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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1030/2012

of 26 October 2012

entering a name in the register of protected designations of origin and protected geographical indications (Isle of Man Queenies (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, the United Kingdom's application to register the name 'Isle of Man Queenies' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

*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, 26 October 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 38, 11.2.2012, p. 32.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom

UNITED KINGDOM

Isle of Man Queenies (PDO)

COMMISSION IMPLEMENTING REGULATION (EU) No 1031/2012**of 26 October 2012****entering a name in the register of protected designations of origin and protected geographical indications (Abensberger Spargel/Abensberger Qualitätsspargel (PGI))**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, Germany's application to register the name 'Abensberger Spargel'/'Abensberger Qualitätsspargel' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 26 October 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 55, 24.2.2012, p. 25.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.6. Fruit, vegetables and cereals, fresh or processed

GERMANY

Abensberger Spargel/Abensberger Qualitätsspargel (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1032/2012**of 26 October 2012****entering a name in the register of protected designations of origin and protected geographical indications (Ciliegia di Vignola (PGI))**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, Italy's application to register the name 'Ciliegia di Vignola' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 26 October 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOȘ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 52, 22.2.2012, p. 17.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.6. Fruit, vegetables and cereals, fresh or processed

ITALY

Ciliegia di Vignola (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1033/2012**of 26 October 2012****entering a name in the register of protected designations of origin and protected geographical indications (Cabrito do Alentejo (PGI))**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and food-stuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, Portugal's application to register the name 'Cabrito do Alentejo' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 26 October 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 52, 22.2.2012, p. 22.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.1. Fresh meat (and offal)

PORTUGAL

Cabrito do Alentejo (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1034/2012**of 26 October 2012****entering a name in the register of protected designations of origin and protected geographical indications (Cordeiro Mirandês/Canhono Mirandês (PDO))**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, Portugal's application to register the name 'Cordeiro Mirandês'/'Canhono Mirandês' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 26 October 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 60, 29.2.2012, p. 16.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.1. Fresh meat (and offal)

PORTUGAL

Cordeiro Mirandês/Canhono Mirandês (PDO)

COMMISSION IMPLEMENTING REGULATION (EU) No 1035/2012**of 26 October 2012****entering a name in the register of protected designations of origin and protected geographical indications (*Kraška panceta* (PGI))**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, Slovenia's application to register the name '*Kraška panceta*' was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 26 October 2012.

*For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission*

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 48, 18.2.2012, p. 32.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.2. Meat products (cooked, salted, smoked, etc.)

SLOVENIA

Kraška panceta (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1036/2012**of 7 November 2012****amending Annex II to Decision 2007/777/EC and Annex II to Regulation (EU) No 206/2010 as regards the entries for Croatia in the lists of third countries or parts thereof from which the introduction of fresh meat and of certain meat products into the Union is authorised****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption⁽¹⁾, and in particular the introductory phrase of Article 8, the first subparagraph of Article 8(1) and Article 8(4) thereof,

Whereas:

- (1) Commission Decision 2007/777/EC⁽²⁾ lays down rules on imports into the Union and the transit and storage in the Union of consignments of meat products and consignments of treated stomachs, bladders and intestines, as defined in Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽³⁾.
- (2) Part 2 of Annex II to Decision 2007/777/EC sets out the list of third countries or parts thereof from which the introduction into the Union of meat products and treated stomachs, bladders and intestines into the Union is authorised, provided that those commodities comply with the treatment referred to in that Part.
- (3) Part 4 of Annex II to Decision 2007/777/EC sets out the treatments referred to in Part 2 of that Annex, assigning a code to each of those treatments. That Part sets out a non-specific treatment 'A' and specific treatments 'B' to 'F' listed in descending order of severity.
- (4) Commission Regulation (EU) No 206/2010⁽⁴⁾ lays down the veterinary certification requirements for the introduction into the Union of certain consignments of live animals or fresh meat. It also lays down the lists of third countries, territories or parts thereof from which those consignments may be introduced into the Union.
- (5) Regulation (EU) No 206/2010 provides that consignments of fresh meat intended for human consumption are to be imported into the Union only if they come from the third countries, territories or parts thereof listed in Part 1 of Annex II to that Regulation for which there is a model veterinary certificate corresponding to the consignment concerned listed in that Part.

