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⁽¹⁾ Text with EEA relevance.

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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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/196

of 25 November 2022

amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances

(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 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors ⁽¹⁾, and in particular Article 15 thereof,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors ⁽²⁾, and in particular Article 30a thereof,

Whereas:

- (1) Regulation (EC) No 273/2004 lays down measures for monitoring trade in drug precursors within the Union, while Regulation (EC) No 111/2005 governs trade in drug precursors between the Union and third countries. Annex I to Regulation (EC) No 273/2004 and the Annex to Regulation (EC) No 111/2005 each contain a list of scheduled substances, which are subject to a number of harmonised control and monitoring measures provided for by those Regulations.
- (2) By means of Decisions 65/4, 65/5 and 65/6 of the Commission on Narcotic Drugs of the United Nations, taken at its sixty-fifth session from 14 to 18 March 2022, the substances N-phenylpiperidin-4-amine (4-AP), tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP) and N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl) have been added to Table I of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances done at Vienna on 19 December 1988 and approved by Council Decision 90/611/EEC ⁽³⁾ ('the 1988 UN Convention').
- (3) 4-AP is a substitute chemical for N-phenethyl-4-piperidone (NPP) to synthesize 4-anilino-N-phenethylpiperidine (ANPP), which itself is an immediate precursor for the manufacture of fentanyl and some of its analogues.
- (4) 1-boc-4-AP is a chemically protected derivative of 4-AP, which could be converted to 4-AP, norfentanyl or a number of norfentanyl analogues.
- (5) Norfentanyl is an immediate precursor of fentanyl and a number of fentanyl analogues.

⁽¹⁾ OJ L 47, 18.2.2004, p. 1.

⁽²⁾ OJ L 22, 26.1.2005, p. 1.

⁽³⁾ Council Decision 90/611/EEC of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (OJ L 326, 24.11.1990, p. 56).

- (6) NPP and ANPP are already scheduled substances in Regulations (EC) No 273/2004 and (EC) No 111/2005. Fentanyl and fentanyl analogues are very potent narcotic drugs, typically 10 to 100 times stronger than heroin. Their high potency continues to result in overdose deaths in users.
- (7) National competent authorities have indicated the seizure of diethyl (phenylacetyl) propanedioate (DEPAPD) and ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate).
- (8) DEPAPD is used to produce 1-Phenyl-2-propanone (P-2-P), also known as benzyl methyl ketone (BMK). BMK is a precursor of amphetamine and methamphetamine, two of the most common drugs illicitly produced in the Union. Both have severe consequences for human health.
- (9) PMK ethyl glycidate is a precursor of 3,4-Methylenedioxyphenylpropan-2-one (PMK), which, in turn, is used to produce 3,4-methylenedioxymethamphetamine (MDMA), commonly known as 'ecstasy'.
- (10) BMK, as well as some of its other pre-precursors which are very similar to DEPAPD (such as methyl *alpha*-phenylacetate (MAPA) or *alpha*-phenylacetamide (APAA)), and PMK are already scheduled substances in Regulations (EC) No 273/2004 and (EC) No 111/2005.
- (11) Amphetamine, methamphetamine and MDMA are some of the most common drugs illicitly produced in the Union. They have severe consequences for human health and are causing serious social and public health problems in some regions of the Union.
- (12) 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate have been designed by criminal organisations to avoid the strict controls of scheduled substances provided for by Regulations (EC) No 273/2004 and (EC) No 111/2005. Therefore, 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate should also be scheduled at Union level to reinforce the control and monitoring of those substances.
- (13) The scheduled substances listed in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 are divided into categories for which different measures apply, so as to achieve a proportionate balance between the level of threat posed by each specific substance and the burden on licit trade. The strictest control and monitoring measures apply to substances of Category 1.
- (14) 4-AP, 1-boc-4-AP and norfentanyl, should be scheduled as Category 1 substances because they can be easily transformed to support the production of fentanyl and its analogues and pose a significant threat to social and public health in the Union.
- (15) DEPAPD and PMK ethyl glycidate should be scheduled as Category 1 substances because they can be easily transformed to support the production of methamphetamine, amphetamine and MDMA and pose a significant threat to social and public health in the Union.
- (16) 4-AP, 1-boc-4-AP, norfentanyl, DEPAPD and PMK ethyl glycidate have no known licit production, trade or use, except for research purposes. Therefore, including those substances under Category 1 in Annex I to Regulation (EC) No 273/2004 and under Category 1 in the Annex to Regulation (EC) No 111/2005 would be an adequate response to avoid their use in the illicit manufacture of narcotic drugs and, at the same time, would not entail any significant extra administrative burden for economic operators and competent authorities in the Union.
- (17) Regulations (EC) No 273/2004 and (EC) No 111/2005 should therefore be amended accordingly.
- (18) The Commission Implementing Regulation (EU) 2021/1832 of 12 October 2021 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (*) reclassified ANPP and NPP. Regulations (EC) No 273/2004 and (EC) No 111/2005 should therefore be amended and corrected accordingly.

(*) OJ L 385, 29.10.2021, p. 1.

- (19) Regulations (EC) No 273/2004 and (EC) No 111/2005 jointly implement the drug precursors related provisions of the 1988 UN Convention. In view of the close substantive link between the empowerments contained in those Regulations, it is appropriate to adopt the amendments by way of one single delegated act,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 273/2004

Annex I to Regulation (EC) No 273/2004 is amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EC) No 111/2005

The Annex to Regulation (EC) No 111/2005 is amended in accordance with Annex II to this Regulation.

Article 3

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, 25 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

In Regulation (EC) No 273/2004, in Annex I, in the table for Category 1,

- (1) the following entries are inserted in the list of substances in the appropriate place sequentially according to the CN Code:

Substance	CN designation (if different)	CN Code	CAS No
'diethyl (phenylacetyl) propanedioate (DEPAPD)		2918 30 00	20320-59-6'
'ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate)		2932 99 00	28578-16-7'
'N-phenylpiperidin-4-amine (4-AP)		2933 39 99	23056-29-3'
'tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP)		2933 39 99	125541-22-2'
'N-phenyl-N-(piperidin-4-yl) propanamide (norfentanyl)		2933 39 99	1609-66-1'

- (2) for:

Substance	CN designation (if different)	CN Code	CAS No
'4-anilino-N-phenethylpiperidine (ANPP)		2933 39 99	21409-26-7'
'N-phenethyl-4-piperidone (NPP)		2933 39 99	39742-60-4'

read:

Substance	CN designation (if different)	CN Code	CAS No
'N-phenyl-1-(2-phenylethyl)piperidin-4-amine	4-anilino-N-phenethylpiperidine (ANPP)	2933 36 00	21409-26-7'
'1-(2-phenylethyl)piperidin-4-one	N-phenethyl-4-piperidone (NPP)	2933 37 00	39742-60-4'

ANNEX II

In Regulation (EC) No 111/2005, in the Annex, in the table for Category 1,

- (1) the following entries are inserted in the list of substances in the appropriate place sequentially according to the CN Code:

Substance	CN designation (if different)	CN Code	CAS No
'diethyl (phenylacetyl) propanedioate (DEPAPD)		2918 30 00	20320-59-6'
'ethyl 3-(2H-1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (PMK ethyl glycidate)		2932 99 00	28578-16-7'
'N-phenylpiperidin-4-amine (4-AP)		2933 39 99	23056-29-3'
'tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP)		2933 39 99	125541-22-2'
'N-phenyl-N-(piperidin-4-yl) propanamide (norfentanyl)		2933 39 99	1609-66-1'

- (2) for:

Substance	CN designation (if different)	CN Code	CAS No
'4-anilino-N-phenethylpiperidine (ANPP)		2933 39 99	21409-26-7'
'N-phenethyl-4-piperidone (NPP)		2933 39 99	39742-60-4'

read:

Substance	CN designation (if different)	CN Code	CAS No
'N-phenyl-1-(2-phenylethyl)piperidin-4-amine	4-anilino-N-phenethylpiperidine (ANPP)	2933 36 00	21409-26-7'
'1-(2-phenylethyl)piperidin-4-one	N-phenethyl-4-piperidone (NPP)	2933 37 00	39742-60-4'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/197**of 24 January 2023****approving non-minor amendments to the product specification for a name entered in the register of protected designations of origin and protected geographical indications ('Steirisches Kürbiskernöl' (PGI))**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Austria's application for the approval of amendments to the specification for the protected geographical indication 'Steirisches Kürbiskernöl', registered under Commission Regulation (EC) No 1263/96 ⁽²⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ⁽³⁾ as required by Article 50(2)(a) of that Regulation.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

*Article 1*The amendments to the product specification published in the *Official Journal of the European Union* regarding the name 'Steirisches Kürbiskernöl' (PGI) are hereby approved.*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, 24 January 2023.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 1263/96 of 1 July 1996 supplementing the Annex to Regulation (EC) No 1107/96 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Regulation (EEC) No 2081/92 (OJ L 163, 2.7.1996, p. 19).

