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

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

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION REGULATION (EU) 2017/1270

of 14 July 2017

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of potassium carbonate (E 501) on peeled, cut and shredded fruit and vegetables**

(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 10(3) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) The Union list of food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council <sup>(2)</sup> either on the initiative of the Commission or following an application.
- (3) An application for authorisation of the use of potassium carbonate (E 501) on peeled, cut and shredded fruit and vegetables was submitted on 15 October 2015 and was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) During preparation of fresh cut fruit and vegetables, enzymatic activities may lead to a loss in quality of the products, such as browning and structural losses and to food waste. In order to avoid browning, ascorbic acid (E 300) can be used. However, ascorbic acid tends to break down cell tissue, leading to softening and discoloration of fruit and vegetables after a few days. The use of potassium carbonate (E 501) allows for a more efficient protection against browning as it functions as a stabilizer and acidity regulator and minimizes the damage to tissue caused by ascorbic acid.
- (5) The Scientific Committee for Food established a group ADI (Acceptable Daily Intake) level of 'not specified' for carbonates <sup>(3)</sup>, implying that it does not represent a hazard to health when used at the levels necessary to achieve the desired technological effect.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in

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

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

<sup>(3)</sup> Report from the Scientific Committee for food, 25th series, 1990.

Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. Since authorisation of use of potassium carbonate (E 501) as stabilizer and acidity regulator on peeled, cut and shredded fruit and vegetables constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.

- (7) Therefore, it is appropriate to authorise the use of potassium carbonate (E 501) as stabilizer and acidity regulator in the food category 04.1.2 'Peeled, cut and shredded fruit and vegetables' in Annex II to Regulation (EC) No 1333/2008 at *quantum satis*. In order to ensure that the consumer is informed about this treatment, the use of potassium carbonate (E 501) should be restricted to prepacked refrigerated unprocessed fruit and vegetables ready for consumption and prepacked unprocessed and peeled potatoes.
- (8) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 14 July 2017.

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

ANNEX

In Part E of Annex II to Regulation (EC) No 1333/2008, in food category 04.1.2 'Peeled, cut and shredded fruit and vegetables', the following entry is inserted before the footnotes:

|  |        |                     |                      |  |  |
|--|--------|---------------------|----------------------|--|--|
|  | 'E 501 | Potassium carbonate | <i>Quantum satis</i> |  | only prepacked refrigerated unprocessed fruit and vegetables ready for consumption and prepacked unprocessed and peeled potatoes'. |
|--|--------|---------------------|----------------------|--|--|

**COMMISSION REGULATION (EU) 2017/1271****of 14 July 2017****amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of silicon dioxide (E 551) in potassium nitrate (E 252)****(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 10(3) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.
- (2) The Union list of food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council <sup>(2)</sup> either on the initiative of the Commission or following an application.
- (3) An application for authorisation of the use of silicon dioxide (E 551) as an anti-caking agent added to potassium nitrate (E 252) was submitted on 7 July 2016 and was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) When stored, potassium nitrate (E 252) shows a strong caking tendency which hinders its use in food processing. Therefore, an anti-caking agent is needed to ensure the flow and correct dosing of this additive. The applicant has demonstrated that the authorised anti-caking agents for potassium nitrate (E 252) are not efficient or may lead to undesired changes in the pH, disturbing food processing. Meanwhile silicon dioxide (E 551) is proven to be efficient and does not react with the food nor influence the further processing of the food.
- (5) The Scientific Committee for Food established a group ADI (Acceptable Daily Intake) level of 'not specified' for silicon dioxide (E 551) and certain silicates (i.e. sodium, potassium, calcium, and magnesium silicates) when used as anticaking agents <sup>(3)</sup>. That implies that silicon dioxide (E 551) does not represent a hazard to health when used at the levels necessary to achieve the desired technological effect. The additional exposure of the consumer to silicon dioxide (E 551) when used as an anticaking agent in potassium nitrate (E 252) would remain limited.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.
- (7) Since the authorisation of the use of silicon dioxide (E 551) in potassium nitrate (E 252) constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (8) It is therefore appropriate to authorise the use of silicon dioxide (E 551) as an anti-caking agent in potassium nitrate (E 252).
- (9) Annex III to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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

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

<sup>(3)</sup> Report from the Scientific Committee for food, 25th series, 1990.

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

*Article 2*

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

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

Done at Brussels, 14 July 2017.

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

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ANNEX

In Part 2 of Annex III to Regulation (EC) No 1333/2008, the following entry is inserted after the last entry for food additive E 551 Silicon dioxide:

|  |        |                 |                                 |                          |
|--|--------|-----------------|---------------------------------|--------------------------|
|  | 'E 551 | Silicon dioxide | 10 000 mg/kg in the preparation | E 252 Potassium nitrate' |
|--|--------|-----------------|---------------------------------|--------------------------|

**COMMISSION IMPLEMENTING REGULATION (EU) 2017/1272****of 14 July 2017****establishing budgetary ceilings for 2017 applicable to certain direct support schemes provided for in Regulation (EU) No 1307/2013 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 <sup>(1)</sup>, and in particular Articles 22(1), 36(4), 42(2), 47(3), 49(2), 51(4) and 53(7) thereof,

Whereas:

- (1) For each Member State implementing the basic payment scheme provided for in Chapter 1 of Title III of Regulation (EU) No 1307/2013, the annual national ceiling referred to in Article 22(1) of that Regulation for 2017 has to be set by the Commission by deducting from the annual national ceiling set out in Annex II to that Regulation the ceilings fixed in accordance with Articles 42, 47, 49, 51 and 53 of that Regulation. In accordance with Article 22(2) of Regulation (EU) No 1307/2013 any increases applied by Member States pursuant to that provision are to be taken into account.
- (2) For each Member State implementing the single area payment scheme provided for in Chapter 1 of Title III of Regulation (EU) No 1307/2013, the annual national ceiling referred to in Article 36(4) of that Regulation for 2017 has to be set by the Commission by deducting from the annual national ceiling set out in Annex II to that Regulation the ceilings fixed in accordance with Articles 42, 47, 49, 51 and 53 of that Regulation.
- (3) For each Member State granting the redistributive payment provided for in Chapter 2 of Title III of Regulation (EU) No 1307/2013, the annual national ceiling referred to in Article 42(2) of that Regulation for 2017 has to be set by the Commission on the basis of the percentage notified by those Member States pursuant to Article 42(1) of that Regulation.
- (4) In relation to the payment for agricultural practices beneficial for the climate and the environment provided for in Chapter 3 of Title III of Regulation (EU) No 1307/2013 in 2017, the annual national ceilings referred to in Article 47(3) of that Regulation for 2017 have to be calculated in accordance with Article 47(1) of that Regulation and amounting to 30 % of the national ceiling of the relevant Member State as set out in Annex II to that Regulation.
- (5) For Member States granting the payment for areas with natural constraints provided for in Chapter 4 of Title III of Regulation (EU) No 1307/2013, the annual national ceilings referred to in Article 49(2) of that Regulation for 2017 have to be set by the Commission on the basis of the percentage notified by the relevant Member States pursuant to Article 49(1) of that Regulation.
- (6) In relation to the payment for young farmers provided for in Chapter 5 of Title III of Regulation (EU) No 1307/2013, the annual national ceilings referred to in Article 51(4) of that Regulation for 2017 have to be set by the Commission on the basis of the percentage notified by Member States pursuant to Article 51(1) of that Regulation and have not to be higher than 2 % of the annual ceiling set out in Annex II.
- (7) Where the total amount of the payment for young farmers applied for in 2017 in a Member State exceeds the ceiling set pursuant to Article 51(4) of Regulation (EU) No 1307/2013 for that Member State, the difference has to be financed by the Member State in accordance with Article 51(2) of that Regulation whilst respecting the maximum amount laid down in Article 51(1) of that Regulation. For the sake of clarity, it is appropriate to set this maximum amount for each Member State.

<sup>(1)</sup> OJ L 347, 20.12.2013, p. 608.

- (8) For each Member State granting voluntary coupled support provided for in Chapter 1 of Title IV of Regulation (EU) No 1307/2013 in 2017, the Commission has to set the annual national ceilings referred to in Article 53(7) of that Regulation for 2017 on the basis of the percentage notified by the relevant Member State pursuant to Article 54(1) of that Regulation.
- (9) Concerning the year 2017, the implementation of direct support schemes provided for in Regulation (EU) No 1307/2013 started on 1 January 2017. For the sake of consistency between the applicability of that Regulation for the claim year 2017 and the applicability of the corresponding budgetary ceilings, this Regulation should apply from the same date.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Direct Payments,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

1. The annual national ceilings for 2017 for the basic payment scheme referred to in Article 22(1) of Regulation (EU) No 1307/2013 are set out in point I of the Annex to this Regulation.
2. The annual national ceilings for 2017 for the single area payment scheme referred to in Article 36(4) of Regulation (EU) No 1307/2013 are set out in point II of the Annex to this Regulation.
3. The annual national ceilings for 2017 for the redistributive payment referred to in Article 42(2) of Regulation (EU) No 1307/2013 are set out in point III of the Annex to this Regulation.
4. The annual national ceilings for 2017 for the payment for agricultural practices beneficial for the climate and the environment referred to in Article 47(3) of Regulation (EU) No 1307/2013 are set out in point IV of the Annex to this Regulation.
5. The annual national ceilings for 2017 for the payment for areas with natural constraints referred to in Article 49(2) of Regulation (EU) No 1307/2013 are set out in point V of the Annex to this Regulation.
6. The annual national ceilings for 2017 for the payment for young farmers referred to in Article 51(4) of Regulation (EU) No 1307/2013 are set out in point VI of the Annex to this Regulation.
7. The maximum amounts for 2017 for the payment for young farmers referred to in Article 51(1) of Regulation (EU) No 1307/2013 are set out in point VII of the Annex to this Regulation.
8. The annual national ceilings for 2017 for voluntary coupled support referred to in Article 53(7) of Regulation (EU) No 1307/2013 are set out in point VIII of the Annex to this Regulation.

#### *Article 2*

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

It shall apply from 1 January 2017.

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

Done at Brussels, 14 July 2017.

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



## ANNEX

**I. Annual national ceilings for the basic payment scheme referred to in Article 22(1) of Regulation (EU) No 1307/2013***(thousand EUR)*

| Calendar year  | 2017      |
|----------------|-----------|
| Belgium        | 222 198   |
| Denmark        | 553 021   |
| Germany        | 3 022 776 |
| Ireland        | 826 181   |
| Greece         | 1 129 245 |
| Spain          | 2 826 613 |
| France         | 3 185 167 |
| Croatia        | 108 746   |
| Italy          | 2 245 528 |
| Luxembourg     | 22 779    |
| Malta          | 648       |
| Netherlands    | 504 278   |
| Austria        | 470 393   |
| Portugal       | 274 189   |
| Slovenia       | 73 619    |
| Finland        | 262 269   |
| Sweden         | 401 863   |
| United Kingdom | 2 112 701 |

**II. Annual national ceilings for the single area payment scheme referred to in Article 36(4) of Regulation (EU) No 1307/2013***(thousand EUR)*

| Calendar year  | 2017    |
|----------------|---------|
| Bulgaria       | 379 042 |
| Czech Republic | 462 074 |
| Estonia        | 80 043  |
| Cyprus         | 30 396  |
| Latvia         | 123 537 |
| Lithuania      | 180 990 |

(thousand EUR)

| Calendar year | 2017      |
|---------------|-----------|
| Hungary       | 733 351   |
| Poland        | 1 559 217 |
| Romania       | 919 141   |
| Slovakia      | 252 841   |

**III. Annual national ceilings for the redistributive payment referred to in Article 42(2) of Regulation (EU) No 1307/2013**

(thousand EUR)

| Calendar year  | 2017    |
|----------------|---------|
| Belgium        | 47 460  |
| Bulgaria       | 55 922  |
| Germany        | 339 366 |
| France         | 723 902 |
| Croatia        | 24 113  |
| Lithuania      | 70 061  |
| Poland         | 289 802 |
| Portugal       | 16 298  |
| Romania        | 97 072  |
| United Kingdom | 48 599  |

**IV. Annual national ceilings for the payment for agricultural practices beneficial for the climate and the environment as referred to in Article 47(3) of Regulation (EU) No 1307/2013**

(thousand EUR)

| Calendar year  | 2017      |
|----------------|-----------|
| Belgium        | 150 629   |
| Bulgaria       | 237 968   |
| Czech Republic | 252 960   |
| Denmark        | 250 437   |
| Germany        | 1 454 424 |
| Estonia        | 37 111    |
| Ireland        | 363 570   |
| Greece         | 562 899   |
| Spain          | 1 460 000 |
| France         | 2 171 705 |

(thousand EUR)

| Calendar year  | 2017      |
|----------------|-----------|
| Croatia        | 72 338    |
| Italy          | 1 139 862 |
| Cyprus         | 14 900    |
| Latvia         | 69 129    |
| Lithuania      | 140 121   |
| Luxembourg     | 10 046    |
| Hungary        | 402 940   |
| Malta          | 1 573     |
| Netherlands    | 217 309   |
| Austria        | 207 526   |
| Poland         | 1 023 556 |
| Portugal       | 174 617   |
| Romania        | 540 401   |
| Slovenia       | 40 801    |
| Slovakia       | 133 391   |
| Finland        | 157 048   |
| Sweden         | 209 303   |
| United Kingdom | 955 896   |

**V. Annual national ceilings for payment for areas with natural constraints referred to in Article 49(2) of Regulation (EU) No 1307/2013**

(thousand EUR)

| Calendar year | 2017  |
|---------------|-------|
| Denmark       | 2 857 |
| Slovenia      | 2 149 |

**VI. Annual national ceilings for the payment for young farmers referred to in Article 51(4) of Regulation (EU) No 1307/2013**

