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<sup>(1)</sup> 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.

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<sup>(1)</sup> Text with EEA relevance

## II

*(Non-legislative acts)*

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2015/1720

of 14 September 2015

**entering a name in the register of protected designations of origin and protected geographical indications (Γαλανό Μεταγγιτσίου Χαλκιδικής (Galano Metaggitsiou Chalkidikis) (PDO))**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Greece's application to register the name 'Γαλανό Μεταγγιτσίου Χαλκιδικής' (Galano Metaggitsiou Chalkidikis) was published in the *Official Journal of the European Union* <sup>(2)</sup>.
- (2) As no statement of objection under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Γαλανό Μεταγγιτσίου Χαλκιδικής' (Galano Metaggitsiou Chalkidikis) should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name 'Γαλανό Μεταγγιτσίου Χαλκιδικής' (Galano Metaggitsiou Chalkidikis) (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.5. Oils and fats (butter, margarine, oil, etc.), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 <sup>(3)</sup>.*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*.<sup>(1)</sup> OJ L 343, 14.12.2012, p. 1.<sup>(2)</sup> OJ C 143, 30.4.2015, p. 23.<sup>(3)</sup> Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

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

Done at Brussels, 14 September 2015.

*For the Commission,  
On behalf of the President,  
Phil HOGAN  
Member of the Commission*

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**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1721**  
**of 22 September 2015**  
**concerning the classification of certain goods in the Combined Nomenclature**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff <sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.
- (4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 12(6) of Council Regulation (EEC) No 2913/92 <sup>(2)</sup>. That period should be set at three months.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

*Article 2*

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 12(6) of Regulation (EEC) No 2913/92 for a period of three months from the date of entry into force of this Regulation.

*Article 3*

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

<sup>(1)</sup> OJ L 256, 7.9.1987, p. 1.

<sup>(2)</sup> Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

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

Done at Brussels, 22 September 2015.

*For the Commission,  
On behalf of the President,  
Heinz ZOUREK  
Director-General for Taxation and Customs Union*

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ANNEX

| Description of the goods                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Classification<br>(CN code) | Reasons                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | (2)                         | (3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p>Whole clams (<i>Meretrix meretrix</i>, <i>Meretrix lyrata</i>) in the shell, having undergone a heat treatment, subsequently frozen, in tightly packed mesh bags, presented in 10 kg packages.</p> <p>During the heat treatment the clams are immersed in water at a temperature of between 98 °C and 100 °C for at least 7 minutes. During that immersion, the temperature of the inside of the clams reaches at least 90 °C for 90 seconds.</p> <p>The product is not suitable for immediate consumption.</p> | 1605 56 00                  | <p>Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 1605 and 1605 56 00.</p> <p>Simple scalding (blanching), consisting of a light heat treatment which does not entail cooking as such, does not exclude classification in Chapter 3 (see also the Explanatory Notes to the Combined Nomenclature (CNEN) to Chapter 3, General, point 2). However, clams that have undergone a heat treatment leading to a temperature on the inside of the clams of at least 90 °C for 90 seconds cannot be considered as blanched but as cooked clams.</p> <p>The product is therefore to be classified under CN code 1605 56 00 as prepared clams.</p> |

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1722**  
**of 22 September 2015**  
**concerning the classification of certain goods in the Combined Nomenclature**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff <sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.
- (4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 12(6) of Council Regulation (EEC) No 2913/92 <sup>(2)</sup>. That period should be set at 3 months.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

*Article 2*

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 12(6) of Regulation (EEC) No 2913/92 for a period of 3 months from the date of entry into force of this Regulation.

<sup>(1)</sup> OJ L 256, 7.9.1987, p. 1.

<sup>(2)</sup> Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

*Article 3*

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

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

Done at Brussels, 22 September 2015.

*For the Commission,  
On behalf of the President,  
Heinz ZOUREK  
Director-General for Taxation and Customs Union*

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*ANNEX*

| Description of the goods                                                                                                                                                                                                                                                                                                                                                                                                                                          | Classification (CN code) | Reasons                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1)                                                                                                                                                                                                                                                                                                                                                                                                                                                               | (2)                      | (3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p>A product in form of a cream put up for retail sale in a plastic jar with a content of 227 g.</p> <p>The product consists of water, fatty acid ester, dimethicone, plant oil, emulsifier, glycerine, flavour, preservatives, thickener and colourants.</p> <p>The packing of the product does not qualify as a packing of a kind sold by retail for the care of the skin as the product is mainly intended to be used for sensual massage and stimulation.</p> | 3307 90 00               | <p>Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature, Note 3 to Chapter 33 and the wording of CN codes 3307 and 3307 90 00.</p> <p>The product cannot be regarded as a preparation for the care of the skin under CN code 3304 as it is not put up in packings of a kind sold by retail for the care of the skin (see also the Harmonised System Explanatory Notes (HSEN) to heading 3304, Part (A), point (3)).</p> <p>The product is suitable for use as another cosmetic preparation and is put up in packings of a kind sold by retail for such use (see Note 3 to Chapter 33 and also the HSEN to Chapter 33, General, fourth paragraph, point (a)).</p> <p>The product is therefore to be classified under CN code 3307 90 00 as other cosmetic preparation.</p> |

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1723**  
**of 22 September 2015**  
**concerning the classification of certain goods in the Combined Nomenclature**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff <sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN codes indicated in column (2), by virtue of the reasons set out in column (3) of that table.
- (4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 12(6) of Council Regulation (EEC) No 2913/92 <sup>(2)</sup>. That period should be set at three months.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

*Article 1*

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN codes indicated in column (2) of that table.

*Article 2*

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 12(6) of Regulation (EEC) No 2913/92 for a period of three months from the date of entry into force of this Regulation.

<sup>(1)</sup> OJ L 256, 7.9.1987, p. 1.

<sup>(2)</sup> Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

*Article 3*

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

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

Done at Brussels, 22 September 2015.

*For the Commission,  
On behalf of the President,  
Heinz ZOUREK  
Director-General for Taxation and Customs Union*

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## ANNEX

| Description of the goods                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Classification<br>(CN code) | Reasons                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (2)                         | (3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <p>1. A product with a stoichiometric composition consisting of magnesium aluminate (magnesium aluminium oxide) with the crystalline structure of spinel, a chemically defined product, in the form of irregular granules, lumps or powder. The product has a magnesium content, calculated as magnesium oxide, of approx. 28 % by weight, and an aluminium content, calculated as aluminium oxide, of approx. 72 % by weight.</p> <p>The product is used in the manufacture of refractory bricks and tiles used in the steel industry.</p> <p>The product is obtained from a chemical reaction between magnesium oxide and aluminium oxide by fusion in a rotary furnace.</p> | 2841 90 85                  | <p>Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature, Note 1 to Chapter 28 and the wording of CN codes 2841, 2841 90 and 2841 90 85.</p> <p>The product is obtained from a chemical reaction by fusion of raw materials in a rotary furnace. It is a stoichiometric compound (chemically defined) in which the numbers of atoms of the elements present can be expressed as a ratio of small whole numbers. It is not a raw mineral product or an ore and therefore cannot be classified in Chapters 25 or 26.</p> <p>Products in the form of irregular granules, lumps or powder are the raw material for the production of products of heading 6815. Classification under heading 6815 is excluded because the products are neither finished articles nor semi-finished products.</p> <p>Because of its stoichiometric composition, the product fulfils Note 1(a) to Chapter 28 which stipulates that the headings of this Chapter apply only to chemically defined compounds (i.e. having a stoichiometric composition).</p> <p>As a chemically defined product, spinel is to be classified as an inorganic chemical of Chapter 28 according to its chemical composition.</p> <p>The product is therefore to be classified under CN code 2841 90 85 as other salts of oxometallic or peroxometallic acids.</p> |
| <p>2. A product with a non-stoichiometric composition with a magnesium content, calculated as magnesium oxide, of approx. 20-35 % by weight and an aluminium content, calculated as aluminium oxide, of approx. 58-78 % by weight. The product has the crystalline structure of spinel, in form of irregular granules, lumps or powder.</p> <p>The product is used in the manufacture of refractory bricks and tiles used in the steel industry.</p> <p>The product is obtained from a chemical reaction between magnesium oxide and aluminium oxide by fusion in a rotary furnace.</p>                                                                                        | 3824 90 96                  | <p>Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 3824, 3824 90 and 3824 90 96.</p> <p>The product is obtained from a chemical reaction by fusion of raw materials in a rotary furnace. It is not a raw mineral product or an ore and therefore cannot be classified in Chapters 25 or 26.</p> <p>Because of its non-stoichiometric composition, the product does not fulfil Note 1(a) to Chapter 28 which stipulates that the headings of this Chapter apply only to chemically defined compounds (i.e. having a stoichiometric composition) and is therefore excluded from Chapter 28.</p> <p>Products in the form of irregular granules, lumps or powder are the raw material for the production of products of heading 6815. They are not classified under heading 6815 because they are neither finished articles nor semi-finished products.</p> <p>The product is therefore to be classified under CN code 3824 90 96 as other chemical products and preparations of the chemical or allied industries, not elsewhere specified or included.</p>                                                                                                                                                                                                                            |

