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EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the entry into force of the Agreement between the European Union and the Republic of Korea on certain aspects of air services

The Agreement between the European Union and the Republic of Korea on certain aspects of air services, signed in Brussels on 25 June 2020, entered into force on 1 November 2021, in accordance with Article 8(1) of the Agreement, as the last notification was deposited on 5 October 2021.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1911

of 27 October 2021

amending Annex II to Implementing Regulation (EU) 2021/620 as regards the disease-free status of the Autonomous Community of Galicia and the Autonomous Community of Principado de Asturias in Spain from infection with *Mycobacterium tuberculosis* complex, amending Annex VIII thereto as regards the disease-free status of Autonomous Community of Islas Baleares, Huelva and Sevilla provinces and the regions of Azuaga, Badajoz, Mérida, Jerez de los Caballeros and Zafra in Badajoz province in Spain and Alentejo region and Santarém district in Lisboa e Vale do Tejo region in Portugal from infection with bluetongue virus, amending Annex IX thereto as regards the disease-free status of the Åland islands in Finland from infestation with *Varroa* spp and amending Annex XIII thereto as regards the disease-free status of Denmark and Finland regarding Infectious haematopoietic necrosis

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')⁽¹⁾, and in particular Article 36(4) and 42(4) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down disease-specific rules for the diseases listed in accordance with Article 5(1) thereof, lays down how those rules are to be applied to different categories of listed diseases and also provides for the approval or withdrawal by the Commission of the disease-free status of Member States or zones thereof with regard to certain listed diseases referred to in Article 9(1), points (b) and (c), thereof.
- (2) Commission Delegated Regulation (EU) 2020/689⁽²⁾ supplements Regulation (EU) 2016/429 and lays down the conditions for granting, maintaining, suspending and withdrawing disease-free status.
- (3) Commission Implementing Regulation (EU) 2021/620⁽³⁾ lists in its Annexes Member States or zones thereof with disease-free status. Among others, it lists zones free from infection with *Mycobacterium tuberculosis* complex (*Mycobacterium bovis*, *M. caprae* and *M. tuberculosis*) (MTBC) in Part I of Annex II thereto, zones free from infection with bluetongue virus (serotypes 1-24) (infection with BTV) in Part I of Annex VIII thereto, zones free from infestation with *Varroa* spp. in Annex IX thereto and zones or compartments with disease-free status from Infectious haematopoietic necrosis (IHN) in Part I of Annex XIII thereto.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

⁽³⁾ Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases (OJ L 131, 16.4.2021, p. 78).