⁽³⁾ OJ C 327, 30.8.2022, p. 5.

COMMISSION REGULATION (EU) 2023/198**of 30 January 2023****amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin in or on certain products****(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 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 ⁽¹⁾, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For abamectin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) During the review of those MRLs in accordance with Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority ('the Authority'), identified in its reasoned opinion ⁽²⁾ some information as unavailable for certain products. The available information was sufficient for the Authority to propose MRLs that are safe for consumers and the data gaps were indicated in Annex II of that Regulation specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.
- (3) The applicant submitted the missing data together with a request based on Article 6 of Regulation (EC) No 396/2005 to modify the existing MRLs for abamectin in certain products.
- (4) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (5) The Authority assessed the application and the evaluation report, examining in particular risks to consumers and, where relevant, to animals.
- (6) On 23 January 2020, the Authority published a reasoned opinion on the evaluation of the confirmatory data submitted following the MRL review under Article 12 of Regulation (EC) No 396/2005 and on the request to modify the existing maximum residue levels for abamectin in various commodities ⁽³⁾.
- (7) For almonds, hazelnuts/cobnuts, walnuts, currants (black, red and white), gooseberries (green, red and yellow), papayas and witloofs/Belgian endives information concerning residue trials was not submitted by the applicant. The Authority concluded that the data gap was thus not sufficiently addressed and that risk managers may consider setting or keeping those MRLs at the limit of determination (LOD). Therefore, for these products, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the LOD. It is therefore appropriate to amend the Annex II and to delete the reference concerning additional information from that Annex.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

⁽²⁾ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(9):3823.

⁽³⁾ European Food Safety Authority; Reasoned opinion on evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for abamectin in various commodities. EFSA Journal 2020;18(1):5989.

- (8) For quinces, medlars, loquats/Japanese medlars, the applicant proposed to derive an MRL based on an alternative Good Agricultural Practices (GAP). This use and the residue trials were already assessed in a previous reasoned opinion ⁽⁴⁾. The Authority concluded that the residue data were sufficient to support lower MRL proposals for those products. Therefore, for those products, MRLs in Annex II to Regulation (EC) No 396/2005 should be set at the level identified by the Authority.
- (9) For celery leaves, beans with pods and peas with pods, Authority concluded that residue data were sufficient to support the MRL for those products. Therefore, for these products, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level requested by the applicant.
- (10) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for abamectin used in the United States on certain products.
- (11) The applicant states that the authorised uses of abamectin on such crops in that country lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (12) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (13) The Authority assessed the applications and the evaluation report, examining in particular risks to consumers and, where relevant, to animals.
- (14) On 10 July 2020, the Authority published a reasoned opinion on setting of import tolerances for abamectin in various crops ⁽⁵⁾.
- (15) As regards modifications to MRLs requested by the applicant for avocados, cresses and other sprouts and shoot, land cresses, Roman rocket/rucola, baby leaf crops (including brassica species), other lettuces and salad plants, purslanes, Florence fennels and cotton seeds, the Authority concluded, that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of the substance. Neither the lifetime exposure to the substance via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded. Therefore, for these products, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level requested by the applicant.
- (16) In the context of the procedure for the renewal of the approval of the active substance abamectin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽⁶⁾, the Authority published a conclusion on the peer review of the risk assessment ⁽⁷⁾ of that active substance. The Authority proposed, based on the developmental neurotoxicity studies, that a lower acceptable daily intake (ADI) and acute reference dose (ARfD) should be established.
- (17) On 3 February 2021 and in accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion assessing the risks on certain existing MRLs for abamectin that may pose to consumers in light of the lower ADI and ARfD.

⁽⁴⁾ European Food Safety Authority; Reasoned opinion on the modification of the existing MRLs for abamectin in various crops. EFSA Journal 2015;13(7):4189.

⁽⁵⁾ European Food Safety Authority; Reasoned opinion on setting of import tolerances for abamectin in various crops. EFSA Journal 2020;18(7):6173.

⁽⁶⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309 24.11.2009, p. 1).

⁽⁷⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance abamectin. EFSA Journal 2020;18(8):6227.

- (18) On 6 October 2021, the Authority published a reasoned opinion on the focussed assessment of certain existing maximum residues levels of concern for abamectin ⁽⁸⁾.
- (19) For apples, pears and escaroles/broad-leaved endives, the Authority identified unacceptable risks concerning the current MRLs. Member States were consulted and requested to report potential fall-back GAPs which would lead to safe MRLs for consumers. For apples and pears, a fall-back GAP could not be proposed by the Member States. Supporting data was not available for the GAP reported for escaroles/broad-leaved endives. Therefore, no MRL could be derived for apples, pears and escaroles/broad-leaved endives. Therefore, for these products, it is appropriate to set the MRLs in Annex II to Regulation (EC) No 396/2005 at the LOD.
- (20) For strawberries, tomatoes, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, chervil and parsley, the Authority identified unacceptable risks concerning the current MRLs. Member States were consulted and requested to report potential fall-back GAPs which would lead to safe MRLs for consumers. Member States identified such GAPs for strawberries, tomatoes, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, chervil and parsley. The Authority therefore recommended lowering the MRLs for those products. Therefore, for these products, MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (21) For sweet peppers/bell peppers, the Authority identified unacceptable risks for consumers with the current MRLs. Member States were consulted and requested to report potential fall-back GAPs which would lead to safe MRLs for consumers. The Authority concluded that although Member States identified a fall-back GAP for sweet peppers/bell peppers, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for sweet peppers/bell peppers should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. This MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (22) The Commission consulted the European Union reference laboratories for residues of pesticides on the need to adapt certain LODs. For abamectin, those laboratories proposed product specific LODs that are analytically feasible.
- (23) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (24) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (25) In order to allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced in the Union or imported into the Union before the modified MRLs start applying and for which information shows that a high level of consumer protection is maintained. This is the case for all products except for apples, pears, strawberries, tomatoes, sweet peppers/bell peppers, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, chervil and parsley.
- (26) A reasonable period should be allowed to elapse before the modified MRLs become applicable, in order to permit Member States, third countries and food business operators to adapt themselves to meet the new requirements which will result from the modification of the MRLs.
- (27) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

⁽⁸⁾ European Food Safety Authority; Focused assessment of certain existing MRLs of concern for abamectin. EFSA Journal 2021;19(10):6842.

Article 2

As regards active substance abamectin in and on all products except apples, pears, strawberries, tomatoes, sweet peppers/bell peppers, cucumbers, courgettes, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, chervil and parsley, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 20 August 2023.

Article 3

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

It shall apply from 20 August 2023.

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

Done at Brussels, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II to Regulation (EC) No 396/2005, the column for abamectin is replaced by the following:

"Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (*)	Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (R) (F)
(1)	(2)	(3)
010000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0,04
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	0,01 (*)
0120010	Almonds	
0120020	Brazil nuts	
0120030	Cashew nuts	
0120040	Chestnuts	
0120050	Coconuts	
0120060	Hazelnuts/cobnuts	
0120070	Macadamias	
0120080	Pecans	
0120090	Pine nut kernels	
0120100	Pistachios	
0120110	Walnuts	
0120990	Others (2)	
0130000	Pome fruits	
0130010	Apples	0,006 (*)
0130020	Pears	0,006 (*)
0130030	Quinces	0,02

(1)	(2)	(3)
0130040	Medlars	0,02
0130050	Loquats/Japanese medlars	0,02
0130990	Others (2)	0,01 (*)
0140000	Stone fruits	
0140010	Apricots	0,02
0140020	Cherries (sweet)	0,01 (*)
0140030	Peaches	0,02
0140040	Plums	0,01 (*)
0140990	Others (2)	0,01 (*)
0150000	Berries and small fruits	
0151000	(a) grapes	0,01 (*)
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) strawberries	0,08
0153000	(c) cane fruits	
0153010	Blackberries	0,08
0153020	Dewberries	0,01 (*)
0153030	Raspberries (red and yellow)	0,08
0153990	Others (2)	0,01 (*)
0154000	(d) other small fruits and berries	0,01 (*)
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	
0154990	Others (2)	
0160000	Miscellaneous fruitswith	
0161000	(a) edible peel	0,01 (*)
0161010	Dates	
0161020	Figs	
0161030	Table olives	
0161040	Kumquats	
0161050	Carambolas	