| Description of the goods                                                                                                                                                                                                                                                                                                                                                                                                                                     | Classification<br>(CN code) | Reasons                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1)                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (2)                         | (3)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p>3. A product named 'fused magnesia chrome' in form of irregular grey granules, fragments or powder of varying grain size, with a non-stoichiometric composition of magnesium oxide and chromium oxide. The product has the crystalline structure of spinel and is used in the manufacture of refractory bricks and tiles used in the steel industry.</p> <p>This product is obtained by fusion of magnesium oxide and chromium ore in an arc furnace.</p> | 3824 90 96                  | <p>Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 3824, 3824 90 and 3824 90 96.</p> <p>The product is obtained from a chemical reaction by fusion of raw materials in an arc furnace. It is not a raw mineral product or an ore and therefore cannot be classified in Chapters 25 or 26.</p> <p>Because of its non-stoichiometric composition, the product does not fulfil Note 1(a) to Chapter 28 which stipulates that the headings of this Chapter apply only to chemically defined compounds (i.e. having a stoichiometric composition) and is therefore excluded from Chapter 28.</p> <p>Products in the form of irregular granules, lumps or powder are the raw material for the production of products of heading 6815. They are not classified under heading 6815 because they are neither finished articles nor semi-finished products.</p> <p>The product is therefore to be classified under CN code 3824 90 96 as other chemical products and preparations of the chemical or allied industries, not elsewhere specified or included.</p> |

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1724****of 23 September 2015****entering a name in the register of protected designations of origin and protected geographical indications [Silter (PDO)]**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Italy's application to register the name 'Silter' was published in the *Official Journal of the European Union* <sup>(2)</sup>.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Silter' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name 'Silter' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.3. Cheeses, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 <sup>(3)</sup>.

*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, 23 September 2015.

*For the Commission,*  
*On behalf of the President,*  
Phil HOGAN  
*Member of the Commission*

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<sup>(1)</sup> OJ L 343, 14.12.2012, p. 1.

<sup>(2)</sup> OJ C 142, 29.4.2015, p. 29.

<sup>(3)</sup> Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

**COMMISSION REGULATION (EU) 2015/1725****of 28 September 2015****amending Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for Ethyl lauroyl arginate (E 243)****(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(1)</sup>, and in particular Article 14 thereof,

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

Whereas:

- (1) Commission Regulation (EU) No 231/2012 <sup>(3)</sup> lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) Those specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (3) On 17 November 2014, an application was submitted for the amendment of specifications concerning the food additive Ethyl lauroyl arginate (E 243). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) The current specification defines ethyl lauroyl arginate as synthesized by esterifying arginine with ethanol, followed by reacting the ester with lauroyl chloride. The resultant ethyl lauroyl arginate is recovered as the hydrochloride salt, which is filtered and dried.
- (5) The applicant demonstrated that the current definition is too broad and should reflect details as regards temperature and pH, that were included in the original application and that are important in order to obtain the same profile that was evaluated by the European Food Safety Authority in its opinion on the safety of the use of Ethyl lauroyl arginate as a food preservative <sup>(4)</sup>.
- (6) Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (7) 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 Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(3)</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1.).

<sup>(4)</sup> The EFSA Journal (2007) 511, 1-27.

*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*.

Done at Brussels, 28 September 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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*ANNEX*

In the Annex to Regulation (EU) No 231/2012, in the entry for 'E 243 Ethyl lauroyl arginate' the definition is replaced by the following:

|                   |                                                                                                                                                                                                                                                                                                                                                 |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Definition</b> | Ethyl lauroyl arginate is synthesized by esterifying arginine with ethanol, followed by reacting the ester with lauroyl chloride, in aqueous media at a controlled temperature between 10 and 15 °C and at a pH between 6,7 and 6,9. The resultant ethyl lauroyl arginate is recovered as the hydrochloride salt, which is filtered and dried.' |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1726**  
**of 28 September 2015**  
**approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products**  
**for product-type 13**

(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 <sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012.
- (2) That list includes 2-methylisothiazol-3(2H)-one.
- (3) 2-methylisothiazol-3(2H)-one has been evaluated in accordance Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup> for use in product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which corresponds to product-type 13, as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Slovenia was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 11 April 2012 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 <sup>(4)</sup>.
- (5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 2 October 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 13 and containing 2-methylisothiazol-3(2H)-one may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.
- (7) It is therefore appropriate to approve 2-methylisothiazol-3(2H)-one for use in biocidal products for product-type 13 subject to compliance with the specific conditions in the Annex.
- (8) Since 2-methylisothiazol-3(2H)-one meets the criteria for classification as skin sensitiser sub-category 1A as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(5)</sup>, treated articles treated with or incorporating 2-methylisothiazol-3(2H)-one should be appropriately labelled when placed on the market.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

- (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*

2-methylisothiazol-3(2H)-one is approved as an active substance for use in biocidal products for product-type 13, 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, 28 September 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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## ANNEX

| Common Name                      | IUPAC Name<br>Identification Numbers                                                     | Minimum<br>degree of purity<br>of the active<br>substance <sup>(1)</sup> | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------|----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2-methylisothiazol-3<br>(2H)-one | IUPAC Name:<br>2-methylisothiazol-3<br>(2H)-one<br>EC No: 220-239-6<br>CAS No: 2682-20-4 | 95 % w/w                                                                 | 1 October<br>2016   | 30 September<br>2026       | 13              | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</li> <li>(2) In view of the risks to the professional users, loading of the products into metalworking fluids shall be semi-automated or automated unless it can be demonstrated that risks can be reduced to an acceptable level by other means.</li> <li>(3) In view of the risks to the professional users, labels and, where provided, safety data sheets of products shall indicate that preserved metalworking fluids shall be used in semi-automated or automated machines unless it can be demonstrated that risks can be reduced to an acceptable level by other means.</li> </ol> <p>The placing on the market of treated articles is subject to the following condition:</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating 2-methylisothiazol-3(2H)-one shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p> |

<sup>(1)</sup> 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 16(2) of Directive 98/8/EC. 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.

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1727****of 28 September 2015****approving 5-Chloro-2-(4-chlorophenoxy)phenol as an existing 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 <sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes 5-Chloro-2-(4-chlorophenoxy)phenol.
- (2) 5-Chloro-2-(4-chlorophenoxy)phenol has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup> for use in product-type 1, human hygiene biocidal products, product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 4, food and feed area disinfectants, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 2 and 4, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Austria was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 13 February 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 <sup>(4)</sup>.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 4 December 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 5-Chloro-2-(4-chlorophenoxy)phenol may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve 5-Chloro-2-(4-chlorophenoxy)phenol for use in biocidal products for product-types 1, 2 and 4 subject to compliance with certain specifications and conditions.
- (7) The opinions conclude that 5-Chloro-2-(4-chlorophenoxy)phenol meets the criteria for being very bioaccumulative (vB) and toxic (T) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(5)</sup>.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

- (8) Since, pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 10 years in accordance with the practice established under Directive 98/8/EC.
- (9) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, 5-Chloro-2-(4-chlorophenoxy)phenol meets the conditions of Article 10(1)(d) of that Regulation and should therefore be considered a candidate for substitution.
- (10) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing 5-Chloro-2-(4-chlorophenoxy)phenol in materials and articles intended to come into contact directly or indirectly with food within the meaning of Regulation (EC) No 1935/2004 of the European Parliament and of the Council <sup>(1)</sup>. 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.
- (11) Since 5-Chloro-2-(4-chlorophenoxy)phenol meets the criteria for being very bioaccumulative (vB), treated articles treated with or incorporating 5-Chloro-2-(4-chlorophenoxy)phenol should be appropriately labelled when placed on the market.
- (12) 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.
- (13) 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*

5-Chloro-2-(4-chlorophenoxy)phenol is 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, 28 September 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNKER

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<sup>(1)</sup> 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).

