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Contents

[1] Text with EEA relevance

EN

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

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

Corrigenda

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2015/402

of 11 March 2015

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 18(5) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from ICP Ltd, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of *Padina pavonica*-extract in Dictyolone® and increase in bone mineral density (Question No EFSA-Q-2013-00249) ([2]). The claim proposed by the applicant was worded as follows: 'improves bone density through calcitrophic effects and through the physiological restoration of proteinous bone, particular in bone loss brought about by the aging process on normal healthy persons'.

(6) On 10 January 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of *Padina pavonica*-extract in Dictyolone® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Omikron Italia S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of cytidine 5′-diphosphocholine (CDP-choline or citicoline) and maintenance of normal vision (Question No EFSA-Q-2013-00757) ([3]). The claim proposed by the applicant was worded as follows: 'CDP-choline in oral solution as source of choline contributes to the maintenance of normal function of the ophthalmic nervous structures'.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2014;12(1):3518.
([3]) *EFSA Journal* 2014;12(2):3575.

(8) On 21 February 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of cytidine 5′-diphosphocholine and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Hassia Mineralquellen GmbH & Co KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Rosbacher drive® and increased attention (Question No EFSA-Q-2013-00444) ([1]). The claim proposed by the applicant was, inter alia, worded as follows: 'helps/supports/maintains concentration'.

(10) On 24 February 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Rosbacher drive® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(12) 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 health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

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, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

([1]) *EFSA Journal* 2014;12(2):3576.

ANNEX

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	*Padina pavonica*-extract in Dictyolone®	Improves bone density through calcitrophic effects and through the physiological restoration of proteinous bone, particular in bone loss brought about by the aging process on normal healthy persons	Q-2013-00249
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Cytidine 5′-diphosphocholine (CDP-choline or citicoline)	CDP-choline in oral solution as source of choline contributes to the maintenance of normal function of the ophthalmic nervous structures	Q-2013-00757
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Rosbacher drive®	Helps/supports/maintains concentration	Q-2013-00444

COMMISSION REGULATION (EU) 2015/403

of 11 March 2015

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards *Ephedra* species and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

(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 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ([1]), and in particular Article 8(2) thereof,

Whereas:

(1) Pursuant to Article 8(2) of Regulation (EC) No 1925/2006, a Member State may request the Commission to initiate a procedure to include a substance or an ingredient containing a substance other than a vitamin or a mineral in Annex III to Regulation (EC) No 1925/2006 listing the substances whose use in foods is prohibited, restricted or under Union scrutiny, if that substance is associated with a potential risk to consumers as defined by Article 8(1) of Regulation (EC) No 1925/2006.

(2) On 7 September 2009, Germany sent a request to the Commission regarding the possible harmful effects associated with the intake of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) and *Ephedra* species and their preparations, and asked the Commission to initiate the procedure under Article 8 of Regulation (EC) No 1925/2006 for those two substances.

(3) The request by Germany fulfilled the necessary conditions and requirements laid down in Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012 ([2]).

(4) On 9 September 2011, the Commission asked the European Food Safety Authority (hereafter 'the Authority') to evaluate the safety in use of *Ephedra* and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) species in food.

(5) On 3 July 2013, the Authority adopted a scientific opinion on the evaluation of the safety in use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) ([3]). It concluded that the chemical and toxicological characterisation of yohimbe bark and its preparations used in food originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) are not adequate to conclude on their safety as ingredients of food. Therefore, it was not possible for the Authority to provide advice on a daily intake of yohimbe bark and its preparations that does not give rise to concerns for human health.

(6) On 6 November 2013, the Authority adopted a scientific opinion on the safety evaluation of *Ephedra* species for use in food ([4]). It found that although the marketing of foods containing Ephedra herb and its preparations in retail outlets is not documented in Europe, food supplements containing Ephedra herbs or their preparations that are typically used for weight loss and athletic performance can easily be purchased via the internet. The Authority concluded that it cannot be excluded that consumers may purchase herbal tea from Ephedra herb via the internet. Given that Ephedra herb and its preparations are marketed almost exclusively as food supplements, the Authority calculated potential exposure levels to the herb from food supplements. It concluded that Ephedra herb and its preparations in food supplements may result in exposure to total ephedra alkaloids or ephedrine which falls within or may exceed the therapeutic dose ranges for the individual ephedra alkaloids or ephedrine, in medicinal products.

([1]) OJ L 404, 30.12.2006, p. 26.
([2]) Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).
([3]) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the evaluation of the safety in use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille). EFSA Journal 2013;11(7):3302.
([4]) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on safety evaluation of *Ephedra* species for use in food. EFSA Journal 2013;11(11):3467.

(7) The Authority concluded that due to the absence of adequate toxicity data, it could not provide advice on a daily intake of Ephedra herb and its preparations from all foods that does not give rise to concerns for human health. Nevertheless, it concluded that exposure to total ephedra alkaloids or ephedrine in foods, mainly in food supplements could lead to severe adverse effects on the cardiovascular and central nervous systems (such as hypertension and stroke), which may be enhanced in combination with caffeine. Therefore, the use of Ephedra herb and its preparations containing ephedra alkaloids in food is of significant safety concern for human health.