(1)	(2)	(3)
0161060	Kaki/Japanese persimmons	
0161070	Jambuls/jambolans	
0161990	Others (2)	
0162000	(b) inedible peel, small	0,01 (*)
0162010	Kiwi fruits (green, red, yellow)	
0162020	Litchis/lychees	
0162030	Passionfruits/maracujas	
0162040	Prickly pears/cactus fruits	
0162050	Star apples/cainitos	
0162060	American persimmons/Virginia kaki	
0162990	Others (2)	
0163000	(c) inedible peel, large	
0163010	Avocados	0,02
0163020	Bananas	0,02
0163030	Mangoes	0,01 (*)
0163040	Papayas	0,01 (*)
0163050	Granate apples/pomegranates	0,01 (*)
0163060	Cherimoyas	0,01 (*)
0163070	Guavas	0,01 (*)
0163080	Pineapples	0,01 (*)
0163090	Breadfruits	0,01 (*)
0163100	Durians	0,01 (*)
0163110	Soursops/guanabanas	0,01 (*)
0163990	Others (2)	0,01 (*)
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	0,01 (*)
0211000	(a) potatoes	
0212000	(b) tropical root and tuber vegetables	
0212010	Cassava roots/manioc	
0212020	Sweet potatoes	
0212030	Yams	
0212040	Arrowroots	
0212990	Others (2)	
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	
0213020	Carrots	
0213030	Celeriacs/turnip rooted celeries	
0213040	Horseradishes	

(1)	(2)	(3)
0213050	Jerusalem artichokes	
0213060	Parsnips	
0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	
0213110	Turnips	
0213990	Others (2)	
0220000	Bulb vegetables	0,01 (*)
0220010	Garlic	
0220020	Onions	
0220030	Shallots	
0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	
0231010	Tomatoes	0,015
0231020	Sweet peppers/bell peppers	0,03(+)
0231030	Aubergines/eggplants	0,09
0231040	Okra/lady's fingers	0,01 (*)
0231990	Others (2)	0,01 (*)
0232000	(b) cucurbits with edible peel	
0232010	Cucumbers	0,02
0232020	Gherkins	0,04
0232030	Courgettes	0,02
0232990	Others (2)	0,04
0233000	(c) cucurbits with inedible peel	0,01 (*)
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	0,01 (*)
0239000	(e) other fruiting vegetables	0,01 (*)
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	
0241000	(a) flowering brassica	0,01 (*)
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	

(1)	(2)	(3)
0242000	(b) head brassica	0,01 (*)
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) leafy brassica	
0243010	Chinese cabbages/pe-tsai	0,05
0243020	Kales	0,01 (*)
0243990	Others (2)	0,01 (*)
0244000	(d) kohlrabies	0,01 (*)
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	
0251010	Lamb's lettuces/corn salads	0,08
0251020	Lettuces	0,03
0251030	Escaroles/broad-leaved endives	0,01 (*)
0251040	Cresses and other sprouts and shoots	0,08
0251050	Land cresses	0,08
0251060	Roman rocket/rucola	0,08
0251070	Red mustards	0,01 (*)
0251080	Baby leaf crops (including brassica species)	3
0251990	Others (2)	0,08
0252000	(b) spinaches and similar leaves	
0252010	Spinaches	0,01 (*)
0252020	Purslanes	0,1
0252030	Chards/beet leaves	0,01 (*)
0252990	Others (2)	0,1
0253000	(c) grape leaves and similar species	0,01 (*)
0254000	(d) watercresses	0,01 (*)
0255000	(e) witloofs/Belgian endives	0,01 (*)
0256000	(f) herbs and edible flowers	
0256010	Chervil	0,03
0256020	Chives	2
0256030	Celery leaves	0,03
0256040	Parsley	0,03
0256050	Sage	2
0256060	Rosemary	2
0256070	Thyme	2

(1)	(2)	(3)
0256080	Basil and edible flowers	2
0256090	Laurel/bay leaves	2
0256100	Tarragon	2
0256990	Others (2)	0,02 (*)
0260000	Legume vegetables	
0260010	Beans (with pods)	0,08
0260020	Beans (without pods)	0,01 (*)
0260030	Peas (with pods)	0,08
0260040	Peas (without pods)	0,01 (*)
0260050	Lentils	0,01 (*)
0260990	Others (2)	0,01 (*)
0270000	Stem vegetables	
0270010	Asparagus	0,01 (*)
0270020	Cardoons	0,01 (*)
0270030	Celeries	0,05
0270040	Florence fennels	0,03
0270050	Globe artichokes	0,01 (*)
0270060	Leeks	0,01 (*)
0270070	Rhubarbs	0,01 (*)
0270080	Bamboo shoots	0,01 (*)
0270090	Palm hearts	0,01 (*)
0270990	Others (2)	0,01 (*)
0280000	Fungi, mosses and lichens	0,01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	Algae and prokaryotes organisms	0,01 (*)
0300000	PULSES	0,01 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	
0401000	Oilseeds	
0401010	Linseeds	0,01 (*)
0401020	Peanuts/groundnuts	0,01 (*)

(1)	(2)	(3)
0401030	Poppy seeds	0,01 (*)
0401040	Sesame seeds	0,01 (*)
0401050	Sunflower seeds	0,01 (*)
0401060	Rapeseeds/canola seeds	0,01 (*)
0401070	Soyabeans	0,01 (*)
0401080	Mustard seeds	0,01 (*)
0401090	Cotton seeds	0,02
0401100	Pumpkin seeds	0,01 (*)
0401110	Safflower seeds	0,01 (*)
0401120	Borage seeds	0,01 (*)
0401130	Gold of pleasure seeds	0,01 (*)
0401140	Hemp seeds	0,01 (*)
0401150	Castor beans	0,01 (*)
0401990	Others (2)	0,01 (*)
0402000	Oil fruits	0,01 (*)
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	0,01 (*)
0500010	Barley	
0500020	Buckwheat and other pseudocereals	
0500030	Maize/corn	
0500040	Common millet/proso millet	
0500050	Oat	
0500060	Rice	
0500070	Rye	
0500080	Sorghum	
0500090	Wheat	
0500990	Others (2)	
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	0,05 (*)
0610000	Teas	
0620000	Coffee beans	
0630000	Herbal infusions from	
0631000	(a) flowers	
0631010	Chamomile	
0631020	Hibiscus/roselle	

(1)	(2)	(3)
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	
0631990	Others (2)	
0632000	(b) leaves and herbs	
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	(c) roots	
0633010	Valerian	
0633020	Ginseng	
0633990	Others (2)	
0639000	(d) any other parts of the plant	
0640000	Cocoa beans	
0650000	Carobs/Saint John's breads	
0700000	HOPS	0,1
0800000	SPICES	
0810000	Seed spices	0,05 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	Fruit spices	0,05 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	

(1)	(2)	(3)
0820070	Vanilla	
0820080	Tamarind	
0820990	Others (2)	
0830000	Bark spices	0,05 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	0,05 (*)
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0,05 (*)
0840040	Horseradish (11)	
0840990	Others (2)	0,05 (*)
0850000	Bud spices	0,05 (*)
0850010	Cloves	
0850020	Capers	
0850990	Others (2)	
0860000	Flower pistil spices	0,05 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0,05 (*)
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	0,01 (*)
0900010	Sugar beet roots	
0900020	Sugar canes	
0900030	Chicory roots	
0900990	Others (2)	
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
1010000	Commodities from	
1011000	(a) swine	0,01 (*)
1011010	Muscle	
1011020	Fat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offals (other than liver and kidney)	
1011990	Others (2)	