- (6) Croatia is currently listed in Part 1 of Annex II to Regulation (EU) No 206/2010 as a third country from which imports of fresh meat of certain animals into the Union are authorised. However, Croatia is currently not listed as a third country from which imports of fresh meat, including minced meat, of domestic porcine animals into the Union are authorised.
- (7) Croatia has submitted to the Commission a request to be authorised to export fresh meat of domestic porcine animals into the Union. According to the information submitted by Croatia, preventive vaccination against classical swine fever is prohibited on the territory of that third country since January 2005. In addition, there is no evidence of classical swine fever virus circulation in domestic porcine animals on the territory of Croatia since March 2008. The information available therefore indicates that Croatia is free from classical swine fever in domestic porcine animals, without vaccination.
- (8) The Croatian competent authority has also provided sufficient guarantees as regards compliance with the Union legislation regarding classical swine fever and it is implementing an enhanced surveillance programme for domestic porcine animals and wild boar.
- (9) In addition, the results of an inspection carried out by the Commission in Croatia in 2010 were largely positive. Croatia has also submitted to the Commission the confirmation that certain planned corrective actions regarding the shortcomings identified during that inspection were satisfactorily implemented in 2011.
- (10) The evaluation of the information submitted by Croatia leads to the conclusion that the introduction into the Union of fresh meat of domestic porcine animals from that third country does not constitute a risk to the Union health status with regard to classical swine fever. Imports from Croatia of fresh meat, including minced meat, of domestic porcine animals into the Union should therefore be permitted.
- (11) In addition, Croatia is currently listed in Part 2 of Annex II to Decision 2007/777/EC for the introduction into the Union of meat products and treated stomachs, bladders and intestines from domestic porcine animals and farmed cloven-hoofed game (swine) which have undergone the specific treatment 'D'.

⁽¹⁾ OJ L 18, 23.1.2003, p. 11.

⁽²⁾ OJ L 312, 30.11.2007, p. 49.

⁽³⁾ OJ L 139, 30.4.2004, p. 55.

⁽⁴⁾ OJ L 73, 20.3.2010, p. 1.

- (12) In view of the fact that imports of fresh meat, including minced meat, of domestic porcine animals into the Union from Croatia are to be authorised, it is appropriate to also permit imports into the Union from that third country of meat products which were obtained from such fresh meat, without requiring that they undergo a specific treatment. Part 2 of Annex II to Decision 2007/777/EC should therefore be amended accordingly.
- (13) Decision 2007/777/EC and Regulation (EU) No 206/2010 should therefore be amended accordingly.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In Part 2 of Annex II to Decision 2007/777/EC, the entry for Croatia is replaced by the following:

'HR	Croatia	A	A	A	A	A	A	A	A	D	XXX	A	A	XXX'
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Article 2

In Part 1 of Annex II to Regulation (EU) No 206/2010, the entry for Croatia is replaced by the following:

'HR — Croatia	HR-0	Whole country	BOV, OVI, EQU, RUF, RUW				
			POR				8 November 2012'

Article 3

This Regulation shall enter into force on the 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, 7 November 2012.

For the Commission
The President
 José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 1037/2012

of 7 November 2012

approving the active substance isopyrazam, 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 the Annex to 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) and Article 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For isopyrazam the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2010/132/EU ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received on 25 November 2008 an application from Syngenta Crop Protection AG for the inclusion of the active substance isopyrazam in Annex I to Directive 91/414/EEC. Decision 2010/132/EU confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 4 May 2010.
- (4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the review of the pesticide risk assessment of the active substance isopyrazam ⁽⁴⁾ on 27 February 2012. The draft assessment report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and

Animal Health and was finalised on 28 September 2012 in the format of the Commission review report for isopyrazam.

