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## Contents

### II *Non-legislative acts*

#### REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2015/1978 of 28 August 2015 amending Regulation (EU) No 978/2012 of the European Parliament and the Council as regards the modalities for the application of Article 8 listed in Annex VI to that Regulation** ..... 1
- ★ **Commission Delegated Regulation (EU) 2015/1979 of 28 August 2015 amending Annexes II, III and IV to Regulation (EU) No 978/2012 of the European Parliament and of the Council applying a scheme of generalised tariff preferences** ..... 3
- ★ **Commission Implementing Regulation (EU) 2015/1980 of 4 November 2015 correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries <sup>(1)</sup>** ..... 6
- ★ **Commission Implementing Regulation (EU) 2015/1981 of 4 November 2015 approving Formaldehyde released from N,N-Methylenebismorpholine as an existing active substance for use in biocidal products for product-types 6 and 13 <sup>(1)</sup>** ..... 9
- ★ **Commission Implementing Regulation (EU) 2015/1982 of 4 November 2015 approving hexaflumuron as an existing active substance for use in biocidal products for product-type 18 <sup>(1)</sup>** ..... 13
- Commission Implementing Regulation (EU) 2015/1983 of 4 November 2015 establishing the standard import values for determining the entry price of certain fruit and vegetables ..... 16

<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.

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

## DECISIONS

- ★ **Commission Implementing Decision (EU) 2015/1984 of 3 November 2015 defining the circumstances, formats and procedures of notification pursuant to Article 9(5) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market** (*notified under document C(2015) 7369*)<sup>(1)</sup> ..... 18
- ★ **Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid** <sup>(1)</sup> ..... 26

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

## II

*(Non-legislative acts)*

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2015/1978

of 28 August 2015

**amending Regulation (EU) No 978/2012 of the European Parliament and the Council as regards the modalities for the application of Article 8 listed in Annex VI to that Regulation**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008 <sup>(1)</sup>, and in particular Article 8(6) thereof,

Whereas:

- (1) Pursuant to Article 8(1) of Regulation (EU) No 978/2012, the tariff preferences under the general arrangement of a generalised scheme of tariff preferences ('GSP') shall be suspended, in respect of products of a GSP section originating in a GSP beneficiary country, when the average value of Union imports of such products over three consecutive years from that GSP beneficiary country exceeds the thresholds listed in Annex VI. The thresholds shall be calculated as a percentage of the total value of Union imports of the same products from all GSP beneficiary countries.
- (2) Where the list of GSP beneficiary countries is amended, Regulation (EU) No 978/2012 empowers the Commission to adopt delegated acts to amend Annex VI in order to adjust the modalities listed in that Annex so as to maintain proportionally the same weight of the graduated product sections as defined in Article 8(1).
- (3) With effect from 1 January 2015, Commission Delegated Regulation (EU) No 1421/2013 <sup>(2)</sup> removed China, Ecuador, the Maldives and Thailand from the list of GSP beneficiary countries listed in Annex II to Regulation (EU) No 978/2012. Due to the substantial share of GSP imports represented by those countries, their removal from the list of beneficiaries necessitates the amendment of the modalities listed in Annex VI to Regulation (EU) No 978/2012.
- (4) As a result of all the amendments to the list of countries in Annex II to Regulation (EU) No 978/2012 between the entry into force of that Regulation and 1 January 2015, the total imports into the Union from all GSP beneficiary countries taken as an average during the last three consecutive years (2012-2014) would decrease to 30,71 %. Sections S-2a, S-3 and S-5 of Annex V are outliers in the sense that for these sections the total imports into the Union from all GSP beneficiary countries would drop insignificantly (less than 10 %). Therefore, in order to maintain proportionally the same weight of the graduated product sections, the two thresholds listed in Annex VI should be increased to 47,2 % and 57,0 % respectively, except for Sections S-2a, S-3 and S-5 of Annex V, for which the threshold should remain at its present level.

<sup>(1)</sup> OJ L 303, 31.10.2012, p. 1.

<sup>(2)</sup> Commission Delegated Regulation (EU) No 1421/2013 of 30 October 2013 amending Annexes I, II and IV to Regulation (EU) No 978/2012 of the European Parliament and of the Council applying a scheme of generalised tariff preferences (OJ L 355, 31.12.2013, p. 1).

