an endogenous maize RNAi regulatory element to suppress its expression in pollen which is part of a hybridisation system to be used in inbred lines to facilitate the hybrid seeds production.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified maize MON-87429-9, with the exception of products referred to in point (b)(1) of this Annex.

(d) **Method for detection:**

(1) Event specific real-time PCR based method for the quantification of genetically modified maize MON-87429-9.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

(3) Reference Material: AOCS 0321-A and AOCS 0406-A2 are accessible via the American Oil Chemists Society at https://www.aocs.org/crm

(e) **Unique identifier:**

MON-87429-9

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2023/1212

of 21 June 2023

renewing the authorisation for placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87701 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023) 3944)

(Only the text in Dutch is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Implementing Decision 2012/83/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87701. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified soybean MON 87701, for the same uses as any other soybean, with the exception of cultivation.

(2) On 18 December 2020, Bayer Agriculture BV, based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of that authorisation.

(3) On 15 November 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]). It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified soybean MON 87701, adopted by the Authority in 2011 ([4]).

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Implementing Decision 2012/83/EU of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 (MON-877Ø1-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 40, 14.2.2012, p. 18).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on the assessment on genetically modified soybean MON 87701 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-021). EFSA Journal 2022;20(12):7683, 12 pp.; https://doi.org/10.2903/j.efsa.2022.7683.

([4]) EFSA GMO Panel, 2011. Scientific Opinion on application (EFSA-GMO-BE-2010-79) for the placing on the market of insect resistant genetically modified soybean MON 87701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2011; 9(7):2309, 31 pp.; https://doi.org/10.2903/j.efsa.2011.2309.

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 87701 and of products containing it or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.

(7) A unique identifier has been assigned to genetically modified soybean MON 87701, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Implementing Decision 2012/83/EU. That unique identifier should continue to be used.

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([6]), appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified soybean MON 87701 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([7]).

(10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified soybean MON 87701, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([8]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

([5]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([6]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([7]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([8]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean *(Glycine max)* MON 87701, as specified in the Annex, is assigned the unique identifier MON-877Ø1-2, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

The authorisation for placing on the market of the following products is renewed as regards:

(a) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-877Ø1-2;

(b) feed containing, consisting of or produced from genetically modified soybean MON-877Ø1-2;

(c) products containing or consisting of genetically modified soybean MON-877Ø1-2, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean MON-877Ø1-2.

Article 5

Monitoring plan for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, United States, represented in the Union by Bayer Agriculture BV.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Haven 627, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States,

represented in the Union by: Bayer Agriculture BV, Haven 627, Scheldelaan 460, B-2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-877Ø1-2;

(2) feed containing, consisting of or produced from genetically modified soybean MON-877Ø1-2;

(3) products containing or consisting of genetically modified soybean MON-877Ø1-2 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-877Ø1-2 expresses the *cry1Ac* gene, which confers resistance to certain lepidopteran pests.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the name of the organism shall be 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified soybean MON-877Ø1-2, with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event-specific method for the quantification of genetically modified soybean MON-877Ø1-2 using real-time PCR;

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx;

(3) Reference Material: AOCS 0809-A and AOCS 0906-2 for the non-genetically modified counterpart are accessible via the American Oil Chemists Society (AOCS) at https://www.aocs.org/crm.

(e) **Unique identifier:**

MON-877Ø1-2

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ([1]).

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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

COMMISSION IMPLEMENTING DECISION (EU) 2023/1213

of 21 June 2023

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean 40-3-2 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2023)3945)

(Only the text in Dutch is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Implementing Decision 2012/82/EU ([2]) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean 40-3-2. The scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of genetically modified soybean 40-3-2, for the same uses as any other soybean, with the exception of cultivation.

(2) On 22 January 2021, Bayer Agriculture BV, based in Belgium, submitted an application on behalf of Bayer CropScience LP, based in the United States, to the Commission for the renewal of that authorisation.

(3) On 19 December 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ([3]). It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified soybean 40-3-2, adopted by the Authority in 2010 ([4]).

(4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean 40-3-2 and of products consisting of it or containing it for uses other than food and feed, with the exception of cultivation, should be renewed.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Implementing Decision 2012/82/EU of 10 February 2012 as regards the renewal of the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-2 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 40, 14.2.2012, p. 14).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022. Scientific Opinion on the assessment on genetically modified soybean 40-3-2 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-023). EFSA Journal 2022;20(12):7685. https://doi.org/10.2903/j.efsa.2022.7685

([4]) EFSA GMO Panel, 2010. Scientific Opinion on application (EFSA-GMO-RX-40-3-2) for the placing on the market of herbicide tolerant genetically modified soybean 40-3-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 2010;8(12):1908. https://doi.org/10.2903/j.efsa.2010.1908

(7) A unique identifier has been assigned to genetically modified soybean 40-3-2, in accordance with Commission Regulation (EC) No 65/2004 ([5]), in the context of its initial authorisation by Decision 2012/82/EU. That unique identifier should continue to be used.

(8) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([6]), appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified soybean 40-3-2 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([7]).

(10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified soybean 40-3-2, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([8]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation.The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max*) 40-3-2, as specified in the Annex, is assigned the unique identifier MON-Ø4Ø32-6, in accordance with Regulation (EC) No 65/2004.

([5]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([6]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([7]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([8]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

Article 2

Renewal of the authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-Ø4Ø32-6;

(b) feed containing, consisting of or produced from genetically modified soybean MON-Ø4Ø32-6;

(c) products containing or consisting of genetically modified soybean MON-Ø4Ø32-6, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean (*Glycine max*) 40-3-2.

Article 5

Monitoring plan for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 21 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States

Represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-Ø4Ø32-6;

(2) feed containing, consisting of or produced from genetically modified soybean MON-Ø4Ø32-6;

(3) products containing or consisting of genetically modified soybean MON-Ø4Ø32-6 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-Ø4Ø32-6 expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified soybean MON-Ø4Ø32-6, with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event-specific method for the quantification of genetically modified soybean MON-Ø4Ø32-6 using real-time PCR.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx;

(3) Reference Materials: ERM®-BF410a-ep are accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

(e) **Unique identifier:**

MON-Ø4Ø32-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ([1]).

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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

CORRIGENDA

Corrigendum to Council Regulation (EU) 2023/194 of 30 January 2023 fixing for 2023 the fishing opportunities for certain fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, as well as fixing for 2023 and 2024 such fishing opportunities for certain deep-sea fish stocks

(Official Journal of the European Union L 28 of 31 January 2023)

1. On page 16, Article 5(2) and (3):

for: '2. Union fishing vessels may be authorised to fish in waters under the fisheries jurisdiction of the Faroe Islands, Greenland, Norway and in the fishing zone around Jan Mayen subject to the TACs set out in Annex I to this Regulation and subject to the conditions provided for in Article 19 and Part A of Annex V to this Regulation and in Regulation (EU) 2017/2403 of the European Parliament and of the Council ([32]) and its implementing provisions.