(thousand EUR)

| Calendar year  | 2017   |
|----------------|--------|
| Belgium        | 8 367  |
| Bulgaria       | 1 310  |
| Czech Republic | 1 686  |
| Denmark        | 4 341  |
| Germany        | 48 481 |

(thousand EUR)

| Calendar year  | 2017   |
|----------------|--------|
| Estonia        | 408    |
| Ireland        | 24 238 |
| Greece         | 37 527 |
| Spain          | 97 333 |
| France         | 72 390 |
| Croatia        | 4 823  |
| Italy          | 37 995 |
| Cyprus         | 397    |
| Latvia         | 3 200  |
| Lithuania      | 5 838  |
| Luxembourg     | 502    |
| Hungary        | 5 373  |
| Malta          | 21     |
| Netherlands    | 14 487 |
| Austria        | 13 835 |
| Poland         | 34 119 |
| Portugal       | 11 641 |
| Romania        | 18 013 |
| Slovenia       | 2 040  |
| Slovakia       | 604    |
| Finland        | 5 235  |
| Sweden         | 10 465 |
| United Kingdom | 16 308 |

**VII. Maximum amounts for the payment for young farmers referred to in Article 51(1) of Regulation (EU) No 1307/2013**

(thousand EUR)

| Calendar year  | 2017   |
|----------------|--------|
| Belgium        | 10 042 |
| Bulgaria       | 15 865 |
| Czech Republic | 16 864 |
| Denmark        | 16 696 |
| Germany        | 96 962 |

(thousand EUR)

| Calendar year  | 2017    |
|----------------|---------|
| Estonia        | 2 474   |
| Ireland        | 24 238  |
| Greece         | 37 527  |
| Spain          | 97 333  |
| France         | 144 780 |
| Croatia        | 4 823   |
| Italy          | 75 991  |
| Cyprus         | 993     |
| Latvia         | 4 609   |
| Lithuania      | 9 341   |
| Luxembourg     | 670     |
| Hungary        | 26 863  |
| Malta          | 105     |
| Netherlands    | 14 487  |
| Austria        | 13 835  |
| Poland         | 68 237  |
| Portugal       | 11 641  |
| Romania        | 36 027  |
| Slovenia       | 2 720   |
| Slovakia       | 8 893   |
| Finland        | 10 470  |
| Sweden         | 13 954  |
| United Kingdom | 63 726  |

**VIII. Annual national ceilings for voluntary coupled support referred to in Article 53(7) of Regulation (EU) No 1307/2013**

(thousand EUR)

| Calendar year  | 2017    |
|----------------|---------|
| Belgium        | 83 985  |
| Bulgaria       | 118 984 |
| Czech Republic | 126 480 |
| Denmark        | 24 135  |
| Estonia        | 6 142   |

*(thousand EUR)*

| Calendar year  | 2017      |
|----------------|-----------|
| Ireland        | 3 000     |
| Greece         | 186 061   |
| Spain          | 584 919   |
| France         | 1 085 853 |
| Croatia        | 36 169    |
| Italy          | 455 945   |
| Cyprus         | 3 973     |
| Latvia         | 34 565    |
| Lithuania      | 70 060    |
| Luxembourg     | 160       |
| Hungary        | 201 470   |
| Malta          | 3 000     |
| Netherlands    | 3 500     |
| Austria        | 14 527    |
| Poland         | 505 160   |
| Portugal       | 117 535   |
| Romania        | 226 708   |
| Slovenia       | 17 680    |
| Slovakia       | 57 800    |
| Finland        | 102 605   |
| Sweden         | 90 698    |
| United Kingdom | 52 815    |

**COMMISSION IMPLEMENTING REGULATION (EU) 2017/1273****of 14 July 2017****approving active chlorine released from sodium hypochlorite as an existing active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5****(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 active chlorine released from sodium hypochlorite (hereafter referred to as 'sodium hypochlorite').
- (2) Sodium hypochlorite 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 products of 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, and product-type 5, drinking water disinfectants, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 2, 3, 4 and 5 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 on 17 May 2010.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 14 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 1, 2, 3, 4 and 5 containing sodium hypochlorite may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve sodium hypochlorite for use in biocidal products of product-types 1, 2, 3, 4 and 5, 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,

<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).

HAS ADOPTED THIS REGULATION:

*Article 1*

Active chlorine released from sodium hypochlorite is approved as an active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5, 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, 14 July 2017.

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

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## ANNEX

| Common Name   | IUPAC Name<br>Identification Numbers  | Minimum degree of<br>purity of the active<br>substance (1)   | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions   |
|---|---|--|---------------------|----------------------------|-----------------|---|
| Active chlorine released from sodium hypochlorite (hereafter referred to as 'sodium hypochlorite'). | IUPAC Name:<br>Sodium hypochlorite<br>EC No: 231-668-3<br>CAS No: 7681-52-9 | Minimum purity of the releaser sodium hypochlorite: aqueous solution with an active chlorine concentration $\leq 180$ g/kg (i.e. $\leq 18$ % w/w). | 1 January 2019      | 31 December 2028           | 1               | The authorisations of biocidal products are subject to the following condition:<br><br>The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.  |
|   |   |  |                     |                            | 2               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br><br>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:<br><br>(a) professional users and non-professional users;<br><br>(b) surface water and sediment for disinfection of sewage / waste water in the effluent stream of the sewage treatment plant (post-chlorination).  |
|   |   |  |                     |                            | 3               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br><br>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users and non-professional users.<br><br>(3) 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 (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. |

| Common Name | IUPAC Name Identification Numbers | Minimum degree of purity of the active substance <sup>(1)</sup> | Date of approval | Expiry date of approval | Product type | Specific conditions   |
|-------------|-----------------------------------|---|------------------|-------------------------|--------------|---|
|             |                                   |   |                  |                         | 4            | <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.</p> <p>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.</p> <p>(3) For products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p>  |
|             |                                   |   |                  |                         | 5            | <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.</p> <p>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.</p> <p>(3) For products that may lead to residues in food or feed, the need to set new or to amend existing (MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p> |

<sup>(1)</sup> The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to 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) 2017/1274****of 14 July 2017****approving active chlorine released from calcium hypochlorite as an existing active substance for use in biocidal products of product-types 2, 3, 4 and 5****(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 active chlorine released from calcium hypochlorite (hereafter referred to as 'calcium hypochlorite').
- (2) Calcium hypochlorite 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 products of 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, and product-type 5, drinking water disinfectants, as defined in Annex V to that Directive, which correspond respectively to product-types 2, 3, 4 and 5 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 on 7 July 2010.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 14 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2, 3, 4 and 5 containing calcium hypochlorite may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve calcium hypochlorite for use in biocidal products of product-types 2, 3, 4 and 5, 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*

Active chlorine released from calcium hypochlorite is approved as an active substance for use in biocidal products of product-types 2, 3, 4 and 5, 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).

*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, 14 July 2017.

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

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## ANNEX

| Common Name   | IUPAC Name<br>Identification Numbers   | Minimum degree of<br>purity of the active<br>substance (1)  | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions  |
|---|--|---|---------------------|----------------------------|-----------------|--|
| Active chlorine released from calcium hypochlorite (hereafter referred to as 'calcium hypochlorite'). | IUPAC Name:<br>Calcium hypochlorite<br>EC No: 231-908-7<br>CAS No: 7778-54-3 | Minimum purity of the releaser calcium hypochlorite:<br>≥ 655 g/kg (i.e. ≥ 65,5 % w/w, equivalent to an active chlorine content of 65 % w/w). | 1 January 2019      | 31 December 2028           | 2               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance;<br><br>(2) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:<br><br>(a) professional users and non-professional users;<br><br>(b) surface water and sediment for disinfection of sewage/waste water in the effluent stream of the sewage treatment plant (post-chlorination).   |
|   |  |   |                     |                            | 3               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance;<br><br>(2) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users;<br><br>(3) 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 (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. |
|   |  |   |                     |                            | 4               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use 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<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>(2) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users;</p> <p>(3) for products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p>  |
|             |                                      |   |                     |                            | 5               | <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance;</p> <p>(2) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users;</p> <p>(3) for products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p> |

- <sup>(1)</sup> The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to 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) 2017/1275****of 14 July 2017****approving active chlorine released from chlorine as an existing active substance for use in biocidal products of product-types 2 and 5****(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 active chlorine released from chlorine (hereafter referred to as 'chlorine').
- (2) Chlorine 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 products of product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 5, drinking water disinfectants, as defined in Annex V to that Directive, which correspond respectively to product-types 2 and 5 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 on 17 May 2010.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 14 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2 and 5 containing chlorine may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve chlorine for use in biocidal products of product-types 2 and 5, 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*

Active chlorine released from chlorine is approved as an active substance for use in biocidal products of product-types 2 and 5, 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).

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*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, 14 July 2017.

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

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## 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 of<br>approval | Product<br>type | Specific conditions   |
|--|--|--|---------------------|----------------------------|-----------------|---|
| Active chlorine<br>released from<br>chlorine<br>(hereafter<br>referred to as<br>'chlorine'). | IUPAC Name:<br>Chlorine<br>EC No: 231-959-5<br>CAS No: 7782-50-5 | Minimum purity of<br>the releaser chlorine:<br>≥ 995 g/kg (i.e.<br>≥ 99,5 % w/w) | 1 January<br>2019   | 31 Decem-<br>ber 2028      | 2               | The authorisations of biocidal products are subject to the following conditions:<br>1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br>2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:<br>(a) professional users;<br>(b) surface water and sediment for disinfection of sewage/waste water in the effluent stream of the sewage treatment plant (post-chlorination).   |
|  |  |  |                     |                            | 5               | The authorisations of biocidal products are subject to the following conditions:<br>1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br>2. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.<br>3. 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. |

<sup>(1)</sup> The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to 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) 2017/1276****of 14 July 2017****approving peracetic acid generated from tetraacetylenediamine and sodium percarbonate as an existing active substance for use in biocidal products of product-types 2, 3 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 peracetic acid generated from tetraacetylenediamine and sodium percarbonate.
- (2) Peracetic acid generated from tetraacetylenediamine and sodium percarbonate 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 products of product-type 2, private area and public health area disinfectants and other biocidal products; product-type 3, veterinary hygiene 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 2, 3 and 4 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 on 16 January 2013.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 13 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2, 3 and 4 based on peracetic acid generated from tetraacetylenediamine and sodium percarbonate may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning its use are complied with.
- (6) It is therefore appropriate to approve peracetic acid generated from tetraacetylenediamine and sodium percarbonate for use in biocidal products of product-types 2, 3 and 4, 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,

<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).

HAS ADOPTED THIS REGULATION:

*Article 1*

Peracetic acid generated from tetraacetylenediamine and sodium percarbonate is approved as an active substance for use in biocidal products of product-types 2, 3 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, 14 July 2017.

*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<br>the active substance <sup>(1)</sup>  | Date of<br>approval | Expiry date of<br>approval | Product<br>type | Specific conditions  |
|--|--|---|---------------------|----------------------------|-----------------|--|
| Peracetic acid<br>generated from<br>tetraacetylene-<br>diamine<br>and sodium<br>percarbonate | IUPAC Name:<br>Peroxyethanoic acid<br>EC No: 201-186-8<br>CAS No: 79-21-0<br>Precursors:<br>IUPAC Name:<br>N,N'-ethane-1,2-diyl-<br>bis(N-acetylacetamide)<br>EC No: 234-123-8<br>CAS No: 10543-57-4<br>IUPAC Name: Sodium<br>percarbonate<br>EC No: 239-707-6<br>CAS No: 15630-89-4 | The specification for per-<br>acetic acid generated <i>in<br/>situ</i> is based on the pre-<br>cursors tetraacetylene-<br>diamine and sodium<br>percarbonate.<br><br>The minimum degree of<br>purity of tetraacetylene-<br>diamine is 99,0 % and<br>the minimum degree of<br>purity of the sodium per-<br>carbonate is 85,1 % | 1 January<br>2019   | 31 Decem-<br>ber 2028      | 2               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br><br>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:<br>(a) industrial and professional users;<br>(b) surface water for products used in laundry disinfection in closed washing machines in households. |
|  |  |   |                     |                            | 3               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br><br>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to industrial and professional users.  |
|  |  |   |                     |                            | 4               | The authorisations of biocidal products are subject to the following conditions:<br><br>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.<br><br>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to industrial and professional users.  |

<sup>(1)</sup> The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

**COMMISSION IMPLEMENTING REGULATION (EU) 2017/1277****of 14 July 2017****approving 2-octyl-isothiazol-3(2H)-one as an active substance for use in biocidal products of 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 Article 90(2) thereof,

Whereas:

- (1) The United Kingdom received on 27 April 2010 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 2-octyl-isothiazol-3(2H)-one in Annex I to that Directive for use in products of product-type 8, wood preservatives, as described in Annex V to that Directive, which corresponds to product-type 8 as described in Annex V to Regulation (EU) No 528/2012.
- (2) The United Kingdom submitted the assessment report together with its recommendations on 4 February 2016 in accordance with Article 90(2) of Regulation (EU) No 528/2012.
- (3) The opinion of the European Chemicals Agency was formulated on 15 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products of product-type 8 and containing 2-octyl-isothiazol-3(2H)-one may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.
- (5) It is therefore appropriate to approve 2-octyl-isothiazol-3(2H)-one for use in biocidal products of product-type 8, subject to compliance with certain specifications and conditions.
- (6) Since 2-octyl-isothiazol-3(2H)-one meets the criteria for classification as skin sensitiser sub-category 1A as specified in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(3)</sup>, treated articles treated with or incorporating 2-octyl-isothiazol-3(2H)-one should be appropriately labelled when placed on the market.
- (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*

2-octyl-isothiazol-3(2H)-one is approved as an active substance for use in biocidal products of 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> 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 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).