- (5) As Delegated Regulation (EU) No 1421/2013 removed China, Ecuador, the Maldives and Thailand from the list of GSP beneficiary countries with effect from 1 January 2015, for the sake of coherence and legal certainty this Regulation should apply retroactively from 1 January 2015,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex VI to Regulation (EU) No 978/2012 is replaced by the following:

‘ANNEX VI

**Modalities for the application of Article 8**

1. Article 8 shall apply when the percentage share referred to in paragraph 1 of that Article exceeds 57,0 %.
2. Article 8 shall apply for each of the GSP sections S-2a, S-3 and S-5 of Annex V, when the percentage share referred to in paragraph 1 of that Article exceeds 17,5 %.
3. Article 8 shall apply for each of the GSP sections S-11a and S-11b of Annex V, when the percentage share referred to in paragraph 1 of that Article exceeds 47,2 %.’

*Article 2*

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

It shall apply from 1 January 2015.

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

Done at Brussels, 28 August 2015.

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

**COMMISSION DELEGATED REGULATION (EU) 2015/1979****of 28 August 2015****amending Annexes II, III and IV to Regulation (EU) No 978/2012 of the European Parliament and of the Council applying a scheme of generalised tariff preferences**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008 <sup>(1)</sup>, and in particular Articles 5(3), 10(5) and 17(2) thereof,

Whereas:

- (1) Article 4 of Regulation (EU) No 978/2012 establishes the criteria for granting tariff preferences under the general arrangement of the Generalised Scheme of Preferences ('GSP').
- (2) Article 4(1)(a) of Regulation (EU) No 978/2012 provides that a country that has been classified by the World Bank as a high-income or an upper-middle income country for 3 consecutive years should not benefit from GSP.
- (3) Article 4(1)(b) of Regulation (EU) No 978/2012 provides that a country that benefits from a preferential market access arrangement which provides the same tariff preferences as the GSP, or better, for substantially all trade, should not enjoy GSP.
- (4) The list of beneficiary countries of the general GSP referred to in point (a) of Article 1(2) of Regulation (EU) No 978/2012 is established in Annex II to that Regulation. Article 5 of Regulation (EU) No 978/2012 lays down that Annex II is to be reviewed by 1 January of each year in order to reflect changes in relation to the criteria laid down in Article 4. Furthermore, it provides that a GSP beneficiary country and economic operators are to be given sufficient time for an orderly adaptation to the country's GSP status revision. Accordingly, the GSP arrangement is to continue for 1 year after the date of entry into force of a change in a country's status on the basis of Article 4(1)(a) and for 2 years from the date of application of a preferential market access arrangement, as provided in Article 4(1)(b).
- (5) Fiji, Iraq, the Marshall Islands and Tonga have been classified by the World Bank as upper-middle income countries in 2013, 2014 and 2015. Accordingly, those countries no longer qualify for GSP beneficiary status under Article 4(1)(a) and should be removed from Annex II to Regulation (EU) No 978/2012. The Regulation to remove a beneficiary country from the list of GSP beneficiary countries should apply as from 1 year after the date of entry into force of that Regulation. In the interests of simplicity and legal certainty, Fiji, Iraq, the Marshall Islands and Tonga should be removed from Annex II with application from 1 January 2017.
- (6) Preferential market access arrangements with the following countries started to apply at various dates in 2014: Georgia on 1 September 2014, Cameroon on 4 August 2014, and Fiji on 28 July 2014. In the interests of simplicity and legal certainty, Georgia and Cameroon should also be removed from Annex II with application from 1 January 2017. As explained in recital 5, Fiji would already be removed from Annex II on the basis of becoming an upper-middle income country.
- (7) Article 9(1) of Regulation (EU) No 978/2012 establishes specific eligibility criteria for granting tariff preferences under the special incentive arrangement for sustainable development and good governance ('GSP+'). One key condition is that the country must be a GSP beneficiary. The list of GSP+ beneficiaries is established in Annex III to Regulation (EU) No 978/2012.

<sup>(1)</sup> OJ L 303, 31.10.2012, p. 1.

- (8) As a consequence of its ceasing to be GSP beneficiary as from 1 January 2017, Georgia also ceases to be a GSP+ beneficiary under Article 9(1) of Regulation (EU) No 978/2012. Georgia should therefore also be removed from Annex III to Regulation (EU) No 978/2012 with application from 1 January 2017.
- (9) Article 17(1) of Regulation (EU) No 978/2012 provides that a country which is identified by the United Nations ('UN') as a least-developed country should benefit from the tariff preferences under the special arrangement for the least-developed countries (Everything But Arms ('EBA')). The list of EBA beneficiary countries is established in Annex IV to that Regulation.
- (10) The UN removed Samoa from least developed country status on 1 January 2014. Accordingly, Samoa no longer qualifies for EBA beneficiary status under Article 17(1) and should be removed from Annex IV to Regulation (EU) No 978/2012. The Regulation to remove a beneficiary country from the list of EBA beneficiary countries should apply following a transitional period of 3 years as from the date on which that Regulation enters into force. Samoa should therefore be removed from Annex IV, with application from 1 January 2019,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendments to Regulation (EU) No 978/2012**

Regulation (EU) No 978/2012 is amended as follows.