3. Union fishing vessels may be authorised to fish in waters under the fisheries jurisdiction of the United Kingdom subject to the TACs in Annex I to this Regulation and subject to the conditions provided for in Article 19 of this Regulation and in Regulation (EU) 2017/2403 and its implementing provisions.',

read: '2. Union fishing vessels may be authorised to fish in waters under the fisheries jurisdiction of the Faroe Islands, Greenland, Norway and in the fishing zone around Jan Mayen subject to the TACs set out in Annex I to this Regulation and subject to the conditions provided for in Article 20 and Part A of Annex V to this Regulation and in Regulation (EU) 2017/2403 of the European Parliament and of the Council ([32]) and its implementing provisions.

3. Union fishing vessels may be authorised to fish in waters under the fisheries jurisdiction of the United Kingdom subject to the TACs in Annex I to this Regulation and subject to the conditions provided for in Article 20 of this Regulation and in Regulation (EU) 2017/2403 and its implementing provisions.'.

2. On page 21, Article 14(1)(g):

for: '(g) quota transfers and exchanges pursuant to Articles 20 and 52 of this Regulation.',

read: '(g) quota transfers and exchanges pursuant to Articles 21 and 51 of this Regulation.'.

3. On page 31, Article 36(2), the introductory wording:

for: '2. During the 15 days before the start of the closure period selected in accordance with Article 34(1), point (a), of this Regulation a purse-seine vessel shall, in the IATTC Convention area:',

read: '2. During the 15 days before the start of the closure period selected in accordance with Article 35(1), point (a), of this Regulation a purse-seine vessel shall, in the IATTC Convention area:'.

4. On page 35, Article 54:

for: 'The conditions laid down in Article 7 of this Regulation shall apply to the catches and by-catches of third-country vessels fishing under the authorisations referred to in Article 54 of this Regulation.',

read: 'The conditions laid down in Article 8 of this Regulation shall apply to the catches and by-catches of third-country vessels fishing under the authorisations referred to in Article 53 of this Regulation.'.

5. In Annex IA for 'Article 6a(1) applies' read everywhere 'Article 7(1) of this Regulation applies'.

6. In Annex IA for 'Article 7(2) of this Regulation applies' read everywhere 'Article 8(2) of this Regulation applies'.

7. In Annex IA for 'Article 8 of this Regulation applies' read everywhere 'Article 9 of this Regulation applies'.

8. On page 56, Annex IA, Part B, table for tusk (USK/1214EI):

for:

'Species:	Tusk *Brosme brosme*		Zone:	United Kingdom and international waters of 1, 2 and 14 (USK/1214EI)
Germany	6	(1)	Precautionary TAC	
France	6	(1)		
Others	3	(1)(2)		
Union	16	(1)		
United Kingdom	6	(1)		
TAC	22			

(1) Exclusively for by-catches. No directed fisheries are permitted under this quota.

(2) Catches to be counted against this shared quota shall be reported separately (USK/1214EI_AMS).'

read:

'Species:	Tusk *Brosme brosme*		Zone:	United Kingdom and international waters of 1, 2 and 14 (USK/1214EI)
Germany	6,5	(1)	Precautionary TAC	
France	6,5	(1)		
Others	3	(1)(2)		
Union	16	(1)		
United Kingdom	6	(1)		
TAC	22			

(1) Exclusively for by-catches. No directed fisheries are permitted under this quota.

(2) Catches to be counted against this shared quota shall be reported separately (USK/1214EI_AMS).'

9. On page 82, Annex IA, Part B, table for skates and rays (SRX/2AC4-C), footnote 4, first sentence:

for: '(4) Special condition: of which up to 10 % may be fished in 7d (SRX/*07D2.), without prejudice to the prohibitions set out in Articles 17 and 56 of this Regulation and in the relevant provisions of the United Kingdom law for the areas specified therein.',

read: '(4) Special condition: of which up to 10 % may be fished in 7d (SRX/*07D2.), without prejudice to the prohibitions set out in Articles 18 and 55 of this Regulation and in the relevant provisions of the United Kingdom law for the areas specified therein.'.

10. On page 83, Annex IA, Part B, table for skates and rays (SRX/67AKXD), footnote 2, first sentence:

for: '(2) Special condition: of which up to 5 % may be fished in 7d (SRX/*07D.), without prejudice to the prohibitions set out in Articles 17 and 50 of this Regulation for the areas specified therein.',

read: '(2) Special condition: of which up to 5 % may be fished in 7d (SRX/*07D.), without prejudice to the prohibitions set out in Articles 18 and 55 of this Regulation for the areas specified therein.'.

11. On page 83, Annex IA, Part B, table for skates and rays (SRX/67AKXD), footnote 3, second sentence:

for: 'Catches of this species in 7e shall be counted against the quantities provided for in that separate TAC (RJU/7DE).',

read: 'Catches of this species in 7e shall be counted against the quantities provided for in that separate TAC (RJU/7DE.).'.

12. On page 84, Annex IA, Part B, table for small-eyed ray (RJE/7FG.), special condition:

for: 'Special condition: of which up to 5 % may be fished in 7d and reported under the following code: (RJE/*07D.). This special condition is without prejudice to the prohibitions set out in Articles 17 and 55 of this Regulation and in the relevant provisions of the United Kingdom law for the areas specified therein.',

read: 'Special condition: of which up to 5 % may be fished in 7d and reported under the following code: (RJE/*07D.). This special condition is without prejudice to the prohibitions set out in Articles 18 and 55 of this Regulation and in the relevant provisions of the United Kingdom law for the areas specified therein.'.

13. On page 84, Annex IA, Part B, table for skates and rays (SRX/07D.), footnote 4:

for: '(4) Shall not apply to undulate ray (Raja undulata). Catches of this species shall be counted against the quantities provided for in that separate TAC (RJU/7DE).',

read: '(4) Shall not apply to undulate ray (Raja undulata). Catches of this species shall be counted against the quantities provided for in that separate TAC (RJU/7DE.).'.

14. On page 85, Annex IA, Part B, table for undulate ray (RJU/7DE.), footnote 1, first and second sentence:

for: '(1) The specimens may only be landed whole or gutted. For Union fishing vessels, this is without prejudice to the prohibitions set out in Articles 17 and 56 of this Regulation for the areas specified therein.',

read: '(1) The specimens may only be landed whole or gutted. For Union fishing vessels, this is without prejudice to the prohibitions set out in Articles 18 and 55 of this Regulation for the areas specified therein.'.

15. On page 86, Annex IA, Part B, table for skates and rays (SRX/89-C.), footnote 2, fifth sentence:

for: 'These provisions are without prejudice to the prohibitions set out in Articles 17 and 56 of this Regulation for the areas specified therein.',

read: 'These provisions are without prejudice to the prohibitions set out in Articles 18 and 55 of this Regulation for the areas specified therein.'.

16. On page 97, Annex IA, Part B, table for herring (HER/03A-BC), footnote 2, introductory wording:

for: '(2) Only the following amounts of the herring stocks HER/03A. (HER/*03A) and HER/03A-BC (HER/*03A-BC) may be fished in 3a:',

read: '(2) Only the following amounts of the herring stocks HER/03A. (HER/*03A.) and HER/03A-BC (HER/*03A-BC) may be fished in 3a:'.

17. On page 116, Annex IA, Part B, table for sprat (SPR/7DE.), footnote 1:

for: '(1) The quota may only be fished from 1 January 2023 to 30 June 2024.',

read: '(1) The quota may only be fished from 1 July 2023 to 30 June 2024.'.

18. On page 118, Annex IA, Part C, introductory wording:

for: 'The TACs referred to in Article 8(4) of this Regulation are the following:',

read: 'The TACs referred to in Article 9(4) of this Regulation are the following:'.