(1)	(2)	(3)
1012000	(b) bovine	
1012010	Muscle	0,01 (*)
1012020	Fat	0,01 (*)
1012030	Liver	0,02
1012040	Kidney	0,01 (*)
1012050	Edible offals (other than liver and kidney)	0,02
1012990	Others (2)	0,01 (*)
1013000	(c) sheep	
1013010	Muscle	0,02
1013020	Fat	0,05
1013030	Liver	0,025
1013040	Kidney	0,02
1013050	Edible offals (other than liver and kidney)	0,05
1013990	Others (2)	0,01 (*)
1014000	d) goat	
1014010	Muscle	0,01 (*)
1014020	Fat	0,01 (*)
1014030	Liver	0,02
1014040	Kidney	0,01 (*)
1014050	Edible offals (other than liver and kidney)	0,02
1014990	Others (2)	0,01 (*)
1015000	(e) equine	
1015010	Muscle	0,01 (*)
1015020	Fat	0,01 (*)
1015030	Liver	0,02
1015040	Kidney	0,01 (*)
1015050	Edible offals (other than liver and kidney)	0,02
1015990	Others (2)	0,01 (*)
1016000	(f) poultry	0,01 (*)
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offals (other than liver and kidney)	
1016990	Others (2)	
1017000	(g) other farmed terrestrial animals	
1017010	Muscle	0,01 (*)
1017020	Fat	0,01 (*)

(1)	(2)	(3)
1017030	Liver	0,02
1017040	Kidney	0,01 (*)
1017050	Edible offals (other than liver and kidney)	0,02
1017990	Others (2)	0,01 (*)
1020000	Milk	0,01 (*)
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0,01 (*)
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,01 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	

(*) Indicates lower limit of analytical determination

(^e) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I

Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (R) (F)

(R) The residue definition differs for the following combinations pesticide-code number: Abamectin — code 1000000 except 1040000: avermectin B1a

(F) Fat soluble

The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 31 January 2025, or, if that information is not submitted by that date, the lack of it.

0231020 Sweet peppers/bell peppers⁷

COMMISSION IMPLEMENTING REGULATION (EU) 2023/199**of 30 January 2023****approving the low-risk active substance *Trichoderma atroviride* AT10 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) On 30 October 2018, France received an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 from Agrotecnologías Naturales S.L. for the approval of the active substance *Trichoderma atroviride* AT10.
- (2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, France, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 15 February 2019 of the admissibility of the application.
- (3) On 18 September 2020, after assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority.
- (4) Pursuant to Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the draft assessment report to the applicant and the other Member States.
- (5) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested the applicant to supply additional information to the Member States, the Commission and the Authority.
- (6) The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the form of an updated draft assessment report.
- (7) On 20 January 2022, the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance *Trichoderma atroviride* AT10 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (8) On 14 July 2022, the Commission presented a review report regarding *Trichoderma atroviride* AT10 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed.
- (9) The Commission invited the applicant to submit its comments on the review report. The applicant submitted its comments, which have been carefully examined.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AT10. <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7200>. EFSA Journal 2022;7200. DOI: 10.2903/j.efsa.2022.7200.

- (10) It has been established, with respect to one representative use of at least one plant protection product containing the active substance, which was examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) The Commission further considers that *Trichoderma atroviride* AT10 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Trichoderma atroviride* AT10 is not a microorganism of concern and fulfils the conditions set in Annex II point 5.2 to Regulation (EC) No 1107/2009.
- (12) It is therefore appropriate to approve *Trichoderma atroviride* AT10 as a low-risk active substance.
- (13) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions.
- (14) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 in conjunction with Article 22(2) thereof, Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of the active substance

The active substance *Trichoderma atroviride* AT10, is approved subject to the conditions set out in Annex I to this Regulation.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

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, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Trichoderma atroviride</i> AT10	n.a.	The nominal content of <i>Trichoderma atroviride</i> AT10 in the technical product should be Minimal: 1×10^{11} CFU/kg Nominal: 5×10^{11} CFU/kg Maximal: 1×10^{12} CFU/kg No relevant impurities	20 February 2023	20 February 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> AT10 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be considered to reduce dermal and inhalation exposure.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'43	<i>Trichoderma atroviride</i> AT10	n.a.	The nominal content of <i>Trichoderma atroviride</i> AT10 in the technical product and formulation is Minimal: 1×10^{11} CFU/kg Nominal: 5×10^{11} CFU/kg Maximal: 1×10^{12} CFU/kg No relevant impurities	20 February 2023	20 February 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> AT10 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be considered to reduce dermal and inhalation exposure.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/200**of 30 January 2023****concerning the non-approval of lemon essential oil (*Citrus limon* essential oil) as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) in conjunction with Article 23(5) thereof,

Whereas:

- (1) On 6 June 2020, the Commission received an application from Cugargestion Management S. L. ('the applicant') for the approval of lemon essential oil as a basic substance to be used in plant protection as an acaricide, insecticide and fungicide on citrus fruit trees. In November 2020, the Commission received a revised application, which was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (2) The relevant evaluations, carried out in accordance with other Union legislation, as referred to in Article 23(2) of Regulation (EC) No 1107/2009, were available. As regards the lemon essential oil, an evaluation from the FEEDAP Panel of the European Food Safety Authority ('the Authority') was available ⁽²⁾. As regards the main component of lemon essential oil, namely d-limonene, the available relevant evaluations included a Conclusion on the peer review of the pesticide risk assessment issued by the Authority ⁽³⁾ as well as an opinion of the Risk Assessment Committee of the European Chemicals Agency (ECHA) ⁽⁴⁾. The outcome of these evaluations have been taken into account by the Authority as well as by the Commission.
- (3) The Commission asked the Authority for scientific assistance. The Authority provided the Commission with a technical report on lemon essential oil on 20 September 2021 ⁽⁵⁾.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Kouba M, Fašmon Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brantom P, Chesson A, Westendorf J, Galobart J, Manini P, Pizzo F and Dusemund B, 2021. Scientific Opinion on the safety and efficacy of feed additives consisting of expressed lemon oil and its fractions from *Citrus limon* (L.) Osbeck and of lime oil from *Citrus aurantiifolia* (Christm.) Swingle for use in all animal species (FEFANA asbl). EFSA Journal 2021;19(4):6548, 55 pp. <https://doi.org/10.2903/j.efsa.2021.6548>.

⁽³⁾ EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance orange oil. EFSA Journal 2013;11(2):3090. 55 pp. <https://doi.org/10.2903/j.efsa.2013.3090>.

⁽⁴⁾ ECHA (European Chemicals Agency) Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of (R)-p-mentha-1,8-diene; d-limonene. Adopted 15 March 2019. Available at <https://echa.europa.eu/documents/10162/10c233b2-019e-4e59-e0c1-550133aed912>.

⁽⁵⁾ EFSA (European Food Safety Authority), 2021. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for approval of lemon essential oil to be used in plant protection as an acaricide, insecticide and fungicide in fruit trees (citrus). EFSA supporting publication 2021: EN-6873. 147 pp. doi:10.2903/sp.efsa.2021.EN-6873.

- (4) With regard to human health, the Authority concluded that, even though no Union harmonised classification has been established for lemon essential oil under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁶⁾ on classification, labelling and packaging of chemical substances and mixtures, the main hazard associated with lemon essential oil is its toxicity by inhalation and skin sensitisation properties. The main component of lemon essential oil, d-limonene, is classified ⁽⁷⁾ as a substance that may be fatal if swallowed and when it enters airways (Asp. Tox.1), as a skin irritant (Skin Irrit 2) and as a substance that may cause an allergic skin reaction (Skin Sens.1B). Additionally, due to the absence of data, the Authority could not conclude its assessment of non-dietary risks for operators, workers, bystanders and residents.
- (5) As regards the effect of lemon essential oil on the environment, the Authority noted that lemon essential oil is toxic to aquatic organisms. D-limonene is classified ⁽⁸⁾ as very toxic to aquatic life (Aquatic Acute 1) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 3). Moreover, the available data were not sufficient to demonstrate acceptable risk to non-target organisms.
- (6) The Commission presented the review report, concluding that the approval criteria for basic substances are not fulfilled in the case of lemon essential oil and that it is therefore not to be approved as a basic substance, as well as a draft of this Implementing Regulation to the Standing Committee on Plants, Animals, Food and Feed on 12 April 2022 and 14 October 2022, respectively.
- (7) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's review report. The applicant submitted its comments, which were taken into due consideration.
- (8) However, despite the arguments put forward by the applicant, the concerns related to the safety of using this substance with regard to the protection of human health and environment could not be eliminated.
- (9) Consequently, it has not been established that the conditions laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to establish that lemon essential oil is not approved as a basic substance.
- (10) This Regulation does not prevent the submission of a further application for the approval of lemon essential oil as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance lemon essential oil (*Citrus limon* essential oil) is not approved as a basic substance.

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*.

⁽⁶⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽⁷⁾ Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 188, 28.5.2021, p. 27).

⁽⁸⁾ Delegated Regulation (EU) 2021/849.