(8) The Commission received no comments from interested parties following publication by the Authority of its opinions on *Ephedra* species and on Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille).

(9) As there is a possibility of harmful effects on health associated with the use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) and its preparations in foods, but scientific uncertainty persists, the substance should be placed under Union scrutiny and therefore, should be included in Part C of Annex III to Regulation (EC) No 1925/2006. Consequently, during the period of Union scrutiny and pending a decision on whether to allow the use of the substance or to place it in Part A or B of Annex III to Regulation (EC) No 1925/2006 at the end of the scrutiny period, national provisions regulating the use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) in food should still apply.

(10) Considering the significant safety concern associated with the use of Ephedra herb and its preparations in foods, in particular with regard to exposure to ephedra alkaloids present in food supplements, and considering that no daily intake of Ephedra herb and its preparations that does not give rise to concerns for human health could be set, the use of that substance in foods should be prohibited. Therefore, Ephedra herb and its preparations should be included in Annex III, Part A of Regulation (EC) No 1925/2006.

(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 III to Regulation (EC) No 1925/2006 is amended as follows:

(1) in Part A, the following entry is added:

'Ephedra herb and its preparations originating from *Ephedra* species';

(2) in Part C, the following entry is added:

'Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)'.

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, 11 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2015/404

of 11 March 2015

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl and propamocarb

(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 the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) The approvals of the active substances captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl and propamocarb will expire on 30 September 2017 and that of the active substance beflubutamid will expire on 30 November 2017. Applications have been submitted for the renewal of the approval of those active substances. As the requirements laid down in Commission Implementing Regulation (EU) No 844/2012 ([3]) apply to those active substances, it is necessary to provide for sufficient time to complete the renewal procedure in accordance with that Regulation. Consequently, the approvals of those active substances are likely to expire before a decision has been taken on their renewal. It is therefore necessary to extend their approval periods.

(3) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(4) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the respective expiry date laid down in the Annex to this Regulation, the Commission will set the expiry date at the same date as before this Regulation or at the earliest date thereafter.

(5) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later.

(6) 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

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) 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).

([3]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

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, 11 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 145, captan, the date of '30 September 2017' is replaced by '31 July 2018';

(2) in the sixth column, expiration of approval, of row 146, folpet, the date of '30 September 2017' is replaced by '31 July 2018';

(3) in the sixth column, expiration of approval, of row 147, formetanate, the date of '30 September 2017' is replaced by '31 July 2018';

(4) in the sixth column, expiration of approval, of row 148, methiocarb, the date of '30 September 2017' is replaced by '31 July 2018';

(5) in the sixth column, expiration of approval, of row 149, dimethoate, the date of '30 September 2017' is replaced by '31 July 2018';

(6) in the sixth column, expiration of approval, of row 150, dimethomorph, the date of '30 September 2017' is replaced by '31 July 2018';

(7) in the sixth column, expiration of approval, of row 151, glufosinate, the date of '30 September 2017' is replaced by '31 July 2018';

(8) in the sixth column, expiration of approval, of row 152, metribuzin, the date of '30 September 2017' is replaced by '31 July 2018';

(9) in the sixth column, expiration of approval, of row 153, phosmet, the date of '30 September 2017' is replaced by '31 July 2018';

(10) in the sixth column, expiration of approval, of row 154, propamocarb, the date of '30 September 2017' is replaced by '31 July 2018';

(11) in the sixth column, expiration of approval, of row 155, ethoprophos, the date of '30 September 2017' is replaced by '31 July 2018';

(12) in the sixth column, expiration of approval, of row 156, pirimiphos-methyl, the date of '30 September 2017' is replaced by '31 July 2018';

(13) in the sixth column, expiration of approval, of row 157, fipronil, the date of '30 September 2017' is replaced by '31 July 2018';

(14) in the sixth column, expiration of approval, of row 158, beflubutamid, the date of '30 November 2017' is replaced by '31 July 2018'.

COMMISSION IMPLEMENTING REGULATION (EU) 2015/405

of 11 March 2015

approving alpha-cypermethrin as an active substance for use in biocidal products for product-type 18

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes alpha-cypermethrin.

(2) Alpha-cypermethrin has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Belgium was designated as evaluating competent authority and submitted an assessment report, together with its recommendations, to the Commission on 17 November 2011 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([3]).

(4) The opinion of the European Chemicals Agency was formulated on 17 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products used for product-type 18 and containing alpha-cypermethrin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council ([4]) provided that certain specifications and conditions relating to its use are satisfied.

(6) It is therefore appropriate to approve alpha-cypermethrin for use in biocidal products for product-type 18 subject to compliance with certain specifications and conditions.

(7) Since the evaluations did not address nanomaterials, the approval should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.