## ANNEX

| Common Name                               | IUPAC Name<br>Identification Numbers                                                       | Minimum<br>degree of purity<br>of the active<br>substance <sup>(1)</sup> | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------|----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5-Chloro-2-(4-chlorophenoxy)phenol (DCPP) | IUPAC Name:<br>5-Chloro-2-(4-chlorophenoxy)phenol<br>EC No: 429-290-0<br>CAS No: 3380-30-1 | 995 g/kg                                                                 | 1 December<br>2016  | 30 November<br>2026        | 1               | <p>5-Chloro-2-(4-chlorophenoxy)phenol is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012.</p> <p>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.</p> <p>The placing on the market of treated articles is subject to the following condition.</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating 5-Chloro-2-(4-chlorophenoxy)phenol shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p>                                                                                                                                                                                                                                                                                                                                                               |
|                                           |                                                                                            |                                                                          |                     |                            | 2               | <p>5-Chloro-2-(4-chlorophenoxy)phenol is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012.</p> <p>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.</p> <p>The authorisations of biocidal products are subject to the following condition.</p> <p>For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> <p>The placing on the market of treated articles is subject to the following condition.</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating 5-Chloro-2-(4-chlorophenoxy)phenol shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p> |

| Common Name | IUPAC Name<br>Identification Numbers | Minimum<br>degree of purity<br>of the active<br>substance <sup>(1)</sup> | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------|--------------------------------------|--------------------------------------------------------------------------|---------------------|----------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                      |                                                                          |                     |                            | 4               | <p>5-Chloro-2-(4-chlorophenoxy)phenol is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012.</p> <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions.</p> <p>(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 <sup>(2)</sup> or Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(3)</sup> shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p> <p>(2) Products 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 5-Chloro-2-(4-chlorophenoxy)phenol into food or it has been established pursuant to that Regulation that such limits are not necessary.</p> <p>The placing on the market of treated articles is subject to the following condition.</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating 5-Chloro-2-(4-chlorophenoxy)phenol shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p> |

<sup>(1)</sup> 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 16(2) of Directive 98/8/EC. 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.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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) 2015/1728**  
**of 28 September 2015**  
**approving IPBC as an existing active substance for use in biocidal products for product-type 13**  
**(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 <sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes IPBC.
- (2) IPBC has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup> for use in product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which corresponds to product-type 13, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Denmark was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 23 August 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 <sup>(4)</sup>.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 3 December 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 13 and containing IPBC may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve IPBC for use in biocidal products for product-type 13 subject to compliance with certain specifications and conditions.
- (7) Since IPBC meets the criteria for classification as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(5)</sup>, treated articles treated with or incorporating IPBC should be appropriately labelled when placed on the market.
- (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,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

HAS ADOPTED THIS REGULATION:

*Article 1*

IPBC is approved as an active substance for use in biocidal products for product-type 13, 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, 28 September 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

| Common Name | IUPAC Name<br>Identification Numbers                                                      | Minimum degree of purity of the active substance <sup>(1)</sup> | Date of approval | Expiry date of approval | Product type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------|------------------|-------------------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IPBC        | IUPAC Name:<br>3-iodo-2-propynyl butylcarbamate<br>EC No: 259-627-5<br>CAS No: 55406-53-6 | 980 g/kg                                                        | 1 December 2016  | 30 November 2026        | 13           | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) For professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means,.</p> <p>(2) In view of the risks to the professional users, loading of the products into metal working fluids shall be semi-automated or automated, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.</p> <p>The placing on the market of treated articles is subject to the following condition:</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating IPBC shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p> |

<sup>(1)</sup> 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 16(2) of Directive 98/8/EC. 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.

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1729****of 28 September 2015****approving potassium sorbate as an existing active substance for use in biocidal products for product-type 8****(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 <sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes potassium sorbate.
- (2) Potassium sorbate has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup> for use in product-type 8, wood preservatives, as defined in Annex V to that Directive, which corresponds to product-type 8, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Germany was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 10 October 2010 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 <sup>(4)</sup>.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 4 December 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 8 and containing potassium sorbate may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve potassium sorbate for use in biocidal products for product-type 8 subject to compliance with certain specifications and conditions.
- (7) 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.
- (8) 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*

Potassium sorbate is approved as an active substance for use in biocidal products for product-type 8, subject to the specifications and conditions set out in the Annex.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

*Article 2*

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

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

Done at Brussels, 28 September 2015.

*For the Commission*

*The President*

Jean-Claude JUNKER

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## ANNEX

| Common Name       | IUPAC Name<br>Identification Numbers                                                                                | Minimum<br>degree of purity<br>of the active<br>substance <sup>(1)</sup> | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------|----------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Potassium sorbate | IUPAC Name:<br>2,4-Hexadienoic acid,<br>potassium salt (1:1),<br>(2E, 4E)<br>EC No: 246-376-1<br>CAS No: 24634-61-5 | 990 g/kg                                                                 | 1 December<br>2016  | 30 November<br>2026        | 8               | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> <p>(2) Appropriate risk mitigation measures shall be taken to protect the groundwater. In particular labels and, where provided, safety data sheets of products shall indicate that:</p> <ul style="list-style-type: none"> <li>a. industrial application shall be conducted within a contained area or on impermeable hard standing with bunding;</li> <li>b. freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water;</li> <li>c. any losses from the application of the product shall be collected for reuse or disposal.</li> </ul> |

<sup>(1)</sup> 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 16(2) of Directive 98/8/EC. 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.

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1730****of 28 September 2015****approving hydrogen peroxide as an existing active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6****(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 <sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes hydrogen peroxide.
- (2) Hydrogen peroxide has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup> for use in product-type 1, human hygiene biocidal products, product-type 2, private area and public health area disinfectants and other biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, product-type 5, drinking water disinfectants, and product-type 6, in-can preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 2, 3, 4, 5 and 6, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Finland was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 2 August 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 <sup>(4)</sup>.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 2 February 2015 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, 3, 4, 5 and 6 and containing hydrogen peroxide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve hydrogen peroxide for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6 subject to compliance with certain specifications and conditions.
- (7) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing hydrogen peroxide in materials and articles intended to come into contact directly or indirectly with food within the meaning of Regulation (EC) No 1935/2004 of the European Parliament and of the Council <sup>(5)</sup>. 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.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

<sup>(5)</sup> 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).

- (8) Regulation (EU) No 98/2013 of the European Parliament and of the Council <sup>(1)</sup> on the marketing and use of explosive precursors applies to hydrogen peroxide.
- (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*

Hydrogen peroxide is approved as an active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6, 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, 28 September 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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<sup>(1)</sup> Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors (OJ L 39, 9.2.2013, p. 1).