- (1) In Annex II, the following countries and the corresponding alphabetical codes are removed from columns A and B, respectively:

|    |                  |
|----|------------------|
| CM | Cameroon         |
| FJ | Fiji             |
| GE | Georgia          |
| IQ | Iraq             |
| MH | Marshall Islands |
| TO | Tonga            |

- (2) In Annex III, the following country and the corresponding alphabetical code is removed from columns A and B, respectively:

|    |         |
|----|---------|
| GE | Georgia |
|----|---------|

- (3) In Annex IV, the following country and the corresponding alphabetical code is removed from columns A and B, respectively:

|    |       |
|----|-------|
| WS | Samoa |
|----|-------|

*Article 2***Entry into force and application**

This Regulation shall enter into force on 1 January 2016.

Article 1(1) and (2) shall apply from 1 January 2017.

Article 1(3) shall apply from 1 January 2019.

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

Done at Brussels, 28 August 2015.

*For the Commission*

*The President*

Jean-Claude JUNKER

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**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1980****of 4 November 2015****correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 <sup>(1)</sup>, and in particular Article 33(2) and (3) and Article 38(d) thereof,

Whereas:

- (1) Annex IV to Commission Regulation (EC) No 1235/2008 <sup>(2)</sup>, as last amended by Commission Implementing Regulation (EU) 2015/931 <sup>(3)</sup>, lists Kiwa BCS Öko-Garantie GmbH as a recognised control body for product category D for South Korea, despite this recognition having been withdrawn by Commission Implementing Regulation (EU) 2015/131 <sup>(4)</sup> following the inclusion of the Republic of Korea in Annex III to Regulation (EC) No 1235/2008. Since the Republic of Korea is listed as a recognised third country in Annex III to Regulation (EC) No 1235/2008 for product category D, including for the processing of imported ingredients, Kiwa BCS Öko-Garantie GmbH cannot be recognised for the Republic of Korea for that product category under Article 10(2)(b) of that Regulation. The recognition for product category D should therefore be deleted from Annex IV. To ensure consistency with the terms used in Implementing Regulation (EU) 2015/131, 'South Korea' should be replaced by 'Republic of Korea' in the remaining recognitions for Kiwa BCS Öko-Garantie GmbH.
- (2) The recognition of Kiwa BCS Öko-Garantie GmbH for product categories A, D and F for Guinea-Bissau granted previously by Commission Implementing Regulation (EU) No 1287/2014 <sup>(5)</sup> does not appear in the table in Annex IV to Regulation (EC) No 1235/2008, although the recognition of that control body for that country has not been withdrawn. This recognition should therefore be reinserted in Annex IV.
- (3) Since Annex IV to Regulation (EC) No 1235/2008 as amended by Implementing Regulation (EU) 2015/931 also contains certain errors in relation to the code numbers, those errors should be corrected as well. The code numbers for Bosnia and Herzegovina for the control body 'Abcert AG', for Côte d'Ivoire for the control body 'Istituto Certificazione Etica e Ambientale' and for Kazakhstan and Kyrgyzstan for the control body 'Organic Standard' should therefore be corrected. At the same time it is appropriate to correct an error in relation to the code number for Kyrgyzstan for the control body 'Bio.inspecta AG', made by Commission Implementing Regulation (EU) No 355/2014 <sup>(6)</sup>.
- (4) Annex IV to Regulation (EC) No 1235/2008 should therefore be corrected accordingly.

<sup>(1)</sup> OJ L 189, 20.7.2007, p. 1.

<sup>(2)</sup> Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 334, 12.12.2008, p. 25).

<sup>(3)</sup> Commission Implementing Regulation (EU) 2015/931 of 17 June 2015 amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 151, 18.6.2015, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) 2015/131 of 26 January 2015 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 23, 29.1.2015, p. 1).

<sup>(5)</sup> Commission Implementing Regulation (EU) No 1287/2014 of 28 November 2014 amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 348, 4.12.2014, p. 1).

<sup>(6)</sup> Commission Implementing Regulation (EU) No 355/2014 of 8 April 2014 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 106, 9.4.2014, p. 15).