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*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, 14 July 2017.

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

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## 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 of<br>approval | Product-<br>type | Specific conditions   |
|------------------------------|---|---|---------------------|----------------------------|------------------|---|
| 2-octyl-isothiazol-3(2H)-one | IUPAC Name:<br>2-octyl-isothiazol-3(2H)-one<br>EC No: 247-761-7<br>CAS No: 26530-20-1 | 960 g/kg w/w  | 1 January<br>2018   | 31 Decem-<br>ber 2027      | 8                | <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.</li> <li>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to industrial and professional users.</li> <li>(3) In view of the risks identified for the surface water, sediment and soil, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil sewer or water, and that any losses shall be collected for reuse or disposal.</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-octyl-isothiazol-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 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 evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

**COMMISSION IMPLEMENTING REGULATION (EU) 2017/1278****of 14 July 2017****approving 2-methylisothiazol-3(2H)-one as an existing active substance for use in biocidal products of product-type 11****(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 2-methylisothiazol-3(2H)-one.
- (2) 2-methylisothiazol-3(2H)-one has been evaluated for use in products of product-type 11, preservatives for liquid-cooling and processing systems, as described in Annex V to Regulation (EU) No 528/2012.
- (3) Slovenia was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 7 April 2016.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 15 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products of product-type 11 containing 2-methylisothiazol-3(2H)-one may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.
- (6) It is therefore appropriate to approve 2-methylisothiazol-3(2H)-one for use in biocidal products of product-type 11, subject to compliance with certain specifications and conditions.
- (7) Since 2-methylisothiazol-3(2H)-one meets the criteria for classification as skin sensitiser sub-category 1A as specified in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(3)</sup>, treated articles treated with or incorporating 2-methylisothiazol-3(2H)-one 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> 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*

2-methylisothiazol-3(2H)-one is approved as an active substance for use in biocidal products of product-type 11, 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, 14 July 2017.

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

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## 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 of<br>approval | Product<br>type | Specific conditions   |
|------------------------------|--|---|---------------------|----------------------------|-----------------|---|
| 2-methylisothiazol-3(2H)-one | IUPAC Name:<br>2-methylisothiazol-3(2H)-one<br>EC No: 220-239-6<br>CAS No: 2682-20-4 | 950 g/kg  | 1 January<br>2019   | 31 December<br>2028        | 11              | <p>The authorisations of biocidal products are subject to the following conditions:</p> <p>(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.</p> <p>(2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:</p> <p>(a) industrial and professional users;</p> <p>(b) surface water and soil for products used in large and small open recirculating cooling systems with direct emission to surface water.</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 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 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 evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

# DIRECTIVES

## COMMISSION IMPLEMENTING DIRECTIVE (EU) 2017/1279

of 14 July 2017

**amending Annexes I to V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community <sup>(1)</sup>, and in particular points (c) and (d) of the second paragraph of Article 14 thereof,

Whereas:

- (1) Following the recently published revision of the respective scientific denomination, *Anoplophora malasiaca* (Forster) is considered a synonym of *Anoplophora chinensis* (Thomson), already included in Section I of Part A of Annex I to Directive 2000/29/EC. Therefore, *Anoplophora malasiaca* (Forster) should be deleted from Section I of Part A of Annex I to Directive 2000/29/EC.
- (2) With a view to protecting plants, plant products and other objects, in light of increased international trade and following pest risk assessments performed and recently published by the European and Mediterranean Plant Protection Organisation, it is technically justified and consistent with the pest risks involved to add the harmful organisms *Bactericera cockerelli* (Sulc.), *Keiferia lycopersicella* (Walsingham), *Saperda candida* Fabricius and *Thaumatotibia leucotreta* (Meyrick) to Section I of Part A of Annex I to Directive 2000/29/EC.
- (3) It is technically justified to delete *Xylella fastidiosa* (Wells *et al.*) from Section I of Part A of Annex I to Directive 2000/29/EC and add it to Section II of that Part as this harmful organism is known to occur in the Union.
- (4) The presence of the harmful organism *Xanthomonas campestris* (all strains pathogenic to *Citrus*) poses an unacceptable risk to the production and the trade of plants, plant products and other objects. In addition, the strains of *Xanthomonas campestris* pathogenic to citrus have been reclassified. *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii* are the causal agents of citrus canker disease. Therefore, it is scientifically justified and consistent with the pest risk involved to delete *Xanthomonas campestris* in Section I of Part A of Annex II to Directive 2000/29/EC and include it in Section I of Part A of Annex I to that Directive under the names *Xanthomonas citri* pv. *aurantifolii* and *Xanthomonas citri* pv. *citri*.
- (5) Following the revision of the respective scientific denomination, the harmful organism *Guignardia citricarpa* Kiely (all strains pathogenic to *Citrus*) has been renamed *Phyllosticta citricarpa* (McAlpine) Van der Aa, the causal agent of citrus black spot. It also poses an unacceptable risk to the production and the trade of plants, plant products and other objects. Therefore, it is technically justified and consistent with the pest risk involved to move that harmful organism from Section I of Part A of Annex II to Directive 2000/29/EC to Section I of Part A of Annex I to that Directive and rename it *Phyllosticta citricarpa* (McAlpine) Van der Aa.
- (6) The typographic mistakes regarding the scientific names of the harmful organisms *Phyllosticta solitaria* Ell. and Ev. and *Popillia japonica* Newman in Sections I and II, respectively, of Part A of Annex I to Directive 2000/29/EC and *Aleurocantus* spp. and *Aonidiella citrina* Coquillet in Section I of Part A of Annex II to that Directive should be corrected and replaced, as applicable, by *Phyllosticta solitaria* Ellis & Everhart, *Popillia japonica* Newman, *Aleurocanthus* spp. and *Aonidiella citrina* Coquillet respectively. Similarly, typographic mistakes in the scientific denomination of *Zea mays* L. should also be corrected in all annexes where reference is made to that species. The typographic mistake in the scientific denomination of *Amiris* P. Browne in Section I of Part B of Annex V to that Directive should be corrected and replaced by *Amyris* P. Browne.

<sup>(1)</sup> OJ L 169, 10.7.2000, p. 1.

- (7) Following the recently published revision of the respective scientific denomination, Elm phloem necrosis mycoplasma has been renamed '*Candidatus Phytoplasma ulmi*'. In addition, it is technically justified to delete that organism from Section I of Part A of Annex I to Directive 2000/29/EC (where it is listed as Elm phloem necrosis mycoplasma) and include it in Section II of that Part as '*Candidatus Phytoplasma ulmi*' as this harmful organism is known to occur in the Union. This is in accordance with the pest categorisation of the organism, performed by the European Food Safety Authority (EFSA) <sup>(1)</sup>. The new name should also be reflected in Annex IV to Directive 2000/29/EC.
- (8) It is technically justified and consistent with the pest risk involved to delete the harmful organism Potato spindle tuber viroid from Section I of Part A of Annex I to Directive 2000/29/EC, since that harmful organism has spread and is established in a number of host plants within a large part of the Union. The organism is included in Section II of Part A of Annex II to that Directive in order to protect the commodities that are currently free and where its presence would pose a significant risk and causes significant losses.
- (9) Following the recently published revision of the respective scientific denomination, the harmful organism *Xanthomonas campestris* pv. *pruni* (Smith) Dye should be renamed *Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin *et al.*
- (10) The special requirements for wood included in Section I of Part A of Annex IV to Directive 2000/29/EC should be revised in order to align them with the relevant International Standard of Phytosanitary Measures (ISPM 15) and further clarify them. In addition, the exemption of wood packing material from the specific requirements for wood of *Platanus* L. in that Section should be updated as it was omitted in the last amendment of that Section.
- (11) It is technically acceptable, on the basis of scientific and technical knowledge, to include special requirements for the introduction of certain plants, plant products and other objects into the Union due to their likelihood of hosting the harmful organisms referred to in recital (2). Therefore, the relevant plants, plant products and other objects should be listed in Part A of Annex IV to Directive 2000/29/EC.
- (12) In respect of the harmful organisms referred to in recitals (4), (5), and (7) it is necessary to amend the special requirements set out in Part A of Annex IV to Directive 2000/29/EC due to developments in scientific and technical knowledge and the recently published pest risk assessments carried out by EFSA. The aim of the amended requirements is to reduce the phytosanitary risk caused by the introduction into the Union of those plants, plant products and other objects originating in third countries to an acceptable level.
- (13) Following pest risk assessments, it is technically justified and consistent with the risks associated with the harmful organism *Trioza erythrae* Del Guercio to add *Murraya* J. Koenig *ex* L. to the list of host plants of that harmful organism in the relevant points in Sections I and II of Part A of Annex IV to Directive 2000/29/EC. Furthermore, *Choisya* Kunt should be included in the list of host plants of that harmful organism following the findings in Member States. Therefore, the special requirements for the import into and movement within the Union of the host plants in the relevant points in Sections I and II of Part A of Annex IV to Directive 2000/29/EC should be amended.
- (14) In addition, the plants, plant products or other objects referred to in recitals (10) to (13) should be subject to plant health inspections before being introduced into or moved within the Union. Therefore, those plants, plant products and other objects should be listed in Part A or B of Annex V to Directive 2000/29/EC.
- (15) The CN codes for wood set out in Annex V to Directive 2000/29/EC should be updated in order to align them with the current CN codes used in Council Regulation (EEC) No 2658/87 <sup>(2)</sup> as amended by Commission Implementing Regulation (EU) 2016/1821 <sup>(3)</sup>.

<sup>(1)</sup> EFSA PLH Panel (EFSA Panel on Plant Health), 2014. Scientific Opinion on the pest categorisation of Elm phloem necrosis mycoplasma. *EFSA Journal* 2014; 12(7):3773, 34 pp. doi:10.2903/j.efsa.2014.3773

<sup>(2)</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

<sup>(3)</sup> Commission Implementing Regulation (EU) 2016/1821 of 6 October 2016 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 294, 28.10.2016, p. 1).

- (16) In accordance with Commission Regulation (EC) No 690/2008 <sup>(1)</sup> certain zones have been recognised as protected zones in respect of various harmful organisms. That Regulation has recently been amended to take account of the latest developments with regard to the protected zones within the Union and the following harmful organisms: *Bemisia tabaci* Genn. (European populations), '*Candidatus Phytoplasma ulmi*', *Ceratocystis platani* (J. M. Walter) Engelbr. & T. C. Harr., Citrus tristeza virus (European strains), *Curtobacterium flaccumfaciens* pv. *flaccumfaciens* (Hedges) Col., *Dryocosmus kuriphilus* Yasumatsu, *Erwinia amylovora* (Burr.) Winsl. et al., *Globodera pallida* (Stone) Behrens, *Globodera rostochiensis* (Wollenweber) Behrens, *Paysandisia archon* (Burmeister), *Rhynchophorus ferrugineus* (Olivier), *Thaumetopoea pityocampa* Denis & Schiffermüller, *Thaumetopoea processionea* L., Tomato spotted wilt virus and *Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin et al. In order to ensure that the requirements concerning protected zones with regard to the respective harmful organisms are consistent, the relevant requirements in Annexes I to V to Directive 2000/29/EC should be updated.
- (17) Moreover, several areas within the Union that have been recognised as protected zones with regard to certain harmful organisms no longer fulfil the requirements because those harmful organisms have become established there or the Member States concerned requested that the status as a protected zone be revoked. Those areas are the following: the region of Ribatejo e Oeste in Portugal with regard to *Bemisia tabaci* Genn. (European populations); the county of Odemira in Alentejo in Portugal with regard to Citrus tristeza virus (European strains); the territory of Portugal with regard to *Curtobacterium flaccumfaciens* pv. *flaccumfaciens* (Hedges) Col. and *Dryocosmus kuriphilus* Yasumatsu; the autonomous communities of Andalucía and Madrid and the districts (Comarcas) of Segrià, Noguera, Pla d'Urgell, Garrigues and Urgell in the province of Lleida (Comunidad autonoma de Catalunya) in Spain; the provinces of Milano and Varese (Lombardy) and the communes of Busca, Centallo and Tarantasca in the province of Cuneo (Piedmont) in Italy; the townlands of Ballinran Upper, Carrigenagh Upper, Ballinran, and Carrigenagh in County Down, and the Electoral Area of Dunmurry Cross in Belfast, County Antrim (Northern Ireland) in the United Kingdom and the entire territory of the county of Dunajská Streda in Slovakia with regard to *Erwinia amylovora* (Burr.) Winsl. et al.; the local authority areas of Guildford and Woking in the United Kingdom with regard to *Thaumetopoea processionea* L. and the territory of Finland with regard to Tomato spotted wilt virus. This should be reflected in Part B of Annexes I to IV to Directive 2000/29/EC.
- (18) The mistakes in the delimitation of the protected zones for *Leptinotarsa decemlineata* Say in Finland and Sweden in Part B of Annex I to Directive 2000/29/EC should be corrected and brought in line with Regulation (EC) No 690/2008.
- (19) In order to protect the production and trade of plants, plant products and other objects, it is technically justified and consistent with the pest risk involved to add the harmful organism *Globodera rostochiensis* (Wollenweber) Behrens to Part B of Annex I to Directive 2000/29/EC and *Paysandisia archon* (Burmeister), *Rhynchophorus ferrugineus* (Olivier), *Thaumetopoea pityocampa* Denis & Schiffermüller and *Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin et al. to Part B of Annex II to that Directive.
- (20) From information provided by Portugal, it appears that the territory of the Azores is free from *Globodera pallida* (Stone) Behrens, *Globodera rostochiensis* (Wollenweber) Behrens and *Rhynchophorus ferrugineus* (Olivier) and that the Azores fulfil the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to those harmful organisms. Part B of Annexes I, II and IV to Directive 2000/29/EC should be amended accordingly. Similarly, Part B of Annex IV and Part A of Annex V to that Directive should be amended in order to introduce requirements for the movement of certain plants, plant products and other objects into the protected zones.
- (21) From information provided by Ireland, Malta and the United Kingdom, it appears that the territories of those Member States are free from *Paysandisia archon* (Burmeister) and that those territories fulfil the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of Annexes II and IV to Directive 2000/29/EC should be amended accordingly. Similarly, Part B of Annex IV and Part A of Annex V to that Directive should be amended in order to introduce requirements for the movement of certain plants, plant products and other objects into the protected zones.
- (22) From information provided by Ireland and the United Kingdom, it appears that the territories of those Member States are free from *Rhynchophorus ferrugineus* (Olivier) and that those territories fulfil the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of Annexes II and IV to Directive 2000/29/EC should be amended accordingly. Similarly, Part B of Annex IV and Part A of Annex V to that Directive should be amended in order to introduce requirements for the movement of certain plants, plant products and other objects into the protected zones.