## ANNEX

| Common Name          | IUPAC Name<br>Identification Numbers                                      | Minimum degree of purity of the active<br>substance (1)                                                                                                                                                                                                                                | Date of approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hydrogen<br>peroxide | IUPAC Name:<br>Hydrogen peroxide<br>EC No: 231-765-0<br>CAS No: 7722-84-1 | The active substance as manufactured<br>is an aqueous solution containing<br>350 - < 700 g/kg (35 - < 70 % by<br>weight) hydrogen peroxide.<br><br>The theoretical (calculated) dry<br>weight specification: minimum purity<br>of hydrogen peroxide is 995 g/kg<br>(99,5 % by weight). | 1 February 2017  | 31 January 2027            | 1               | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.</p> <p>(2) For professional users, safe operational procedures and appropriate organisational measures shall be established for the handling of concentrated products.</p>                                                                                                     |
|                      |                                                                           |                                                                                                                                                                                                                                                                                        |                  |                            | 2               | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.</p> <p>(2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> |

| Common Name | IUPAC Name<br>Identification Numbers | Minimum degree of purity of the active<br>substance <sup>(1)</sup> | Date of approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|--------------------------------------|--------------------------------------------------------------------|------------------|----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                      |                                                                    |                  |                            | 3               | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.</p> <p>(2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> |
|             |                                      |                                                                    |                  |                            | 4               | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.</p> <p>(2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> |

| Common Name | IUPAC Name<br>Identification Numbers | Minimum degree of purity of the active<br>substance <sup>(1)</sup> | Date of approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------|--------------------------------------|--------------------------------------------------------------------|------------------|----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                      |                                                                    |                  |                            |                 | (3) Products 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 hydrogen peroxide into food or it has been established pursuant to that Regulation that such limits are not necessary.                                                                                                                                                                                                                                                                                                                                                                                                        |
|             |                                      |                                                                    |                  |                            | 5               | <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.</p> <p>(2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> |
|             |                                      |                                                                    |                  |                            | 6               | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

| Common Name | IUPAC Name<br>Identification Numbers | Minimum degree of purity of the active<br>substance <sup>(1)</sup> | Date of approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------|--------------------------------------|--------------------------------------------------------------------|------------------|----------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                      |                                                                    |                  |                            |                 | <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors.</p> <p>(2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</p> |

<sup>(1)</sup> 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 16(2) of Directive 98/8/EC. 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.

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1731**  
**of 28 September 2015**  
**approving medetomidine as an active substance for use in biocidal products for product-type 21**  
**(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 <sup>(1)</sup>, and in particular Article 90(2) thereof,

Whereas:

- (1) The United Kingdom received on 27 April 2009 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup>, for the inclusion of the active substance medetomidine in its Annex I for use in product-type 21, antifouling products, as defined in Annex V to that Directive, which corresponds to product-type 21 as defined in Annex V to Regulation (EU) No 528/2012.
- (2) Medetomidine was not on the market on 14 May 2000 as an active substance of a biocidal product.
- (3) The United Kingdom submitted an assessment report, together with its recommendations, to the European Chemicals Agency on 12 March 2014 in accordance with Article 8(1) of Regulation (EU) No 528/2012.
- (4) The opinion of the European Chemicals Agency was formulated on 3 February 2015 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 21 and containing medetomidine may be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve medetomidine for use in biocidal products for product-type 21 subject to compliance with certain specifications and conditions.
- (7) The opinion concludes that the characteristics of medetomidine render it very persistent (vP) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(3)</sup>. In addition, the opinion concludes that the active substance contains a significant proportion of non-active isomers or impurities.
- (8) Medetomidine meets the conditions set out in points (d) and (f) of Article 10(1) of Regulation (EU) No 528/2012 and should therefore be considered a candidate for substitution.
- (9) Pursuant to Article 10(4) of Regulation (EU) No 528/2012, the approval of an active substance that is considered as a candidate for substitution should be for a period not exceeding seven years.
- (10) Since medetomidine meets the criteria for being very persistent (vP) according to Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating medetomidine should be appropriately labelled when placed on the market.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

- (11) 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*

Medetomidine is approved as an active substance for use in biocidal products for product-type 21, 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, 28 September 2015.

*For the Commission*

*The President*

Jean-Claude JUNKER

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| Common name  | IUPAC name<br>Identification Numbers                                                                               | Minimum degree of<br>purity of the active<br>substance <sup>(1)</sup>                                                          | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Medetomidine | IUPAC name:<br>(RS)-4-[1-(2,3-dimethylphenyl)ethyl]-<br>1H-imidazole<br>EC No: not available<br>CAS No: 86347-14-0 | 99,5 % w/w.<br>Medetomidine is manufactured as a racemic mixture of R and S enantiomers: dexmedetomidine and levomedetomidine. | 1 January 2016      | 31 December 2022           | 21              | <p>Medetomidine is considered a candidate for substitution in accordance with Article 10(1)(d) and (f) of Regulation (EU) No 528/2012.</p> <p>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.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.</li> <li>(2) Persons making products containing medetomidine available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves. Labels and, where provided, instructions for use shall indicate whether other personal protective equipment shall be used.</li> <li>(3) Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry.</li> <li>(4) Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on an impermeable hard standing with bunding or on soil covered with an impermeable material to prevent direct losses and minimise emissions to the environment, and that any losses or waste containing medetomidine shall be collected for reuse or disposal.</li> <li>(5) 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 <sup>(2)</sup> or Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(3)</sup> shall be verified, and any appropriate risk-mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</li> </ol> |

| Common name | IUPAC name<br>Identification Numbers | Minimum degree of<br>purity of the active<br>substance <sup>(1)</sup> | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                         |
|-------------|--------------------------------------|-----------------------------------------------------------------------|---------------------|----------------------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                      |                                                                       |                     |                            |                 | <p>The placing on the market of treated articles is subject to the following condition:</p> <p>The person responsible for the placing on the market of a treated article treated with or incorporating medetomidine shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.</p> |

- <sup>(1)</sup> 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(1) 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.
- <sup>(2)</sup> 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).
- <sup>(3)</sup> 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) 2015/1732****of 28 September 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 <sup>(1)</sup>,

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 <sup>(2)</sup>, 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, 28 September 2015.

*For the Commission,  
On behalf of the President,  
Jerzy PLEWA*

*Director-General for Agriculture and Rural Development*

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<sup>(1)</sup> OJ L 347, 20.12.2013, p. 671.

<sup>(2)</sup> 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 <sup>(1)</sup> | Standard import value |
| 0702 00 00   | MA                                | 196,8                 |
|              | MK                                | 50,7                  |
|              | TR                                | 81,7                  |
|              | XS                                | 45,1                  |
|              | ZZ                                | 93,6                  |
| 0707 00 05   | MK                                | 34,4                  |
|              | TR                                | 137,2                 |
|              | ZZ                                | 85,8                  |
| 0709 93 10   | TR                                | 138,3                 |
|              | ZZ                                | 138,3                 |
| 0805 50 10   | AG                                | 150,3                 |
|              | AR                                | 141,0                 |
|              | BO                                | 143,0                 |
|              | CL                                | 169,0                 |
|              | EG                                | 55,4                  |
|              | UY                                | 77,1                  |
|              | ZA                                | 120,5                 |
|              | ZZ                                | 122,3                 |
| 0806 10 10   | EG                                | 172,8                 |
|              | MK                                | 32,3                  |
|              | TR                                | 135,4                 |
|              | ZZ                                | 113,5                 |
| 0808 10 80   | AR                                | 264,2                 |
|              | CL                                | 141,4                 |
|              | NZ                                | 136,7                 |
|              | US                                | 107,9                 |
|              | UY                                | 48,0                  |
|              | ZA                                | 144,4                 |
|              | ZZ                                | 140,4                 |
| 0808 30 90   | AR                                | 132,1                 |
|              | CL                                | 148,3                 |
|              | NZ                                | 175,8                 |
|              | TR                                | 127,4                 |
|              | ZA                                | 220,9                 |
|              | ZZ                                | 160,9                 |

| (EUR/100 kg)           |                                   |                       |
|------------------------|-----------------------------------|-----------------------|
| CN code                | Third country code <sup>(1)</sup> | Standard import value |
| 0809 30 10, 0809 30 90 | MK                                | 82,9                  |
|                        | TR                                | 144,7                 |
|                        | ZZ                                | 113,8                 |
| 0809 40 05             | BA                                | 53,5                  |
|                        | MK                                | 47,1                  |
|                        | XS                                | 61,9                  |
|                        | ZZ                                | 54,2                  |

<sup>(1)</sup> 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'.