19. On page 120, Annex IA, Part E, table for black scabbardfish (BSF/C3412-), the quota for Portugal for 2024 is inserted as 'To be established'.

20. On page 123, Annex IA, Part F, table for red seabream (SBR/678-):

for:

'Species:	Red seabream *Pagellus bogaraveo*				Zone:	6, 7 and 8 (SBR/678-)
Year	2023		2024		Precautionary TAC	
Ireland	3	(1)	To be established	(1)		
Spain	85	(1)	To be established	(1)		
France	4	(1)	To be established	(1)		
Others	3	(1)(2)	To be established	(1)(2)		
Union	95	(1)	To be established	(1)		
United Kingdom	11	(1)	To be established	(1)		
TAC	105	(1)	To be established	(1)		

(1) Exclusively for by-catches. No directed fisheries are permitted under this quota.

(2) Catches to be counted against this shared quota shall be reported separately (SBR/678_AMS).'

read:

'Species:	Red seabream *Pagellus bogaraveo*				Zone:	6, 7 and 8 (SBR/678-)
Year	2023		2024		Precautionary TAC	
Ireland	3	(1)	To be established	(1)		
Spain	84	(1)	To be established	(1)		
France	4	(1)	To be established	(1)		
Others	3	(1)(2)	To be established	(1)(2)		
Union	94	(1)	To be established	(1)		
United Kingdom	11	(1)	To be established	(1)		
TAC	105	(1)	To be established	(1)		

(1) Exclusively for by-catches. No directed fisheries are permitted under this quota.

(2) Catches to be counted against this shared quota shall be reported separately (SBR/678_AMS).'

21. On pages 184-185, Annex V, Part A, table:

for:

'Area of fishing	Fishery	Number of fishing authorisations	Allocation of fishing authorisations amongst Member States		Maximum number of vessels present at any time
Norwegian waters and fishery zone around Jan Mayen	Herring, north of 62° 00' N	59	DK	25	51
			DE	5	
			FR	1	
			IE	8	
			NL	9	
			PL	1	
			SE	10	
	Demersal species, north of 62° 00' N	pm	DE	16	pm
			IE	1	
			ES	20	
			FR	18	
			PT	9	
			Unallocated	2	
	Industrial species, south of 62° 00' N	pm	DK	450	141
Svalbard waters; international waters of 1 and 2b[1]	Fishery for snow crab with pots	pm	EE	1	Not applicable
			ES	1	
			LV	11	
			LT	4	
			PL	3	

[1] The allocation of fishing opportunities available to the Union in the Spitzbergen and Bear Island zone is without prejudice to the rights and obligations deriving from the 1920 Treaty of Paris.'

read:

'Area of fishing	Fishery	Number of fishing authorisations	Allocation of fishing authorisations amongst Member States		Maximum number of vessels present at any time
Norwegian waters and fishery zone around Jan Mayen	Herring, north of 62° 00' N	59	DK	25	51
			DE	5	
			FR	1	
			IE	8	
			NL	9	
			PL	1	
			SE	10	
	Demersal species, north of 62° 00' N	66	DE	16	41
			IE	1	
			ES	20	
			FR	18	
			PT	9	
			Unallocated	2	
	Industrial species, south of 62° 00' N	450	DK	450	141
Svalbard waters; international waters of 1 and 2b[1]	Fishery for snow crab with pots	20	EE	1	Not applicable
			ES	1	
			LV	11	
			LT	4	
			PL	3	

[1] The allocation of fishing opportunities available to the Union in the Spitzbergen and Bear Island zone is without prejudice to the rights and obligations deriving from the 1920 Treaty of Paris.'

Corrigendum to Commission Implementing Regulation (EU) 2022/250 of 21 February 2022 amending Implementing Regulation (EU) 2021/403 as regards the addition of a new model animal health/official certificate for the entry into Northern Ireland of ovine and caprine animals from Great Britain and amending Implementing Regulation (EU) 2021/404 as regards the list of third countries authorised for the entry into the Union of ovine and caprine animals

(Official Journal of the European Union L 41 of 22 February 2022)

On page 30, Annex II is replaced by the following:

'*ANNEX II*

In Part 1 of Annex II to Implementing Regulation (EU) 2021/404, the entry for the United Kingdom is replaced by the following:

'**GB** United Kingdom	GB-1	Bovine animals	Animals for further keeping (1) and intended for slaughter	BOV-X, BOV-Y		BRU, BTV, EBL, EVENTS		
		Ovine and caprine animals	Animals for further keeping (1) and intended for slaughter	OV/CAP-X, OV/CAP-X-NI (3) OV/CAP-Y		BRU, BTV, EVENTS		
		Porcine animals	Animals for further keeping (1) and intended for slaughter	SUI-X, SUI-Y		ADV		
		Camelid animals	Animals for further keeping (1)	CAM-CER		BTV		
		Cervid animals	Animals for further keeping (1)	CAM-CER		BTV		
		Other ungulates	Animals for further keeping (1)	RUM, RHINO, HIPPO		BTV (2)		
	GB-2	Bovine animals	Animals for further keeping (1) and intended for slaughter	BOV-X, BOV-Y		BRU, TB, BTV, EBL, EVENTS		
		Ovine and caprine animals	Animals for further keeping (1) and intended for slaughter	OV/CAP-X, OV/CAP-X-NI (3) OV/CAP-Y		BRU, BTV, EVENTS		
		Porcine animals	Animals for further keeping (1) and intended for slaughter	SUI-X, SUI-Y		ADV		

		Camelid animals	Animals for further keeping (1)	CAM-CER		BTV		
		Cervid animals	Animals for further keeping (1)	CAM-CER		BTV		
		Other ungulates	Animals for further keeping (1)	RUM, RHINO, HIPPO		BTV (2)		

(1) 'Animals for further keeping' means animals intended for establishments keeping live animals other than slaughterhouses.
(2) Only for listed species in accordance with Regulation (EU) 2018/1882 (OJ L 308, 4.12.2018, p. 21).
(3) OV/CAP-X-NI only applies for the entry into Northern Ireland of ovine and caprine animals from Great Britain until 31 December 2024 in accordance with Article 14, point (m), of Commission Implementing Regulation (EU) 2021/403."