<sup>(1)</sup> Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones exposed to particular plant health risks in the Community (OJ L 193, 22.7.2008, p. 1).

- (23) From information provided by the United Kingdom, it appears that its territory is free from *Thaumetopoea pityocampa* Denis & Schiffermüller and *Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin *et al.* and that it fulfils the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to those harmful organisms. Part B of Annexes II and IV to Directive 2000/29/EC should be amended accordingly. Similarly, Part B of Annex IV and Part A of Annex V to that Directive should be amended in order to introduce requirements for the movement of certain plants, plant products and other objects into the protected zones.
- (24) From information provided by Ireland, it appears that its territory is free from *Ceratocystis platani* (J. M. Walter) Engelbr. & T. C. Harr. and that it fulfils the conditions set out in point (h) of Article 2(1) of Directive 2000/29/EC for the establishment of a protected zone with respect to that harmful organism. Part B of Annexes II and IV to Directive 2000/29/EC should be amended accordingly.
- (25) A recent pest risk analysis shows that the current requirements for the introduction and movement of certain plants, plant products and other objects into and within certain protected zones with regard to *Bemisia tabaci* Genn. (European populations) and *Daktulosphaira vitifoliae* (Fitch) are inadequate to reduce the phytosanitary risk in question to acceptable levels. Those requirements should be reformulated in Part B of Annex IV to Directive 2000/29/EC.
- (26) Annexes I to V to Directive 2000/29/EC should therefore be amended accordingly.
- (27) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Annexes I to V to Directive 2000/29/EC are amended in accordance with the Annex to this Directive.

*Article 2*

1. Member States shall adopt and publish, by 31 December 2017 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 January 2018.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

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

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 14 July 2017.

For the Commission  
The President  
Jean-Claude JUNCKER

## ANNEX

Annexes I to V to Directive 2000/29/EC are amended as follows:

(1) Annex I is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

— heading (a) is amended as follows:

— point 5 is deleted;

— the following point is inserted after point 6:

‘6.1. *Bactericera cockerelli* (Sulc.)’

— the following point is inserted after point 11.1:

‘11.2. *Keiferia lycopersicella* (Walsingham)’

— the following point is inserted after point 19.1:

‘19.2. *Saperda candida* Fabricius’

— the following point is inserted after point 25:

‘25.1. *Thaumatotibia leucotreta* (Meyrick)’

— heading (b) is amended as follows:

— point 1 is deleted;

— the following points are inserted after point 0.1:

‘2. *Xanthomonas citri* pv. *aurantifolii*

2.1. *Xanthomonas citri* pv. *citri*’

— heading (c) is amended as follows:

— the following point is inserted after point 12:

‘12.1. *Phyllosticta citricarpa* (McAlpine) Van der Aa’

— in point 13, ‘*Phyllosticta solitaria* Ell. and Ev.’ is replaced by ‘*Phyllosticta solitaria* Ellis & Everhart’

— heading (d) is amended as follows:

— point 1 is deleted;

— in point 2, subpoint (e) is deleted;

(ii) Section II is amended as follows:

— in heading (a), point 8, ‘*Popilia japonica* Newman’, is replaced by ‘*Popillia japonica* Newman’

— in heading (b), the following point is inserted after point 2:

‘3. *Xylella fastidiosa* (Wells *et al.*)’

— in heading (d), the following point is inserted after point 2:

‘2.1. ‘*Candidatus Phytoplasma ulmi*’

(b) Part B is amended as follows:

(i) heading (a) is amended as follows:

— point 1 is replaced by the following:

‘1. *Bemisia tabaci* Genn. (European populations)

IRL, P (Azores, Beira Interior, Beira Litoral, Entre Douro e Minho and Trás-os-Montes), UK, S, FI’

— point 1.2 is replaced by the following:

‘1.2. *Dryocosmus kuriphilus* Yasumatsu

IRL, UK’

— point 2 is replaced by the following:

|  |                             |
|--|-----------------------------|
| ‘2. <i>Globodera pallida</i> (Stone) Behrens | FI, LV, P (Azores), SI, SK’ |
|--|-----------------------------|

— the following point is inserted after point 2:

|  |             |
|--|-------------|
| ‘2.1. <i>Globodera rostochiensis</i> (Wollenweber) Behrens | P (Azores)’ |
|--|-------------|

— point 3 is replaced by the following:

|  |  |
|--|--|
| ‘3. <i>Leptinotarsa decemlineata</i> Say | E (Ibiza and Menorca), IRL, CY, M, P (Azores and Madeira), UK, S (counties of Blekinge, Gotland, Halland, Kalmar and Skåne), FI (districts of Åland, Häme, Kymi, Pirkanmaa, Satakunta, Turku and Uusimaa)’ |
|--|--|

— point 5 is replaced by the following:

|   |  |
|---|--|
| ‘5. <i>Thaumetopoea processionea</i> L. | IRL, UK (excluding the local authority areas of Barnet; Brent; Bromley; Camden; City of London; City of Westminster; Croydon; Ealing; Elmbridge District; Epsom and Ewell District; Guildford; Hackney; Hammersmith & Fulham; Haringey; Harrow; Hillingdon; Hounslow; Islington; Kensington & Chelsea; Kingston upon Thames; Lambeth; Lewisham; Merton; Reading; Richmond Upon Thames; Runnymede District; Slough; South Oxfordshire; Southwark; Spelthorne District; Sutton; Tower Hamlets; Wandsworth; West Berkshire and Woking)’ |
|---|--|

(ii) in heading (b), point 2, in the right hand column, ‘S, FI’ is replaced by ‘S’.

(2) Annex II is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

— heading (a) is amended as follows:

— in point 2, in the left hand column, ‘*Aleurocantus* spp.’ is replaced by ‘*Aleurocanthus* spp.’

— in point 5, in the left hand column, ‘*Aonidella citrina* Coquillet’, is replaced by ‘*Aonidiella citrina* Coquillet’

— heading (b) is amended as follows:

— in point 3, in the right hand column, ‘Seeds of *Zea mais* L.’ is replaced by ‘Seeds of *Zea mays* L.’

— point 4 is deleted;

— in heading (c), point 11 is deleted;

(ii) Section II is amended as follows:

— in heading (b), point 8, in the left hand column, ‘*Xanthomonas campestris* pv. *pruni* (Smith) Dye’ is replaced by ‘*Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin *et al.*’

— in heading (d), the following point is inserted after point 7:

|                                   |  |
|-----------------------------------|--|
| ‘7.1. Potato spindle tuber viroid | Plants for planting (including seeds) of <i>Solanum lycopersicum</i> L. and its hybrids, <i>Capsicum annuum</i> L., <i>Capsicum frutescens</i> L. and plants of <i>Solanum tuberosum</i> L.’ |
|-----------------------------------|--|



(b) Part B is amended as follows:

(i) heading (a) is amended as follows:

— the following points are inserted after point 6:

|   |  |                      |
|---|--|----------------------|
| ‘6.1. <i>Paysandisia archon</i> (Burmeister)    | Plants of <i>Palmae</i> , intended for planting, having a diameter of the stem at the base of over 5 cm and belonging to the following genera: <i>Brahea</i> Mart., <i>Butia</i> Becc., <i>Chamaerops</i> L., <i>Jubaea</i> Kunth, <i>Livistona</i> R. Br., <i>Phoenix</i> L., <i>Sabal</i> Adans., <i>Syagrus</i> Mart., <i>Trachycarpus</i> H. Wendl., <i>Trithrinax</i> Mart., <i>Washingtonia</i> Raf.   | IRL, MT, UK          |
| 6.2. <i>Rhynchophorus ferrugineus</i> (Olivier) | Plants of <i>Palmae</i> , intended for planting, having a diameter of the stem at the base of over 5 cm and belonging to the following taxa: <i>Areca catechu</i> L., <i>Arenga pinnata</i> (Wurmb) Merr., <i>Bismarckia</i> Hildebr. & H. Wendl., <i>Borassus flabellifer</i> L., <i>Brahea armata</i> S. Watson, <i>Brahea edulis</i> H. Wendl., <i>Butia capitata</i> (Mart.) Becc., <i>Calamus merrillii</i> Becc., <i>Caryota maxima</i> Blume, <i>Caryota cumingii</i> Lodd. ex Mart., <i>Chamaerops humilis</i> L., <i>Cocos nucifera</i> L., <i>Copernicia</i> Mart., <i>Corypha utan</i> Lam., <i>Elaeis guineensis</i> Jacq., <i>Howea forsteriana</i> Becc., <i>Jubaea chilensis</i> (Molina) Baill., <i>Livistona australis</i> C. Martius, <i>Livistona decora</i> (W. Bull) Dowe, <i>Livistona rotundifolia</i> (Lam.) Mart., <i>Metroxylon sagu</i> Rottb., <i>Phoenix canariensis</i> Chabaud, <i>Phoenix dactylifera</i> L., <i>Phoenix reclinata</i> Jacq., <i>Phoenix roebelenii</i> O’Brien, <i>Phoenix sylvestris</i> (L.) Roxb., <i>Phoenix theophrasti</i> Greuter, <i>Pritchardia</i> Seem. & H. Wendl., <i>Ravenea rivularis</i> Jum. & H. Perrier, <i>Roystonea regia</i> (Kunth) O. F. Cook, <i>Sabal palmetto</i> (Walter) Lodd. ex Schult. & Schult. f., <i>Syagrus romanzoffiana</i> (Cham.) Glassman, <i>Trachycarpus fortunei</i> (Hook.) H. Wendl. and <i>Washingtonia</i> Raf. | IRL, P (Azores), UK’ |

— the following point is added after point 9:

|  |  |     |
|--|--|-----|
| ‘10. <i>Thaumetopoea pityocampa</i> Denis & Schiffermüller | Plants of <i>Pinus</i> L., intended for planting, other than fruit and seeds | UK’ |
|--|--|-----|

(ii) heading (b) is amended as follows:

— in point 1, in the third column, ‘P’ is deleted;

— in point 2, the text in the third column is replaced by the following:

‘E (except the autonomous communities of Andalucía, Aragón, Castilla la Mancha, Castilla y León, Extremadura, the autonomous community of Madrid, Murcia, Navarra and La Rioja, the province of Guipuzcoa (Basque Country), the Comarcas of Garrigues, Noguera, Pla d’Urgell, Segrià and Urgell in the province of Lleida (Comunidad autonoma de Catalunya), the Comarcas de L’Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway city), I (Abruzzo, Apulia,

Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua, Milano, Sondrio and Varese), Marche, Molise, Piedmont (except the communes of Busca, Centallo and Tarantasca in the province of Cuneo), Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes of Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the county of Dunajská Streda, Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málíneck (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin (Trebišov County)), FI, UK (Northern Ireland: excluding the townlands of Ballinran Upper, Carrigenagh Upper, Ballinran, and Carrigenagh in County Down, and the Electoral Area of Dunmurry Cross in Belfast, County Antrim; Isle of Man and Channel Islands).'

— the following point is added after point 2:

|  |   |     |
|--|---|-----|
| '3. <i>Xanthomonas arboricola</i> pv. <i>pruni</i><br>(Smith) Vauterin <i>et al.</i> | Plants of <i>Prunus</i> L., intended for planting, other than seeds | UK' |
|--|---|-----|

(iii) in heading (c), point 0.0.1, in the third column, 'UK' is replaced by 'IRL, UK'

(iv) heading (d) is amended as follows:

— the following point is inserted before point 1:

|  |  |     |
|--|--|-----|
| '01. ' <i>Candidatus</i> Phytoplasma ulmi' | Plants of <i>Ulmus</i> L., intended for planting, other than seeds | UK' |
|--|--|-----|

— in point 1, the text in the third column is replaced by the following:

'EL (except the Regional Units of Argolida and Chania), M, P (except Algarve, Madeira and the county of Odemira in Alentejo).'

(3) Part B of Annex III, is amended as follows:

(a) in point 1, the text in the right hand column is replaced by the following:

'E (except the autonomous communities of Andalucía, Aragón, Castilla la Mancha, Castilla y León, Extremadura, the autonomous community of Madrid, Murcia, Navarra and La Rioja, the province of Guipuzcoa (Basque Country), the Comarcas of Garrigues, Noguera, Pla d'Urgell, Segrià and Urgell in the province of Lleida (Comunidad autonoma de Catalunya), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway city), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua, Milano, Sondrio and Varese), Marche, Molise, Piedmont (except the communes of Busca, Centallo and Tarantasca in the province of Cuneo), Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes of Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the county of Dunajská Streda, Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málíneck (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin (Trebišov County)), FI, UK (Northern Ireland: excluding the townlands of Ballinran Upper, Carrigenagh Upper, Ballinran, and Carrigenagh in County Down, and the Electoral Area of Dunmurry Cross in Belfast, County Antrim; Isle of Man and Channel Islands).'