- (5) In the interests of clarity and legal certainty, these corrections should be made without delay. This Regulation should therefore enter into force on the day following that of its publication in the *Official Journal of the European Union*. However, for certain corrections made by this Regulation in respect of errors in Implementing Regulation (EU) 2015/931, it is appropriate that they apply retroactively from the date of entry into force of this Regulation.
- (6) The provisions of this Regulation are in accordance with the opinion of the regulatory committee on organic production,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex IV to Regulation (EC) No 1235/2008 is corrected in accordance with the Annex to this Regulation.

*Article 2*

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

Points (1), (3), (4)(b) and (5) of the Annex shall apply from 8 July 2015.

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

Done at Brussels, 4 November 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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## ANNEX

Annex IV to Regulation (EC) No 1235/2008 is corrected as follows:

- (1) In the entry relating to '**Abcert AG**', in point 3, the row for Bosnia and Herzegovina is replaced by the following:

|                         |            |   |   |   |   |   |    |
|-------------------------|------------|---|---|---|---|---|----|
| 'Bosnia and Herzegovina | BA-BIO-137 | x | — | — | x | — | —' |
|-------------------------|------------|---|---|---|---|---|----|

- (2) In the entry relating to '**Bio.inspecta AG**', in point 3, the row for Kyrgyzstan is replaced by the following:

|             |            |   |   |   |   |   |    |
|-------------|------------|---|---|---|---|---|----|
| 'Kyrgyzstan | KG-BIO-161 | x | — | — | x | — | —' |
|-------------|------------|---|---|---|---|---|----|

- (3) In the entry relating to '**Istituto Certificazione Etica e Ambientale**', in point 3, the row for Côte d'Ivoire is replaced by the following:

|                |            |   |   |   |   |   |    |
|----------------|------------|---|---|---|---|---|----|
| 'Côte d'Ivoire | CI-BIO-115 | x | — | — | x | — | —' |
|----------------|------------|---|---|---|---|---|----|

- (4) In the entry relating to '**Kiwa BCS Öko-Garantie GmbH**', point 3 is amended as follows:

- (a) the row for South Korea is replaced by the following:

|                    |            |   |   |   |   |   |    |
|--------------------|------------|---|---|---|---|---|----|
| 'Republic of Korea | KR-BIO-141 | x | — | x | — | x | —' |
|--------------------|------------|---|---|---|---|---|----|

- (b) the following row is inserted:

|                |            |   |   |   |   |   |    |
|----------------|------------|---|---|---|---|---|----|
| 'Guinea-Bissau | GW-BIO-141 | x | — | — | x | — | X' |
|----------------|------------|---|---|---|---|---|----|

- (5) In the entry relating to '**Organic Standard**', point 3 is amended as follows:

- (a) the row for Kazakhstan is replaced by the following:

|             |            |   |   |   |   |   |    |
|-------------|------------|---|---|---|---|---|----|
| 'Kazakhstan | KZ-BIO-108 | x | — | — | x | — | —' |
|-------------|------------|---|---|---|---|---|----|

- (b) the row for Kyrgyzstan is replaced by the following:

|             |            |   |   |   |   |   |    |
|-------------|------------|---|---|---|---|---|----|
| 'Kyrgyzstan | KG-BIO-108 | x | — | — | x | — | —' |
|-------------|------------|---|---|---|---|---|----|

**COMMISSION IMPLEMENTING REGULATION (EU) 2015/1981****of 4 November 2015****approving Formaldehyde released from N,N-Methylenebismorpholine as an existing active substance for use in biocidal products for product-types 6 and 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.
- (2) That list includes N,N-Methylenebismorpholine, to be renamed formaldehyde released from N,N-Methylenebismorpholine (hereafter referred to as 'MBM'), as the result of its evaluation.
- (3) MBM 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 6, in-can preservatives, and product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 6 and 13 as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Austria was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 25 July 2013 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 opinions of the European Chemicals Agency were formulated on 3 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.
- (6) According to those opinions, biocidal products used for product-types 6 and 13 and containing MBM 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 MBM for use in biocidal products for product-types 6 and 13 subject to compliance with the specific conditions in the Annex.
- (8) The opinions conclude that MBM meets the criteria for classification as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 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 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) 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 5 years in accordance with the practice established under that Directive.
- (10) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, MBM meets the conditions of Article 10(1)(a) of that Regulation and should therefore be considered a candidate for substitution.
- (11) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities should also evaluate whether the conditions of Article 5(2) can be satisfied to decide if a biocidal product containing MBM can be authorised or not.
- (12) Since MBM meets the criteria for classification as carcinogenic category 1B, and as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating MBM should be appropriately labelled when placed on the market.
- (13) 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.
- (14) 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*