Corrigendum to Commission Implementing Regulation (EU) 2023/1110 of 6 June 2023 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council

(Official Journal of the European Union L 147 of 7 June 2023)

On page 119, the Annex is replaced as follows:

'ANNEX

"ANNEX I

Food and feed of non-animal origin from certain third countries subject to a temporary increase of official controls at border control posts and control points

Row	Country of origin	Food and feed (intended use)	CN code [1]	TARIC sub-division	Hazard	Frequency of identity and physical checks (%)
1	**Azerbaijan (AZ)**	— Hazelnuts (*Corylus* sp.), in shell	0802 21 00		Aflatoxins	20
		— Hazelnuts (*Corylus* sp.), shelled	0802 22 00			
		— Mixtures of nuts or dried fruits containing hazelnuts	ex 0813 50 39;	**70**		
			ex 0813 50 91;	**70**		
			ex 0813 50 99	**70**		
		— Hazelnut paste	ex 2007 10 10;	**70**		
			ex 2007 10 99;	**40**		
			ex 2007 99 39;	**05; 06**		
			ex 2007 99 50;	**33**		
			ex 2007 99 97	**23**		
		— Hazelnuts, otherwise prepared or preserved, including mixtures	ex 2008 19 12;	**30**		
			ex 2008 19 19;	**30**		
			ex 2008 19 92;	**30**		
			ex 2008 19 95;	**20**		
			ex 2008 19 99;	**30**		
			ex 2008 97 12;	**15**		
			ex 2008 97 14;	**15**		
			ex 2008 97 16;	**15**		
			ex 2008 97 18;	**15**		
			ex 2008 97 32;	**15**		
			ex 2008 97 34;	**15**		

			ex 2008 97 36;	**15**		
			ex 2008 97 38;	**15**		
			ex 2008 97 51;	**15**		
			ex 2008 97 59;	**15**		
			ex 2008 97 72;	**15**		
			ex 2008 97 74;	**15**		
			ex 2008 97 76;	**15**		
			ex 2008 97 78;	**15**		
			ex 2008 97 92;	**15**		
			ex 2008 97 93;	**15**		
			ex 2008 97 94;	**15**		
			ex 2008 97 96;	**15**		
			ex 2008 97 97;	**15**		
			ex 2008 97 98;	**15**		
		— Flours, meals and powder of hazelnuts	ex 1106 30 90	**40**		
		— Hazelnut oil	ex 1515 90 99	**20**		
		(Food)				
2	**Brazil (BR)**	— Brazil nuts in shell	0801 21 00;		Aflatoxins	50
		— Mixtures of nuts or dried fruits containing Brazil nuts in shell ***(Food)***	ex 0813 50 31;	**20**		
			ex 0813 50 39;	**20**		
			ex 0813 50 91;	**20**		
			ex 0813 50 99	**20**		
		— Groundnuts (peanuts), in shell	1202 41 00		Pesticide residues ([3])	30
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved	2008 11 91;			
			2008 11 96;			
			2008 11 98			
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
		(***Food and feed***)	ex 2007 10 99	**50**		
			ex 2007 99 39	**07; 08**		

3	**Côte d'Ivoire (CI)**	Palm oil ***(Food)***	1511 10 90 1511 90 11 ex 1511 90 19 1511 90 99	**90**	Sudan dyes ([14])	20
4	**China (CN)**	— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled — Peanut butter — Groundnuts (peanuts), otherwise prepared or preserved — Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil — Groundnut flours and meals — Groundnuts paste (***Food and feed***)	1202 41 00 1202 42 00 2008 11 10 2008 11 91; 2008 11 96; 2008 11 98 2305 00 00 ex 1208 90 00 ex 2007 10 10 ex 2007 99 39	**20** **80** **50** **07; 08**	Aflatoxins	10
		Sweet peppers (*Capsicum annuum*) ***(Food – crushed or ground)***	ex 0904 22 00	**11**	*Salmonella*([4])	10
		Tea, whether or not flavoured ***(Food)***	0902		Pesticide residues([3])([5])	20
5	**Colombia (CO)**	Granadilla and passion fruit (*Passiflora ligularis* and *Passiflora edulis*) ***(Food)***	ex 0810 90 20	**30**	Pesticide residues ([3])	10
6	**Dominican Republic (DO)**	— Sweet peppers (*Capsicum annuum*) — Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	0709 60 10 0710 80 51 ex 0709 60 99 ex 0710 80 59	**20** **20**	Pesticide residues ([3]) ([17])	50

7	**Egypt (EG)**	— Sweet peppers (*Capsicum annuum*) — Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	0709 60 10 0710 80 51 ex 0709 60 99 ex 0710 80 59	 **20** **20**	Pesticide residues([3])([6])	30
		Oranges ***(Food – fresh or dried)***	0805 10		Pesticide residues ([3])	30
		Sugar apple (*Annona squamosa*) ***(Food – fresh or chilled)***	ex 0810 90 75	**20**	Pesticide residues ([3])	20
8	**Georgia (GE)**	— Hazelnuts (*Corylus* sp.), in shell	0802 21 00		Aflatoxins	30
		— Hazelnuts (*Corylus* sp.), shelled	0802 22 00			
		— Mixtures of nuts or dried fruits containing hazelnuts	ex 0813 50 39;	**70**		
			ex 0813 50 91;	**70**		
			ex 0813 50 99	**70**		
		— Hazelnut paste	ex 2007 10 10;	**70**		
			ex 2007 10 99;	**40**		
			ex 2007 99 39;	**05; 06**		
			ex 2007 99 50;	**33**		
			ex 2007 99 97	**23**		
		— Hazelnuts, otherwise prepared or preserved, including mixtures	ex 2008 19 12;	**30**		
			ex 2008 19 19;	**30**		
			ex 2008 19 92;	**30**		
			ex 2008 19 95;	**20**		
			ex 2008 19 99;	**30**		
			ex 2008 97 12;	**15**		
			ex 2008 97 14;	**15**		
			ex 2008 97 16;	**15**		
			ex 2008 97 18;	**15**		
			ex 2008 97 32;	**15**		
			ex 2008 97 34;	**15**		
			ex 2008 97 36;	**15**		
			ex 2008 97 38;	**15**		
			ex 2008 97 51;	**15**		
			ex 2008 97 59;	**15**		

			ex 2008 97 72;	**15**		
			ex 2008 97 74;	**15**		
			ex 2008 97 76;	**15**		
			ex 2008 97 78;	**15**		
			ex 2008 97 92;	**15**		
			ex 2008 97 93;	**15**		
			ex 2008 97 94;	**15**		
			ex 2008 97 96;	**15**		
			ex 2008 97 97;	**15**		
			ex 2008 97 98;	**15**		
		— Flours, meals and powder of hazelnuts	ex 1106 30 90	**40**		
		— Hazelnut oil	ex 1515 90 99	**20**		
		(Food)				
9	**The Gambia (GM)**	— Groundnuts (peanuts), in shell	1202 41 00		Aflatoxins	50
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved, including mixtures	2008 11 91;			
			2008 11 96;			
			2008 11 98;			
			ex 2008 19 12;	**40**		
			ex 2008 19 19;	**50**		
			ex 2008 19 92;	**40**		
			ex 2008 19 95;	**40**		
			ex 2008 19 99	**50**		
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
		(***Food and feed***)	ex 2007 10 99	**50**		
			ex 2007 99 39	**07; 08**		

10	**Israel (IL)** [16]	Basil (*Ocimum basilicum*) ***(Food)***	ex 1211 90 86	**20**	Pesticide residues ([3])	10
		Mint (*Mentha*) ***(Food)***	ex 1211 90 86	**30**	Pesticide residues ([3])	10
11	**India (IN)**	Betel leaves (*Piper betle L.*) ***(Food)***	ex 1404 90 00 ([10])	**10**	*Salmonella*([4])	30
		Okra	ex 0709 99 90;	**20**	Pesticide residues ([3]) ([7]) ([13])	20
		(Food – fresh, chilled or frozen)	ex 0710 80 95	**30**		
		Drumsticks (*Moringa oleifera*)	ex 0709 99 90	**10**	Pesticide residues ([3])	20
		(Food fresh, chilled or frozen)	ex 0710 80 95	**75**		
		Rice ***(Food)***	1006		Aflatoxins and Ochratoxin A	5
					Pesticide residues ([3])	10
		Yardlong beans (*Vigna unguiculata* ssp. *sesquipedalis*, *Vigna unguiculata* ssp. *unguiculata*) ***(Food – fresh, chilled or frozen vegetables)***	ex 0708 20 00; ex 0710 22 00	**10** **10**	Pesticide residues ([3])	20
		Guava (*Psidium guajava*) ***(Food)***	ex 0804 50 00	**30**	Pesticide residues ([3])	30
		Nutmeg (*Myristica fragrans*) ***(Food – dried spices)***	0908 11 00; 0908 12 00		Aflatoxins	30
		Peppers of the genus *Capsicum* (sweet or other than sweet) ***(Food – dried, roasted, crushed or ground)***	0904 21 10 ex 0904 22 00 ex 0904 21 90 ex 2005 99 10 ex 2005 99 80	 **11; 19** **20** **10; 90** **94**	Aflatoxins	10