(b) in point 2, the text in the right hand column is replaced by the following:

'E (except the autonomous communities of Andalucía, Aragón, Castilla la Mancha, Castilla y León, Extremadura, the autonomous community of Madrid, Murcia, Navarra and La Rioja, the province of Guipuzcoa (Basque Country), the Comarcas of Garrigues, Noguera, Pla d'Urgell, Segrià and Urgell in the province of Lleida (Comunidad autonoma de Catalunya), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway city), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua, Milano, Sondrio and Varese), Marche, Molise, Piedmont (except the communes of Busca, Centallo and Tarantasca in the province of Cuneo), Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes of Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Babtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the county of Dunajská Streda, Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málíneč (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhýňa, Malý Horeš, Svätuš and Zátín (Trebišov County)), FI, UK (Northern Ireland: excluding the townlands of Ballinran Upper, Carrigenagh Upper, Ballinran, and Carrigenagh in County Down, and the Electoral Area of Dunmurry Cross in Belfast, County Antrim; Isle of Man and Channel Islands).'

(4) Annex IV is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

— in point 2, the text in the right hand column is replaced by the following:

'The wood packaging material shall:

- be made of debarked wood, as specified in Annex I to FAO International Standard for Phytosanitary Measures No 15 on Regulation of wood packaging material in international trade
- be subject to one of the approved treatments as specified in Annex I to that International standard, and
- display a mark as specified in Annex II to that International standard, indicating that the wood packaging material has been subjected to an approved phytosanitary treatment in accordance with this standard.'

— in point 5, the text in the left hand column is replaced by the following:

'Wood of *Platanus* L., except that in the form of:

- chips, particles, sawdust, shavings, wood waste and scrap,
- wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignment and which meets the same Union phytosanitary requirements as the wood in the consignment,

but including wood which has not kept its natural round surface, originating in Armenia, Switzerland or the USA.'

— the following points are inserted after point 7.3:

'7.4. Whether or not listed among the CN codes in Part B of Annex V, wood of *Amelanchier* Medik., *Aronia* Medik., *Cotoneaster* Medik., *Crataegus* L., *Cydonia* Mill., *Malus* Mill., *Prunus* L., *Pyracantha* M. Roem., *Pyrus* L. and *Sorbus* L., other than in the form of:

- chips, sawdust and shavings, obtained in whole or part from these plants,

Official statement that the wood:

- (a) originates in an area free from *Saperda candida* Fabricius, established by the national plant protection organisation in the country of origin, in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

or

- wood packaging material, in the form of packing cases, boxes, crates, drums and similar packings, pallets, box pallets and other load boards, pallet collars, dunnage, whether or not actually in use in the transport of objects of all kinds, except dunnage supporting consignments of wood, which is constructed from wood of the same type and quality as the wood in the consignments and which meets the same Union phytosanitary requirements as the wood in the consignment,
- (b) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 continuous minutes throughout the entire profile of the wood, which is to be indicated on the certificates referred to in Article 13(1)(ii),
- or
- (c) has undergone an appropriate ionising radiation to achieve a minimum absorbed dose of 1 kGy throughout the wood, to be indicated on the certificates referred to in Article 13(1)(ii).

but including that which has not kept its natural round surface, originating in Canada and the USA.

- 7.5. Whether or not listed among the CN codes in Part B of Annex V, wood in the form of chips obtained in whole or part from *Amelanchier* Medik., *Aronia* Medik., *Cotoneaster* Medik., *Crataegus* L., *Cydonia* Mill., *Malus* Mill., *Prunus* L., *Pyracantha* M. Roem., *Pyrus* L. and *Sorbus* L., originating in Canada and the USA.

Official statement that the wood:

- (a) originates in an area established by the national plant protection organisation in the country of origin as being free from *Saperda candida* Fabricius in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',
- or
- (b) has been processed into pieces of not more than 2,5 cm thickness and width,
- or
- (c) has undergone an appropriate heat treatment to achieve a minimum temperature of 56 °C for a minimum duration of 30 minutes throughout the entire profile of the chips, which is to be indicated on the certificates referred to in Article 13(1)(ii).'

- in point 14, the text in the right hand column is replaced by the following:

'Without prejudice to the provisions applicable to the plants in Annex IV(A)(I)(11.4), official statement that no symptoms of '*Candidatus* Phytoplasma ulmi' have been observed at the place of production or in its immediate vicinity since the beginning of the last complete cycle of vegetation.'

- the following point is inserted after point 14:

- '14.1. Plants intended for planting, other than scions, cuttings, plants in tissue culture, pollen and seeds, of *Amelanchier* Medik., *Aronia* Medik., *Cotoneaster* Medik., *Crataegus* L., *Cydonia* Mill., *Malus* Mill., *Prunus* L., *Pyracantha* M. Roem., *Pyrus* L. and *Sorbus* L. originating in Canada and the USA.

Without prejudice to the provisions applicable to the plants in Annex III(A)(9) and (18), Annex III(B)(1), (2) or Annex IV(A)(I), (17), (19.1), (19.2), (20), (22.1), (22.2), (23.1) and (23.2) where appropriate, official statement that the plants:

- (a) have been grown throughout their life in an area free from *Saperda candida* Fabricius, established by the national plant protection organisation in the country of origin, in accordance with relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii), under the rubric 'Additional declaration',
- or

- (b) have been grown during a period of at least two years prior to export, or in the case of plants which are younger than two years have been grown throughout their life, in a place of production established as free from *Saperda candida* Fabricius in accordance with relevant International Standards for Phytosanitary Measures:
- (i) which is registered and supervised by the national plant protection organisation in the country of origin,
- and
- (ii) which has been subjected annually to two official inspections for any signs of *Saperda candida* Fabricius carried out at appropriate times,
- and
- (iii) where the plants have been grown in a site:
- with complete physical protection against the introduction of *Saperda candida* Fabricius,
- or
- with the application of appropriate preventive treatments and surrounded by a buffer zone with a width of at least 500 m where the absence of *Saperda candida* Fabricius was confirmed by official surveys carried out annually at appropriate times,
- and
- (iv) immediately prior to export the plants have been subjected to a meticulous inspection for the presence of *Saperda candida* Fabricius, in particular in the stems of the plant, including, where appropriate, destructive sampling.'

— point 16.2 is replaced by the following:

'16.2. Fruits of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., *Microcitrus* Swingle, *Naringi* Adans., *Swinglea* Merr., and their hybrids, originating in third countries

Without prejudice to the provisions applicable to the fruits in Annex IV(A)(I)(16.1), (16.3), (16.4), (16.5) and (16.6), official statement that:

- (a) the fruits originate in a country recognised as being free of *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii* in accordance with relevant International Standards for Phytosanitary Measures, provided that this freedom status has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(b) the fruits originate in an area established by the national plant protection organisation in the country of origin as being free from *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii*, in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration', provided that this freedom status has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(c) the fruits originate in a place of production established by the national plant protection organisation in the country of origin as being free from *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii* in accordance with relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

or

(d) the site of production and the immediate vicinity are subject to appropriate treatments and cultural practices against *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii*,

and

the fruits have been subjected to a treatment with sodium orthophenylphenate, or another effective treatment mentioned on the certificates referred to in Article 13(1)(ii), provided that the treatment method has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

and

official inspections carried out at appropriate times prior to export have shown that the fruits are free from symptoms of *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii*,

and

information on traceability is included in the certificates referred to in Article 13(1)(ii),

or

(e) in the case of fruits destined for industrial processing, official inspections prior to export have shown that the fruits are free from symptoms of *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii*,

and

the site of production and the immediate vicinity are subject to appropriate treatments and cultural practices against *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii*,

and

movement, storage and processing takes place under conditions, approved in accordance with the procedure referred to in Article 18(2),

and

the fruits have been transported in individual packages bearing a label, which contains a traceability code and the indication that the fruits are destined for industrial processing,

and

information on traceability is included in the certificates referred to in Article 13(1)(ii).'

— point 16.3 is replaced by the following:

'16.3. Fruits of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, originating in third countries

Without prejudice to the provisions applicable to the fruits in Annex IV(A)(l)(16.1), (16.2), (16.4) and (16.5), official statement that:

(a) the fruits originate in a country recognised as being free from *Cercospora angolensis* Carv. et Mendes in accordance with relevant International Standards for Phytosanitary Measures, provided that this freedom status has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(b) the fruits originate in an area recognised as being free from *Cercospora angolensis* Carv. et Mendes, in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration', provided that this freedom status has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(c) no symptoms of *Cercospora angolensis* Carv. et Mendes have been observed in the site of production and in its immediate vicinity since the beginning of the last cycle of vegetation, and none of the fruits harvested in the site of production has shown, in appropriate official examination, symptoms of this organism.'

— point 16.4 is replaced by the following:

'16.4. Fruits of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, other than fruits of *Citrus aurantium* L. and *Citrus latifolia* Tanaka, originating in third countries

Without prejudice to the provisions applicable to the fruits in Annex IV(A)(I)(16.1), (16.2), (16.3), (16.5), and (16.6), official statement that:

(a) the fruits originate in a country recognised as free from *Phyllosticta citricarpa* (McAlpine) Van der Aa, in accordance with relevant International Standards for Phytosanitary Measures, provided that this freedom status has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(b) the fruits originate in an area established by the national plant protection organisation in the country of origin as being free from *Phyllosticta citricarpa* (McAlpine) Van der Aa in accordance with relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration', provided that this freedom status has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(c) the fruits originate in a place of production established by the national plant protection organisation in the country of origin as being free from *Phyllosticta citricarpa* (McAlpine) Van der Aa in accordance with relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

and

the fruits are found free of symptoms of *Phyllosticta citricarpa* (McAlpine) Van der Aa by official inspection of a representative sample, defined in accordance with international standards,

or

(d) the fruits originate in a site of production subjected to appropriate treatments and cultural measures against *Phyllosticta citricarpa* (McAlpine) van der Aa,

and

official inspections have been carried out in the site of production during the growing season since the beginning of the last cycle of vegetation, and no symptoms of *Phyllosticta citricarpa* (McAlpine) van der Aa have been detected in the fruits,

and



the harvested fruits from that site of production are found free of symptoms of *Phyllosticta citricarpa* (McAlpine) Van der Aa during an official inspection prior to export, of a representative sample, defined in accordance with international standards,

and

information on traceability is included in the certificates referred to in Article 13(1)(ii),

or

- (e) in the case of fruits destined for industrial processing, the fruits have been found free of symptoms of *Phyllosticta citricarpa* (McAlpine) Van der Aa prior to the export during an official inspection of a representative sample, defined in accordance with international standards,

and

a statement that the fruits originate in a site of production subjected to appropriate treatments against *Phyllosticta citricarpa* (McAlpine) Van der Aa carried out at the appropriate time is included in the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

and

movement, storage and processing takes place under conditions, approved in accordance with the procedure referred to in Article 18(2),

and

the fruits have been transported in individual packages bearing a label, which contains a traceability code and the indication that the fruits are destined for industrial processing,

and

information on traceability is included in the certificates referred to in Article 13(1)(ii).'

— the following point is inserted after point 16.5:

'16.6. Fruits of *Capsicum* (L.), *Citrus* L., other than *Citrus limon* (L.) Osbeck. and *Citrus aurantifolia* (Christm.) Swingle, *Prunus persica* (L.) Batsch and *Punica granatum* L. originating in countries of the African continent, Cape Verde, Saint Helena, Madagascar, La Reunion, Mauritius and Israel

Without prejudice to the provisions applicable to the fruits in Annex IV(A)(I)(16.1), (16.2), (16.3), (16.4), (16.5) and (36.3), official statement that the fruits:

- (a) originate in a country recognised as being free of *Thaumatotibia leucotreta* (Meyrick) in accordance with relevant International Standards for Phytosanitary Measures,

or

(b) originate in an area established by the national plant protection organisation in the country of origin as being free from *Thaumatotibia leucotreta* (Meyrick), in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

or

(c) originate in a place of production established by the national plant protection organisation in the country of origin as being free from *Thaumatotibia leucotreta* (Meyrick) in accordance with relevant International Standards for Phytosanitary Measures and information on traceability is included in the certificates referred to in the Article 13(1)(ii),

and

official inspections have been carried out in the place of production at appropriate times during the growing season, including a visual examination on representative samples of fruit, shown to be free from *Thaumatotibia leucotreta* (Meyrick),

or

(d) have been subjected to an effective cold treatment to ensure freedom from *Thaumatotibia leucotreta* (Meyrick) or another effective treatment to ensure freedom from *Thaumatotibia leucotreta* (Meyrick) and the treatment data should be indicated on the certificates referred to in Article 13(1)(ii), provided that the treatment method has been communicated in advance in writing by the national plant protection organisation of the third country concerned to the Commission.'

— point 18.2 is replaced by the following:

'18.2. Plants of *Casimiroa* La Llave, *Choisya* Kunth *Clausena* Burm. f., *Murraya* J.Koenig ex L., *Vepris* Comm, *Zanthoxylum* L., other than fruits and seeds, originating in third countries

Without prejudice to the provisions applicable to the plants referred to in Annex IV(A)I(18.1) and (18.3), official statement that:

(a) the plants originate in a country in which *Trioza erytrae* Del Guercio is known not to occur,

or

(b) the plants originate in an area free from *Trioza erytrae* Del Guercio, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures, and which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

or

- (c) the plants have been grown in a place of production, which is registered and supervised by the national plant protection organisation in the country of origin,  
and  
where the plants are placed in a site with complete physical protection against the introduction of *Trioza erytreae* Del Guercio,  
and  
where, during the last complete cycle of vegetation prior to the movement, two official inspections were carried out at appropriate times and no signs of *Trioza erytreae* Del Guercio have been observed in that site, and in the surrounding area with a width of at least 200 m.'