- (4) The changing epidemiological situation of certain diseases makes it necessary to amend annexes II, VIII, IX and XIII to Implementing Regulation (EU) 2021/620 in order to list new disease-free Member States or zones and to delist areas where disease outbreaks are confirmed and therefore the conditions for maintaining the disease-free status are no longer met.
- (5) Spain submitted to the Commission information demonstrating that the conditions for recognition of disease-free status from MTBC laid down in Delegated Regulation (EU) 2020/689 are fulfilled in the provinces of La Coruña, Orense and Lugo in the Autonomous Community of Galicia. The fourth province in that Autonomous Community, Pontevedra, had been already listed as a zone free from MTBC in Part I of Annex II Implementing Regulation (EU) 2021/620. Therefore, the whole Autonomous Community of Galicia should be listed as a zone free from MTBC.
- (6) Spain submitted to the Commission information demonstrating that the conditions for recognition of disease-free status from MTBC laid down in Delegated Regulation (EU) 2020/689 are fulfilled in the Autonomous Community of Principado de Asturias. Therefore, that Autonomous Community is to be listed as a zone free from MTBC.
- (7) Spain notified to the Commission an outbreak of infection with BTV Serotype 4 in the Autonomous Community of Islas Baleares and subsequently additional outbreaks affecting the regions of Sierra Oriental and Sierra Occidental in the province of Huelva, the region of Sierra Norte in the province of Sevilla, and Azuaga, Badajoz, Mérida, Jerez de los Caballeros and Zafra regions in the province of Badajoz. Since the Autonomous Community of Islas Baleares, the regions of Sierra Oriental and Sierra Occidental in the province of Huelva, the region of Cazalla de la Sierra (Sierra Norte) in the province of Sevilla and, implicitly as part of Autonomous Community of Extremadura, the regions of Azuaga, Badajoz, Mérida, Jerez de los Caballeros and Zafra are all listed as disease-free status zones in Part I of Annex VIII to Implementing Regulation (EU) 2021/620, they should be deleted from that list.
- (8) Portugal notified to the Commission outbreaks of infection with BTV Serotype 4 in Alentejo region and subsequently an additional outbreak in Santarém district in Lisboa e Vale do Tejo region. Since Alentejo as a whole and Santarém district, as part of Portugal, are implicitly included as disease-free status areas in Part I of Annex VIII to Implementing Regulation (EU) 2021/620, the Alentejo region and the Santarém district should be excluded from that list.
- (9) Finland notified to the Commission an outbreak of infestation with *Varroa* spp. in the Brändö municipality of the Åland Islands. The Åland Islands are listed as a disease-free status zone in Annex IX to Implementing Regulation (EU) 2021/620. Finland also informed the Commission that, based on an epidemiological investigation, other municipalities are not affected by that outbreak. The municipality of Brändö should be deleted from the disease-free zone list.
- (10) Denmark notified to the Commission, recent outbreaks of the aquatic disease Infectious haematopoietic necrosis (IHN) in the water catchment areas of Varde Å, and Kolding Å and in a put and take lake Hove Kalkgrav. These areas are currently included in the territory of Denmark which is listed as disease-free in Part I of Annex XIII to Implementing Regulation (EU) 2021/620. Part I of Annex XIII should therefore, be amended to exclude those infected areas from the disease-free territory of Denmark.
- (11) Finland has successfully completed an eradication programme for IHN which included a compartment in Ii, Kuivaniemi, and four zones Virmasvesi, Nilakka, Saarijarvi and Pielinen, and has subsequently made a declaration of disease-freedom in accordance with Article 83 of Delegated Regulation (EU) 2020/689, for that compartment and those zones. It is therefore appropriate, that they are no longer excluded from the IHN free territory of that Member State. Part I of Annex XIII to Implementing Regulation (EU) 2021/620 should therefore, be amended accordingly.
- (12) Annexes II, VIII, IX and XIII to Implementing Regulation (EU) 2021/620 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, VIII, IX and XIII to Implementing Regulation (EU) 2021/620 are amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 27 October 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II, VIII, IX and XIII to Implementing Regulation (EU) 2021/620 are amended as follows:

1. in Annex II, part I, the entry for Spain is replaced by the following:

Member State	Territory
'Spain	Comunidad Autónoma de Canarias Comunidad Autónoma de Galicia Comunidad Autónoma del Principado de Asturias'

;

2. in Annex VIII, part I, the entry for Spain is modified as follows:

a. the following areas are deleted:

'Comunidad Autónoma de Islas Baleares', 'Province of Huelva, the following regions: Aracena (Sierra Oriental) and Cortegana (Sierra Occidental)' 'Province of Sevilla, the following region: Cazalla de la Sierra (Sierra Norte)' in 'Comunidad Autónoma de Andalucía';

b. the entry for Comunidad Autónoma de Extremadura is replaced by the following:

'Comunidad Autónoma de Extremadura, except the following regions: Azuaga, Badajoz, Mérida, Jerez de los Caballeros and Zafra in the province of Badajoz';

3. in Annex VIII, part I, the entry for Portugal is replaced by the following:

Member State	Territory
'Portugal	Whole territory, except Algarve and Alentejo regions and Santarém district in the region of Lisboa e Vale do Tejo'

;

4. in Annex IX, the entry for Finland is replaced by the following:

Member State	Territory
'Finland	Åland Islands, except the municipality of Brändö'

;

5. in Annex XIII, Part I, the entry for Denmark is replaced by the following:

Member State	Territory
'Denmark	Whole territory, except the area around Hove Kalkgrav up to a distance of 1 km from the centre of the lakes and the water catchment areas of Rohden Å, Sneum Å, Vidå, Lindenberg Å, Århus Å, Varde Å, Kolding Å'

;

6. in Annex XIII, Part I, the entry for Finland is replaced by the following:

Member State	Territory
Finland	Whole territory, except the coastal compartment comprised by the parts of Föglö, Lumparland, Lemland, Vårdö municipalities that are contained within a circle of radius 11,466 kilometres, centered on WGS84 coordinates Lat 60,013565060°, Lon 20,317617393°

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1912**of 28 October 2021****approving amendments to the specification for a protected designation of origin or a protected geographical indication ‘Ardèche’ (PGI)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) The Commission has examined France’s application for the approval of amendments to the specification for the protected geographical indication ‘Ardèche’, submitted pursuant to Article 105 of Regulation (EU) No 1308/2013.
- (2) The Commission published the application for the approval of amendments to the specification in the *Official Journal of the European Union* ⁽²⁾, as required by Article 97(3) of Regulation (EU) No 1308/2013.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) The amendments to the specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

*Article 1*The amendments to the specification published in the *Official Journal of the European Union* regarding the name ‘Ardèche’ (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, 28 October 2021.