(8) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

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

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([3]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([4]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Alpha-cypermethrin shall be approved as an active substance for use in biocidal products for product-type 18, subject to the specifications and conditions set out in the Annex.

Article 2

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

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

Done at Brussels, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions (2)
Alpha-cypermethrin	IUPAC Name: Reaction mass of (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2 dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2 imethylcyclopropanecarboxylate (1:1) EC No: Not available CAS No: 67375-30-8	930 g/kg Sum of the isomers in a 1:1 ratio	1 July 2016	30 June 2026	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. (2) To prevent risks for the aquatic compartment, for the treament of surfaces prone to frequent wet cleaning, products shall only be used to treat crack and crevices, unless it can be demonstrated in the application for product authorisation that risks for the aquatic compartment can be reduced to an acceptable level.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 8 of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm.

COMMISSION IMPLEMENTING REGULATION (EU) 2015/406

of 11 March 2015

approving *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A as an active substance for use in biocidal products for product-type 18

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes *Bacillus thuringiensis* subsp. *israelensis* serotype H14.

(2) *Bacillus thuringiensis* subsp. *israelensis* serotype H14 has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Regulation (EU) No 528/2012.

(3) The data submitted for the purpose of the evaluation allowed conclusions to be drawn only regarding a certain form of *Bacillus thuringiensis* subsp. *israelensis* serotype H14, i.e. *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A. The evaluation did not allow conclusions to be drawn regarding any other substance complying with the definition of *Bacillus thuringiensis* subsp. *israelensis* serotype H14 in the abovementioned list of active substances in Delegated Regulation (EU) No 1062/2014. Therefore, only *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A should be covered by this approval.

(4) Italy was designated as evaluating competent authority and submitted an assessment report, together with its recommendations, to the Commission on 12 June 2009 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([3]).

(5) The opinion of the European Chemicals Agency was formulated on 19 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to that opinion, biocidal products used for product-type 18 and containing *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council ([4]) provided that certain specifications and conditions relating to its use are satisfied.

(7) It is therefore appropriate to approve *Bacillus thuringiensis* subsp. *israelensis* serotype H14, strain SA3A for use in biocidal products for product-type 18 subject to compliance with certain specifications and conditions.

(8) Since the evaluations did not address nanomaterials, the approval should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([3]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([4]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

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

HAS ADOPTED THIS REGULATION:

Article 1

Bacillus thuringiensis subsp. *israelensis* serotype H14, strain SA3A shall be approved as an active substance for use in biocidal products for product-type 18, subject to the specifications and conditions set out in the Annex.

Article 2

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

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

Done at Brussels, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions (2)
Bacillus thuringiensis subsp. *israelensis* serotype H14, strain SA3A	Not applicable	No relevant impurities	1 July 2016	30 June 2026	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. (2) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (3) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (4) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 8 of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm

(3) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

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

COMMISSION IMPLEMENTING REGULATION (EU) 2015/407

of 11 March 2015

approving propan-2-ol as an active substance for use in biocidal products for product-types 1, 2 and 4

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes propan-2-ol.

(2) Propan-2-ol has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 1, human hygiene disinfectants, product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and product-type 4, food and feed area disinfectants, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 5 November 2012 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([3]).

(4) The opinions of the European Chemicals Agency were formulated on 18 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 2 and 4 and containing propan-2-ol may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council ([4]) provided that certain specifications and conditions relating to its use are satisfied.

(6) It is therefore appropriate to approve propan-2-ol for use in biocidal products for product-types 1, 2 and 4 subject to compliance with certain specifications and conditions.

(7) Since the evaluations did not address nanomaterials, the approvals should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.

(8) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing propan-2-ol in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([5]). Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of Regulation (EC) No 1935/2004. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

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

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

([4]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

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

HAS ADOPTED THIS REGULATION:

Article 1

Propan-2-ol shall be approved as an active substance for use in biocidal products for product-types 1, 2 and 4, subject to the specifications and conditions set out in the Annex.

Article 2

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

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

Done at Brussels, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions (2)
Propan-2-ol	IUPAC Name: 2-Propanol EC No: 200-661-7 CAS No: 67-63-0	99 % w/w	1 July 2016	30 June 2026	1	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
					2	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
					4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions: (1) for products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (3) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (4) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded; (2) biocidal products containing propan-2-ol shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of propan-2-ol into food or it has been established pursuant to that Regulation that such limits are not necessary.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 8 of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm

(3) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

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

COMMISSION IMPLEMENTING REGULATION (EU) 2015/408

of 11 March 2015

on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution

(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 78(2) thereof,

Whereas:

(1) Active substances are to be identified as candidates for substitution if they meet one or more criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009.

(2) Pursuant to Article 80(7) of Regulation (EC) No 1107/2009, the Commission has to establish a list of substances included in Annex I to Council Directive 91/414/EEC ([2]) which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009, hereinafter: 'list of candidates for substitution'.