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

Done at Brussels, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2023/201

of 30 January 2023

setting the date on which operations of the Schengen Information System start pursuant to Regulation (EU) 2018/1861 of the European Parliament and of the Council and Regulation (EU) 2018/1862 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1861 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of border checks, and amending the Convention implementing the Schengen Agreement, and amending and repealing Regulation (EC) No 1987/2006 ⁽¹⁾, and in particular Article 66(2) thereof,

Having regard to Regulation (EU) 2018/1862 of the European Parliament and of the Council of 28 November 2018 on the establishment, operation and use of the Schengen Information System (SIS) in the field of police cooperation and judicial cooperation in criminal matters, amending and repealing Council Decision 2007/533/JHA, and repealing Regulation (EC) No 1986/2006 of the European Parliament and of the Council and Commission Decision 2010/261/EU ⁽²⁾, and in particular Article 79(2) thereof,

Whereas:

- (1) Regulation (EU) 2018/1861 and Regulation (EU) 2018/1862 lay down the new rules on the establishment, operation and use of the Schengen Information System. They increase the effectiveness and strengthen the technical and operational efficiency of the Schengen Information System and extend its use by introducing new alert categories and functionalities. In addition, Regulation (EU) 2018/1860 of the European Parliament and of the Council ⁽³⁾ established a new type of alert on the return of third-country nationals.
- (2) Regulation (EU) 2018/1861 constitutes the legal basis for the Schengen Information System in respect of matters falling within the scope of Chapter 2 of Title V of Part Three of the Treaty and Regulation (EU) 2018/1862 constitutes the legal basis for the Schengen Information System in respect of matters falling within the scope of Chapters 4 and 5 of Title V of Part Three of the Treaty. The fact that the legal basis for the Schengen Information System consists of separate instruments does not affect the principle that the Schengen Information System constitutes one single information system that should operate as such.
- (3) Since the entry into force of Regulations (EU) 2018/1860, (EU) 2018/1861 and (EU) 2018/1862, the Commission, Member States and the European Union Agency for the Operational Management of Large-Scale IT Systems in the Area of Freedom, Security and Justice (eu-LISA) have been completing the necessary technical and legal arrangements to implement the new rules at both central and national level, to be able to process data and exchange supplementary information according to the new rules.

⁽¹⁾ OJ L 312, 7.12.2018, p. 14.

⁽²⁾ OJ L 312, 7.12.2018, p. 56.

⁽³⁾ Regulation (EU) 2018/1860 of the European Parliament and of the Council of 28 November 2018 on the use of the Schengen Information System for the return of illegally staying third-country nationals (OJ L 312, 7.12.2018, p. 1).

- (4) Pursuant to Regulation (EU) 2018/1861 and Regulation (EU) 2018/1862, the new rules are to apply in successive stages in order to allow sufficient time for the necessary legal, operational and technical measures and arrangements to be put in place. On that basis, various provisions of Regulations (EU) 2018/1861 and (EU) 2018/1862 have started to apply on 28 December 2018, 28 December 2019 and 28 December 2020, respectively. As regards the start of application of the provisions that provide for the most complex changes having an overall impact on the technical implementation and operations of the Schengen Information System, those Regulations provide for a specific mechanism for a deferred start of application to ensure that those elements only become applicable after the necessary preparatory steps have been taken allowing for the continuous and uninterrupted operations of the system.
- (5) In accordance with that mechanism, the Commission is to set the date on which the operations of the Schengen Information System start, following verification that the legal, technical and operational conditions laid down in Regulations (EU) 2018/1860, (EU) 2018/1861 and (EU) 2018/1862 are met.
- (6) The Commission has verified that the implementing acts necessary for the application of Regulations (EU) 2018/1860, (EU) 2018/1861 and (EU) 2018/1862 were adopted; that Member States notified the Commission that they have made the necessary technical and legal arrangements to process Schengen Information System data and exchange supplementary information pursuant to the said Regulations and that eu-LISA notified the Commission of the successful completion of all testing activities with regard to Central SIS and the interaction between the a technical support function of Central SIS (CS-SIS) and the national systems (N.SIS). It is therefore appropriate to set the date on which the operations of the Schengen Information System pursuant to Regulations (EU) 2018/1860, (EU) 2018/1861 and (EU) 2018/1862 are to start.
- (7) By virtue of Article 66(5) of Regulation (EU) 2018/1861 of the European Parliament and of the Council and Article 79(5) of Regulation (EU) 2018/1862 of the European Parliament and of the Council, these regulations shall apply from the date set in this Decision. In addition, by virtue of Article 20 of Regulation (EU) 2018/1860 of the European Parliament and of the Council, the provisions establishing a new type of alert on the return of third-country nationals in the Schengen Information System provided for in that Regulation are to apply from the start date set in this Decision.
- (8) Given that, the Commission is to set a future date on which the operations of the Schengen Information System start, there is no need for any intermediate time period between the date of publication and the date of entry into force of this Decision. Therefore, this Decision should enter into force on the day of its publication.
- (9) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark did not take part in the adoption of Regulation (EU) 2018/1861 and Regulation (EU) 2018/1862 and is not bound by them or subject to their application. However, given that Regulation (EU) 2018/1861 and Regulation (EU) 2018/1862 build upon the Schengen *acquis*, Denmark, in accordance with Article 4 of that Protocol, notified on 26 April 2019 its decision to implement Regulation (EU) 2018/1861 and Regulation (EU) 2018/1862 in its national law. Denmark is therefore bound under international law to implement this Decision.
- (10) Ireland is taking part in this Decision to the extent that it concerns Regulation (EU) 2018/1862 in accordance with Article 5(1) of Protocol No 19 on the Schengen *acquis* integrated into the framework of the European Union, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union and Article 6(2) of Council Decision 2002/192/EC ⁽⁴⁾, read in conjunction with Council Implementing Decision (EU) 2020/1745 ⁽⁵⁾.

⁽⁴⁾ Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* (OJ L 64, 7.3.2002, p. 20).

⁽⁵⁾ Council Implementing Decision (EU) 2020/1745 of 18 November 2020 on the putting into effect of the provisions of the Schengen *acquis* on data protection and on the provisional putting into effect of certain provisions of the Schengen *acquis* in Ireland (OJ L 393, 23.11.2020, p. 3).

- (11) As regards Iceland and Norway, this Decision constitutes a development of provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning these States' association with the implementation, application and development of the Schengen *acquis* ⁽⁶⁾, which fall within the area referred to in Article 1, point (G) of Council Decision 1999/437/EC ⁽⁷⁾.
- (12) As regards Switzerland, this Decision constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽⁸⁾, which fall within the area referred to in Article 1, point (G), of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC ⁽⁹⁾ and Article 3 of Council Decision 2008/149/JHA ⁽¹⁰⁾.
- (13) As regards Liechtenstein, this Decision constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* ⁽¹¹⁾, which fall within the area referred to in Article 1, point (G), of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU ⁽¹²⁾ and Article 3 of Council Decision 2011/349/EU ⁽¹³⁾.
- (14) As regards Bulgaria and Romania, this Decision constitutes an act building upon, or otherwise relating to, the Schengen *acquis* within the meaning of Article 4(2) of the 2005 Act of Accession and should be read in conjunction with Council Decisions 2010/365/EU ⁽¹⁴⁾ and (EU) 2018/934 ⁽¹⁵⁾.
- (15) Concerning Cyprus, this Decision constitutes an act building upon, or otherwise relating to, the Schengen *acquis* within the meaning of Article 3(2) of the 2003 Act of Accession,

⁽⁶⁾ OJ L 176, 10.7.1999, p. 36.

⁽⁷⁾ Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* (OJ L 176, 10.7.1999, p. 31).

⁽⁸⁾ OJ L 53, 27.2.2008, p. 52.

⁽⁹⁾ Council Decision 2008/146/EC of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 1).

⁽¹⁰⁾ Council Decision 2008/149/JHA of 28 January 2008 on the conclusion on behalf of the European Union of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis* (OJ L 53, 27.2.2008, p. 50).

⁽¹¹⁾ OJ L 160, 18.6.2011, p. 21.

⁽¹²⁾ Council Decision 2011/350/EU of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

⁽¹³⁾ Council Decision 2011/349/EU of 7 March 2011 on the conclusion on behalf of the European Union of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen *acquis*, relating in particular to judicial cooperation in criminal matters and police cooperation (OJ L 160, 18.6.2011, p. 1).

⁽¹⁴⁾ Council Decision 2010/365/EU of 29 June 2010 on the application of the provisions of the Schengen *acquis* relating to the Schengen Information System in the Republic of Bulgaria and Romania (OJ L 166, 1.7.2010, p. 17).