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 288, 19.7.2021, p. 20.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1913**of 28 October 2021****approving amendments to the specification for a Protected Designation of Origin or a Protected Geographical Indication ‘Cotnari’ (PDO)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) The Commission has examined the application for the approval of amendments to the specification for the Protected Designation of Origin ‘Cotnari’, forwarded by Romania in accordance with Article 105 of Regulation (EU) No 1308/2013.
- (2) The Commission has published the application for the approval of the amendments to the specification in the *Official Journal of the European Union*, as required by Article 97(3) of Regulation (EU) No 1308/2013 ⁽²⁾.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) The amendments to the specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

*Article 1*The amendments to the specification published in the *Official Journal of the European Union* regarding the name ‘Cotnari’ (PDO) 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, 28 October 2021.

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 284, 16.7.2021, p. 20.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1914**of 28 October 2021****conferring protection under Article 99 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council on the name 'Île-de-France' (PGI)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) In accordance with Article 97(2) and (3) of Regulation (EU) No 1308/2013, the Commission has examined the application to register the name 'Île-de-France' forwarded by France and has published it in the *Official Journal of the European Union* ⁽²⁾.
- (2) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (3) In accordance with Article 99 of Regulation (EU) No 1308/2013, the name 'Île-de-France' should be protected and entered in the register referred to in Article 104 of that Regulation.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Île-de-France' (PGI) is hereby protected.

*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, 28 October 2021.

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 290, 20.7.2021, p. 20.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1915**of 28 October 2021****conferring protection under Article 99 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council on the name 'Urueña' (PDO)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) In accordance with Article 97(2) and (3) of Regulation (EU) No 1308/2013, the Commission has examined the application to register the name 'Urueña' forwarded by Spain and has published it in the *Official Journal of the European Union* ⁽²⁾.
- (2) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (3) In accordance with Article 99 of Regulation (EU) No 1308/2013, the name 'Urueña' should be protected and entered in the register referred to in Article 104 of that Regulation.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Urueña' (PDO) is hereby protected.

*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, 28 October 2021.

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 139, 20.4.2021, p. 21.

COMMISSION REGULATION (EU) 2021/1916**of 3 November 2021****amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid in the Union list of flavourings****(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ⁽¹⁾, and in particular Article 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.
- (2) Commission Implementing Regulation (EU) No 872/2012 ⁽³⁾ adopted the list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.
- (3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.
- (4) On 24 February 2015, an application was submitted to the Commission for authorisation of the use of the substance 4-amino-5-(3-(isopropylamino)-2,2-dimethyl-3oxopropoxy)-2-methylquinoline-3-carboxylic acid (FL No 16.130) and one of its salts, namely, its hemisulfate monohydrate salt, as flavouring substances in various foods falling, in substance, under a number of the food categories referred to in the Union list of flavourings and source materials. According to the application, only that substance and its hemisulfate monohydrate salt, but not other salts of that substance, are intended to be added to food as flavourings. The Commission notified to the European Food Safety Authority ('the Authority') and requested its opinion. The Commission also made the application available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The Authority, in its opinion ⁽⁴⁾ adopted on 30 November 2016, evaluated the safety of substance and of its hemisulfate monohydrate salt both under the FL No 16.130. It noted that this substance is a substance with flavouring modifying properties and concluded that its use and also that of only its hemisulfate monohydrate salt do not give rise to safety concerns when used at the estimated levels of dietary intake.

⁽¹⁾ OJ L 354, 31.12.2008, p. 34.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

⁽⁴⁾ EFSA Journal 2017;15(1):4660.