Formaldehyde released from N,N-Methylenebismorpholine is approved as an active substance for use in biocidal products for product-types 6 and 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, 4 November 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 (%) | Date of approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------|------------------|----------------------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Formaldehyde released from N,N-Methylenebismorpholine (hereafter referred to as 'MBM') | IUPAC Name:<br>N,N-Methylenebismorpholine<br>EC No: 227-062-3<br>CAS No: 5625-90-1 | 92,1 % w/w                                                    | 1 April 2017     | 31 March 2022              | 6               | <p>MBM is considered a candidate for substitution in accordance with Article 10(1)(a) 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.</li> <li>(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.</li> <li>(3) In view of the risks to professional users, mixing and loading of products to formulation vessels shall be automated, unless it can be demonstrated that potential exposure of skin, eye and respiratory tracts to MBM 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 MBM shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of 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 approval | Expiry date of<br>approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------|--------------------------------------|--------------------------------------------------------------------------|------------------|----------------------------|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             |                                      |                                                                          |                  |                            | 13              | <p>MBM is considered a candidate for substitution in accordance with Article 10(1)(a) 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.</li> <li>(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.</li> <li>(3) In view of the risks to professional users, mixing and loading of products to formulation vessels shall be automated, unless it can be demonstrated that potential exposure of skin, eye and respiratory tracts to MBM 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 MBM shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of 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) 2015/1982****of 4 November 2015****approving hexaflumuron 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 hexaflumuron.
- (2) Hexaflumuron 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) Portugal was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 11 July 2011 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 18 and containing hexaflumuron 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 hexaflumuron for use in biocidal products for product-type 18 subject to compliance with certain specifications and conditions.
- (7) The opinion concludes that the characteristics of hexaflumuron render it very persistent (vP), very bioaccumulative (vB) 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>(5)</sup>.
- (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 5 years in accordance with the practice established under that Directive.

<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).

- (9) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, hexaflumuron meets the conditions of Article 10(1)(a) and (d) of that Regulation and should therefore be considered a candidate for substitution.
- (10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities should also evaluate whether the conditions of Article 5(2) can be satisfied to decide if a biocidal product containing hexaflumuron can be authorised or not.
- (11) Since hexaflumuron meets the criteria for being very persistent (vP), very bioaccumulative (vB) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating hexaflumuron 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*

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

#### *Article 2*

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

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

Done at Brussels, 4 November 2015.

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

## ANNEX

| 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<br>of approval | Product<br>type | Specific conditions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|---------------------|----------------------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hexaflumuron | IUPAC Name:<br>1-[3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea<br>EC No: 401-400-1<br>CAS No: 86479-06-3 | 984 g/kg                                                              | 1 April<br>2017     | 31 March<br>2022           | 18              | <p>Hexaflumuron is considered a candidate for substitution in accordance with Article 10(1)(a) and (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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.</p> <p>The authorisations of biocidal products are subject to the following conditions.</p> <p>(1) Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.</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> <p>(3) As hexaflumuron is considered to be very persistent, very bioaccumulative and toxic, exposure of non-target animals and the environment should be minimised by considering and applying all appropriate risk mitigation measures. These include the restriction to professional use only and the obligation to use confined bait stations.</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 hexaflumuron shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of 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) 2015/1983****of 4 November 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, 4 November 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                                        | AL                                | 46,6                  |
|                                                   | MA                                | 68,6                  |
|                                                   | MK                                | 44,1                  |
|                                                   | TR                                | 74,5                  |
|                                                   | ZZ                                | 58,5                  |
| 0707 00 05                                        | AL                                | 92,7                  |
|                                                   | TR                                | 140,9                 |
|                                                   | ZZ                                | 116,8                 |
| 0709 93 10                                        | MA                                | 143,3                 |
|                                                   | TR                                | 153,3                 |
|                                                   | ZZ                                | 148,3                 |
| 0805 20 10                                        | CL                                | 168,9                 |
|                                                   | MA                                | 95,6                  |
|                                                   | PE                                | 167,8                 |
|                                                   | ZA                                | 150,6                 |
| 0805 20 30, 0805 20 50,<br>0805 20 70, 0805 20 90 | ZZ                                | 145,7                 |
|                                                   | PE                                | 132,9                 |
|                                                   | TR                                | 112,5                 |
|                                                   | ZA                                | 107,4                 |
|                                                   | ZZ                                | 117,6                 |
| 0805 50 10                                        | TR                                | 115,3                 |
|                                                   | UY                                | 53,9                  |
|                                                   | ZZ                                | 84,6                  |
| 0806 10 10                                        | BR                                | 309,5                 |
|                                                   | EG                                | 231,7                 |
|                                                   | PE                                | 300,3                 |
|                                                   | TR                                | 171,5                 |
|                                                   | ZZ                                | 253,3                 |
| 0808 10 80                                        | CL                                | 173,0                 |
|                                                   | MK                                | 23,1                  |
|                                                   | NZ                                | 123,4                 |
|                                                   | ZA                                | 165,9                 |
|                                                   | ZZ                                | 121,4                 |
| 0808 30 90                                        | TR                                | 137,7                 |
|                                                   | ZZ                                | 137,7                 |