⁽¹⁵⁾ Council Decision (EU) 2018/934 of 25 June 2018 on the putting into effect of the remaining provisions of the Schengen *acquis* relating to the Schengen Information System in the Republic of Bulgaria and Romania (OJ L 165, 2.7.2018, p. 37).

HAS ADOPTED THIS DECISION:

Article 1

The operations of the Schengen Information System pursuant to Regulations (EU) 2018/1861 and (EU) 2018/1862 shall start on 7 March 2023.

Article 2

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

Done at Brussels, 30 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 01/2022 OF THE COMMITTEE ON CUSTOMS OF THE FREE TRADE AGREEMENT BETWEEN THE EUROPEAN UNION AND THE REPUBLIC OF SINGAPORE

of 20 December 2022

modifying certain elements in Protocol 1 concerning the definition of the concept of ‘originating products’ and methods of administrative cooperation and its Annexes [2023/202]

THE COMMITTEE ON CUSTOMS,

Having regard to the Free Trade Agreement between the European Union and the Republic of Singapore (hereinafter, ‘the Agreement’), and in particular Article 34 of Protocol 1 and Article 16.2 of the Agreement,

Whereas:

- (1) Article 34 (Amendments to this Protocol) of Protocol 1 to the Agreement provides that the Parties may, by decision in the Committee on Customs established pursuant to Article 16.2 (Specialised Committees) of the Agreement, amend the provisions of Protocol 1 to the Agreement.
- (2) Amendments were introduced on 1 January 2012, on 1 January 2017 and on 1 January 2022 in relation to the nomenclature governed by the Convention on the Harmonized Commodity Description and Coding System (‘HS’). The Parties have agreed to update Protocol 1 to reflect the latest version of the HS.
- (3) The Parties have agreed to modify the scope of the annual quotas set out in Annex B(a) to Protocol 1 for canned luncheon meat, curry fish balls and cuttlefish balls.
- (4) Article 17 (Conditions for Making Out an Origin Declaration) of Protocol 1 establishes that an origin declaration may be made out, in the European Union by, inter alia, an exporter who is an approved exporter, and in Singapore by, inter alia, a registered exporter. To provide for equal treatment of the economic operators in both Parties, Protocol 1 should be amended so that each Party may decide, according to its laws and regulations, which exporter may make out an origin declaration. For that purpose, a definition of ‘exporter’ would therefore be necessary.
- (5) Considering the new definition of ‘exporter’, the term ‘exporter’ in the definition of ‘consignment’ in point (d) of Article 1(1), Article 13 (Non Alteration) and Article 14 (Exhibitions) of Protocol 1 needs to be replaced by the term ‘consignor’.
- (6) Paragraph 5 of Article 17 (Conditions for Making Out an Origin Declaration) provides that an origin declaration is to bear the original signature of the exporter in manuscript. The Parties have agreed to waive this requirement to facilitate trade and to decrease the administrative burden of benefiting from the tariff preferences of the Agreement.
- (7) In the definition of ‘ex-works price’ in point (f) of Article 1(1), it is necessary to clarify how the term ‘manufacturer’ is to be understood when the last working or processing is subcontracted.
- (8) Considering that both Parties are to apply a system of registered exporters, the document on origin made out in the Parties should be renamed from ‘origin declaration’ to ‘statement on origin’.

- (9) As a transitional measure, it should be provided that for a period of 3 months starting from the date of entry into force of this Decision, Singapore will accept origin declarations made out in accordance with Article 17 (Conditions for Making Out an Origin Declaration) and Article 18 (Approved Exporter) of Protocol 1 to the Agreement in force prior to the date of entry into force of this Decision.
- (10) Protocol 1 to the Agreement and several of its Annexes should therefore be modified,

HAS ADOPTED THIS DECISION:

Article 1

Protocol 1 to the Agreement is amended as follows:

- (1) the table of contents of Protocol 1 is replaced by the following:

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SECTION 1 GENERAL PROVISIONS

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SECTION 2 DEFINITION OF THE CONCEPT OF “ORIGINATING PRODUCTS”

ARTICLE 2 General requirements

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SECTION 3 TERRITORIAL REQUIREMENTS

ARTICLE 12 Principle of Territoriality

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SECTION 4 DRAWBACK OR EXEMPTION

ARTICLE 15 Prohibition of Drawback of, or Exemption from, Customs Duties

SECTION 5 STATEMENT ON ORIGIN

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ARTICLE 17 Conditions for Making Out a Statement on Origin

ARTICLE 19 Validity of Statement on Origin

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ARTICLE 22 Exemptions from Statement on Origin

ARTICLE 23 Supporting Documents

ARTICLE 24 Preservation of Statement on Origin and Supporting Documents

ARTICLE 25 Discrepancies and Formal Errors

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SECTION 7 CEUTA AND MELILLA

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ANNEX B: LIST OF WORKING OR PROCESSING REQUIRED TO BE CARRIED OUT ON NON-ORIGINATING MATERIALS IN ORDER THAT THE PRODUCT MANUFACTURED CAN OBTAIN ORIGINATING STATUS

ANNEX B (a): ADDENDUM TO ANNEX B

ANNEX C: MATERIALS EXCLUDED FROM CUMULATION UNDER PARAGRAPH 2 OF ARTICLE 3

ANNEX D: PRODUCTS REFERRED TO IN PARAGRAPH 9 OF ARTICLE 3 FOR WHICH MATERIALS ORIGINATING IN AN ASEAN COUNTRY SHALL BE CONSIDERED AS MATERIALS ORIGINATING IN A PARTY

ANNEX E: TEXT OF THE STATEMENT ON ORIGIN

Joint Declarations

JOINT DECLARATION CONCERNING THE PRINCIPALITY OF ANDORRA

JOINT DECLARATION CONCERNING THE REPUBLIC OF SAN MARINO

JOINT DECLARATION CONCERNING THE REVISION OF THE RULES OF ORIGIN CONTAINED IN PROTOCOL 1';

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

'ARTICLE 1

Definitions

1. For the purposes of this Protocol:

- (a) "ASEAN country" means a member state of the Association of Southeast Asian Nations which is not a Party to this Agreement;
- (b) "chapters" and "headings" and "sub-headings" mean the chapters, the headings (four digit codes) and sub-headings (six digit codes) used in the nomenclature which makes up the Harmonized Commodity Description and Coding System, referred to in this Protocol as the "Harmonized System" or "HS";
- (c) "classified" refers to the classification of a product or material under a particular chapter, heading, or sub-heading of the Harmonized System;
- (d) "consignment" means products which are either sent simultaneously from one consignor to one consignee or covered by a single transport document covering their shipment from the consignor to the consignee or, in the absence of such a document, by a single invoice;
- (e) "customs value" means the value as determined in accordance with the Customs Valuation Agreement;
- (f) "ex-works price" means the price paid for the product ex-works to the manufacturer in whose undertaking the last working or processing is carried out, provided that the price includes the value of all the materials used and all other costs related to its production, minus any internal taxes which are, or may be, repaid when the product obtained is exported.

Where the actual price paid does not reflect all costs related to the manufacturing of the product which are actually incurred in the Union or in Singapore, the ex-works price means the sum of all those costs, minus any internal taxes which are, or may be, repaid when the product obtained is exported.

Where the last working or processing has been subcontracted to a manufacturer, the term "manufacturer" may refer to the enterprise that has employed the subcontractor.

- (g) "exporter" means a person, located in a Party, who, in accordance with the requirements in the laws and regulations of the Party, exports or produces the originating product and who may make out a statement on origin;
- (h) "fungible materials" means materials that are of the same kind and commercial quality, with the same technical and physical characteristics, and which cannot be distinguished from one another once they are incorporated into the finished product;
- (i) "goods" means both materials and products;
- (j) "juridical person" means any legal entity duly constituted or otherwise organised under applicable law, whether for profit or otherwise, and whether privately-owned or governmentally-owned, including any corporation, trust, partnership, joint venture, sole proprietorship, or association;
- (k) "manufacture" means any kind of working or processing including assembly;
- (l) "material" means any ingredient, raw material, component or part, etc., used in the manufacture of the product;
- (m) "person" means a natural person or juridical person;
- (n) "product" means the product being manufactured, even if it is intended for later use in another manufacturing operation;
- (o) "value of materials" means the customs value at the time of importation of the non-originating materials used, or, if this is not known and cannot be ascertained, the first ascertainable price paid for the materials in the Union or in Singapore.;

- (3) Article 13(3) is replaced by the following:

'3. Without prejudice to Section 5, the splitting of consignments may take place where carried out by the consignor or under his responsibility provided they remain under customs supervision in the country(ies) of transit.;

(4) points (a) and (b) of Article 14(1) are replaced by the following:

'(a) a consignor has consigned these products from a Party to the country in which the exhibition is held and has exhibited them there;

(b) the products have been sold or otherwise disposed of by that consignor to a person in a Party;';

(5) Article 17 is replaced by the following:

'ARTICLE 17

Conditions for Making Out a Statement on Origin

1. A statement on origin as referred to in Article 16 (General Requirements) may be made out by the exporter.

2. A statement on origin may be made out if the products concerned can be considered as products originating in the Union or in Singapore and fulfil the other requirements of this Protocol.