(3) To ensure the consistency of the policy of the Union as regards active substances that have properties identifying them as candidates for substitution and to apply equal treatment to such substances, the Commission should also include in that list active substances approved under Regulation (EC) No 1107/2009 pursuant to the transitional provisions of Article 80(1).

(4) From the information contained in either the review report, or the conclusions of the European Food Safety Authority ([3]) or the Draft Assessment Report and related addenda and peer review reports, or from the classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]), it was possible to identify the substances which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009. These documents provide information, where relevant, concerning the applicable Acceptable Daily Intake (ADI), Acute Reference Dose (ARfD) or Acceptable Operator Exposure Level (AOEL), the information concerning persistent, bio-accumulative and toxic (PBT) properties of the substances, information concerning critical effects referred to in the third indent of point 4 of Annex II to Regulation (EC) No 1107/2009, the proportion of non-active isomers, the classification in accordance with Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B and toxic for reproduction category 1A or 1B, the endocrine disrupting properties. Based on that information, the substances set out in the Annex to this Regulation were identified as satisfying one or more criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009. The information has been consolidated and can be found in a support tool for the establishment of the list of candidates for substitution, which is available on the Commission website ([5]).

(5) The Acceptable Daily Intake (ADI) of the active substances 1-methylcyclopropene, amitrole, diclofop, dimethoate, ethoprophos, fenamiphos, fipronil, fluometuron, haloxyfop-P, metam, oxamyl, sulcotrione and triazoxide is significantly lower than that of the majority of the approved active substances within their respective groups of substances/use categories. The Acute Reference Dose (ARfD) of the active substances dimoxystrobin, fenamiphos, methomyl and oxamyl is significantly lower than that of the majority of the approved active substances within their respective groups of substances/use categories. The Acceptable Operator Exposure Level (AOEL) of the active substances amitrole, bromadiolone, difenacoum, dimethoate, diquat, ethoprophos, fenamiphos, fluquinconazole, metam, sulcotrione, triazoxide and warfarin is significantly lower than that of the majority of the approved active substances within their respective groups of substances/use categories. It is therefore appropriate to include those active substances in the list of candidates for substitution.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).
([3]) http://www.efsa.europa.eu/en/publications/efsajournal.htm
([4]) 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).
([5]) http://ec.europa.eu/food/plant/pesticides/index_en.htm

(6) The active substances lufenuron, oxyfluorfen and quinoxyfen meet the criteria to be considered a persistent and bioaccumulative substance. The active substances amitrole, bifenthrin, bromuconazole, chlorotoluron (unstated stereochemistry), copper compounds (variants copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture and tribasic copper sulphate), cyproconazole, cyprodinil, difenoconazole, diflufenican, dimoxystrobin, diquat, epoxiconazole, fenbutatin oxide, fludioxonil, flufenacet, fluopicolide, fluquinconazole, haloxyfop-P, imazamox, imazosulfuron, isoproturon, isopyrazam, lenacil, lufenuron, metconazole, metribuzin, metsulfuron-methyl, myclobutanil, nicosulfuron, oxadiazon, oxyfluorfen, paclobutrazol, pirimicarb, prochloraz, propiconazole, propoxycarbazone, prosulfuron, quinoxyfen, tebuconazole, tebufenpyrad, tepraloxydim, tri-allate, triasulfuron and ziram meet the criteria to be considered a persistent and toxic substance. The active substances aclonifen, difenacoum, esfenvalerate, etofenprox, etoxazole, famoxadone, lambda-cyhalothrin, lufenuron, oxyfluorfen, pendimethalin and quinoxyfen meet the criteria to be considered a bioaccumulative and toxic substance. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(7) The active substances mecoprop and metalaxyl contain a significant proportion of non-active isomers. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(8) The active substances carbendazim, epoxiconazole, flumioxazine, glufosinate, linuron, oxadiargyl, quizalofop-P (variant quizalofop-P-tefuryl) and warfarin are or are to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(9) Since measures concerning specific scientific criteria for the determination of endocrine disrupting properties, as referred to in the first paragraph of point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, have not yet been adopted, it was to be established in accordance with the third paragraph thereof whether a substance is to be considered as having such properties. In accordance with that provision the active substances chlorotoluron (unstated stereochemistry), dimoxystrobin, epoxiconazole, molinate, profoxydim, tepraloxydim and thiacloprid are to be considered as having endocrine disrupting properties that may cause adverse effects in humans. It is therefore appropriate to include those active substances in the list of candidates for substitution.

(10) Member States and interested parties should be provided with a reasonable period to adapt to the provisions of this Regulation.

(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

Candidates for substitution

Active substances included in Annex I to Directive 91/414/EEC which fulfil the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009 shall be as set out in the list in the Annex to this Regulation.

The first paragraph shall also apply to active substances approved under Regulation (EC) No 1107/2009 pursuant to the transitional measures of Article 80(1).