<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'.

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2015/1984

of 3 November 2015

**defining the circumstances, formats and procedures of notification pursuant to Article 9(5) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market**

*(notified under document C(2015) 7369)*

**(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 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC <sup>(1)</sup>, and in particular Article 9(5) thereof,

Whereas:

- (1) Notification of electronic identification schemes by Member States is a prerequisite of mutual recognition of electronic identification means.
- (2) Cooperation on interoperability and security of electronic identification schemes requires simplified procedures. Since the cooperation between Member States referred to in Article 12(6) of Regulation (EU) No 910/2014 and regulated in detail in Commission Implementing Decision (EU) 2015/296 <sup>(2)</sup> already requires the use of the English language, the same solution for the purposes of the notification of electronic identification schemes should facilitate reaching interoperability and security of the schemes. However, translation of already existing documentation should not cause unreasonable burden.
- (3) Schemes may involve multiple parties issuing the electronic identification means and/or multiple levels of assurance. For the sake of clarity and legal certainty, the notification of such schemes should however be a single process, with separate notification forms for each party issuing the electronic identification means and/or for each level of assurance.
- (4) The organisation of electronic identification schemes varies among Member States involving public and private sector entities. Although the purpose of the notification form should be to give as precise information as possible, among others, on the various authorities or entities involved in the electronic identification process, it should not aim at listing e.g. all local municipalities when those are involved. In that case, the respective field of the notification form should identify the level of the authority or entity involved.
- (5) Providing a description of electronic identification schemes prior to notification to other Member States as set out in Article 7(g) of Regulation (EU) No 910/2014 is a prerequisite of mutual recognition of electronic identification means. The notification form set out in this implementing act should be used in the context of providing a description of the scheme to other Member States, in order to enable peer review as set out in Article 10(2) of Implementing Decision (EU) 2015/296.

<sup>(1)</sup> OJ L 257, 28.8.2014, p. 73.

<sup>(2)</sup> Commission Implementing Decision (EU) 2015/296 of 24 February 2015 establishing procedural arrangements for cooperation between Member States on electronic identification pursuant to Article 12(7) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market (OJ L 53, 25.2.2015, p. 14).

- (6) The deadline for the Commission to publish a notification, as provided for in Article 9(3) of Regulation (EU) No 910/2014, should be counted from the day when the complete form is submitted. The notification form should not be considered complete if the Commission needs to request additional information or clarification.
- (7) In order to ensure uniform use of the notification form, it is appropriate for the Commission to provide guidance to the Member States in particular with regard to whether changes to the notification form may lead to re-notification.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 48 of Regulation (EU) No 910/2014,

HAS ADOPTED THIS DECISION:

#### *Article 1*

### **Objective**

Pursuant to Article 9(5) of Regulation (EU) No 910/2014, this Decision lays down the circumstances, formats and procedures of notifications of electronic identification schemes to the Commission.

#### *Article 2*

### **Language of notification**

1. The language of notification shall be English. The notification form referred to in Article 3(1) shall be completed in English.
2. Without prejudice to paragraph 1, Member States shall not be obliged to translate supporting documents referred to in point 4.4 of the Annex where this would create an unreasonable burden.

#### *Article 3*

### **Notification procedure and formats**

1. Notification shall be made electronically in the format compliant with the form set out in the Annex.
2. Where a scheme involves multiple responsible parties issuing the electronic identification means and/or covers multiple levels of assurance, points 3.2 and/or where appropriate 4.2 of the notification form set out in the Annex shall be completed separately for each party issuing the electronic identification means and/or for each level of assurance.
3. Where the authorities, parties, entities or bodies to be notified in the form set out in the Annex, in particular the parties managing the registration process of the unique person identification data or the parties issuing the electronic identification means, are acting under the same set of rules and using the exact same procedures, in particular where they are regional or local authorities, the following specific rules shall apply:
  - (a) the notification form may be filled in once in respect of all such parties;
  - (b) the notification form may be filled with information necessary to identify the respective functional or territorial organisation level.
4. The Commission shall confirm receipt of the notification by electronic means.