		— Locust beans (carob) — Locust beans seeds, not decorticated, crushed or ground — Mucilages and thickeners, whether or not modified, derived from locust beans or locust bean seeds ***(Food and feed)***	1212 92 00 1212 99 41 1302 32 10		Pesticide residues ([13])	20
		Guar gum ***(Food and feed)***	ex 1302 32 90		Pesticide residues ([13])	20
					Pentachlorophenol and dioxins	50
		— Cumin seeds — Cumin seeds crushed or ground ***(Food)***	0909 31 00 0909 32 00		Pesticide residues ([3])	20
12	**Kenya (KE)**	Beans (*Vigna* spp., *Phaseolus* spp.) ***(Food – fresh or chilled)***	0708 20		Pesticide residues ([3])	10
		Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99; ex 0710 80 59	**20** **20**	Pesticide residues ([3])	20
13	**South Korea (KR)**	Food supplements containing botanicals ([17]) ***(Food)***	ex 1302 ex 2106		Pesticide residues ([13])	30
		Instant noodles containing spices/seasonings or sauces ***(Food)***	ex 1902 30 10	**30**	Pesticide residues ([13])	20
14	**Sri Lanka (LK)**	Gotukola (*Centella asiatica*) ***(Food)***	ex 1211 90 86	**60**	Pesticide residues ([3])	50
		Mukunuwenna (*Alternanthera sessilis*) ***(Food)***	ex 0709 99 90	**35**	Pesticide residues ([3])	50
15	**Madagascar (MG)**	Black eyed beans (*Vigna unguiculata*) ***(Food)***	0713 35 00		Pesticide residues ([3])	10
16	**Mexico (MX)**	Green papaya (*Carica papaya*) ***(Food – fresh and chilled)***	0807 20 00		Pesticide residues ([3])	20

17	**Malaysia (MY)**	Jackfruit (*Artocarpus heterophyllus*) ***(Food – fresh)***	ex 0810 90 20	**20**	Pesticide residues ([3])	50
18	**Pakistan (PK)**	Spice mixes ***(Food)***	0910 91 10; 0910 91 90		Aflatoxins	50
		Rice ***(Food)***	1006		Aflatoxins and Ochratoxin A	10
					Pesticide residues ([3])	5
		Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99; ex 0710 80 59	**20** **20**	Pesticide residues ([3])	20
19	**Rwanda (RW)**	Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99; ex 0710 80 59	**20** **20**	Pesticide residues ([3])	20
20	**Sudan (SD)**	— Groundnuts (peanuts), in shell	1202 41 00		Aflatoxins	50
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved, including mixtures	2008 11 91; 2008 11 96; 2008 11 98;			
			ex 2008 19 12;	**40**		
			ex 2008 19 19;	**50**		
			ex 2008 19 92;	**40**		
			ex 2008 19 95;	**40**		
			ex 2008 19 99	**50**		
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
			ex 2007 10 99	**50**		
		(***Food and feed***)	ex 2007 99 39	**07; 08**		

21	**Syria (SY)**	Tahini and halva from *Sesamum* seeds ***(Food)***	ex 1704 90 99 ex 1806 20 95 ex 1806 90 50 ex 1806 90 60 ex 2008 19 19 ex 2008 19 99	**12; 92** **13; 93** **10** **11; 91** **40** **40**	*Salmonella*([2])	20
22	**Thailand (TH)**	Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99; ex 0710 80 59	**20** **20**	Pesticide residues([3])([8])	30
23	**Türkiye (TR)**	Lemons (*Citrus limon, Citrus limonum*) (***Food – fresh, chilled or dried***)	0805 50 10		Pesticide residues ([3])	30
		Grapefruits ***(Food)***	0805 40 00		Pesticide residues ([3])	30
		Pomegranates ***(Food – fresh or chilled)***	ex 0810 90 75	**30**	Pesticide residues([3])([9])	30
		— Sweet peppers (*Capsicum annuum*) — Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	0709 60 10 0710 80 51 ex 0709 60 99 ex 0710 80 59	 **20** **20**	Pesticide residues ([3]) ([10])	20
		— Cumin seeds — Cumin seeds crushed or ground ***(Food)***	0909 31 00 0909 32 00		Pyrrolizidine alkaloids	20
		Dried oregano ***(Food)***	ex 1211 90 86	**40**	Pyrrolizidine alkaloids	20
		Sesamum seeds ***(Food)***	1207 40 90 ex 2008 19 19 ex 2008 19 99	 **40** **40**	*Salmonella*([2])	20
		— Locust beans (carob) — Locust beans seeds, not decorticated, crushed or ground — Mucilages and thickeners, whether or not modified, derived from locust beans or locust beans seeds ***(Food and feed)***	1212 92 00 1212 99 41 1302 32 10		Pesticide residues ([13])	20

24	**Uganda (UG)**	Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99;	**20**	Pesticide residues ([3])	50
			ex 0710 80 59	**20**	Pesticide residues ([13])	10
25	**United States (US)**	— Groundnuts (peanuts), in shell	1202 41 00		Aflatoxins	20
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved	2008 11 91; 2008 11 96; 2008 11 98			
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
		(***Food and feed***)	ex 2007 10 99	**50**		
			ex 2007 99 39	**07; 08**		
26	**Vietnam (VN)**	Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99;	**20**	Pesticide residues ([3]) ([12])	50
			ex 0710 80 59	**20**		
		Instant noodles containing spices/seasonings or sauces ***(Food)***	ex 1902 30 10	**30**	Pesticide residues ([13])	20

([1]) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.
([2]) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(a) of Annex III.
([3]) Residues of at least those pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) that can be analysed with multi-residue methods based on GC-MS and LC-MS (pesticides to be monitored in/on products of plant origin only).
([4]) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(b) of Annex III.
([5]) Residues of Tolfenpyrad.
([6]) Residues of Dicofol (sum of p, p' and o,p' isomers), Dinotefuran, Folpet, Prochloraz (sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz), Thiophanate-methyl and Triforine.
([7]) Residues of Diafenthiuron.
([8]) Residues of Formetanate (sum of formetanate and its salts expressed as formetanate (hydrochloride)), Prothiofos and Triforine.
([9]) Residues of Prochloraz.
([10]) Residues of Diafenthiuron, Formetanate (sum of formetanate and its salts expressed as formetanate (hydrochloride)) and Thiophanate-methyl.
([11]) Reference methods: EN 1988-1:1998, EN 1988-2:1998 or ISO 5522:1981.