— the following point is inserted after point 18.3:

'18.4. Plants of *Microcitrus* Swingle, *Naringi* Adans. and *Swinglea* Merr., other than fruits and seeds, originating in third countries

Without prejudice to the provisions applicable to the plants in Annex IV(A)I (18.1), (18.2) and (18.3), official statement that the plants:

(a) originate in a country recognised as being free of *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii* in accordance with relevant International Standards for Phytosanitary Measures, provided that this freedom status has been communicated in writing by the national plant protection organisation of the third country concerned to the Commission,

or

(b) originate in an area established by the national plant protection organisation in the country of origin as being free from *Xanthomonas citri* pv. *citri* and *Xanthomonas citri* pv. *aurantifolii*, in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration', provided that this freedom status has been communicated in writing by the national plant protection organisation of the third country concerned to the Commission.'

— in point 19.2, in the left hand column, '*Xanthomonas campestris* pv. *pruni* (Smith) Dye' is replaced by '*Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin et al.'

— the following points are inserted after point 25.7:

'25.7.1. Plants of *Solanum lycopersicum* L. and *Solanum melongena* L., other than fruits and seeds

Without prejudice to the provisions applicable to the plants in Annex III(A)(13) and Annex IV(A)I(25.5), (25.6), (25.7), (28.1), and (45.3), official statement that the plants:

(a) originate in a country recognised as being free of *Keiferia lycopersicella* (Walsingham) in accordance with relevant International Standards for Phytosanitary Measures,

or

25.7.2. Fruits of *Solanum lycopersicum* L. and *Solanum melongena* L.

(b) originate in an area established by the national plant protection organisation in the country of origin as being free from *Keiferia lycopersicella* (Walsingham) in accordance with the relevant International Standards for Phytosanitary Measures, and which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration'.

Official statement that the fruits:

(a) originate in a country recognised as being free of *Keiferia lycopersicella* (Walsingham) in accordance with relevant International Standards for Phytosanitary Measures,

or

(b) originate in an area established by the national plant protection organisation in the country of origin as being free from *Keiferia lycopersicella* (Walsingham) in accordance with the relevant International Standards for Phytosanitary Measures, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration',

or

(c) originate in a place of production, established by the national plant protection organisation in the country of origin as being free from *Keiferia lycopersicella* (Walsingham), on the basis of official inspections and surveys carried out during the last three months prior to export, which is mentioned on the certificates referred to in Article 13(1)(ii) under the rubric 'Additional declaration'.

— in point 52, in the left hand column, 'Seeds of *Zea mais* L.' is replaced by 'Seeds of *Zea mays* L.'

(ii) Section II is amended as follows:

— the following point is inserted after point 8:

'8.1. Plants of *Ulmus* L., intended for planting, other than seeds

Official statement that no symptoms of '*Candidatus Phytoplasma ulmi*' have been observed at the place of production or in its immediate vicinity since the beginning of the last complete cycle of vegetation.'

— point 10.1 is replaced by the following:

'10.1. Plants of *Citrus* L., *Choisya* Kunth, *Fortunella* Swingle, *Poncirus* Raf., and their hybrids and *Casimiroa* La Llave, *Clausena* Burm f., *Murraya* J. Koenig ex L., *Vepris* Comm., *Zanthoxylum* L., other than fruits and seeds

Official statement that the plants:

a) originate in an area free from *Trioza erytrae* Del Guercio, established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures,

or

b) have been grown in a place of production, which is registered and supervised by the competent authorities in the Member State of origin, and

where the plants are placed in a site with complete physical protection against the introduction of *Trioza erytrae* Del Guercio,

and  
 where, during the last complete cycle of vegetation prior to the movement, two official inspections were carried out at appropriate times and no signs of *Trioza erytrae* Del Guercio have been observed in that site, and in the surrounding area with a width of at least 200 m.'

— in point 12, in the right hand column, '*Xanthomonas campestris* pv. *pruni* (Smith) Dye' is replaced by '*Xanthomonas arboricola* pv. *pruni* (Smith) Vauterin et al.'

(b) Part B is amended as follows:

(i) in point 6.4, the text in the third column is replaced by the following:

'IRL, UK'

(ii) in point 12.1, the text in the third column is replaced by the following:

'IRL, UK'

(iii) the following point 16.1 is inserted after point 16:

'16.1. Plants of *Pinus* L., intended for planting, other than fruits and seeds

Without prejudice to the provisions applicable to the plants listed in Annex III(A)(1), Annex IV(A)(I) (8.1), (8.2), (9), (10), Annex IV(A)(II) (4), (5) or Annex IV(B) (7), (8), (9), (10), (11), (12) and (16), official statement that:

UK'

(a) the plants have been grown throughout their life in places of production in countries where *Thaumetopoea pityocampa* Denis & Schiffermüller is not known to occur,

or

(b) the plants have been grown throughout their life in an area free from *Thaumetopoea pityocampa* Denis & Schiffermüller established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures,

or

(c) the plants have been produced in nurseries which, including their vicinity, have been found free from *Thaumetopoea pityocampa* Denis & Schiffermüller on the basis of official inspections and official surveys carried out at appropriate times,

or

(d) the plants have been grown throughout their life in a site with complete physical protection against the introduction of *Thaumetopoea pityocampa* Denis & Schiffermüller and have been inspected at appropriate times and found to be free from *Thaumetopoea pityocampa* Denis & Schiffermüller.

- (iv) in point 20.3, the text in the third column is replaced by the following:

'FI, LV, P (Azores), SI, SK'

- (v) the following points are inserted after point 20.3:

|   |  |                   |
|---|--|-------------------|
| <p>20.4. Plants with roots, planted or intended for planting, grown in the open air</p> | <p>There shall be evidence that the plants originate from a field known to be free from <i>Globodera rostochiensis</i> (Wollenweber) Behrens.</p>  | <p>P (Azores)</p> |
| <p>20.5. Plants of <i>Prunus</i> L. intended for planting, other than seeds</p>         | <p>Without prejudice to the provisions applicable to the plants listed in Annex III(A)(9) and (18) or Annex IV(A)(I)(19.2), (23.1) and (23.2) or Annex IV(A)(II)(12) and (16), official statement that:</p> <p>(a) the plants have been grown throughout their life in places of production in countries where <i>Xanthomonas arboricola</i> pv. <i>pruni</i> (Smith) Vauterin <i>et al.</i> is not known to occur,</p> <p>or</p> <p>(b) the plants have been grown throughout their life in an area free from <i>Xanthomonas arboricola</i> pv. <i>pruni</i> (Smith) Vauterin <i>et al.</i> established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures,</p> <p>or</p> <p>(c) the plants have been derived in direct line from mother plants which have shown no symptoms of <i>Xanthomonas arboricola</i> pv. <i>pruni</i> (Smith) Vauterin <i>et al.</i> during the last complete cycle of vegetation,</p> <p>and</p> <p>no symptoms of <i>Xanthomonas arboricola</i> pv. <i>pruni</i> (Smith) Vauterin <i>et al.</i> have been observed on the plants at the place of production since the beginning of the last complete cycle of vegetation,</p> <p>or</p> <p>(d) for plants of <i>Prunus laurocerasus</i> L. and <i>Prunus lusitanica</i> L. for which there shall be evidence by their packing or by other means that they are intended for sale to final consumers not involved in professional plant production no symptoms of <i>Xanthomonas arboricola</i> pv. <i>pruni</i> (Smith) Vauterin <i>et al.</i> have been observed on plants at the place of production since the beginning of the last complete growing season.</p> | <p>UK'</p>        |

- (vi) in point 21, the text in the third column is replaced by the following:

'E (except the autonomous communities of Andalucía, Aragón, Castilla la Mancha, Castilla y León, Extremadura, the autonomous community of Madrid, Murcia, Navarra and La Rioja, the province of Guipuzcoa (Basque Country), the Comarcas of Garrigues, Noguera, Pla d'Urgell, Segrià and Urgell in the province of Lleida (Comunidad autonoma de Catalunya), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway city), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua, Milano, Sondrio and Varese), Marche, Molise, Piedmont (except the communes of Busca, Centallo and Tarantasca in the province of Cuneo), Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes of Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Bābtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the county of Dunajská Streda, Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málíneck (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátín (Trebíšov County)), FI, UK (Northern Ireland: excluding the townlands of Ballinran Upper, Carrigenagh Upper, Ballinran, and Carrigenagh in County Down, and the Electoral Area of Dunmurry Cross in Belfast, County Antrim; Isle of Man and Channel Islands).'

- (vii) in point 21.1, the text in the second column is replaced by the following:

'Without prejudice to the prohibition in Annex III(A)(15), on introducing plants of *Vitis* L. other than fruits from third countries (except Switzerland) into the Union, official statement that the plants:

- (a) originate in the protected zones listed in the right hand column;

or

- (b) have been subjected to an appropriate treatment to ensure freedom from *Daktulosphaira vitifoliae* (Fitch) according to a specification approved in accordance with the procedure referred to in Article 18(2).'

- (viii) in point 21.3, the text in the third column is replaced by the following:

'E (except the autonomous communities of Andalucía, Aragón, Castilla la Mancha, Castilla y León, Extremadura, the autonomous community of Madrid, Murcia, Navarra and La Rioja, the province of Guipuzcoa (Basque Country), the Comarcas of Garrigues, Noguera, Pla d'Urgell, Segrià and Urgell in the province of Lleida (Comunidad autonoma de Catalunya), the Comarcas de L'Alt Vinalopó and El Vinalopó Mitjà in the province of Alicante and the municipalities of Alborache and Turís in the province of Valencia (Comunidad Valenciana)), EE, F (Corsica), IRL (except Galway city), I (Abruzzo, Apulia, Basilicata, Calabria, Campania, Emilia-Romagna (the provinces of Parma and Piacenza), Lazio, Liguria, Lombardy (except the provinces of Mantua, Milano, Sondrio and Varese), Marche, Molise, Piedmont (except the communes of Busca, Centallo and Tarantasca in the province of Cuneo), Sardinia, Sicily, Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes of Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and, Vescovana in the province of Padova and the area situated to the south of highway A4 in the province of Verona)), LV, LT (except the municipalities of Bābtai and Kėdainiai (region of Kaunas)), P, SI (except the regions Gorenjska, Koroška, Maribor and Notranjska, and the communes of Lendava and Renče-Vogrsko (south from the highway H4)), SK (except the county of Dunajská Streda, Hronovce and Hronské Kľačany (Levice County), Dvory nad Žitavou (Nové Zámky County), Málíneck (Poltár County), Hrhov (Rožňava County), Veľké Ripňany (Topoľčany County), Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátín (Trebíšov County)), FI, UK (Northern Ireland: excluding the townlands of Ballinran Upper, Carrigenagh Upper, Ballinran, and Carrigenagh in County Down, and the Electoral Area of Dunmurry Cross in Belfast, County Antrim; Isle of Man and Channel Islands).'

- (ix) the following points are inserted after point 21.3:

|   |   |             |
|---|---|-------------|
| '21.4. Plants of <i>Palmae</i> , intended for planting, having a diameter of the stem at the base of over 5 cm and belonging to the following genera: <i>Brahea</i> Mart., <i>Butia</i> Becc., <i>Chamaerops</i> L., <i>Jubaea</i> Kunth, <i>Livistona</i> R. Br., <i>Phoenix</i> L., <i>Sabal</i> Adans., <i>Syagrus</i> Mart., <i>Trachycarpus</i> H. Wendl., <i>Trithrinax</i> Mart., <i>Washingtonia</i> Raf. | Without prejudice to the provisions applicable to the plants listed in Annex III(A)(17). or Annex IV(A)(I)(37) and (37.1) or Annex IV(A)(II)(19.1), official statement that the plants:<br>(a) have been grown throughout their life in places of production in countries where <i>Paysandisia archon</i> (Burmeister) is known not to occur; | IRL, MT, UK |
|   | or  |             |

|  |   |                            |
|--|---|----------------------------|
|  | <p>(b) have been grown throughout their life in an area free from <i>Paysandisia archon</i> (Burmeister) established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures,</p> <p>or</p> <p>(c) have, during a period of at least two years prior to export or movement, been grown in a place of production:</p> <ul style="list-style-type: none"> <li>— which is registered and supervised by the national plant protection organisation in the country of origin,</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— where the plants were placed in a site with complete physical protection against the introduction of <i>Paysandisia archon</i> (Burmeister),</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— where, during three official inspections per year carried out at appropriate times, including immediately prior to movement from this place of production, no signs of <i>Paysandisia archon</i> (Burmeister) have been observed.</li> </ul> |                            |
| <p>21.5. Plants of <i>Palmae</i>, intended for planting, having a diameter of the stem at the base of over 5 cm and belonging to the following taxa: <i>Areca catechu</i> L., <i>Arenga pinnata</i> (Wurmb) Merr., <i>Bismarckia</i> Hildebr. &amp; H. Wendl., <i>Borassus flabellifer</i> L., <i>Brahea armata</i> S. Watson, <i>Brahea edulis</i> H. Wendl., <i>Butia capitata</i> (Mart.) Becc., <i>Calamus merrillii</i> Becc., <i>Caryota maxima</i> Blume, <i>Caryota cumingii</i> Lodd. ex Mart., <i>Chamaerops humilis</i> L., <i>Cocos nucifera</i> L., <i>Copernicia</i> Mart., <i>Corypha utan</i> Lam., <i>Elaeis guineensis</i> Jacq., <i>Howea forsteriana</i> Becc., <i>Jubea chilensis</i> (Molina) Baill., <i>Livistona australis</i> C. Martius, <i>Livistona decora</i> (W. Bull) Dowe, <i>Livistona rotundifolia</i> (Lam.) Mart., <i>Metroxylon sagu</i> Rottb., <i>Phoenix canariensis</i> Chabaud, <i>Phoenix dactylifera</i> L., <i>Phoenix reclinata</i> Jacq., <i>Phoenix roebelenii</i> O'Brien, <i>Phoenix sylvestris</i> (L.) Roxb., <i>Phoenix theophrasti</i> Greuter, <i>Pritchardia</i> Seem. &amp; H. Wendl., <i>Ravenea rivularis</i> Jum. &amp; H. Perrier, <i>Roystonea regia</i> (Kunth) O. F. Cook, <i>Sabal palmetto</i> (Walter) Lodd. ex Schult. &amp; Schult. f., <i>Syagrus roman-zoffiana</i> (Cham.) Glassman, <i>Trachycarpus fortunei</i> (Hook.) H. Wendl. and <i>Washingtonia</i> Raf.</p> | <p>Without prejudice to the provisions applicable to the plants listed in Annex III(A)(17) or Annex IV(A)(I)(37) and (37.1) or Annex IV(A)(II)(19.1), official statement that the plants:</p> <p>(a) have been grown throughout their life in places of production in countries where <i>Rhynchophorus ferrugineus</i> (Olivier) is known not to occur</p> <p>or</p> <p>(b) have been grown throughout their life in an area free from <i>Rhynchophorus ferrugineus</i> (Olivier) established by the national plant protection organisation in accordance with relevant International Standards for Phytosanitary Measures,</p> <p>or</p> <p>(c) have, during a period of at least two years prior to export or movement, been grown in a place of production:</p> <ul style="list-style-type: none"> <li>— which is registered and supervised by the national plant protection organisation in the country of origin,</li> </ul> <p>and</p>  | <p>IRL, P (Azores), UK</p> |



- where the plants were placed in a site with complete physical protection against the introduction of *Rhynchophorus ferrugineus* (Olivier), and
- where, during three official inspections per year carried out at appropriate times, including immediately prior to movement from this place of production, no signs of *Rhynchophorus ferrugineus* (Olivier) have been observed.