5. The Commission may request additional information or clarification in the following circumstances:
- (a) the notification form is not properly filled in;
  - (b) there is a manifest error in the form or in the supporting documents;
  - (c) a description of the electronic identification scheme prior to notification was not provided to other Member States pursuant to Article 7(g) of Regulation (EU) No 910/2014.
6. Where additional information or clarification referred to in paragraph 5 is requested, the notification shall only be considered complete when such additional information or clarification is submitted to the Commission.

*Article 4*

**Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 3 November 2015.

*For the Commission*  
Günther OETTINGER  
*Member of the Commission*

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## ANNEX

**NOTIFICATION FORM FOR ELECTRONIC IDENTITY SCHEME UNDER ARTICLE 9(5) OF REGULATION (EU)  
No 910/2014**

(Insert the name of the Member State) hereby notifies the European Commission of an electronic identification scheme to be published in the list referred to in Article 9(3) of Regulation (EU) No 910/2014 and confirms the following:

- the information communicated in this notification is consistent with the information which has been communicated to the Cooperation Network in accordance with Article 7(g) of Regulation (EU) No 910/2014, and
- the electronic identification scheme can be used to access at least one service provided by a public sector body in (insert the name of the Member State).

**Date**

**[signed electronically]**

**1. General information**

|                          |                                                  |
|--------------------------|--------------------------------------------------|
| Title of scheme (if any) | Level(s) of assurance (low, substantial or high) |
| <br>                     | <br>                                             |

**2. Authority(ies) responsible for the scheme**

|                           |                    |                    |              |
|---------------------------|--------------------|--------------------|--------------|
| Name(s) of authority(ies) | Postal address(es) | E-mail address(es) | Telephone No |
| <br>                      | <br>               | <br>               | <br>         |

**3. Information on relevant parties, entities and bodies (where there are multiple parties, entities or bodies, please list them all, in accordance with Article 3(2) and (3))**

**3.1. Entity which manages the registration process of the unique person identification data**

Name of entity which manages the registration process of the unique person identification data

**3.2. Party issuing the electronic identification means**

Name of the party issuing the electronic identity means and indication of whether the party is referred to in Article 7(a)(i), (ii) or (iii) of Regulation (EU) No 910/2014

Article 7(a)(i) ☐

Article 7(a)(ii) ☐

Article 7(a)(iii) ☐

**3.3. Party operating the authentication procedure**

Name of party operating the authentication procedure

**3.4. Supervisory body**

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Name of the supervisory body

*(provide the name(s) where applicable)*

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**4. Description of the electronic identification scheme**

Document(s) may be enclosed for each of the following descriptions.

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(a) Briefly describe the scheme including the context within which it operates and its scope

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(b) Where applicable, list the additional attributes which may be provided for natural persons under the scheme if requested by a relying party

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(c) Where applicable, list the additional attributes which may be provided for legal persons under the scheme if requested by a relying party

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**4.1. Applicable supervisory, liability and management regime****4.1.1. Applicable supervisory regime**

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Describe the supervisory regime of the scheme with respect to the following:

*(where applicable, information shall include the roles, responsibilities and powers of the supervising body referred to in point 3.4, and the entity to which it reports. If the supervising body does not report to the authority responsible for the scheme, full details of the entity to which it reports shall be provided)*

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(a) supervisory regime applicable to the party issuing the electronic identification means

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(b) supervisory regime applicable to the party operating the authentication procedure

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**4.1.2. Applicable liability regime**

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Describe briefly the applicable national liability regime for the following scenarios:

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(a) liability of the Member State under Article 11(1) of Regulation (EU) No 910/2014

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(b) liability of the party issuing the electronic identification means under Article 11(2) of Regulation (EU) No 910/2014

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(c) liability of the party operating the authentication procedure under Article 11(3) of Regulation (EU) No 910/2014

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#### 4.1.3. Applicable management arrangements

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Describe the arrangements for suspending or revoking of either the entire identification scheme or authentication, or their compromised parts

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#### 4.2. Description of the scheme components

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Describe how the following elements of Commission Implementing Regulation (EU) 2015/1502 <sup>(1)</sup> have been met in order to reach a level of assurance of an electronic identification means under the scheme the Commission is being notified of:

*(include any standards adopted)*

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##### 4.2.1. Enrolment

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(a) Application and registration

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(b) Identity proofing and verification (natural person)

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(c) Identity proofing and verification (legal person)

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(d) Binding between the electronic identification means of natural and legal persons

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##### 4.2.2. Electronic identification means management

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(a) Electronic identification means characteristics and design (including, where appropriate, information on security certification)

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<sup>(1)</sup> Commission Implementing Regulation (EU) 2015/1502 of 8 September 2015 on setting out minimum technical specifications and procedures for assurance levels for electronic identification means pursuant to Article 8(3) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market (OJ L 235, 9.9.2015, p. 7).