([12]) Residues of Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram), Phenthoate and Quinalphos.

([13]) Residues of Ethylene Oxide (sum of ethylene oxide and 2-chloro-ethanol, expressed as ethylene oxide). In case of food additives, the applicable maximum residue level (MRL) is 0,1 mg/kg (limit of quantification (LOQ)). Prohibition of use of Ethylene Oxide provided for in Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

([14]) For the purposes of this Annex, 'Sudan dyes' refers to the following chemical substances: (i) Sudan I (CAS Number 842-07-9); (ii) Sudan II (CAS Number 3118-97-6); (iii) Sudan III (CAS Number 85-86-9); (iv) Scarlet Red or Sudan IV (CAS Number 85-83-6). Residues of Sudan dyes, using a method of analysis with an LOQ, shall be lower than 0,5 mg/kg).

([15]) Both finished products and raw materials containing any botanicals intended for the production of food supplements declared under CN codes mentioned in column 'CN code'.

([16]) Hereinafter understood as the State of Israel, excluding the territories under the administration of the State of Israel after 5 June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.

([17]) Residues of Acephate.

ANNEX II

Food and feed from certain third countries subject to special conditions for the entry into the Union due to contamination risk by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, microbiological contamination, Sudan dyes, Rhodamine B and plant toxins

1. **Food and feed of non-animal origin referred to in Article 1(1), point (b)(i)**

Row	Country of origin	Food and feed (intended use)	CN code (1)	TARIC sub-division	Hazard	Frequency of identity and physical checks (%)
1	**Bangladesh (BD)**	Foodstuffs containing or consisting of betel leaves (*Piper betle*) ***(Food)***	ex 1404 90 00 (8)	**10**	*Salmonella*(5)	50
2	**Bolivia (BO)**	— Groundnuts (peanuts), in shell	1202 41 00		Aflatoxins	50
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved, including mixtures	2008 11 91;			
			2008 11 96;			
			2008 11 98;			
			ex 2008 19 12;	**40**		
			ex 2008 19 19;	**50**		
			ex 2008 19 92;	**40**		
			ex 2008 19 95;	**40**		
			ex 2008 19 99	**50**		
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
		(***Food and feed***)	ex 2007 10 99	**50**		
			ex 2007 99 39	**07; 08**		
3	**Brazil (BR)**	Black pepper (*Piper nigrum*) ***(Food – neither crushed nor ground)***	ex 0904 11 00	**10**	*Salmonella*(2)	50

4	**China (CN)**	Xanthan gum ***(Food and feed)***	ex 3913 90 00	**40**	Pesticide residues ([9])	20
5	**Dominican Republic (DO)**	Aubergines (*Solanum melongena*) ***(Food – fresh or chilled)***	0709 30 00		Pesticide residues ([3])	50
		Yardlong beans (*Vigna unguiculata* ssp. *sesquipedalis*, *Vigna unguiculata* ssp. *unguiculata*) ***(Food – fresh, chilled or frozen)***	ex 0708 20 00 ex 0710 22 00	**10** **10**	Pesticide residues ([3]) ([11])	30
6	**Egypt (EG)**	— Groundnuts (peanuts), in shell	1202 41 00		Aflatoxins	30
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved, including mixtures	2008 11 91; 2008 11 96; 2008 11 98; ex 2008 19 12; ex 2008 19 19; ex 2008 19 92; ex 2008 19 95; ex 2008 19 99	 **40** **50** **40** **40** **50**		
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
		(***Food and feed***)	ex 2007 10 99 ex 2007 99 39	**50** **07; 08**		

7	**Ethiopia (ET)**	— Pepper of the genus *Piper*; dried or crushed or ground fruit of the genus *Capsicum* or of the genus *Pimenta* — Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices ***(Food – dried spices)***	0904 0910		Aflatoxins	50
		Sesamum seeds ***(Food)***	1207 40 90 ex 2008 19 19 ex 2008 19 99	**40** **40**	*Salmonella*([5])	50
8	**Ghana (GH)**	— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled — Peanut butter — Groundnuts (peanuts), otherwise prepared or preserved, including mixtures — Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil — Groundnut flours and meals — Groundnuts paste (***Food and feed***)	1202 41 00 1202 42 00 2008 11 10 2008 11 91; 2008 11 96; 2008 11 98; ex 2008 19 12; ex 2008 19 19; ex 2008 19 92; ex 2008 19 95; ex 2008 19 99 2305 00 00 ex 1208 90 00 ex 2007 10 10 ex 2007 10 99 ex 2007 99 39	**40** **50** **40** **40** **50** **20** **80** **50** **07; 08**	Aflatoxins	50
		Palm oil ***(Food)***	1511 10 90 1511 90 11 ex 1511 90 19 1511 90 99	**90**	Sudan dyes ([10])	50

9	**Indonesia (ID)**	Nutmeg (*Myristica fragrans*) ***(Food – dried spices)***	0908 11 00; 0908 12 00		Aflatoxins	30
10	**India (IN)**	Curry leaves (*Bergera/Murraya koenigii*) ***(Food – fresh, chilled, frozen or dried)***	ex 1211 90 86	**10**	Pesticide residues ([3]) ([12])	50
		— Groundnuts (peanuts), in shell	1202 41 00		Aflatoxins	50
		— Groundnuts (peanuts), shelled	1202 42 00			
		— Peanut butter	2008 11 10			
		— Groundnuts (peanuts), otherwise prepared or preserved, including mixtures	2008 11 91;			
			2008 11 96;			
			2008 11 98;			
			ex 2008 19 12;	**40**		
			ex 2008 19 19;	**50**		
			ex 2008 19 92;	**40**		
			ex 2008 19 95;	**40**		
			ex 2008 19 99	**50**		
		— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	2305 00 00			
		— Groundnut flours and meals	ex 1208 90 00	**20**		
		— Groundnuts paste	ex 2007 10 10	**80**		
		(***Food and feed***)	ex 2007 10 99	**50**		
			ex 2007 99 39	**07; 08**		
		Peppers of the genus *Capsicum* (other than sweet) ***(Food – fresh, chilled or frozen)***	ex 0709 60 99;	**20**	Pesticide residues([3])([4])	20
			ex 0710 80 59	**20**		
		Sesamum seeds (***Food***)	1207 40 90		*Salmonella*([5])	20
			ex 2008 19 19	**40**		
			ex 2008 19 99	**40**		
		Sesamum seeds (***Food and feed***)	1207 40 90		Pesticide residues ([9])	50
			ex 2008 19 19	**40**		
			ex 2008 19 99	**40**		

		Mixtures of food additives containing locust bean gum or guar gum ***(Food)***	ex 2106 90 92 ex 2106 90 98 ex 3824 99 93 ex 3824 99 96		Pesticide residues ([9])	20
		Pepper of the genus *Piper*; dried or crushed or ground fruit of the genus *Capsicum* or of the genus *Pimenta* ***(Food – dried spices)***	0904		Pesticide residues ([9])	20
		Vanilla ***(Food – dried spices)***	0905		Pesticide residues ([9])	20
		Cinnamon and cinnamon-tree flowers ***(Food – dried spices)***	0906		Pesticide residues ([9])	20
		Cloves (whole fruit, cloves and stems) ***(Food – dried spices)***	0907		Pesticide residues ([9])	20
		Nutmeg, mace and cardamoms ***(Food – dried spices)***	0908		Pesticide residues ([9])	20
		Seeds of anise, badian, fennel, coriander, cumin or caraway, juniper berries ***(Food – dried spices)***	0909		Pesticide residues ([9])	20
		Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices ***(Food – dried spices)***	0910		Pesticide residues ([9])	20
		Sauces and preparations thereof; mixed condiments and mixed seasonings; mustard flours and meals and prepared mustard ***(Food)***	2103		Pesticide residues ([9])	20
		Calcium carbonate ***(Food and feed)***	ex 2106 90 92 ex 2106 90 98 ex 2530 90 70 2836 50 00	**55** **60** **10**	Pesticide residues ([9])	30
		Food supplements containing botanicals ([13]) ***(Food)***	ex 1302 ex 2106		Pesticide residues ([9])	20