(x) in points 24.1 and 24.2, the text in the third column is replaced by the following:

'IRL, P (Azores, Beira Interior, Beira Litoral, Entre Douro e Minho and Trás-os-Montes), UK, S, FI'

(xi) point 24.3 is replaced by the following:

'24.3. Plants of *Begonia* L., intended for planting, other than seeds, tubers and corms, and plants of *Dipladenia* A.DC., *Ficus* L., *Hibiscus* L., *Mandevilla* Lindl. and *Nerium oleander* L., intended for planting, other than seeds

Without prejudice to the requirements applicable to the plants listed in Annex IV(A)(I)(45.1), where appropriate, official statement that:

(a) the plants originate in an area known to be free from *Bemisia tabaci* Genn. (European populations),

or

(b) no signs of *Bemisia tabaci* Genn. (European populations) have been observed on plants at the place of production on official inspections carried out at least once each three weeks during the nine weeks prior to marketing,

or

(c) in cases where *Bemisia tabaci* Genn. (European populations) has been found at the place of production, the plants, held or produced in this place of production have undergone an appropriate treatment to ensure freedom from *Bemisia tabaci* Genn. (European populations) and subsequently this place of production shall have been found free from *Bemisia tabaci* Genn. (European populations) as a consequence of the implementation of appropriate procedures aiming at eradicating *Bemisia tabaci* Genn. (European populations), in both official inspections carried out weekly during the three weeks prior to the movement from this place of production and in monitoring procedures throughout the said period,

or

IRL, P (Azores, Beira Interior, Beira Litoral, Entre Douro e Minho and Trás-os-Montes), UK, S, FI'

(d) for those plants for which there shall be evidence by their packing or their flower development or by other means that they are intended for direct sale to final consumers not involved in professional plant production, the plants have been officially inspected and found free from *Bemisia tabaci* Genn. (European populations) immediately prior to their movement.

(xii) in point 33, the text in the third column is replaced by the following:

'IRL, UK'

(5) Annex V is amended as follows:

(a) Part A is amended as follows:

(i) Section I is amended as follows:

— point 1.4 is replaced by the following:

'1.4. Plants of *Choisya* Kunth, *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, *Casimiroa* La Llave, *Clausena* Burm. f., *Murraya* J. Koenig ex L., *Vepris* Comm., *Zanthoxylum* L. and *Vitis* L., other than fruits and seeds.'

— in point 1.7, the table in point (b) is replaced by the following:

| 'CN code      | Description   |
|---------------|---|
| 4401 12 00    | Non-coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms   |
| 4401 22 00    | Non-coniferous wood, in chips or particles  |
| 4401 40 90    | Wood waste and scrap (other than sawdust), not agglomerated   |
| ex 4403 12 00 | Non-coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared  |
| ex 4403 99 00 | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), birch ( <i>Betula</i> spp.), poplar and aspen ( <i>Populus</i> spp.) or eucalyptus ( <i>Eucalyptus</i> spp.)), in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives                        |
| ex 4404 20 00 | Non-coniferous split poles; piles, pickets and stakes of non-coniferous wood, pointed but not sawn lengthwise   |
| ex 4407 99    | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), maple ( <i>Acer</i> spp.), cherry ( <i>Prunus</i> spp.), ash ( <i>Fraxinus</i> spp.), birch ( <i>Betula</i> spp.) or poplar and aspen ( <i>Populus</i> spp.)), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm.' |

— point 2.1 is replaced by the following:

'2.1. Plants intended for planting, other than seeds, of the genera *Abies* Mill., *Apium graveolens* L., *Argyranthemum* spp., *Asparagus officinalis* L., *Aster* spp., *Brassica* spp., *Castanea* Mill., *Cucumis* spp., *Dendranthema* (DC.) Des Moul., *Dianthus* L. and hybrids, *Exacum* spp., *Fragaria* L., *Gerbera* Cass., *Gypsophila* L., all varieties of New Guinea hybrids of *Impatiens* L., *Lactuca* spp., *Larix* Mill., *Leucanthemum* L., *Lupinus* L., *Pelargonium* l'Hérit. ex Ait., *Picea* A. Dietr., *Pinus* L., *Platanus* L., *Populus* L., *Prunus laurocerasus* L., *Prunus lusitanica* L., *Pseudotsuga* Carr., *Quercus* L., *Rubus* L., *Spinacia* L., *Tanacetum* L., *Tsuga* Carr., *Ulmus* L., *Verbena* L. and other plants of herbaceous species, other than plants of the family *Gramineae*, intended for planting, and other than bulbs, corms, rhizomes, seeds and tubers.'

(ii) Section II is amended as follows:

— point 1.2 is replaced by the following:

'1.2. Plants intended for planting, other than seeds, of *Beta vulgaris* L., *Platanus* L., *Populus* L., *Prunus* L. and *Quercus* spp., other than *Quercus suber* and *Ulmus* L.'

— the following point is inserted after point 1.3:

'1.3.1. Plants of *Palmae*, intended for planting, having a diameter of the stem at the base of over 5 cm and belonging to the following taxa: *Areca catechu* L., *Arenga pinnata* (Wurmb) Merr., *Bismarckia* Hildebr. & H. Wendl., *Borassus flabellifer* L., *Brahea* Mart., *Butia* Becc., *Calamus merrillii* Becc., *Caryota maxima* Blume, *Caryota cumingii* Lodd. ex Mart., *Chamaerops* L., *Cocos nucifera* L., *Copernicia* Mart., *Corypha utan* Lam., *Elaeis guineensis* Jacq., *Howea forsteriana* Becc., *Jubaea* Kunth, *Livistona* R. Br., *Metroxylon sagu* Rottb., *Phoenix* L., *Pritchardia* Seem. & H. Wendl., *Ravenea rivularis* Jum. & H. Perrier, *Roystonea regia* (Kunth) O. F. Cook, *Sabal* Adans., *Syagrus* Mart., *Trachycarpus* H. Wendl., *Trithrinax* Mart., *Washingtonia* Raf.'

— in point 1.10, the table in point (b) is replaced by the following:

| 'CN code      | Description  |
|---------------|--|
| 4401 11 00    | Coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms  |
| 4401 12 00    | Non-coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms  |
| 4401 21 00    | Coniferous wood, in chips or particles   |
| 4401 22 00    | Non-coniferous wood, in chips or particles   |
| 4401 40 90    | Wood waste and scrap (other than sawdust), not agglomerated  |
| ex 4403 11 00 | Coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared   |
| ex 4403 12 00 | Non-coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared   |
| ex 4403 21    | Coniferous wood of pine ( <i>Pinus</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more            |
| ex 4403 22 00 | Coniferous wood of pine ( <i>Pinus</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more |

| 'CN code      | Description  |
|---------------|--|
| ex 4403 23    | Coniferous wood of fir ( <i>Abies</i> spp.) and spruce ( <i>Picea</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more   |
| ex 4403 24 00 | Coniferous wood of fir ( <i>Abies</i> spp.) and spruce ( <i>Picea</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more  |
| ex 4403 25    | Coniferous wood, other than of pine ( <i>Pinus</i> spp.), fir ( <i>Abies</i> spp.) or spruce ( <i>Picea</i> spp.), in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more  |
| ex 4403 26 00 | Coniferous wood, other than of pine ( <i>Pinus</i> spp.), fir ( <i>Abies</i> spp.) or spruce ( <i>Picea</i> spp.), in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more   |
| ex 4403 99 00 | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), birch ( <i>Betula</i> spp.), poplar and aspen ( <i>Populus</i> spp.) or eucalyptus ( <i>Eucalyptus</i> spp.)), in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives                       |
| ex 4404       | Split poles; piles, pickets and stakes of wood, pointed but not sawn lengthwise  |
| 4406          | Railway or tramway sleepers (cross-ties) of wood   |
| ex 4407       | Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm   |
| ex 4407 99    | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), maple ( <i>Acer</i> spp.), cherry ( <i>Prunus</i> spp.), ash ( <i>Fraxinus</i> spp.), birch ( <i>Betula</i> spp.) or poplar and aspen ( <i>Populus</i> spp.)), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm' |

— point 2.1 is replaced by the following:

'2.1. Plants of *Begonia* L., intended for planting, other than corms, seeds and tubers, and plants of *Dipladenia* A.DC., *Euphorbia pulcherrima* Willd., *Ficus* L., *Hibiscus* L., *Mandevilla* Lindl. and *Nerium oleander* L., intended for planting, other than seeds.'

(b) Part B is amended as follows:

(i) Section I is amended as follows:

— in point 1, '*Zea mais* L.' is replaced by '*Zea mays* L.'

— in point 2, the tenth indent, '*Amiris* P. Browne' is replaced by '*Amyris* P. Browne'

— point 3 is amended as follows:

— the first indent is replaced by the following:

'— *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., *Microcitrus* Swingle, *Naringi* Adans., *Swinglea* Merr. and their hybrids, *Momordica* L., *Solanum lycopersicum* L., and *Solanum melongena* L.'

— the following indent is added:

‘— *Punica granatum* L. originating in countries of the African continent, Cape Verde, Saint Helena, Madagascar, La Reunion, Mauritius and Israel.’

— point 6 is amended as follows:

— in point (a), the following indent is added:

‘— *Amelanchier* Medik., *Aronia* Medik., *Cotoneaster* Medik., *Crataegus* L., *Cydonia* Mill., *Malus* Mill., *Prunus* L., *Pyracantha* M. Roem., *Pyrus* L. and *Sorbus* L., including wood which has not kept its natural round surface, except sawdust or shavings, originating in Canada or the USA.’

— the table in point (b) is replaced by the following:

| ‘CN code      | Description   |
|---------------|---|
| 4401 11 00    | Coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms   |
| 4401 12 00    | Non-coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms   |
| 4401 21 00    | Coniferous wood, in chips or particles  |
| 4401 22 00    | Non-coniferous wood, in chips or particles  |
| 4401 40 10    | Sawdust, not agglomerated   |
| 4401 40 90    | Wood waste and scrap (other than sawdust), not agglomerated   |
| ex 4403 11 00 | Coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared  |
| ex 4403 12 00 | Non-coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared  |
| ex 4403 21    | Coniferous wood of pine ( <i>Pinus</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more   |
| ex 4403 22 00 | Coniferous wood of pine ( <i>Pinus</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more                                |
| ex 4403 23    | Coniferous wood of fir ( <i>Abies</i> spp.) and spruce ( <i>Picea</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more            |
| ex 4403 24 00 | Coniferous wood of fir ( <i>Abies</i> spp.) and spruce ( <i>Picea</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more |

| 'CN code      | Description  |
|---------------|--|
| ex 4403 25    | Coniferous wood, other than of pine ( <i>Pinus</i> spp.), fir ( <i>Abies</i> spp.) or spruce ( <i>Picea</i> spp.), in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more  |
| ex 4403 26 00 | Coniferous wood, other than of pine ( <i>Pinus</i> spp.), fir ( <i>Abies</i> spp.) or spruce ( <i>Picea</i> spp.), in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more   |
| 4403 91 00    | Oak wood ( <i>Quercus</i> spp.) in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives   |
| 4403 95       | Wood of birch ( <i>Betula</i> spp.) in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more  |
| 4403 96 00    | Wood of birch ( <i>Betula</i> spp.) in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more   |
| 4403 97 00    | Wood of poplar and aspen ( <i>Populus</i> spp.) in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives   |
| ex 4403 99 00 | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), birch ( <i>Betula</i> spp.), poplar and aspen ( <i>Populus</i> spp.) or eucalyptus ( <i>Eucalyptus</i> spp.)), in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives |
| ex 4404       | Split poles; piles, pickets and stakes of wood, pointed but not sawn lengthwise  |
| 4406          | Railway or tramway sleepers (cross-ties) of wood   |
| ex 4407       | Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm   |
| 4407 91       | Oak wood ( <i>Quercus</i> spp.), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm   |
| ex 4407 93    | Wood of <i>Acer saccharum</i> Marsh, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm   |
| 4407 94       | Wood of cherry ( <i>Prunus</i> spp.) sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm   |

| 'CN code   | Description   |
|------------|---|
| 4407 95    | Wood of ash ( <i>Fraxinus</i> spp.), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm  |
| 4407 96    | Wood of birch ( <i>Betula</i> spp.), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm  |
| 4407 97    | Wood of poplar and aspen ( <i>Populus</i> spp.), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm  |
| ex 4407 99 | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), maple ( <i>Acer</i> spp.), cherry ( <i>Prunus</i> spp.), ash ( <i>Fraxinus</i> spp.), birch ( <i>Betula</i> spp.) or poplar and aspen ( <i>Populus</i> spp.)), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm |
| 4408 10    | Coniferous sheets for veneering (including those obtained by slicing laminated wood), for plywood or for similar laminated wood and other wood, sawn lengthwise, sliced or peeled, whether or not planed, sanded, spliced or end-jointed, of a thickness not exceeding 6 mm   |
| 4416 00 00 | Casks, barrels, vats, tubs and other cooper's products and parts thereof, of wood, including staves   |
| 9406 10 00 | Prefabricated buildings of wood'  |