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1733****of 28 September 2015****fixing the allocation coefficient to be applied to the quantities covered by applications for import licences lodged from 8 to 14 September 2015 under the tariff quotas opened by Regulation (EC) No 891/2009 in the sugar sector and suspending submission of applications for such licences**

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 <sup>(1)</sup>, and in particular Article 188(1) and (3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 891/2009 <sup>(2)</sup> opened annual tariff quotas for imports of sugar products.
- (2) The quantities covered by import licence applications lodged from 8 to 14 September 2015 for the subperiod from 1 to 31 October 2015 exceed the quantities available under order numbers 09.4320 and 09.4321. The extent to which import licences may be issued should therefore be determined by fixing the allocation coefficient to be applied to the quantities requested, calculated in accordance with Article 7(2) of Commission Regulation (EC) No 1301/2006 <sup>(3)</sup>. Submission of further applications for import licences under those order numbers should be suspended until the end of the quota period.
- (3) The quantities covered by import licence applications lodged from 8 to 14 September 2015 for the subperiod from 1 to 31 October 2015 are equal to the quantities available under order numbers 09.4317 and 09.4319. Submission of further applications for import licences under those order numbers should be suspended until the end of the quota period.
- (4) In order to ensure the efficient management of the measure, 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*

1. The quantities covered by import licence applications lodged under Regulation (EC) No 891/2009 from 8 to 14 September 2015 shall be multiplied by the allocation coefficient set out in the Annex to this Regulation.
2. Submission of further applications for import licences under the order numbers indicated in the Annex shall be suspended until the end of the 2015/2016 quota period.

*Article 2*

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

<sup>(1)</sup> OJ L 347, 20.12.2013, p. 671.

<sup>(2)</sup> Commission Regulation (EC) No 891/2009 of 25 September 2009 opening and providing for the administration of certain Community tariff quotas in the sugar sector (OJ L 254, 26.9.2009, p. 82).

<sup>(3)</sup> Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences (OJ L 238, 1.9.2006, p. 13).

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

Done at Brussels, 28 September 2015.

*For the Commission,*

*On behalf of the President,*

Jerzy PLEWA

*Director-General for Agriculture and Rural Development*

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## ANNEX

## ‘CXL concessions sugar’

2015/2016 Quota period

Applications lodged from 8 to 14 September 2015

| Order No | Country           | Allocation coefficient (%) | Further applications |
|----------|-------------------|----------------------------|----------------------|
| 09.4317  | Australia         | —                          | Suspended            |
| 09.4318  | Brazil            | —                          | —                    |
| 09.4319  | Cuba              | —                          | Suspended            |
| 09.4320  | Any third country | 6,204204                   | Suspended            |
| 09.4321  | India             | 7,773027                   | Suspended            |

## ‘Balkans sugar’

2015/2016 Quota period

Applications lodged from 8 to 14 September 2015

| Order No | Country                               | Allocation coefficient (%) | Further applications |
|----------|---------------------------------------|----------------------------|----------------------|
| 09.4324  | Albania                               | —                          | —                    |
| 09.4325  | Bosnia and Herzegovina                | —                          | —                    |
| 09.4326  | Serbia                                | —                          | —                    |
| 09.4327  | Former Yugoslav Republic of Macedonia | —                          | —                    |

## ‘Exceptional import sugar’ and ‘industrial sugar’

2015/2016 Quota period

Applications lodged from 8 to 14 September 2015

| Order No | Type               | Allocation coefficient (%) | Further applications |
|----------|--------------------|----------------------------|----------------------|
| 09.4380  | Exceptional import | —                          | —                    |
| 09.4390  | Industrial sugar   | —                          | —                    |

# DECISIONS

## COUNCIL DECISION (EU) 2015/1734

of 18 September 2015

**establishing the position to be adopted on behalf of the European Union at the 12th General Assembly of the Intergovernmental Organisation for International Carriage by Rail (OTIF) as regards certain amendments to the Convention concerning International Carriage by Rail (COTIF) and to its Appendices**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Union acceded to the Convention concerning International Carriage by Rail of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 ('COTIF Convention'), by virtue of Council Decision 2013/103/EU <sup>(1)</sup>.
- (2) All Member States, with the exception of Cyprus and Malta are contracting parties to and apply the COTIF Convention.
- (3) The General Assembly set up in accordance with point (a) of Article 13§ 1 of the COTIF Convention ('General Assembly'), at its 12<sup>th</sup> session due to take place from 29 to 30 September 2015, is expected to decide upon certain amendments to the COTIF Convention as well as to its Appendices D (Uniform Rules concerning Contracts of Use of Vehicles in International Rail Traffic — CUV), F (Uniform Rules concerning the Validation of Technical Standards and the Adoption of Uniform Technical Prescriptions applicable to Railway Material intended to be used in International Traffic — APTU) and G (Uniform Rules concerning the Technical Admission of Railway Material used in International Traffic — ATMF).
- (4) The position of the Union on certain items should be adopted under Article 218(9) of the Treaty, since the decisions on those amendments to be taken by the General Assembly are acts having legal effects and their subject matter falls under Union competence.
- (5) The amendments to the COTIF Convention have the objectives of updating the tasks of the Committee of Technical Experts and a reference to the definition of 'keeper' in line with Union law, and of modifying certain rules concerning the financing, auditing, and reporting of the Intergovernmental Organisation for International Carriage by Rail (OTIF), as well as certain minor administrative changes.
- (6) The amendments to Appendix D (CUV) presented by the Secretary-General of OTIF have the objective of clarifying the roles of the keeper and the entity in charge of maintenance in the contracts of use of vehicles in international rail traffic.
- (7) The amendments to Appendices F (APTU) and G (ATMF) aim at clarifying their scope by the deletion of the reference to 'other railway material'.

<sup>(1)</sup> Council Decision 2013/103/EU of 16 June 2011 on the signing and conclusion of the Agreement between the European Union and the Intergovernmental Organisation for International Carriage by Rail on the Accession of the European Union to the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 (OJ L 51, 23.2.2013, p. 1).

- (8) The amendments to Appendices D (CUV), F (APTU) and G (ATMF) to the COTIF Convention, as well as certain amendments to the COTIF Convention itself fall under Union competence and are in line with the law and with the strategic objectives of the Union, and should therefore be supported by the Union.
- (9) The position of the Union at the 12<sup>th</sup> General Assembly should therefore be based on the Annex to this Decision,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The position to be adopted on behalf of the European Union at the 12<sup>th</sup> General Assembly in the framework of the COTIF Convention shall be in accordance with the Annex to this Decision.
2. Minor changes to the documents mentioned in the Annex to this Decision may be agreed upon by the representatives of the Union in the General Assembly without further decision of the Council.

*Article 2*

The Decisions of the 12<sup>th</sup> General Assembly, once adopted, shall be published in the *Official Journal of the European Union*, indicating their entry into force.

*Article 3*

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

Done at Brussels, 18 September 2015.

*For the Council*  
*The President*  
C. DIESCHBOURG

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## ANNEX

## 1. Referenced documents

Documents concerning the revision of COTIF and of its Appendices are available on the website of OTIF:

<http://www.otif.org/en/law/general-assembly/working-documents-concerning-revision-of-cotif.html>.

## 2. Comments and positions on the agenda items

**Item 1. Election of the Chairman and Vice-Chairmen**

Document: none.

Exercising voting rights: MS.

Coordinated position: none.

**Item 2. Adoption of the agenda**

Documents: AG 12/2, AG 12/2 Add.1.

Exercising voting rights: MS.

Coordinated position: none.

**Item 3. Formation of the Credentials Committee**

Document: none.

Exercising voting rights: MS.

Coordinated position: none.

**Item 4. Organisation of the work and designation of any Committees considered necessary**

Document: none.

Exercising voting rights: MS.

Coordinated position: none.

**Item 5. Election of a Secretary-General for the period from 1 January 2016 to 31 December 2018**

Documents: AG 12/5, AG 12/5.1, AG 12/5.2.

Exercising voting rights: MS.

Coordinated position: none.

Both candidates for the post are from EU Member States (Austria and France).

**Item 6. Members of OTIF — general situation**

Document: AG 12/6.

Exercising voting rights: not applicable.

Coordinated position: none.

**Item 7. Budget framework**

Documents: AG 12/7.1, AG 12/7.2.

Exercising voting rights: MS.

Coordinated position: none.

**Item 8. Partial revision of COTIF — Basic Convention**

Documents: AG 12/8, AG 12/8 Add. 1, AG 12/8 Add. 2.

Exercising voting rights: MS.

Coordinated position:

Amendments for Article 3 (International cooperation) to be supported (editorial change to replace the reference to the 'European Communities' with a reference to the 'European Union').

Amendments for Article 12 (Execution of judgements. Attachment) to be supported as it amends the definition of 'keeper' in line with EU law.