		— Pistachios, in shell	0802 51 00			
		— Pistachios, shelled	0802 52 00			
		— Mixtures of nuts or dried fruits containing pistachios	ex 0813 50 39;	**60**		
			ex 0813 50 91;	**60**		
			ex 0813 50 99	**60**		
		— Pistachio paste	ex 2007 10 10;	**60**		
			ex 2007 10 99;	**30**		
			ex 2007 99 39;	**03; 04**		
			ex 2007 99 50;	**32**		
			ex 2007 99 97	**22**		
11	**Iran (IR)**	— Pistachios, prepared or preserved, including mixtures	ex 2008 19 13;	**20**	Aflatoxins	50
			ex 2008 19 93;	**20**		
			ex 2008 97 12;	**19**		
			ex 2008 97 14;	**19**		
			ex 2008 97 16;	**19**		
			ex 2008 97 18;	**19**		
			ex 2008 97 32;	**19**		
			ex 2008 97 34;	**19**		
			ex 2008 97 36;	**19**		
			ex 2008 97 38;	**19**		
			ex 2008 97 51;	**19**		
			ex 2008 97 59;	**19**		
			ex 2008 97 72;	**19**		
			ex 2008 97 74;	**19**		
			ex 2008 97 76;	**19**		
			ex 2008 97 78;	**19**		
			ex 2008 97 92;	**19**		
			ex 2008 97 93;	**19**		
			ex 2008 97 94;	**19**		
			ex 2008 97 96;	**19**		
			ex 2008 97 97;	**19**		
			ex 2008 97 98	**19**		
		— Flours, meals and powder of pistachios	ex 1106 30 90	**50**		
		(Food)				

12	**Lebanon (LB)**	Turnips (*Brassica rapa* ssp. *rapa*) ***(Food – prepared or preserved by vinegar or acetic acid)***	ex 2001 90 97	**11; 19**	Rhodamine B ([14])	50
		Turnips (*Brassica rapa* ssp. *rapa*) ***(Food – prepared or preserved by brine or citric acid, not frozen)***	ex 2005 99 80	**93**	Rhodamine B ([14])	50
13	**Sri Lanka (LK)**	Peppers of the genus *Capsicum* (sweet or other than sweet) ***(Food – dried, roasted, crushed or ground)***	0904 21 10 ex 0904 21 90 ex 0904 22 00 ex 2005 99 10 ex 2005 99 80	 **20** **11; 19** **10; 90** **94**	Aflatoxins	50
14	**Malaysia (MY)**	Mixtures of food additives containing locust bean gum ***(Food)***	ex 2106 90 92 ex 2106 90 98 ex 3824 99 93 ex 3824 99 96		Pesticide residues ([9])	20
15	**Nigeria (NG)**	*Sesamum* seeds ***(Food)***	1207 40 90 ex 2008 19 19 ex 2008 19 99	 **40** **40**	*Salmonella*([5])	50
16	**Sudan (SD)**	*Sesamum* seeds ***(Food)***	1207 40 90 ex 2008 19 19 ex 2008 19 99	 **40** **40**	*Salmonella*([5])	50
		— Dried figs — Mixtures of nuts or dried fruits containing figs — Dried fig paste — Dried figs, prepared or preserved, including mixtures	0804 20 90 ex 0813 50 99 ex 2007 10 10; ex 2007 10 99; ex 2007 99 39; ex 2007 99 50; ex 2007 99 97 ex 2008 97 12; ex 2008 97 14; ex 2008 97 16; ex 2008 97 18; ex 2008 97 32; ex 2008 97 34; ex 2008 97 36; ex 2008 97 38;	 **50** **50** **20** **01; 02** **31** **21** **11** **11** **11** **11** **11** **11** **11** **11**		

17	**Türkiye (TR)**		ex 2008 97 51;	**11**	Aflatoxins	30
			ex 2008 97 59;	**11**		
			ex 2008 97 72;	**11**		
			ex 2008 97 74;	**11**		
			ex 2008 97 76;	**11**		
			ex 2008 97 78;	**11**		
			ex 2008 97 92;	**11**		
			ex 2008 97 93;	**11**		
			ex 2008 97 94;	**11**		
			ex 2008 97 96;	**11**		
			ex 2008 97 97;	**11**		
			ex 2008 97 98;	**11**		
			ex 2008 99 28;	**10**		
			ex 2008 99 34;	**10**		
			ex 2008 99 37;	**10**		
			ex 2008 99 40;	**10**		
			ex 2008 99 49;	**60**		
			ex 2008 99 67;	**95**		
			ex 2008 99 99	**60**		
		— Flours, meals and powder of dried figs	ex 1106 30 90	**60**		
		(Food)				
		— Pistachios, in shell	0802 51 00			
		— Pistachios, shelled	0802 52 00			
		— Mixtures of nuts or dried fruits containing pistachios	ex 0813 50 39;	**60**		
			ex 0813 50 91;	**60**		
			ex 0813 50 99	**60**		
		— Pistachio paste	ex 2007 10 10;	**60**		
			ex 2007 10 99;	**30**		
			ex 2007 99 39;	**03; 04**		
			ex 2007 99 50;	**32**		
			ex 2007 99 97	**22**		
		— Pistachios, otherwise prepared or preserved, including mixtures	ex 2008 19 13;	**20**	Aflatoxins	50
			ex 2008 19 93;	**20**		
			ex 2008 97 12;	**19**		
			ex 2008 97 14;	**19**		

			ex 2008 97 16;	**19**		
			ex 2008 97 18;	**19**		
			ex 2008 97 32;	**19**		
			ex 2008 97 34;	**19**		
			ex 2008 97 36;	**19**		
			ex 2008 97 38;	**19**		
			ex 2008 97 51;	**19**		
			ex 2008 97 59;	**19**		
			ex 2008 97 72;	**19**		
			ex 2008 97 74;	**19**		
			ex 2008 97 76;	**19**		
			ex 2008 97 78;	**19**		
			ex 2008 97 92;	**19**		
			ex 2008 97 93;	**19**		
			ex 2008 97 94;	**19**		
			ex 2008 97 96;	**19**		
			ex 2008 97 97;	**19**		
			ex 2008 97 98	**19**		
		— Flours, meals and powder of pistachios ***(Food)***	ex 1106 30 90	**50**		
		Vine leaves ***(Food)***	ex 2008 99 99	**11; 19**	Pesticide residues([3])([6])	50
		Mandarins (including tangerines and satsumas); clementines, wilkings and similar citrus hybrids ***(Food – fresh or dried)***	0805 21; 0805 22 00; 0805 29 00		Pesticide residues ([3])	20
		Oranges ***(Food – fresh or dried)***	0805 10		Pesticide residues ([3])	30
		Mixtures of food additives containing locust bean gum ***(Food)***	ex 2106 90 92 ex 2106 90 98 ex 3824 99 93 ex 3824 99 96		Pesticide residues ([9])	20
		Unprocessed whole, ground, milled, cracked, chopped apricot kernels intended to be placed on the market for the final consumer ([15]) ([16]) ***(Food)***	ex 1212 99 95	**20**	Cyanide	50