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(b) Issuance, delivery and activation

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(c) Suspension, revocation and reactivation

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(d) Renewal and replacement

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#### 4.2.3. Authentication

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Describe the authentication mechanism including terms of access to authentication by relying parties other than public sector bodies

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#### 4.2.4. Management and organisation

Describe the management and organisation of the following aspects:

- (a) General provisions on management and organisation
  - (b) Published notices and user information
  - (c) Information security management
  - (d) Record keeping
  - (e) Facilities and staff
  - (f) Technical controls
  - (g) Compliance and audit
- 

#### 4.3. Interoperability requirements

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Describe how the interoperability and minimum technical and operational security requirements under Commission Implementing Regulation (EU) 2015/1501 <sup>(1)</sup> are met. List and attach any document that may give further information on compliance, such as the opinion of the Cooperation Network, external audits, etc.

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<sup>(1)</sup> Commission Implementing Regulation (EU) 2015/1501 of 8 September 2015 on the interoperability framework pursuant to Article 12(8) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market (OJ L 235, 9.9.2015, p. 1).

List here all supporting documentation submitted and state to which of the elements above they relate. Include any domestic legislation which relates to the electronic identification provision relevant to this notification. Submit an English version or English translation whenever available.

**COMMISSION IMPLEMENTING DECISION (EU) 2015/1985****of 4 November 2015****pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid****(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 3(3) thereof,

Whereas:

- (1) On 28 April 2015, Belgium requested the Commission to decide, pursuant to Article 3(3) of Regulation (EU) No 528/2012, whether an anti-viral tissue placed on the market with the claim 'kills 99,9 % of cold & flu viruses in the tissue' is a biocidal product or a treated article and, if considered a biocidal product, whether it would belong to product-type 1 (human hygiene) or 2 (disinfectants and algicides not intended for direct application to humans or animals).
- (2) According to the information provided by Belgium, the tissue is a 3-ply tissue of which the middle layer is impregnated with citric acid. Citric acid is stated to be irreversibly bound into the tissue's matrix and to remain in the product throughout its lifecycle. After the tissue has been used, i.e. when moisture after sneezing, coughing or blowing of the nose into the tissue hits the middle layer, citric acid is claimed to deactivate the viral load within the tissue in order to prevent transfer back to the hands, transmittance of the virus from hand to hand contact and transmittance to surfaces with which the tissue comes into contact.
- (3) The tissue meets the definition of an article as provided under Article 3(2)(c) of Regulation (EU) No 528/2012.
- (4) The tissue meets the definition of a treated article as provided under Article 3(1)(l) of Regulation (EU) No 528/2012, as citric acid is intentionally incorporated into it with the aim to deactivate viruses and to limit cross-contamination with these viruses.
- (5) Viruses meet the definition of harmful organism as provided under Article 3(1)(g) of Regulation (EU) No 528/2012 since they may have a detrimental effect on humans.
- (6) Destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism is a biocidal function.
- (7) It is therefore essential to establish whether the tissue has a primary biocidal function or not, in order to define whether the tissue is a treated article or a biocidal product.
- (8) The claim made on the tissue packaging and advertising is 'kills 99,9 % of cold & flu viruses in the tissue'. Through such a claim, greater prominence and first importance is given to the biocidal function of the tissue than to its other functions (for example to blow the nose). The anti-viral tissue has therefore a primary biocidal function.
- (9) Since product-type 1 covers biocidal products used to disinfect the skin or the scalp and product-type 2 covers biocidal products used for wider purposes, such as the disinfection of surfaces, materials or air, the use of the tissue would rather correspond to the latter product-type.
- (10) 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.

HAS ADOPTED THIS DECISION:

*Article 1*

An anti-viral tissue impregnated with citric acid and placed on the market with the claim 'kills 99,9 % of cold & flu viruses in the tissue' shall be considered as a biocidal product in accordance with Article 3(1)(a) of Regulation (EU) No 528/2012 and shall fall within product-type 2 as defined in Annex V to that Regulation.

*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, 4 November 2015.

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

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