Amendments for Article 20 (Committee of Technical Experts) to be supported as they are necessary to update the Uniform Rules APTU and ATMF in order to keep them in line with EU law.

Other amendments: no EU position.

**Item 9. Partial Revision of Appendix B (CIM UR)**

Document: AG 12/9.

Exercising voting rights: MS.

Coordinated position: to take note of the Secretary-General's report on the progress and continuation of the work on revising this Appendix.

**Item 10. Partial revision of Appendix D (CUV UR)**

Documents: AG 12/10, AG 12/10 Add. 1, AG 12/10 Add. 2, AG 12/10 Add. 3.

Exercising voting rights: EU.

Coordinated position:

Amendments to Article 9 and to the Explanatory Report to be supported, in line with the EU position represented at the 25<sup>th</sup> session of the Revision Committee of OTIF <sup>(1)</sup>, as they clarify the roles of the keeper and of the entity in charge of maintenance in line with EU law.

The new Article 1a proposed by Germany in document AG 12/10 Add. 3 was discussed and supported by an EU working group of representatives of Member States and of the railway sector which met on 26 November 2014. A similar provision also exists in CIM (Article 2 — Prescriptions of public law). Thus, this proposal is to be supported as well.

<sup>(1)</sup> Council Decision of 24 June 2014 establishing the position to be adopted on behalf of the European Union at the 25<sup>th</sup> session of the OTIF Revision Committee as regards certain amendments to the Convention concerning International Carriage by Rail (COTIF) and to the Appendices thereto (2014/699/EU) (OJ L 293, 9.10.2014, p. 26).

**Item 11. Partial revision of Appendix F (APTU UR)**

Document: AG 12/11.

Exercising voting rights: EU.

Coordinated position: amendment to Article 3 aimed at the clarification of the scope by the deletion of 'other railway material' and the relevant modification of the Explanatory Report to be supported.

**Item 12. Revision of Appendix G (ATMF UR)**

Document: AG 12/12.

Exercising voting rights: EU.

Coordinated position: amendments to Articles 1 and 3 aimed at the clarification of the scope by the deletion of 'other railway material' and the relevant modification of the Explanatory Report to be supported.

**Item 13. Revised and consolidated Explanatory Report**

Documents: AG 12/13, AG 12/13 Add.1-10.

Exercising voting rights: MS.

Coordinated position: to note the revised and consolidated Explanatory Report and to mandate the Secretary-General to include the explanations adopted by this General Assembly which relate to the amendments to COTIF and its Appendices adopted by this General Assembly. However, the phrase '... apply to the activities of the ECM, or ...' is to be deleted in the explanations on Article 3a, 10, second sentence. Furthermore, in the German version the explanations on Article 15, 1, second sentence should be amended as follows:

'In Übereinstimmung mit den gängigen Verfahren verschiedener Vertragsstaaten und zur expliziteren Klarstellung der Pflichten des Halters, obliegt dem Halter die Verpflichtung, den ihm zugeordneten Fahrzeugen eine ECM zuzuweisen.'

**Item 14. Unified Railway Law**

Document: AG 12/14.

Exercising voting rights: MS.

Coordinated position: none.

**Item 15. Report on the activities of the Administrative Committee in the period between 1 October 2012 and 30 September 2015**

Document: AG 12/15.

Exercising voting rights: MS.

Coordinated position: none.

**Item 16. Election of the Administrative Committee for the period between 1 October 2015 and 30 September 2018 (composition and chair)**

Document: AG 12/16.

Exercising voting rights: MS.

Coordinated position: none.

**Item 17. Provisional date of the 13<sup>th</sup> General Assembly**

Document: none.

Exercising voting rights: not applicable.

Coordinated position: none.

**Item 18. Any other business**

Document: not available.

Exercising voting rights: to be decided ('tbd') on the spot if necessary.

Coordinated position: tbd on the spot if necessary.

**Item 19. Any General Assembly mandates**

Document: not available.

Exercising voting rights: tbd on the spot if necessary.

Coordinated position: tbd on the spot if necessary.

**Item 20. Committee reports, if necessary**

Document: not available.

Exercising voting rights: tbd on the spot if necessary.

Coordinated position: tbd on the spot if necessary.

**Item 21. Adoption of decisions, mandates, recommendations and other General Assembly documents (final document)**

Document: not available.

Exercising voting rights: MS.

Coordinated position: tbd on the spot.

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**COMMISSION IMPLEMENTING DECISION (EU) 2015/1735****of 24 September 2015****on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches***(notified under document C(2015) 6455)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC <sup>(1)</sup>, and in particular Article 9(6) thereof,

Whereas:

- (1) Directive 2014/40/EU establishes new rules on health warnings to be placed on tobacco products for smoking including general warnings and information messages, and specifies in particular that both are to cover 50 % of the surfaces on which they are printed. The exact positioning of these warnings on roll-your-own tobacco marketed in pouches should be established. Pouches may either take the form of a rectangular pocket with a flap that covers the opening ('rectangular pouch') or a standing pouch.
- (2) Rectangular pouches may either take the form of a pouch with a wraparound flap that is typically opened in two steps or a flat-bottomed pouch with a fold-over flap that is typically opened in one step. Many of these pouches are made of a transparent plastic cover with a paper insert on which the health warnings can be printed. In some cases, pouches with a wraparound flap are made of polyethylene, polypropylene or laminate material which, according to the industry, would need to be redesigned in order to allow printing on both sides of the flap, in particular if the pouch is not multilayer.
- (3) In order to ensure that health warnings are positioned in the same place on all rectangular pouches and that the general warning and information message are easily visible, they should be printed on the surfaces that become visible when the unit packet is fully opened.
- (4) For packets made of polyethylene, polypropylene or laminate material where there is a risk of ink migration if the inside of the wraparound flap is printed, it should be allowed for a transitional period to reposition the general warning and information message, in order to avoid printing on surfaces that come into direct contact with tobacco. This should allow the industry sufficient time to adapt their production process to the new rules. The costs associated with these adaptations are not considered disproportionate in the light of the advantages in terms of improved visibility of the warnings when the packet is fully opened.
- (5) The most appropriate positioning for the general warning and information message on standing pouches is on the surfaces at the bottom of the pouch, in particular as the inside surfaces are obscured by the contents of the pouch.
- (6) The dimensions of the warnings are to be calculated in relation to the dimensions of the surfaces when the packet is closed, in accordance with Article 8(5) of Directive 2014/40/EU.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

<sup>(1)</sup> OJ L 127, 29.4.2014, p. 1.

HAS ADOPTED THIS DECISION:

#### *Article 1*

##### **Subject matter**

This Decision establishes rules on the precise positioning of general warnings and information messages on roll-your-own tobacco marketed in pouches.

#### *Article 2*

##### **Position of the general warning and the information message on rectangular pouches**

1. For roll-your-own tobacco in rectangular pockets with a flap that covers the opening ('rectangular pouches'), the general warning and information message shall be printed on the two surfaces which become visible when the unit packet is fully opened, as illustrated in Sections 1 and 2 of the Annex.

The general warning and information message shall be positioned at the top edge and shall cover 50 % of the respective surfaces on which they are printed, as illustrated in Sections 1 and 2 of the Annex.

The general warning shall be printed on the top surface.

2. By way of derogation from paragraph 1, until 20 May 2018, the following rules shall apply to roll-your-own tobacco in rectangular wraparound pouches made of polyethylene, polypropylene or laminate material, as illustrated in Section 3 of the Annex:

- (a) the information message may be positioned on the surface that becomes visible when the unit packet is partly unwrapped;
- (b) the general warning may be positioned on the bottom surface, which becomes visible when the unit packet is fully opened;
- (c) the inside of the flap, which becomes visible when the unit packet is fully opened, shall not be printed upon or used in any other way;
- (d) the general warning and information message shall be positioned at the top edge of the respective surfaces on which they are printed.

#### *Article 3*

##### **Position of the general warning and the information message on standing pouches**

1. For roll-your-own tobacco in standing pouches, the general warning and information message shall be positioned on the surfaces on the bottom of the standing pouch that become visible when the pouch is laid on its back ('base of the unit packet'), as illustrated in Section 4 of the Annex.