3. The exporter making out a statement on origin shall be prepared to submit at any time, at the request of the customs authorities of the exporting Party, all appropriate documents as referred to under Article 23 (Supporting Documents) proving the originating status of the products concerned as well as the fulfilment of the other requirements of this Protocol.

4. A statement on origin shall be made out by the exporter by typing, stamping or printing on the invoice, the delivery note or another commercial document, the declaration, the text of which appears in Annex E to this Protocol, in accordance with the domestic law of the exporting Party. If the statement is hand-written, it shall be written in ink in capital characters. In the case of exports from Singapore, the statement on origin shall be set out using the English version and in the case of exports from Union, the statement on origin may be set out in one of the linguistic versions in Annex E to this Protocol.

5. By derogation from paragraph 1, a statement on origin may be made out after exportation ("retrospective statement") on condition that it is presented in the importing Party no later than two years, in the case of the Union, and one year, in the case of Singapore, after the entry of the goods into the territory.;

(6) in the Table of Contents, and in Article 3(6), Article 3(13), Article 11(5), Article 14(2), Article 15(1), Article 15(3), the title of Section 5, Article 16(1), Article 16(2), the title of Article 19, Article 19(1), Article 19(2), Article 19(3), the title of Article 20, Article 20, Article 21, the title of Article 22, Article 22(1), Article 23, the title of Article 24, Article 24(1), Article 24(2), Article 25(1), Article 25(2), Article 27(1), Article 27(2), the title of Article 28, Article 28(1), Article 28(2), Article 30(1), Article 33(3), and Article 35, the term 'origin declaration' is replaced by the term 'statement on origin';

(7) Article 18 is deleted;

(8) Article 26 is replaced by the following:

'ARTICLE 26

Amounts Expressed in Euro

1. For the application of the provisions of paragraph 3 of Article 22 (Exemptions from Statement on Origin) in cases where products are invoiced in a currency other than euro, amounts in the national currencies of the Member States of the Union equivalent to the amounts expressed in euro shall be fixed annually by each of the countries concerned.

2. A consignment shall benefit from the provisions of paragraph 3 of Article 22 (Exemptions from Statement on Origin) by reference to the currency in which the invoice is drawn up, according to the amount fixed by the Party concerned.

3. The amounts to be used in any given national currency shall be the equivalent in that currency of the amounts expressed in euro as at the first working day of October. The amounts shall be communicated to the European Commission by 15 October and shall apply from 1 January the following year. The European Commission shall notify all countries concerned of the relevant amounts.

4. A Member State of the Union may round up or down the amount resulting from the conversion into its national currency of an amount expressed in euro. The rounded amount may not differ from the amount resulting from the conversion by more than five percent. A Member State of the Union may retain unchanged its national currency equivalent of an amount expressed in euro if, at the time of the annual adjustment provided for in paragraph 3, the conversion of that amount, prior to any rounding-off, results in an increase of less than fifteen percent in the national currency equivalent. The national currency equivalent may be retained unchanged if the conversion would result in a decrease in that equivalent value.

5. The amounts expressed in euro shall be reviewed by the Parties in the Committee on Customs established pursuant to Article 16.2 (Specialised Committees) at the request of the Union or of Singapore. When carrying out this review, the Parties shall consider the desirability of preserving the effects of the limits concerned in real terms. For these purposes, the Parties may, by decision in the Committee on Customs, modify the amounts expressed in euro.’;

- (9) Annex B is amended as set out in Annex 1 to this Decision;
- (10) Annex B(a) is amended as set out in Annex 2 to this Decision;
- (11) Annex D is amended as set out in Annex 3 to this Decision;
- (12) Annex E is amended as set out in Annex 4 to this Decision.

Article 2

Entry into force

This Decision shall enter into force on 1 January 2023.

Done at Brussels, 20 December 2022.

For the EU-Singapore Committee on Customs

On behalf of the European Union
Mr Jean-Michel GRAVE

On behalf of the Republic of Singapore
Mr Lim Teck LEONG

ANNEX 1

Annex B to Protocol 1 is amended as follows:

- (1) in the row related to HS Heading '0305', the text in the column 'description of product' is replaced by the following:
'Fish, dried, salted or in brine; smoked fish, whether or not cooked before or during the smoking process';
- (2) in the row related to HS Heading 'ex 0306', the text in the column 'description of product' is replaced by the following:
'Crustaceans, whether in shell or not, dried, salted or in brine; smoked crustaceans, whether in shell or not, whether or not cooked before or during the smoking process; crustaceans, in shell, cooked by steaming or by boiling in water, whether or not chilled, frozen, dried, salted or in brine';
- (3) in the row related to HS Heading 'ex 0307', the text in the column 'description of product' is replaced by the following:
'Molluscs, whether in shell or not, dried, salted or in brine; smoked molluscs, whether in shell or not, whether or not cooked before or during the smoking process';
- (4) between the row related to HS Heading 'ex 0307' and the row related to HS Heading 'Chapter 4', the following rows are inserted:

'ex 0308	Aquatic invertebrates other than crustaceans and molluscs, dried, salted or in brine; smoked aquatic invertebrates other than crustaceans and molluscs, whether or not cooked before or during the smoking process	Manufacture in which all the materials of Chapter 3 used are wholly obtained
0309	Flours, meals and pellets of fish, crustaceans, molluscs and other aquatic invertebrates, fit for human consumption	Manufacture in which all the materials of Chapter 3 used are wholly obtained'

- (5) in the row related to HS Heading 'ex Chapter 15', the text in the column 'description of product ' is replaced by the following:
'Animal, vegetable or microbial fats and oils and their cleavage products; prepared edible fats; animal or vegetable waxes; except for:';
- (6) in the row related to HS Heading '1509 and 1510', the text in the column 'description of product ' is replaced by the following:
'Olive oil and its fractions, other oils and their fractions obtained solely from olives';
- (7) in the row related to HS Heading '1516 and 1517', the text in the column 'description of product ' is replaced by the following:
'Animal, vegetable or microbial fats and oils and their fractions, partly or wholly hydrogenated, inter-esterified, re-esterified or elaidinised, whether or not refined, but not further prepared;

Margarine; edible mixtures or preparations of animal, vegetable or microbial fats or oils or of fractions of different fats or oils of this Chapter, other than edible fats and oils or their fractions of heading 15.16';
- (8) in the row related to HS Heading 'Chapter 16', the text in the column 'description of product ' is replaced by the following:
'Preparations of meat, of fish, of crustaceans, molluscs or other aquatic invertebrates, or of insects';
- (9) in the row related to HS Heading 'ex Chapter 24', the text in the column 'description of product ' is replaced by the following:
'Tobacco and manufactured tobacco substitutes; products, whether or not containing nicotine, intended for inhalation without combustion; other nicotine containing products intended for the intake of nicotine into the human body; except for:';

- (10) between the row related to HS Heading 'ex 2402' and the row related to HS Heading 'ex Chapter 25', the following rows are inserted:

'2404 12	Products intended for inhalation without combustion, not containing tobacco or reconstituted tobacco, and containing nicotine	Manufacture from materials of any heading, except that of the product. However, materials of the same heading as the product may be used, provided that their total value does not exceed 20 % of the ex-works price of the product or Manufacture in which the value of all the materials used does not exceed 40 % of the ex-works price of the product
ex 2404 19	Cartridges and refills, filled for electronic cigarettes	Manufacture from materials of any heading, except that of the product. However, materials of the same heading as the product may be used, provided that their total value does not exceed 20 % of the ex-works price of the product or Manufacture in which the value of all the materials used does not exceed 40 % of the ex-works price of the product
2404 91	Other products than products intended for inhalation without combustion, for oral application	Manufacture from materials of any heading, except that of the product, in which: — the individual weight of sugar and of the materials of Chapter 4 used does not exceed 20 % of the weight of the final product, and — the total combined weight of sugar and the materials of Chapter 4 used does not exceed 40 % of the weight of final product
2404 92, 2404 99	Other products than products intended for inhalation without combustion, for transdermal application and for other than oral application	Manufacture from materials of any heading, except that of the product. However, materials of the same heading as the product may be used, provided that their total value does not exceed 20 % of the ex-works price of the product or Manufacture in which the value of all the materials used does not exceed 40 % of the ex-works price of the product;