Article 2

Transitional measures

Article 1 and the Annex shall not apply to applications for the authorisation of plant protection products submitted before 1 August 2015.

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, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

1-methylcyclopropene

aclonifen

amitrole

bifenthrin

bromadiolone

bromuconazole

carbendazim

chlorotoluron (unstated stereochemistry)

copper compounds (variants copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture and tribasic copper sulphate)

cyproconazole

cyprodinil

diclofop

difenacoum

difenoconazole

diflufenican

dimethoate

dimoxystrobin

diquat

epoxiconazole

esfenvalerate

ethoprophos

etofenprox

etoxazole

famoxadone

fenamiphos

fenbutatin oxide

fipronil

fludioxonil

flufenacet

flumioxazine

fluometuron

fluopicolide

fluquinconazole

glufosinate

haloxyfop-P

imazamox

imazosulfuron

isoproturon

isopyrazam

lambda-cyhalothrin

lenacil

linuron

lufenuron

mecoprop

metalaxyl

metam

metconazole

methomyl

metribuzin

metsulfuron-methyl

molinate

myclobutanil

nicosulfuron

oxadiargyl

oxadiazon

oxamyl

oxyfluorfen

paclobutrazol

pendimethalin

pirimicarb

prochloraz

profoxydim

propiconazole

propoxycarbazone

prosulfuron

quinoxyfen

quizalofop-P (variant quizalofop-P-tefuryl)

sulcotrione

tebuconazole

tebufenpyrad

tepraloxydim

thiacloprid

tri-allate

triasulfuron

triazoxide

warfarin

ziram

COMMISSION IMPLEMENTING REGULATION (EU) 2015/409

of 11 March 2015

amending Council Implementing Regulation (EU) No 917/2011 imposing a definitive anti-dumping duty and collecting definitely the provisional duty imposed on imports of ceramic tiles originating in the People's Republic of China

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community ([1]) ('the basic Regulation'), and in particular Article 11(3) thereof,

Whereas:

1. PROCEDURE

1.1. Measures in force

(1) On 15 September 2011 the Council imposed anti-dumping duties on imports of ceramic tiles originating in the People's Republic of China by Implementing Regulation (EU) No 917/2011 ([2]) ('the original Regulation').

(2) A single duty rate of 26,3 % was imposed on imports of the product concerned manufactured by the following group of exporting producers:

— Dongguan City Wonderful Ceramics Industrial Park Co., Ltd and Guangdong Jiamei Ceramics Co. Ltd (together referred to as the Wonderful group), and

— Qingyuan Gani Ceramics Co. Ltd and Foshan Gani Ceramics Co. Ltd (together referred to as the Gani group).

(3) As set out in recitals 96 to 98 of the original Regulation, the European Commission ('the Commission') was notified after disclosure of provisional findings that the relationship between the companies had been severed and on that basis individual duties for the Gani group and for the Wonderful group should have been applied. The request could not be accepted at that stage as its merits needed to be properly examined.

1.2. Request for a partial interim review

(4) On 2 October 2012 the Commission received a request for a partial interim review from the Gani group.

(5) The Gani group claimed that they were no longer related to the other two companies (the Wonderful group) as the shareholding relationship between them had ceased as of March 2011. The Gani group therefore requested an interim review of the measures in force, as the single duty rate in force was no longer appropriate.

1.3. Initiation of a partial interim review

(6) The Commission determined, after having consulted the Advisory Committee, that such a review should therefore be opened.

(7) On 31 January 2014, the Commission initiated a partial interim review of the measures in force on imports into the Union of ceramic tiles originating in the People's Republic of China under Article 11(3) of the basic Regulation. It published a Notice of Initiation in the *Official Journal of the European Union* ([3]).

(8) The review was limited in scope to the examination of the ownership structure of the Gani group and, if warranted, *ex officio* of the dumping margin as far as the Gani group was concerned.

(9) The review also covered *ex officio* the same matters as far as the Wonderful group was concerned.

([1]) OJ L 343, 22.12.2009, p. 51.
([2]) Council Implementing Regulation (EU) No 917/2011 of 12 September 2011 imposing a definitive anti-dumping duty and collecting definitely the provisional duty imposed on imports of ceramic tiles originating in the People's Republic of China (OJ L 238, 15.9.2011, p. 1).
([3]) OJ C 28, 31.1.2014, p. 11.

1.4. **Review investigation period**

(10) The investigation of dumping covered the period from 1 January 2013 to 31 December 2013 ('the review investigation period').

1.5. **Parties concerned by the investigation**

(11) The Commission invited both the Gani group and the Wonderful group to cooperate with the investigation and to reply to the Commission's questionnaires. In addition, the Commission provided an opportunity for the companies to request market economy treatment under Article 2(7) of the basic Regulation.

(12) In the Notice of Initiation the Commission had provisionally chosen the United States of America as a third market economy country ('analogue country') within the meaning of Article 2(7)(a) of the basic Regulation and invited parties to comment on this choice.