18	**Uganda (UG)**	*Sesamum* seeds ***(Food)***	1207 40 90 ex 2008 19 19 ex 2008 19 99	 **40** **40**	*Salmonella*([5])	20
20	**United States (US)**	Vanilla extract ***(Food)***	1302 19 05		Pesticide residues ([9])	20
21	**Vietnam (VN)**	Okra ***(Food – fresh, chilled or frozen)***	ex 0709 99 90; ex 0710 80 95	**20** **30**	Pesticide residues([3])([7])	50
		Pitahaya (dragon fruit) ***(Food – fresh or chilled)***	ex 0810 90 20	**10**	Pesticide residues([3])([7])	20

([1]) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.

([2]) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(b) of Annex III.

([3]) Residues of at least those pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) that can be analysed with multi-residue methods based on GC-MS and LC-MS (pesticides to be monitored in/on products of plant origin only).

([4]) Residues of Carbofuran.

([5]) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(a) of Annex III.

([6]) Residues of Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram) and Metrafenone.

([7]) Residues of Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram), Phenthoate and Quinalphos.

([8]) Foodstuffs containing or consisting of betel leaves (Piper betle) including, but not limited to, those declared under CN code 1404 90 00.

([9]) Residues of Ethylene Oxide (sum of ethylene oxide and 2-chloro-ethanol, expressed as ethylene oxide). In case of food additives, the applicable MRL is 0,1 mg/kg (LOQ). Prohibition of use of Ethylene Oxide provided for in Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

([10]) For the purposes of this Annex, 'Sudan dyes' refers to the following chemical substances: (i) Sudan I (CAS Number 842-07-9); (ii) Sudan II (CAS Number 3118-97-6); (iii) Sudan III (CAS Number 85-86-9); (iv) Scarlet Red or Sudan IV (CAS Number 85-83-6). Residues of Sudan dyes, using a method of analysis with an LOQ, shall be lower than 0,5 mg/kg.

([11]) Residues of Amitraz (amitraz including the metabolites containing the 2,4-dimethylaniline moiety expressed as amitraz), Diafenthiuron, Dicofol (sum of p, p' and o,p' isomers) and Dithiocarbamates (dithiocarbamates expressed as CS2, including maneb, mancozeb, metiram, propineb, thiram and ziram).

([12]) Residues of Acephate.

([13]) Both finished products and raw materials containing any botanicals intended for the production of food supplements declared under CN codes mentioned in column 'CN code'.

([14]) For purpose of this Annex, residues of Rhodamine B, using a method of analysis with an LOQ, shall be lower than 0,1 mg/kg.

([15]) 'Unprocessed products' as defined in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

([16]) 'Placing on the market' and 'final consumer' as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

2. **Food referred to in Article 1(1), point (b)(ii)**

Row	Food consisting of two or more ingredients, containing any of the individual products listed in the table in point 1 due to risk of contamination by aflatoxins in a quantity above 20 % of either a single product or as the sum of products listed	
	CN code [1]	**Description** [2]
1	**ex 1704 90**	Sugar confectionery (including white chocolate), not containing cocoa, other than chewing gum, whether or not sugar-coated
2	**ex 1806**	Chocolate and other food preparations containing cocoa
3	**ex 1905**	Bread, pastry, cakes, biscuits and other bakers' wares, whether or not containing cocoa, communion wafers, empty cachets of a kind suitable for pharmaceutical use, sealing wafers, rice paper and similar products

[1] Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.
[2] The description of the goods is as laid down in the description column of the CN in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

3. **Food and feed of non-animal origin referred to in Article 1(1), point (b)(iii)**

Row	Country of origin	Country from where consign-ments are dispatched to the Union	Food and feed (intended use)	CN code [1]	TARIC sub-division	Hazard	Frequency of identity and physical checks (%)
1	**United States (US)**	**Türkiye (TR)** [2]	— Pistachios, in shell	0802 51 00		Aflatox-ins	50
			— Pistachios, shelled	0802 52 00			
			— Mixtures of nuts or dried fruits containing pista-chios	ex 0813 50 39;	**60**		
				ex 0813 50 91;	**60**		
				ex 0813 50 99	**60**		
			— Pistachio paste	ex 2007 10 10;	**60**		
				ex 2007 10 99;	**30**		
				ex 2007 99 39;	**03; 04**		
				ex 2007 99 50;	**32**		
				ex 2007 99 97	**22**		
			— Pistachios, otherwise prepared or preserved, including mixtures	ex 2008 19 13;	**20**		
				ex 2008 19 93;	**20**		
				ex 2008 97 12;	**19**		
				ex 2008 97 14;	**19**		
				ex 2008 97 16;	**19**		
				ex 2008 97 18;	**19**		

				ex 2008 97 32;	**19**		
				ex 2008 97 34;	**19**		
				ex 2008 97 36;	**19**		
				ex 2008 97 38;	**19**		
				ex 2008 97 51;	**19**		
				ex 2008 97 59;	**19**		
				ex 2008 97 72;	**19**		
				ex 2008 97 74;	**19**		
				ex 2008 97 76;	**19**		
				ex 2008 97 78;	**19**		
				ex 2008 97 92;	**19**		
				ex 2008 97 93;	**19**		
				ex 2008 97 94;	**19**		
				ex 2008 97 96;	**19**		
				ex 2008 97 97;	**19**		
				ex 2008 97 98	**19**		
			— Flours, meals and powder of pistachios ***(Food)***	ex 1106 30 90	**50**		

([1]) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.
([2]) In accordance with Articles 10 and 11, consignments shall be accompanied by the results of sampling and analyses performed on those consignments and by the official certificate issued by the country from where consignments are dispatched to the Union.'"

Corrigendum to Commission Implementing Regulation (EU) 2022/1998 of 20 September 2022 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff

(Official Journal of the European Union L 282 of 31 October 2022)

On page 138, in the Annex, in the text replacing Annex I to Council Regulation (EEC) No 2658/87, Chapter 15, subheading 1518 00 95:

for:	'Inedible mixtures or preparations of animal or of animal, vegetable or microbial fats and oils and their fractions',
read:	'Inedible mixtures or preparations of animal, or of animal and vegetable or microbial fats and oils and their fractions'.

Corrigendum to Commission Implementing Regulation (EU) 2023/591 of 16 March 2023 accepting a request for new exporting producer treatment with regard to the definitive anti-dumping measures imposed on imports of electric bicycles originating in the People's Republic of China and amending Implementing Regulation (EU) 2019/73

(Official Journal of the European Union L 79 of 17 March 2023)

On page 51, in Article 1:

for:

'Company	TARIC additional code
Zhejiang Jollo Technology Co., Ltd	899A'

read:

'Company	Province	TARIC additional code
Zhejiang Jollo Technology Co., Ltd	Zhejiang	899A'

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