- (5) It has appeared from the various examinations made that plant protection products containing isopyrazam may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve isopyrazam.
- (6) 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, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.
- (7) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing isopyrazam. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the update of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (8) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽⁵⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 52, 3.3.2010, p. 51.

⁽⁴⁾ EFSA Journal 2012; 10(3):2600. Available online: www.efsa.europa.eu

⁽⁵⁾ OJ L 366, 15.12.1992, p. 10.

obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.

- (9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to 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⁽¹⁾ should be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance isopirazam, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing isopirazam as an active substance by 30 September 2013.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing isopirazam as either

the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 March 2013 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing isopirazam as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2014 at the latest; or
- (b) in the case of a product containing isopirazam as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 2014 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or substances, whichever is the latest.

Article 3

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 4

Entry into force and date of application

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 1 April 2013.

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

Done at Brussels, 7 November 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ 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
Isopyrazam CAS No 881685-58-1 (syn-isomer: 683777-13-1/ anti-isomer: 683777-14-2) CIPAC No 963	A mixture of 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (syn-isomer – 50:50 mix of two enantiomers) and 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (anti-isomer– 50:50 mix of two enantiomers) In a range of 78:15 % to 100:0 % <i>syn</i> to <i>anti</i>.	≥ 920 g/kg In a range of 78:15 % to 100:0 % <i>syn</i>- to <i>anti</i>-isomers	1 April 2013	31 March 2023	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 isopyrazam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 September 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic organisms; (b) the risk to earthworms if the substance is applied in the framework of no cultivation/minimum cultivation practices; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, like the exclusion of no cultivation/minimum cultivation practices, and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate. The applicant shall submit confirmatory information as regards the relevance of the metabolites CSCD 459488 and CSCD 459489 for groundwater. The applicant shall submit to the Commission, the Member States and the Authority this information by 31 March 2015.

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

ANNEX II

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'27	Isopyrazam CAS No 881685-58-1 (syn-isomer: 683777-13-1/ anti-isomer: 683777-14-2) CIPAC No 963	<i>A mixture of 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide</i> <i>(syn-isomer – 50:50 mix of two enantiomers)</i> <i>and</i> <i>3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide</i> <i>(anti-isomer– 50:50 mix of two enantiomers)</i> <i>In a range of 78:15 % to 100:0 % syn to anti.</i>	≥ 920 g/kg In a range of 78:15 % to 100:0 % syn- to anti-isomers	1 April 2013	31 March 2023	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 isopyrazam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 September 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic organisms; (b) the risk to earthworms if the substance is applied in the framework of no cultivation/minimum cultivation practices; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, like the exclusion of no cultivation/minimum cultivation practices, and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate. The applicant shall submit confirmatory information as regards the relevance of the metabolites CSCD 459488 and CSCD 459489 for groundwater. The applicant shall submit to the Commission, the Member States and the Authority this information by 31 March 2015.'

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

COMMISSION IMPLEMENTING REGULATION (EU) No 1038/2012**of 7 November 2012****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 7 November 2012.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	AL	29,8
	MA	36,7
	MK	30,8
	TR	65,0
	ZZ	40,6
0707 00 05	AL	31,8
	TR	99,4
	ZZ	65,6
0709 93 10	TR	119,8
	ZZ	119,8
0805 20 10	PE	72,2
	ZA	144,9
	ZZ	108,6
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	AR	96,7
	HR	53,4
	PE	42,6
	TR	75,2
	UY	101,2
	ZA	194,3
	ZZ	93,9
0805 50 10	AR	60,7
	TR	86,6
	ZA	117,2
	ZZ	88,2
0806 10 10	BR	269,3
	PE	317,5
	TR	165,4
	US	362,2
	ZZ	278,6
0808 10 80	CL	150,4
	CN	87,5
	MK	32,3
	NZ	152,1
	ZA	122,2
0808 30 90	ZZ	108,9
	CN	54,3
	TR	122,1
	ZZ	88,2

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 6 November 2012

amending Decision 2010/381/EU on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption and repealing Decision 2010/220/EU on emergency measures applicable to consignments of farmed fishery products imported from Indonesia and intended for human consumption