(13) Interested parties had an opportunity to comment on the initiation of the investigation and to request a hearing with the Commission and/or the Hearing Officer for trade proceedings.

1.6. **Questionnaire replies and verification visits**

(14) The Commission received questionnaire replies from both groups and also from two analogue country producers.

(15) The Commission sought and verified all the information deemed necessary for the review. Verification visits under Article 16 of the basic Regulation were carried out at the premises of the following companies:

— Exporting producers in the country concerned:

  — Dongguan City Wonderful Ceramics Industrial Park Co., Ltd;

  — Guangdong Jiamei Ceramics Co. Ltd;

  — Qingyuan Gani Ceramics Co. Ltd and

  — Foshan Gani Ceramics Co. Ltd

— Producers in the analogue country that requested confidential treatment on the basis of risk of retaliation.

2. **PRODUCT CONCERNED**

(16) The product subject to this review is the same as defined in the original Regulation, namely glazed and unglazed ceramic flags and paving, hearth or wall tiles; glazed and unglazed ceramic mosaic cubes and the like, whether or not on a backing ('the product concerned'), currently falling within CN codes 6907 10 00, 6907 90 20, 6907 90 80, 6908 10 00, 6908 90 11, 6908 90 20, 6908 90 31, 6908 90 51, 6908 90 91, 6908 90 93 and 6908 90 99.

3. **DUMPING**

3.1. **Market Economy Treatment**

(17) Neither group requested market economy treatment under Article 2(7)(c) of the basic Regulation.

3.2. **Analogue Country**

(18) As set out above, the Commission proposed the United States of America as analogue country, as it had been in the previous investigation. The Commission also contacted companies in a number of other possible analogue countries, but received no replies or cooperation from any other company. The choice of the United States of America was therefore confirmed as appropriate.

3.3. **Investigation**

(19) The investigation leading to the imposition of the measures in force established that the Gani group and the Wonderful group were related, in so far as one of the shareholders of the Wonderful group owned more than 5 % of the shares in a company in the Gani group. Dumping margins were calculated separately for each of the groups. The injury margins for the two groups were higher than the dumping margins.

(20) To take into account the risk that, due to their corporate links, the companies with the higher individual dumping margin could channel their exports through the companies with the lower dumping margin, a single weighted average dumping margin was then calculated for both groups and a single duty rate imposed.

(21) The Commission examined whether the alleged change in the relationship would render the single duty rate to be no longer justified. Subsequently, the Commission examined the need for the review of the individual dumping margins.

(22) The review investigation revealed that the shares referred to in recital 19 were sold to the owner of the Gani group and the Wonderful group has no longer a stake in the Gani group. There were no indications that the two groups would have any other structural or corporate links. Accordingly, the change of the relationship between the two groups was accepted as claimed and the Gani group and the Wonderful group were considered no longer related for the purposes of specifying the duty.

(23) It follows that there are no longer reasons for the imposition of a single duty rate. Instead, separate individual duty rates should be assigned to the Gani group and the Wonderful group.

(24) As to the need for reviewing the individual dumping margins as calculated for each of the groups in the investigation leading to the imposition of the measures in force, the Commission assessed whether the circumstances with regard to the two groups concerned had changed significantly so that it would warrant the review of these individual dumping margins.

(25) The investigation leading to the imposition of the measures in force established the following:

(1) they did not share production facilities;

(2) they did not share sales companies; and

(3) they did not subcontract for each other.

(26) The review investigation confirmed that this situation remained unchanged despite the change in relationship.

(27) In these specific circumstances, the Commission considered that the cessation of the relationship did not change the functioning of each of the the two groups in any way that has a bearing on the calculation of their dumping margins. Therefore, amending these dumping margins on the basis of new calculations is not warranted under Article 11(3) of the basic Regulation.

(28) In view of the above, the separate dumping margins calculated in the original investigation should be imposed as individual duties. These dumping margins are 13,9 % for the Gani group and 32,0 % for the Wonderful group.

(29) These findings were disclosed to interested parties and they were given time to comment.

(30) The Wonderful group first claimed that they had informed the Commission during the verification visit in the People's Republic of China that some of the evidence submitted by the Gani group in the request for review was false or misleading. They pointed out that the Commission has at its disposal Article 18 of the basic Regulation for this type of situation. They also questioned whether the provisions of Article 11(3) of the basic Regulation had been complied with in this respect.

(31) The Commission has verified all the relevant and duly documented evidence collected during the investigation, which showed that the two groups were no longer related to each other, as well as the evidence with regard to the functioning of each of the two groups, both before and after the cessation of the relationship. This evidence confirms that the group has irrevocably split in two, a fact that is not contested by the Wonderful Group.

(32) On the basis of these facts, the Commission has no ground for applying Article 18 of the basic Regulation. In addition, these facts confirm that Article 11(3) of the basic Regulation was complied with.