- (6) In light of the opinion of the Authority, it is appropriate to authorise the use of substance FL No 16.130 and its hemisulfate monohydrate salt as flavouring substances under the specified conditions of use since their use under these conditions does not give rise to safety concerns and it is not expected to mislead the consumer. Since only the hemisulfate monohydrate salt of the concerned substance is also intended to be added to food as flavouring, it is also appropriate, for the sake of clarity, to explicitly indicate that Part A, Section 2, Note 1 of Annex I to Regulation (EC) No 1334/2008 does not apply to this substance.
- (7) Annex I, Part A to Regulation (EC) No 1334/2008 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I, Part A to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 3 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

In Part A, Section 2, Table 1 of Annex I to Regulation (EC) No 1334/2008, the following entry concerning FL No 16.130 is inserted after entry 16.127:

16.130	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid	1359963-68-0	2204		At least 99 % minimum assay (IR NMR MS)	<p>Note: Part A, Section 2, Note 1 of Annex I to Regulation (EC) No 1334/2008 does not apply to this substance.</p> <p>Restrictions for use as a flavouring substance expressed as a sum of the carboxylic acid and the hemisulfate monohydrate salt, expressed as the acid:</p>		EFSA'
	4-Amino-5-(3-(isopropylamino)-2,2-dimethyl-3-oxopropoxy)-2-methylquinoline-3-carboxylic acid hemisulfate monohydrate salt	1460210-04-1	2204.1		<p>Synonym: 3-quinolinecarboxylic acid, 4-amino-5-[2,2-dimethyl-3-[(1-methylethyl)amino]-3-oxopropoxy]-2-methyl-, sulfate, hydrate (2:1:2). At least 99 % minimum assay (HPLC).</p>	<p>In category 1.4. – not more than 10 mg/kg.</p> <p>In category 1.6.3. – not more than 30 mg/kg.</p> <p>In category 1.8. – not more than 30 mg/kg.</p> <p>In categories 2.2.1. and 2.2.2. – not more than 30 mg/kg.</p> <p>In category 3. – not more than 30 mg/kg.</p> <p>In category 4.2.3. – not more than 10 mg/kg.</p> <p>In category 4.2.4.1. – not more than 30 mg/kg.</p> <p>In category 4.2.4.2. – not more than 10 mg/kg.</p> <p>In categories 4.2.5.1., 4.2.5.2., 4.2.5.3. and 4.2.5.4. – not more than 30 mg/kg.</p> <p>In categories 5.1. and 5.2. – not more than 30 mg/kg.</p> <p>In category 5.3. – not more than 300 mg/kg.</p> <p>In category 5.4. – not more than 30 mg/kg.</p>		

					<p>In category 6.3. – not more than 45 mg/kg.</p> <p>In category 7.2. – not more than 15 mg/kg.</p> <p>In categories 8.3.1, 8.3.2. and 8.3.3. – not more than 15 mg/kg.</p> <p>In categories 8.3.4.1., 8.3.4.2. and 8.3.4.3. – not more than 15 mg/kg.</p> <p>In category 11.2. – not more than 30 mg/kg.</p> <p>In category 12.4. – not more than 30 mg/kg.</p> <p>In category 12.5. – not more than 10 mg/l.</p> <p>In categories 14.1.2., 14.1.3. and 14.1.4. – not more than 7 mg/l.</p> <p>In categories 14.1.5.1. and 14.1.5.2. – not more than 7 mg/kg.</p> <p>In category 14.2.1. – not more than 7 mg/l.</p> <p>In categories 14.2.2. and 14.2.5. – not more than 10 mg/l.</p> <p>In category 15.1. – not more than 30 mg/kg.</p> <p>In category 16 (excluding products covered in categories 1, 3 and 5) – not more than 15 mg/kg.</p>	
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COMMISSION REGULATION (EU) 2021/1917**of 3 November 2021****amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 2-(4-methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide in the Union list of flavourings****(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ⁽¹⁾, and in particular Article 11(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.
- (2) Commission Implementing Regulation (EU) No 872/2012 ⁽³⁾ adopted the list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.
- (3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application submitted by a Member State or by an interested party.
- (4) On 7 December 2015, an application was submitted to the Commission for the authorisation of the use of 2-(4-methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide (FL No 16.133), as a flavouring substance in various foods falling, in substance, under a number of food categories referred to in the Union list of flavourings and source materials. The application was notified to the European Food Safety Authority ('the Authority') for its opinion. The Commission also made the application available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The Authority in its opinion, adopted on 12 September 2018 ⁽⁴⁾, evaluated the safety of the substance FL No 16.133 when used as a flavouring substance and concluded that its use does not give rise to safety concerns when limited to levels up to those specified for various foods in different food categories. The Authority also indicated that its conclusion on the safety of the substance does not apply to the potential addition of the substance to non-opaque beverages where the substance can be subject to photo-transformation. This flavouring should only be added to opaque foods and packed in containers protected from light.