*(notified under document C(2012) 7637)***(Text with EEA relevance)**

(2012/690/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽¹⁾, and in particular Article 53(1)(b)(ii) thereof,

Whereas:

- (1) Regulation (EC) No 178/2002 lays down the general principles governing food and feed in general, and food and feed safety in particular, at Union and national level. It provides for emergency measures where it is evident that food or feed imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member States.
- (2) Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products⁽²⁾ provides that the production process of animals and primary products of animal origin is to be monitored for the purpose of detecting the presence of certain residues and substances in live animals, their excrements and body fluids and in tissue, animal products, animal feed and drinking water.
- (3) Commission Decision 2010/381/EU of 8 July 2010 on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption⁽³⁾ provides that at least 20 % of the consignments of aquaculture products from India intended for human consumption are to be tested for

the presence of pharmacologically active substances as defined in Article 2(a) of Regulation (EC) No 470/2009 of the European Parliament and of the Council⁽⁴⁾, and in particular of chloramphenicol, tetracycline, oxytetracycline and chlortetracycline and of metabolites of nitrofurans.

- (4) The results of an inspection to India carried out in November 2011 by the Commission inspection service, the Food and Veterinary Office, have confirmed that an adequate official control system covering aquaculture production is now in place and that the recommendation from the 2009 inspection report concerning official monitoring of aquaculture farms has been partly addressed.
- (5) Since the adoption of Decision 2010/381/EU, the number of samples of aquaculture products in which chloramphenicol, tetracycline, oxytetracycline and chlortetracycline or metabolites of nitrofurans were detected in the Member States has decreased. Therefore, it is appropriate to reduce the minimum percentage of consignments that are to be tested for the presence of pharmacologically active substances.
- (6) The obligation for a mandatory testing should however be maintained to continue to provide more accurate information on the possible contamination of aquaculture products originating from India with those residues. The testing should also continue in order to deter producers in India from misusing those substances.
- (7) Decision 2010/381/EU should therefore be amended accordingly.
- (8) Commission Decision 2010/220/EU of 16 April 2010 on emergency measures applicable to consignments of farmed fishery products imported from Indonesia and intended for human consumption⁽⁵⁾ provides that at least 20 % of the consignments of farmed fishery products from Indonesia intended for human consumption are to be tested for the presence of

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 125, 23.5.1996, p. 10.

⁽³⁾ OJ L 174, 9.7.2010, p. 51.

⁽⁴⁾ OJ L 152, 16.6.2009, p. 11.

⁽⁵⁾ OJ L 97, 17.4.2010, p. 17.

residues of pharmacologically active substances defined in Article 2(a) of Regulation (EC) No 470/2009 and in particular of chloramphenicol, metabolites of nitrofurans and tetracyclines.

- (9) Since the adoption of Decision 2010/220/EU, no residues of chloramphenicol, metabolites of nitrofurans or tetracyclines were detected in the consignments of farmed fishery products imported from Indonesia.
- (10) The results of an inspection to Indonesia carried out in February 2012 by Commission inspection service, the Food and Veterinary Office, have concluded that the residue control system in Indonesia provided satisfactory guarantees with an effect equivalent to those provided for in Union law.
- (11) Decision 2010/220/EU should therefore be repealed.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

In Article 3 of Decision 2010/381/EU, paragraph 1 is replaced by the following:

‘1. Member States shall, by using appropriate sampling plans, ensure that official samples are taken from at least 10 % of consignments presented for import at border inspection posts on their territory.’.

Article 2

Decision 2010/220/EU is repealed.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2012.