(ii) Section II is amended as follows:

— in point 7, the table in point (b) is replaced by the following:

| 'CN code      | Description  |
|---------------|--|
| 4401 11 00    | Coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms  |
| 4401 12 00    | Non-coniferous fuel wood, in logs, in billets, in twigs, in faggots or in similar forms  |
| 4401 21 00    | Coniferous wood, in chips or particles   |
| 4401 22 00    | Non-coniferous wood, in chips or particles   |
| 4401 40 90    | Wood waste and scrap (other than sawdust), not agglomerated  |
| ex 4403 11 00 | Coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared     |
| ex 4403 12 00 | Non-coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, not stripped of bark or sapwood, or roughly squared |

| 'CN code      | Description   |
|---------------|---|
| ex 4403 21    | Coniferous wood of pine ( <i>Pinus</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more   |
| ex 4403 22 00 | Coniferous wood of pine ( <i>Pinus</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more  |
| ex 4403 23    | Coniferous wood of fir ( <i>Abies</i> spp.) and spruce ( <i>Picea</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more  |
| ex 4403 24 00 | Coniferous wood of fir ( <i>Abies</i> spp.) and spruce ( <i>Picea</i> spp.) in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more   |
| ex 4403 25    | Coniferous wood, other than of pine ( <i>Pinus</i> spp.), fir ( <i>Abies</i> spp.) or spruce ( <i>Picea</i> spp.), in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, of which any cross-sectional dimension is 15 cm or more   |
| ex 4403 26 00 | Coniferous wood, other than of pine ( <i>Pinus</i> spp.), fir ( <i>Abies</i> spp.) or spruce ( <i>Picea</i> spp.), in the rough, not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives, other than of which any cross-sectional dimension is 15 cm or more  |
| ex 4403 99 00 | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), birch ( <i>Betula</i> spp.), poplar and aspen ( <i>Populus</i> spp.) or eucalyptus ( <i>Eucalyptus</i> spp.)), in the rough, whether or not stripped of bark or sapwood, or roughly squared, other than treated with paint, stains, creosote or other preservatives                      |
| ex 4404       | Split poles; piles, pickets and stakes of wood, pointed but not sawn lengthwise   |
| 4406          | Railway or tramway sleepers (cross-ties) of wood  |
| ex 4407       | Coniferous wood, sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm  |
| ex 4407 99    | Non-coniferous wood (other than tropical wood, oak ( <i>Quercus</i> spp.), beech ( <i>Fagus</i> spp.), maple ( <i>Acer</i> spp.), cherry ( <i>Prunus</i> spp.), ash ( <i>Fraxinus</i> spp.), birch ( <i>Betula</i> spp.) or poplar and aspen ( <i>Populus</i> spp.)), sawn or chipped lengthwise, sliced or peeled, whether or not planed, sanded or end-jointed, of a thickness exceeding 6 mm |
| 4415          | Packing cases, boxes, crates, drums and similar packings, of wood; cable-drums of wood; pallets, box pallets and other load boards, of wood; pallet collars of wood   |
| 9406 10 00    | Prefabricated buildings of wood'  |



# DECISIONS

## POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2017/1280

of 11 July 2017

### extending the mandate of the Head of Mission of the European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah) (EU BAM Rafah/1/2017)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to Council Joint Action 2005/889/CFSP of 25 November 2005 on establishing a European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah) <sup>(1)</sup>, and in particular Article 10(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) Pursuant to Article 10(1) of Joint Action 2005/889/CFSP, the Political and Security Committee (PSC) is authorised, in accordance with Article 38 of the Treaty, to take relevant decisions for the purpose of exercising political control and strategic direction of the European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah), including the decision to appoint a Head of Mission.
- (2) On 7 July 2015, the PSC adopted Decision EU BAM Rafah/1/2015 <sup>(2)</sup>, appointing Ms Natalina CEA as Head of Mission of EU BAM Rafah from 1 July 2015 to 30 June 2016.
- (3) On 12 July 2016, the PSC adopted Decision EU BAM Rafah/1/2016 <sup>(3)</sup>, extending the mandate of Ms Natalina CEA as Head of Mission of EU BAM Rafah for the period until 30 June 2017.
- (4) On 4 July 2017, the Council adopted Decision (CFSP) 2017/1193 <sup>(4)</sup>, extending the mandate of EU BAM Rafah from 1 July 2017 to 30 June 2018.
- (5) The High Representative of the Union for Foreign Affairs and Security Policy has proposed to extend the mandate of Ms Natalina CEA as Head of Mission of EU BAM Rafah from 1 July 2017 to 30 June 2018,

HAS ADOPTED THIS DECISION:

#### Article 1

The mandate of Ms Natalina CEA as Head of Mission of EU BAM Rafah is hereby extended from 1 July 2017 to 30 June 2018.

<sup>(1)</sup> OJ L 327, 14.12.2005, p. 28.

<sup>(2)</sup> Political and Security Committee Decision (CFSP) 2015/1128 of 7 July 2015 on the appointment of the Head of Mission of the European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah) (EU BAM Rafah/1/2015) (OJ L 184, 11.7.2015, p. 16).

<sup>(3)</sup> Political and Security Committee Decision (CFSP) 2016/1194 of 12 July 2016 extending the mandate of the Head of Mission of the European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah) (EU BAM Rafah/1/2016) (OJ L 197, 22.7.2016, p. 3).

<sup>(4)</sup> Council Decision (CFSP) 2017/1193 of 4 July 2017 amending Joint Action 2005/889/CFSP on establishing a European Union Border Assistance Mission for the Rafah Crossing Point (EU BAM Rafah) (OJ L 172, 5.7.2017, p. 12).

*Article 2*

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

It shall apply from 1 July 2017.

Done at Brussels, 11 July 2017.

*For the Political and Security Committee*

*The Chairperson*

W. STEVENS

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**COMMISSION IMPLEMENTING DECISION (EU) 2017/1281****of 13 July 2017****authorising the placing on the market of L-ergothioneine as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2017) 4844)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(1)</sup>, and in particular Article 7 thereof,

Whereas:

- (1) On 25 July 2013, the company Tetrahedron made a request to the competent authorities of France to place synthetic L-ergothioneine ('L-ergothioneine') on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97. The application excluded from the use infants, young children, pregnant and lactating women.
- (2) On 19 February 2015, the competent food assessment body of France issued its initial assessment report. In that report it came to the conclusion that L-ergothioneine meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 9 March 2015, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.
- (5) On 14 October 2015, the Commission consulted the European Food Safety Authority ('EFSA') asking it to carry out an additional assessment for L-ergothioneine as novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 26 October 2016, EFSA in its 'Scientific Opinion on the safety of L-ergothioneine as a novel food pursuant to Regulation (EC) No 258/97' <sup>(2)</sup> concluded that L-ergothioneine is safe for the proposed uses and use levels.
- (7) That opinion gives sufficient grounds to establish that L-ergothioneine in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) Directive 2002/46/EC of the European Parliament and of the Council <sup>(3)</sup> lays down requirements on food supplements. The use of L-ergothioneine should be authorised without prejudice to the provisions of that Directive.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1*

Without prejudice to Directive 2002/46/EC, L-ergothioneine as specified in Annex I may be placed on the Union market as a novel food ingredient to be used in food supplements intended for the general population, excluding infants and young children, and pregnant and lactating women, for the uses defined and at the maximum levels established in Annex II.

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

<sup>(2)</sup> EFSA Journal 2016;14(11):4629.

<sup>(3)</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

*Article 2*

The designation of L-ergothioneine authorised by this Decision on the labelling of the foodstuffs shall be 'L-ergothioneine'.

*Article 3*

This Decision is addressed to Tetrahedron, 14, avenue de l'Opéra, 75001 Paris, France.

Done at Brussels, 13 July 2017.

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

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## ANNEX I

## SPECIFICATIONS OF L-ERGOTHIONEINE

## Definition

|                       |  |
|-----------------------|--|
| Chemical name (IUPAC) | (2S)-3-(2-thioxo-2,3-dihydro-1H-imidazol-4-yl)-2-(trimethylammonio)-propanoate |
| Chemical formula      | C <sub>9</sub> H <sub>15</sub> N <sub>3</sub> O <sub>2</sub> S                 |
| Molecular mass        | 229,3 Da   |
| CAS No                | 497-30-3   |

IUPAC: International Union for Pure and Applied Chemistry

## Specifications

| Parameter  | Specification   | Method   |
|--|---|--|
| Appearance   | White powder  | Visual   |
| Optical rotation   | $[\alpha]_D \geq (+) 122^\circ$ (c = 1, H <sub>2</sub> O) <sup>(a)</sup>                | Polarimetry                                    |
| Chemical purity  | $\geq 99,5 \%$<br>$\geq 99 \%$  | HPLC [Eur. Ph. 2.2.29]<br>1H-NMR               |
| Identification   | Compliant with the structure<br>C: 47,14 ± 0,4 %<br>H: 6,59 ± 0,4 %<br>N: 18,32 ± 0,4 % | 1H-NMR<br>Elemental analysis                   |
| Total residual solvents<br>(methanol, ethyl acetate, isopropanol, ethanol) | [Eur. Ph. 01/2008:50400]<br>< 1 000 ppm   | Gas chromatography<br>[Eur. Ph. 01/2008:20424] |
| Loss on drying   | Internal standard < 0,5 %   | [Eur. Ph. 01/2008:20232]                       |
| Impurities   | < 0,8 %   | HPLC/GPC or 1H-NMR                             |

Heavy metals <sup>(b)</sup> <sup>(c)</sup>

|         |           |   |
|---------|-----------|---|
| Lead    | < 3 ppm   | ICP/AES<br>(Pb, Cd)<br>Atomic fluorescence (Hg) |
| Cadmium | < 1 ppm   |   |
| Mercury | < 0,1 ppm |   |

Microbiological specifications <sup>(b)</sup>

|                                    |                            |                          |
|------------------------------------|----------------------------|--------------------------|
| Total viable aerobic count (TVAC)  | $\leq 1 \times 10^3$ CFU/g | [Eur. Ph. 01/2011:50104] |
| Total yeast and mould count (TYMC) | $\leq 1 \times 10^2$ CFU/g |                          |
| Escherichia coli                   | Absent in 1 g              |                          |

Eur. Ph.: European Pharmacopoeia; 1H-NMR: proton nuclear magnetic resonance; HPLC: high-performance liquid chromatography; GPC: gel permeation chromatography; ICP/AES: Inductively coupled plasma atomic emission spectroscopy; CFU: colony-forming units.

<sup>(a)</sup> Lit.  $[\alpha]_D = (+) 126,6^\circ$  (c = 1, H<sub>2</sub>O)

<sup>(b)</sup> Analyses conducted on each batch

<sup>(c)</sup> Maximum levels in accordance with Commission Regulation (EC) No 1881/2006 (OJ L 364, 20.12.2006, p. 5).

## ANNEX II

**AUTHORISED USES OF L-ERGOTHIONEINE**

| Food category                                       | Maximum levels   |
|---|--|
| Food supplements as defined in Directive 2002/46/EC | 30 mg/day for general population (excluding pregnant and lactating women)<br>20 mg/day for children older than 3 years |

**COMMISSION IMPLEMENTING DECISION (EU) 2017/1282****of 14 July 2017****not approving 2-methyl-1,2-benzisothiazol-3(2H)-one as an active substance for use in biocidal products of 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 Article 90(2) thereof,

Whereas:

- (1) Poland received on 26 November 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 2-methyl-1,2-benzisothiazol-3(2H)-one (EC No: n.a., CAS No 2527-66-4) in Annex I to that Directive for use in products of product-type 13, metalworking-fluid preservatives, as described in Annex V to that Directive, which corresponds to product-type 13 as described in Annex V to Regulation (EU) No 528/2012.
- (2) Poland submitted the assessment report together with its recommendations on 24 March 2016 in accordance with Article 90(2) of Regulation (EU) No 528/2012.
- (3) The opinion of the European Chemicals Agency was formulated on 16 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products used for product-type 13 and containing 2-methyl-1,2-benzisothiazol-3(2H)-one may not be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012. For that product-type, the scenarios evaluated in the environmental risk assessment identified unacceptable risks.
- (5) It is therefore not appropriate to approve 2-methyl-1,2-benzisothiazol-3(2H)-one for use in biocidal products of product-type 13.
- (6) 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*

2-methyl-1,2-benzisothiazol-3(2H)-one (EC No: n.a., CAS No 2527-66-4) is not approved as an active substance for use in biocidal products of product-type 13.

*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, 14 July 2017.

*For the Commission**The President*

Jean-Claude JUNCKER

<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).











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