⁽¹⁾ OJ L 354, 31.12.2008, p. 34.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).

⁽⁴⁾ EFSA Journal 2018;16(10):5421.

- (6) In accordance with Article 15(1), point (c), of Regulation (EC) No 1334/2008, the information on the special conditions for storage and of use should be provided in the labelling to the customer of the flavouring substance and/or preparations to which that flavouring substance has been added. An indication on the containers such as 'keep away from light' should be included in the labelling.
- (7) The Authority also noted that substance FL No 16.133 is a substance with flavouring modifying properties.
- (8) This flavouring substance is not intended for sale to the final consumer and therefore it should be placed on the market ensuring that this purpose is avoided.
- (9) In light of the opinion of the Authority, since the use of the substance FL No 16.133 as a flavouring substance does not give rise to safety concerns with the specified conditions of use and it is not expected to mislead the consumer, it is appropriate to authorise such use.
- (10) Part A of Annex I to Regulation (EC) No 1334/2008 should therefore be amended accordingly to include 2-(4-methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide in the Union list of flavourings.
- (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

Annex I, Part A to Regulation (EC) No 1334/2008 is amended in accordance with the Annex to this Regulation.

Article 2

The flavouring substance 2-(4-methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide is not authorised for sale to the final consumer.

Article 3

In addition to the labelling requirements for flavourings not intended for sale to the final consumer in accordance with Article 15(1), point (c), of Regulation (EC) No 1334/2008, the following additional information shall be provided in the labelling of the packages or containers:

- 'Contains substance FL 16.133. Protect from light to avoid its photo-transformation.',
- an indication such as 'keep away from light'.

Article 4

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

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

Done at Brussels, 3 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex I, Part A, Section 2, Table 1 to Regulation (EC) No 1334/2008 the following entry concerning FL No 16.133 is inserted:

16.133	2-(4-methylphenoxy)-N-(1H-pyrazol-3-yl)-N-(thiophen-2-ylmethyl)acetamide	1374760-95-8	2237	At least 99 %, peak area (UPLC-UV, 254 nm)	<p>1. Restrictions of use as a flavouring substance, in the following food categories:</p> <p>In category 1.4.: Opaque flavoured fermented milk products including heat treated products and packaged in opaque packaging/containers – not more than 3 mg/kg</p> <p>In category 3.0.: opaque edible ices, including sherbet and sorbet, and packaged in opaque packaging/containers – not more than 3 mg/kg</p> <p>In category 5.1.: opaque cocoa products and chocolate products, including imitations and chocolate substitutes, and packaged in opaque packaging/containers – not more than 15 mg/kg</p> <p>In category 5.2.: opaque confectionery, including hard and soft candy, nougats, etc., other than products falling in categories 05.1., 05.3. and 05.4, and packaged in opaque packaging/containers – not more than 15 mg/kg</p> <p>In category 5.3.: opaque chewing gum, and packaged in opaque packaging/containers – not more than 150 mg/kg</p> <p>In category 5.4.: opaque decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces), and packaged in opaque packaging/containers – not more than 15 mg/kg</p> <p>In category 12.5.: opaque soups and broths, and packaged in opaque packaging/containers – not more than 3 mg/kg</p>	EFSA'
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					<p>In category 12.6.: opaque sauces and like products, and packaged in opaque packaging/containers – not more than 15 mg/kg</p> <p>In category 14.1.4.: opaque flavoured drinks, only for dairy based drinks, and packaged in opaque packaging/containers – not more than 3 mg/kg</p> <p>In category 16.: opaque desserts excluding products covered in categories 1., 3. and 4., and packaged in opaque packaging/containers – not more than 3 mg/kg</p> <p>2. This flavouring substance is not authorised for sale to the final consumer.</p> <p>3. The following information shall be provided “contains substance FL 16.133. Protect from light to avoid its photo-transformation”. Containers shall be opaque. An indication on the containers such as “keep away from light” shall also be included in the labelling.</p>		
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DECISIONS

COUNCIL DECISION (EU) 2021/1918

of 28 October 2021

on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning the amendment of Protocol 31 on cooperation in specific fields outside the four freedoms and of Protocol 37 containing the list provided for in Article 101 to the EEA Agreement (Space Programme of the Union)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 189(2), in conjunction with Article 218(9) thereof,