For the Commission

Maroš ŠEFČOVIČ

Vice-President

COMMISSION IMPLEMENTING DECISION

of 6 November 2012

on granting derogations from Regulation (EU) No 691/2011 of the European Parliament and of the Council on European environmental economic accounts with regard to the Kingdom of Spain, the French Republic, the Republic of Cyprus, the Republic of Malta, the Republic of Austria and the Republic of Poland

*(notified under document C(2012) 7645)***(Only the Spanish, French, Greek, Maltese, German and Polish texts are authentic)**

(2012/691/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 691/2011 of the European Parliament and of the Council of 6 July 2011 on European environmental economic accounts⁽¹⁾, and in particular Article 8(1) thereof,

Having regard to the requests made by the Kingdom of Spain, the French Republic, the Republic of Cyprus, the Republic of Malta, the Republic of Austria and the Republic of Poland,

Whereas:

- (1) In accordance with Article 8(1) of Regulation (EU) No 691/2011 the Commission may adopt implementing acts with a view to granting derogations to Member States during the transitional periods referred to in the Annexes to Regulation (EU) No 691/2011 in so far as the national statistical systems require major adaptations.
- (2) Such derogations should be granted, at their justified request, to the Kingdom of Spain, the French Republic, the Republic of Cyprus, the Republic of Malta, the Republic of Austria and the Republic of Poland.

- (3) The measures provided for in this Decision are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS DECISION:

Article 1

Derogations from Regulation (EU) No 691/2011, as set out in the Annex, are granted to the Kingdom of Spain, the French Republic, the Republic of Cyprus, the Republic of Malta, the Republic of Austria and the Republic of Poland.

Article 2

This Decision is addressed to the Kingdom of Spain, the French Republic, the Republic of Cyprus, the Republic of Malta, the Republic of Austria and the Republic of Poland.

Done at Brussels, 6 November 2012.

For the Commission

Algirdas ŠEMETA

Member of the Commission

⁽¹⁾ OJ L 192, 22.7.2011, p. 1.

ANNEX

List of specific derogations from Regulation (EU) No 691/2011:

Member State	Derogation	End of derogation
Kingdom of Spain	Annex I — Air emission accounts, breakdown by economic activity (A*64)	30 September 2015
	Annex II — Environmentally related taxes, breakdown by economic activity (A*64)	30 September 2015
	Annex III — Material flow accounts data for other crop residues, waste imports and adjustment to the residency principle	31 December 2015
French Republic	Annex II — Environmentally related taxes, breakdown by economic activity (A*64)	30 September 2015
Republic of Cyprus	Annex I — Air emission accounts	30 September 2015
	Annex II — Environmentally related taxes	30 September 2015
	Annex III — Economy-wide Material Flow Accounts	31 December 2015
Republic of Malta	Annex I — Air emission accounts	30 September 2015
	Annex II — Environmentally related taxes	30 September 2015
	Annex III — Economy-wide Material Flow Accounts	31 December 2015
Republic of Austria	Annex I — Air emission accounts, series missing for PFC, HFC and SF ₆	30 September 2015
Republic of Poland	Annex II — Environmentally related taxes, breakdown by economic activity (A*64)	30 September 2015

COMMISSION IMPLEMENTING DECISION

of 6 November 2012

amending the Annexes to Decision 2006/766/EC as regards the entries in the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products for human consumption are permitted

*(notified under document C(2012) 7696)***(Text with EEA relevance)**

(2012/692/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽¹⁾, and in particular Article 11(1) thereof,

Whereas:

- (1) Regulation (EC) No 854/2004 provides that products of animal origin are only to be imported from a third country or part of a third country that appears on a list drawn up in accordance with that Regulation.
- (2) Regulation (EC) No 854/2004 also provides that when drawing up and updating such lists, account is to be taken of Union controls in third countries and guarantees provided by the competent authorities of third countries, as regards compliance or equivalence with the Union feed and food law and animal health rules as specified in Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽²⁾.
- (3) Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted ⁽³⁾ lists those third countries which satisfy the criteria referred to in Regulation (EC) No 854/2004 and are therefore able to guarantee that exports of those products to the Union meet the sanitary conditions laid down in Union legislation to protect the health of consumers. In particular, Annex I to that Decision sets

out a list of third countries from which imports are permitted of bivalve molluscs, tunicates, echinoderms and marine gastropods and Annex II to that Decision sets out a list of third countries and territories from which imports of fishery products for human consumption are permitted. Those lists also indicate restrictions concerning such imports from certain third countries.