- (11) between the row related to HS Heading 'ex Chapter 38' and the row related to HS Heading '3823', the following rows are inserted:

'ex 3816	Dolomite ramming mix	Manufacture from materials of any heading, except that of the product or Manufacture in which the value of all the materials used does not exceed 40 % of the ex- works price of the product
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ex 3822	Malaria diagnostic test kits Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale Immunological products, put up in measured doses or in forms or packings for retail sale Blood-grouping reagents	Manufacture from materials of any heading;
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- (12) in the first row related to HS Heading '6306', the text in the column 'description of product' is replaced by the following:

'Tarpaulins, awnings and sunblinds; tents (including temporary canopies and similar articles); sails for boats, sailboards or landcraft; camping goods';

- (13) in the row related to HS Heading '8522', the text in the column 'description of product' is replaced by the following:

'Parts and accessories suitable for use solely or principally with the apparatus of heading 8519 or 8521';

- (14) in the row related to HS Heading '8529', the text in the column 'description of product' is replaced by the following:

'Parts suitable for use solely or principally with the apparatus of headings 8524 to 8528';

- (15) in the row related to HS Heading '8548', the text in the column 'description of product' is replaced by the following:

'Electrical parts of machinery or apparatus, not specified or included elsewhere in this Chapter';

- (16) between the row related to HS Heading '8548' and the row related to HS Heading 'ex Chapter 86', the following row is inserted:

'8549	Electrical and electronic waste and scrap.	Manufacture from materials of any heading, except that of the product or Manufacture in which the value of all the materials used does not exceed 50 % of the ex-works price of the product';
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- (17) in the row related to HS Heading 'ex Chapter 86', the text in the column 'HS Heading' and the text in the column 'description of product' are replaced respectively by the following:

'Chapter 86' and 'Railway or tramway locomotives, rolling-stock and parts thereof; railway or tramway track fixtures and fittings and parts thereof; mechanical (including electro-mechanical) traffic signalling equipment of all kinds';

- (18) between the row related to HS Heading 'ex 8804' and the row related to HS Heading 'Chapter 89', the following row is inserted:

'ex 8806	Unmanned aircraft Television cameras, digital cameras and video camera recorders	Manufacture from materials of any heading, except that of the product and of heading 8529 or Manufacture in which the value of all the materials used does not exceed 50 % of the ex-works price of the product';
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- (19) in the row related to HS Heading '9013', the text in the column 'description of product' is replaced by the following:
 'Lasers, other than laser diodes; other optical appliances and instruments, not specified or included elsewhere in this Chapter';
- (20) between the row related to HS Heading '9016' and the row related to HS Heading '9025', the following row is inserted:

'ex 9021	Materials for orthopaedic or fracture appliances and for dental fitting: — Nails, tacks, drawing pins, corrugated nails, staples (other than those of heading 8305) and similar articles, of iron or steel, whether or not with heads of other material, but excluding such articles with heads of copper — Threaded articles and non-threaded articles of iron or steel, excluding coach screws, wood screws, screw hooks and screw rings, spring washers and other lock washers, rivets	Manufacture from materials of any heading, except that of the product or Manufacture in which the value of all the materials used does not exceed 50 % of the ex-works price of the product
	— Titanium and articles thereof, including waste and scrap	Manufacture from materials of any heading';

- (21) in the row related to HS Heading 'Chapter 94', the text in the column 'description of product' is replaced by the following:
 'Furniture; bedding, mattresses, mattress supports, cushions and similar stuffed furnishings; lamps and lighting fittings, not elsewhere specified or included; illuminated signs, illuminated name-plates and the like; prefabricated buildings'.

ANNEX 2

Annex B(a) to Protocol 1 is amended as follows:

- (1) paragraph 3 of the common provisions is deleted;
- (2) paragraph 4 of the common provisions is renumbered to paragraph 3;
- (3) paragraph 5 of the common provisions is renumbered to paragraph 4;
- (4) in the row related to HS Heading

‘ex 1602 32

ex 1602 41

ex 1602 49

ex 1602 50’,

the text ‘Canned luncheon meat of pork, chicken and beef (午餐肉)’ in the column ‘description of product ’ is replaced by the following:

‘Canned luncheon meat or meat loaf of pork (containing more than 40 % by weight of pork meat or meat offal), canned luncheon meat or meat loaf of chicken (containing more than 20 % by weight of chicken meat or meat offal), canned luncheon meat or meat loaf of beef (containing more than 20 % by weight of beef meat or meat offal)’;

- (5) in the row related to HS Heading ‘ex 1604 20’ the text ‘Curry fish balls made of fish meat, curry, wheat starch, salt, sugar, and compound condiments’ in the column ‘description of product’ is replaced by the following:

‘fish balls and fish cakes made of fish meat except of tuna and of mackerel, starch, salt, sugar, and compound condiments’;

- (6) the row related to HS Heading

‘ex 1605 10

ex 1605 90

ex 1605 20

ex 1605 20

ex 1605 20

ex 1605 30’

is replaced by the following:

‘ex 1605 10	Crab balls made of wheat starch, salt, sugar, compound condiments, crab meat and filling	Manufacture from materials of any heading, except that of the product’
ex 1605 54	Cuttlefish balls made of fish meat, cuttlefish filling, starch, salt, sugar, and compound condiments	
ex 1605 21	Hargow made of prawn, wheat starch, tapioca, water, scallion, ginger, sugar, and salt	
ex 1605 29	Shaomai made of prawn predominantly, chicken, corn starch, vegetable oil, black pepper, sesame oil, and water	
ex 1902 20	Fried prawn wonton made of prawn, salt, oil, sugar, ginger, pepper, egg, vinegar, and soy sauce.	
ex 1605 54	Lobster flavoured balls: cuttlefish meat, fish meat and crab meat.	

ANNEX 3

Annex D to Protocol 1 is amended as follows:

- (1) in the row related to HS Code '2909', the text in the column 'description' is replaced by the following:

'Ethers, ether-alcohols, ether-phenols, ether-alcohol-phenols, alcohol peroxides, ether peroxides, acetal and hemiacetal peroxides, ketone peroxides (whether or not chemically defined), and their halogenated, sulphonated, nitrated or nitrosated derivatives';

- (2) in the row related to HS Code '9013', the text in the column 'description' is replaced by the following:

'Lasers, other than laser diodes; other optical appliances and instruments, not specified or included elsewhere in this Chapter'.

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ANNEX 4

Annex E to Protocol 1 is amended as follows:

- (1) in the title of Annex E, the term 'origin declaration' is replaced by the term 'statement on origin';
 - (2) the first paragraph of Annex E is replaced by the following:

'The statement on origin, the text of which is given below, must be made out in accordance with the footnotes. However, the footnotes do not have to be reproduced.'
 - (3) footnote (1) is replaced by the following:

'Indicate the reference number by which the exporter is identified. For the Union exporter, this will be the number assigned in accordance with the laws and regulations of the Union. For Singapore, this will be the number assigned in accordance with the laws and regulations of Singapore. Where the exporter has not been assigned a number, this field may be left blank';
 - (4) the last sentence before the footnotes is replaced by the following:

'(Name of the exporter)';
 - (5) footnote (4) is deleted.
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**JOINT DECLARATION CONCERNING TRANSITIONAL MEASURES AFTER THE DATE OF ENTRY
INTO FORCE OF THE DECISION**

By way of derogation from Article 17 (Conditions for Making Out a Statement on Origin) of Protocol 1 to the Agreement, as amended by this Decision, Singapore shall continue to grant the preferential tariff treatment under this Agreement to goods originating in the Union and exported from the Union upon the presentation of an origin declaration made out in accordance with Article 17 (Conditions for Making Out an Origin Declaration) and Article 18 (Approved Exporter) of Protocol 1 to the Agreement in force prior to the date of entry into force of this Decision. This transitional measure shall apply for a period of 3 months starting from the date of entry into force of this Decision.

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