(33) Secondly the Wonderful group questioned whether the provision that 'the amount of the anti-dumping duty shall not exceed the margin of dumping established' in Article 9(4) of the basic Regulation has been complied with, on the grounds that new export prices and analogue country normal values were verified during this investigation.

(34) As set out in recitals 24 to 27 above, the investigation revealed that the functioning of each of the two groups did not change as a result of the cessation of the relationship. As also explained in the Notice of Initiation, in this case no new dumping margins were required. Article 9(4) of the basic Regulation has been complied with, as the amount of the anti-dumping duty does not exceed the margin of dumping, as established in the original investigation. The fact that new export prices and analogue country normal values were also verified during this investigation does not change this conclusion.

(35) Finally the Wonderful group suggested that 'giving individual margins to companies which were once related but where that relationship has been ended' is a dangerous precedent to set and allows for a group of companies to manipulate trade defence measures.

(36) The Commission disagreed with this suggestion. Every review is carried out on its own merits as established by the investigation and not on speculation, and where companies are not related to each other they are entitled to their own individual duty as set out in Article 9(5) of the basic Regulation.

(37) The Union industry association Cerame-Unie (CET) argued that the end of the shareholding relationship does not mean that the possibility of circumvention via the group with the lowest duty can be eliminated. To illustrate this, CET noted that the timing of the two groups being split coincided with the imposition of provisional measures in the original case, and that the two groups did not discuss a split prior to the initiation of the original case. During the original investigation the groups were related and therefore CET submitted that the Gani group and the Wonderful group had access to each other's data.

(38) However CET did not provide any evidence to back up these assumptions. In addition, the Commission is under an obligation to impose individual duties on each of the two groups now as it has been established that they are no longer related to each other. The Commission is not entitled to consider two legally separate company groups as related for the purpose of imposing a single duty rate simply because of the mere possibility that the two groups might collaborate together.

(39) CET argued that if the business operations of the two groups have remained unchanged, as has been disclosed, then the risk of circumvention between the two groups must also have remained unchanged.

(40) The Commission dismissed this argument. The only reason why the two groups were treated as one in the original investigation was due to the ownership link, and this fact has now disappeared.

(41) CET also noted that the locations of the production facilities of the two companies are relatively close to each other, which would make physical circumvention of the measures relatively simple.

(42) The Commission dismissed this argument as well. Indeed, there is no legal basis to give unrelated companies the same duty, merely because of the fact that companies are relatively close to each other and therefore circumvention is simpler. It is common in the People's Republic of China to have many producers of a particular product in one city or area.

(43) In view of the above, the comments received after disclosure did not change the conclusion as set out in recital 28 above. Therefore, the separate dumping margins calculated in the original investigation should be imposed as individual duties. These dumping margins are 13,9 % for the Gani group and 32,0 % for the Wonderful group.

(44) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 15(1) of the basic Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The table in Article 1(2) of Implementing Regulation (EU) No 917/2011 shall be amended as follows:

— the line below shall be removed from the table:

Company	Duty	TARIC additional code
'Dongguan City Wonderful Ceramics Industrial Park Co., Ltd; Guangdong Jiamei Ceramics Co. Ltd; Qingyuan Gani Ceramics Co. Ltd; Foshan Gani Ceramics Co. Ltd	26,3 %	B011'

— the following lines shall be inserted into the table:

Company	Duty	TARIC additional code
'Dongguan City Wonderful Ceramics Industrial Park Co., Ltd; Guangdong Jiamei Ceramics Co. Ltd	32,0 %	B938
Qingyuan Gani Ceramics Co. Ltd; Foshan Gani Ceramics Co. Ltd	13,9 %	B939'

Article 2

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

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

Done at Brussels, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2015/410

of 11 March 2015

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 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],

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 multilateral 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, 11 March 2015.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

[1] OJ L 347, 20.12.2013, p. 671.
[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	EG	65,8
	MA	86,2
	TR	87,5
	ZZ	79,8
0707 00 05	JO	229,9
	MA	182,1
	TR	183,7
	ZZ	198,6
0709 93 10	MA	121,0
	TR	191,3
	ZZ	156,2
0805 10 20	EG	46,4
	IL	72,4
	MA	68,8
	TN	53,2
	TR	63,6
	ZZ	60,9
0805 50 10	TR	49,2
	ZZ	49,2
0808 10 80	BR	69,0
	CA	81,0
	CL	100,4
	MK	27,7
	US	197,6
	ZZ	95,1
0808 30 90	AR	113,6
	CL	105,5
	CN	90,9
	ZA	95,6
	ZZ	101,4

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2015/411

of 11 March 2015

pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on cationic polymeric binders with quaternary ammonium compounds incorporated in paints and coatings

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products [1], and in particular Article 3(3) thereof,

Whereas:

(1) Pursuant to Article 3(3) of Regulation (EU) No 528/2012, on 30 October 2013, the Netherlands submitted a request to the Commission to decide whether a series of products (cationic polymeric binders with quaternary ammonium compounds) placed on the market with a view to be incorporated in paints and coatings (hereafter referred as 'paints') and confer to those paints the property to kill harmful and pathogenic microorganisms on the paints dried surface, were biocidal products as defined under Article 3(1)(a) first indent of that Regulation, or not, and whether the paints themselves should be considered as biocidal products or not.