- (4) A Commission inspection was carried out in Croatia from 23 November to 2 December 2010 to evaluate the control systems in place governing the production of live bivalve molluscs intended for export to the Union. A number of deficiencies were identified which were subsequently corrected. The control systems in place in that third country currently provide sufficient guarantees to ensure adequate consumer health protection for bivalve molluscs exported from Croatia to the Union. Croatia should therefore be included in the list set out in Annex I to Decision 2006/766/EC.
- (5) A Commission inspection was carried out in Brunei from 25 to 28 April 2012 to evaluate the control systems in place governing the production of fishery products intended for export to the Union. No deficiencies considered to have significant implications for consumer health protection were identified during that inspection with regard to the production of aquaculture products. Brunei should therefore be included in the list of third countries set out in Annex II to Decision 2006/766/EC, together with an indication that only imports of aquaculture products are permitted into the Union from that third country.
- (6) A Commission inspection was carried out in Togo from 8 to 11 June 2009. Official checks and hygiene certification for the export of live lobsters was found to be satisfactory, but deficiencies were noted in the control system for smoked fishery products intended for export to the Union. In view of those deficiencies, Togo was included in the list set out in Annex II to Decision 2006/766/EC, as amended by Commission Decision 2009/951/EU ⁽⁴⁾, together with an indication that only imports of live lobsters are permitted into the Union from that third country.

⁽¹⁾ OJ L 139, 30.4.2004, p. 206.

⁽²⁾ OJ L 165, 30.4.2004, p. 1.

⁽³⁾ OJ L 320, 18.11.2006, p. 53.

⁽⁴⁾ OJ L 328, 15.12.2009, p. 70.

- (7) The deficiencies identified during the Commission inspection visit to Togo were subsequently addressed. Control systems were established to conduct microbial and chemical analyses of smoked fishery products. Analytical reports and other information submitted by the competent authority provide sufficient guarantees to ensure adequate consumer health protection for all fishery products for human consumption, other than live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods, exported from Togo to the Union.
- (8) Following an internal reform in the Kingdom of the Netherlands, effective as of 10 October 2010, the Netherlands Antilles ceased to exist as an autonomous country within that Kingdom. On that same date, Curaçao and Sint Maarten gained the status of autonomous countries within the Kingdom of the Netherlands, while Bonaire, Sint Eustatius and Saba became special municipalities of the European part of the Kingdom of the Netherlands.
- (9) Bonaire, Sint Eustatius and Saba remain nevertheless included in the list of overseas countries and territories set out in Annex II to the Treaty on the Functioning of the European Union. Thus they are overseas countries and territories to which the provisions of part four of the Treaty apply.
- (10) Being part of the European part of the Kingdom of the Netherlands, the implementation of the Treaties for those territories is ensured by the Netherlands and the tasks of the competent authority for sanitary matters in those special municipalities are carried out by the competent authorities of the Netherlands. The competent authorities of the Netherlands have presented the necessary information to the Commission to prove that the sanitary control system in place in Bonaire, Sint Eustatius and Saba provides sufficient guarantees of compliance with Union requirements. The information provided also shows that those authorities have the same legal powers to conduct controls as the competent authority of the Netherlands Antilles used to have and that food business operators are bound by the same obligations. In addition, according to that information, the official sanitary controls in those special municipalities continue at the same levels as in the period before the Netherlands Antilles ceased to exist.

- (11) Decision 2006/766/EC should therefore be amended accordingly.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2006/766/EC is amended as follows:

- (1) in Annex I, the following entry is inserted between the entries for Greenland and Jamaica:

'HR	CROATIA	Only applicable until this Acceding State becomes a Member State of the Union.'
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- (2) Annex II is amended as follows:

- (a) the following entry is inserted between the entries for Benin and Brazil:

'BN	BRUNEI	Only aquaculture products.'
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- (b) the following entry is inserted between the entries for Brazil and The Bahamas:

'BQ	BONAIRE, SINT EUSTATIUS, SABA'	
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- (c) the entry for Togo is replaced by the following:

'TG	TOGO'	
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Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2012.

For the Commission

Maroš ŠEFČOVIČ

Vice-President

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