2. The general warning shall be printed on the surface above the crease on the base of the unit packet and the information message on the surface below the crease. The general warning and information message are to cover 50 % of the respective surfaces on which they are printed. The surfaces shall be calculated using their dimensions after the edges are sealed.

#### *Article 4*

##### **Transitional provision**

Roll-your-own tobacco in pouches manufactured or released for free circulation until 20 May 2018 and labelled with a general warning and information message in accordance with Article 2(2) may be placed on the market until 20 May 2019.

*Article 5***Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 24 September 2015.

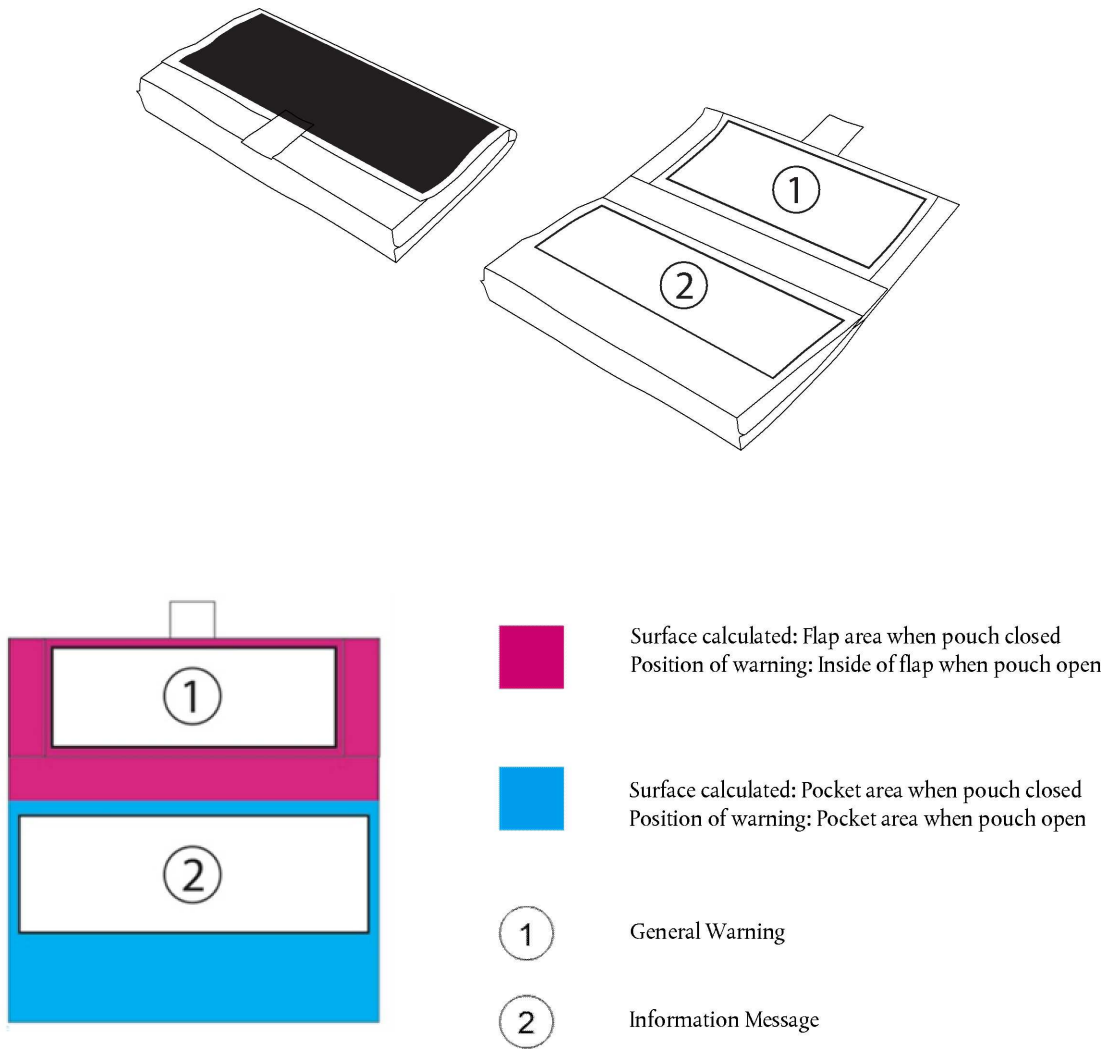
*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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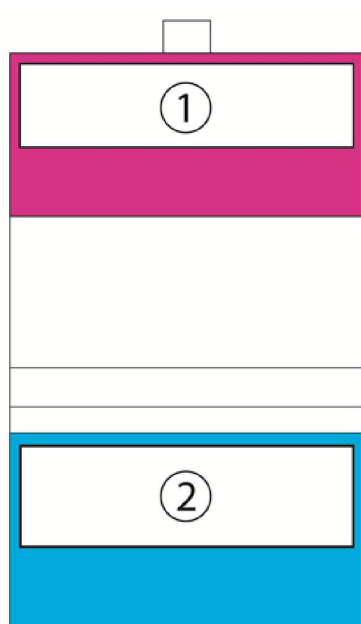
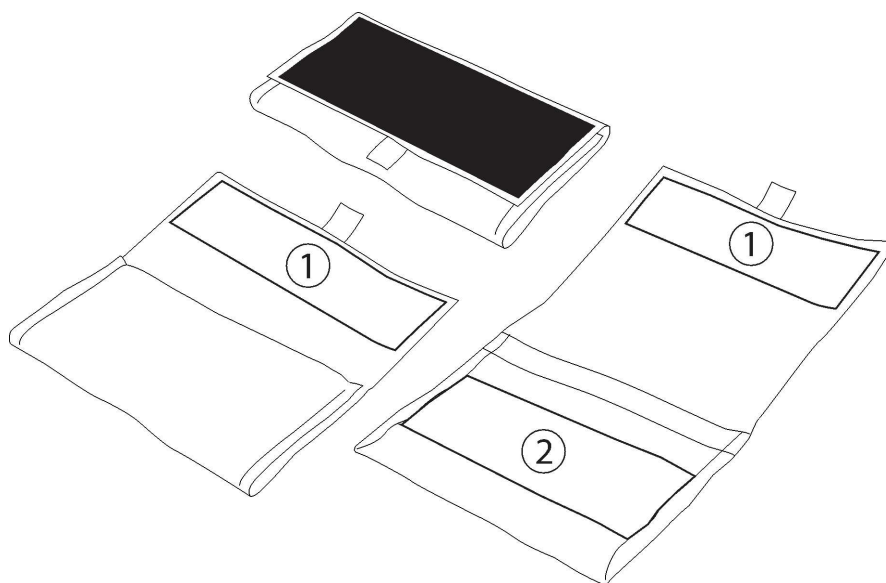
ANNEX

Graphical representations of the precise positioning of the general warning and information message referred to in Article 2 and Article 3

1. FLAT BOTTOMED POUCH (ARTICLE 2(1))



## 2. WRAPAROUND POUCH (ARTICLE 2(1))



Surface calculated: Flap area when pouch closed  
Position of warning: Inside of flap when pouch fully unwrapped (within the area calculated when pouch closed)



Surface calculated: Pocket area when pouch closed  
Position of warning: Pocket area when pouch fully unwrapped (within the area calculated when pouch closed)