Having regard to Council Regulation (EC) No 2894/94 of 28 November 1994 concerning arrangements for implementing the Agreement on the European Economic Area ⁽¹⁾, and in particular Article 1(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement on the European Economic Area ⁽²⁾ ('the EEA Agreement') entered into force on 1 January 1994.
- (2) Pursuant to Article 98 of the EEA Agreement, the EEA Joint Committee may decide to amend, inter alia, Protocol 31 on cooperation in specific fields outside the four freedoms ('Protocol 31') and Protocol 37 containing the list provided for in Article 101 ('Protocol 37') to the EEA Agreement.
- (3) Regulation (EU) 2021/696 of the European Parliament and of the Council ⁽³⁾ is to be incorporated into the EEA Agreement. Only Norway and Iceland are concerned by this amendment.
- (4) Protocol 31 and Protocol 37 to the EEA Agreement should be amended accordingly.
- (5) The position of the Union within the EEA Joint Committee should therefore be based on the draft decision of the EEA Joint Committee,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf within the EEA Joint Committee on the proposed amendment of Protocol 31 on cooperation in specific fields outside the four freedoms and of Protocol 37 containing the list provided for in Article 101 to the EEA Agreement, shall be based on the draft decision of the EEA Joint Committee ⁽⁴⁾.

⁽¹⁾ OJ L 305, 30.11.1994, p. 6.

⁽²⁾ OJ L 1, 3.1.1994, p. 3.

⁽³⁾ Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013, (EU) No 377/2014 and Decision No 541/2014/EU (OJ L 170, 12.5.2021, p. 69).

⁽⁴⁾ See document ST 12908/21 at <http://register.consilium.europa.eu>

Article 2

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

Done at Brussels, 28 October 2021.

For the Council
The President
G. DOVŽAN

COUNCIL DECISION (EU) 2021/1919**of 29 October 2021****on the position to be taken on behalf of the European Union on the adoption of a decision, by written procedure, by the Participants to the Arrangement on Officially Supported Export Credits to review the Coal-Fired Electricity Generation Sector Understanding contained in Annex VI to that Arrangement**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The guidelines contained in the Arrangement on Officially Supported Export Credits (the 'Arrangement') of the Organisation for Economic Cooperation and Development ('OECD'), including the Coal-Fired Electricity Generation Sector Understanding ('CFSU') contained in Annex VI to the Arrangement, have been transposed and thus been made legally binding in the Union by Regulation (EU) No 1233/2011 of the European Parliament and of the Council ⁽¹⁾.
- (2) In accordance with the CFSU, the participants to the Arrangement (the 'Participants') are to adopt a decision, by written procedure, to review the CFSU with the objective of further strengthening its terms and conditions in order to contribute to the common goal of addressing climate change and to continue phasing-down official support for coal-fired power plants.
- (3) The decision to review the CFSU should be in line with the international commitments of the European Union pursuant to the Paris Agreement and the Union's climate policy.
- (4) In its conclusions on Climate and Energy Diplomacy – Delivering on the external dimension of the European Green Deal of 25 January 2021, the Council called for a global phase-out of environmentally harmful fossil-fuel subsidies along a clear timeline and for a resolute and just worldwide transformation towards climate neutrality, including a phasing-out of unabated coal in energy production and, as a first step, an immediate end to all financing of new coal infrastructure in third countries.
- (5) It is appropriate to establish the position to be taken on the Union's behalf regarding the adoption of a decision, by written procedure, by the Participants to review the CFSU, as the decision of the Participants will be binding on the Union and capable of decisively influencing the content of Union law, by virtue of Regulation (EU) No 1233/2011,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf regarding the adoption by the participants of a decision by written procedure to review the Coal-Fired Electricity Generation Sector Understanding contained in Annex VI to the Arrangement on Officially Supported Export Credits of the Organisation for Economic Cooperation and Development shall be based on the position of the European Union ⁽²⁾.

⁽¹⁾ Regulation (EU) No 1233/2011 of the European Parliament and of the Council of 16 November 2011 on the application of certain guidelines in the field of officially supported export credits and repealing Council Decisions 2001/76/EC and 2001/77/EC (OJ L 326, 8.12.2011, p. 45).

⁽²⁾ See document ST 12623/21 on <http://register.consilium.europa.eu>

Article 2

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

Done at Brussels, 29 October 2021.

For the Council
The President
G. DOVŽAN

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