(2) According to the information provided by the company placing the products on the market (hereafter referred as 'the company'), those products consist of polymers modified with quaternary ammonium groups. The polymer used varies from one product to another depending on the request of paint manufacturers. The products themselves do not have an antimicrobial activity. The company sells those products to paint manufacturers, who then mix them with other polymers used for paint manufacturing and a hardener thereby cross-linking all polymers. The cross-linked polymers form a cationic surface in the dried paint, which exerts the antimicrobial effect.

(3) After a first round of discussions with experts from the Member States, the Commission requested on 2 February 2014 an opinion from the European Chemicals Agency in accordance with Article 75(1)(g) of Regulation (EU) No 528/2012 as to whether the products of the company contribute to the antimicrobial properties of paints in which it may be incorporated, if those properties result from the action of an active substance, and if so, what is the identity of the active substance.

(4) The opinion of the European Chemicals Agency was formulated on 9 April 2014 by the Biocidal Product Committee.

(5) According to that opinion, the mode of action under consideration involves an active substance as it is based on a substance, within the meaning of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council [2], which has an action on harmful organisms.

(6) The active substance is formed in the paint in which it is incorporated by a chemical reaction of three constituents: the cationic polymeric binder, with quaternary ammonium groups, of variable chain length and equipped with a functional group; a polymeric dispersion equipped with the same functional group as the cationic polymeric binder and a polymeric hardener for cross-linking the above mentioned polymeric constituents.

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

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(7) Furthermore, according to that opinion, the mode of action of the active substance relies on electrostatic attractions leading to modifications of physiological and biochemical mechanisms (e.g. bacterial signal transduction systems) and to the death of the target organisms. The mode of action can therefore not be considered to be merely physical or mechanical.

(8) In accordance with Article 3(1)(a) of Regulation (EU) No 528/2012, destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism is a biocidal function.

(9) The cationic polymeric binders are not intended to have a biocidal function in the form in which they are supplied by the company to paint manufacturers and therefore do not comply with the definition of a biocidal product.

(10) Paints incorporating those products are mixtures, which, in the form they are supplied by paint manufacturers to their customers, generate an active substance and are intended to have a biocidal function other than by mere physical or mechanical action, and therefore comply with the definition of a biocidal product.

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

HAS ADOPTED THIS DECISION:

Article 1

The cationic polymeric binders with quaternary ammonium compounds placed on the market to be incorporated in paints and coatings (hereafter referred as 'paints') by paint manufacturers with a view to confer to those paints a biocidal function shall not be considered biocidal products.

The paints, in which the cationic polymeric binders with quaternary ammonium compounds are incorporated by paint manufacturers with a view to confer to those paints a biocidal function, shall be considered biocidal products.

Article 2

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

Done at Brussels, 11 March 2015.

For the Commission
The President
Jean-Claude JUNCKER

CORRIGENDA

Corrigendum to Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area

(Official Journal of the European Union L 343 of 14 December 2012)

On page 58, first subparagraph of Article 55(3):

for: '3. …, where relevant, be appointed under clear and transparent rules which guarantee their independence by the national cabinet or council of ministers or by any other public authority which does not directly exert ownership rights over regulated undertakings.',

read: '3. …, where relevant, be appointed, under clear and transparent rules which guarantee their independence, by the national cabinet or council of ministers or by any other public authority which does not directly exert ownership rights over regulated undertakings.';

on page 62, Article 65, first paragraph:

for: '… repealed with effect from 15 December 2012, …',

read: '… repealed with effect from 17 June 2015, …'.

Corrigendum to Council Regulation (EU) 2015/104 of 19 January 2015 fixing for 2015 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union vessels, in certain non-Union waters, amending Regulation (EU) No 43/2014 and repealing Regulation (EU) No 779/2014

(Official Journal of the European Union L 22 of 28 January 2015)

On page 24, the sixth sentence of Article 48:

for: 'The provisions on fishing opportunities set out in Articles 23, 24 and 25 and …',

read: 'The provisions on fishing opportunities set out in Articles 24, 25 and 26 and …'.

Corrigendum to Council Implementing Decision (EU) 2015/215 of 10 February 2015 on the putting into effect of the provisions of the Schengen *acquis* on data protection and on the provisional putting into effect of parts of the provisions of the Schengen *acquis* on the Schengen Information System for the United Kingdom of Great Britain and Northern Ireland

(Official Journal of the European Union L 36 of 12 February 2015)

On page 8, recital 7:

for: '(7) … allowing those provisions and their subsequent developments to be provisionally put into effect for the United Kingdom.',

read: '(7) … allowing those provisions and their subsequent developments to be put into effect for the United Kingdom.'.

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