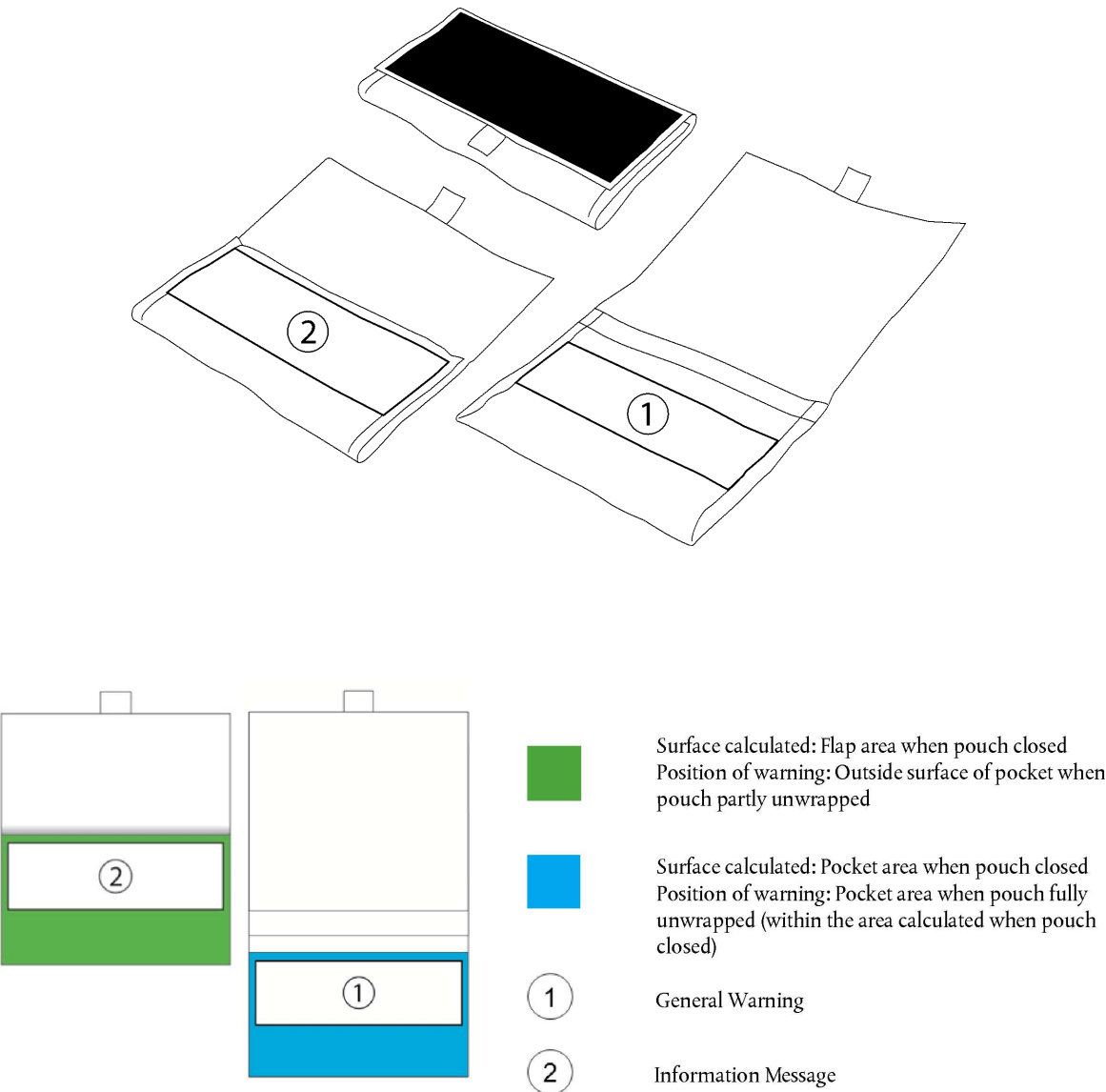


General Warning

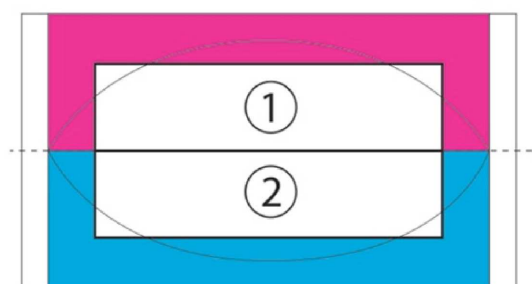
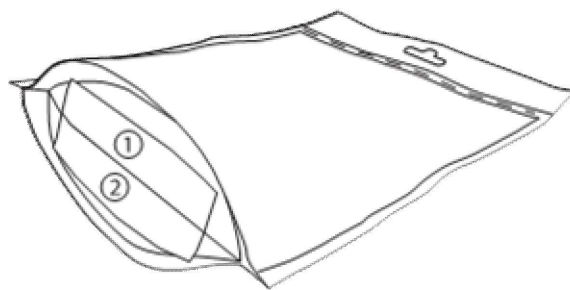
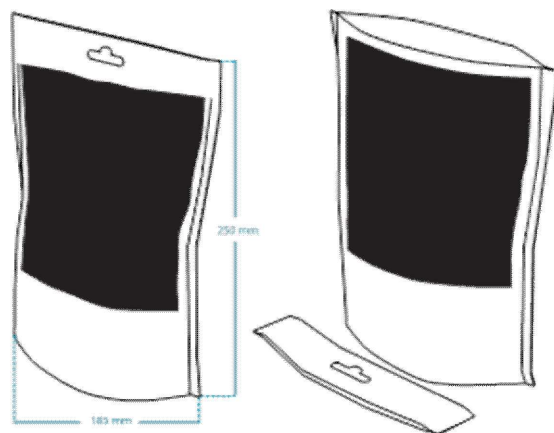


Information Message

3. WRAPAROUND POUCH (ALTERNATIVE POSITIONING ARTICLE 2(2))



## 4. STANDING POUCH (ARTICLE 3)



Surface calculated: Base of pouch, up to the central crease when flattened (not including the sealed edges)



Surface calculated: Base of pouch, up to the central crease when flattened (not including the sealed edges)



General Warning



Information Message

**COMMISSION IMPLEMENTING DECISION (EU) 2015/1736****of 28 September 2015****not approving triflumuron as an existing 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 <sup>(1)</sup>, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 <sup>(2)</sup> establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes triflumuron.
- (2) Triflumuron has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council <sup>(3)</sup> for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive, which corresponds to product-type 18, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Italy was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 30 September 2008 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 <sup>(4)</sup>.
- (4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 3 February 2015 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 triflumuron may not be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. The scenarios evaluated in the environmental risk assessment identified unacceptable risks for the aquatic and terrestrial compartments.
- (6) It is therefore not appropriate to approve triflumuron for use in biocidal products for product-type 18.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

*Article 1*

Triflumuron (EC No 264-980-3; CAS No 64628-44-0) is not approved as an active substance for use in biocidal products for product-type 18.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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).

*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, 28 September 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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**COMMISSION IMPLEMENTING DECISION (EU) 2015/1737****of 28 September 2015****postponing the expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products for product-type 14****(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 <sup>(1)</sup>, and in particular Article 14(5) thereof,

Whereas:

- (1) The active substances bromadiolone, chlorophacinone and coumatetralyl were included into Annex I to Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup> for use in biocidal products for product-type 14, and pursuant to Article 86 of Regulation (EU) No 528/2012 are considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) Their approval will expire on 30 June 2016. In accordance with Article 13(1) of Regulation (EU) No 528/2012, applications have been submitted for the renewal of the approval of these active substances.
- (3) Because of the risks identified when using the active substances bromadiolone, chlorophacinone and coumatetralyl, the renewal of their approval is subject to an assessment of an alternative active substance or substances. In addition, due to these characteristics, the approval of those active substances may be renewed only if it is shown that at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled.
- (4) The Commission has launched a study on the risk-mitigation measures that may be applied to anticoagulant rodenticides with a view to proposing the measures that are most suitable for mitigating the risks associated to the properties of those active substances.
- (5) The possibility should be given to the applicants for the renewal of approval of those active substances to address the conclusions of the study in their application. Furthermore, the conclusions of that study should be taken into account when deciding on the renewal of the approval of all anticoagulant rodenticides.
- (6) In order to facilitate the review and comparison of the risks and benefits of all anticoagulant rodenticides as well as of the risk-mitigation measures applied to them, the assessment of bromadiolone, chlorophacinone and coumatetralyl should be postponed until the last application for the renewal of the last anticoagulant rodenticide is submitted. Applications for the renewal of the approval of the last anticoagulant rodenticides, namely brodifacoum, warfarin and warfarin sodium, are expected to be submitted by 31 July 2015.
- (7) Consequently, for reasons beyond the control of the applicants, the approval of bromadiolone, chlorophacinone and coumatetralyl is likely to expire before a decision has been taken on their renewal. It is therefore appropriate to postpone the expiry date of approval of those active substances for a period of time sufficient to enable the examination of the applications.
- (8) Except for the expiry date of the approval, those substances should remain approved subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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 DECISION:

*Article 1*

The expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products for product-type 14 is postponed to 30 June 2018.

*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, 28 September 2015.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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