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⁽¹⁾ Text with EEA relevance.

EN

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

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

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1500

of 9 October 2018

concerning the non-renewal of approval of the active substance thiram, and prohibiting the use and sale of seeds treated with plant protection products containing thiram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1), Article 49(2) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2003/81/EC ⁽²⁾ included thiram as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance thiram, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2019.
- (4) An application for the renewal of the approval of thiram was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 20 January 2016.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2003/81/EC of 5 September 2003 amending Council Directive 91/414/EEC to include molinate, thiram and ziram as active substances (OJ L 224, 6.9.2003, p. 29).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 27 January 2017 the Authority communicated to the Commission its conclusion ⁽¹⁾ on whether thiram can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority identified a high acute risk to consumers and to workers from application of thiram by foliar spraying. Furthermore, it identified a high risk to birds and mammals from all representative uses assessed, including as a seed treatment, even taking into account the application of higher tier refinements in the risk assessment. Residue definitions for risk assessment purposes could not be derived from the incomplete information available on metabolite M1, consequently the assessment of consumer risk through dietary intake could not be completed and maximum residue levels could not be established. Furthermore, the formation of N,N-dimethylnitrous amide (NDMA), a substance of concern given its intrinsic hazard, in drinking water when surface water and groundwater containing thiram and its metabolite DMCS is subject to water treatment processes could not be excluded by the Authority based on the available information and in addition a high risk to aquatic organisms from exposure to DMCS was concluded by the Authority based on the limited information available. Also, based on the information available the Authority could not conclude on the endocrine disrupting potential of thiram.
- (9) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.
- (10) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.
- (11) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance thiram in accordance with Article 20(1)(b) of that Regulation.
- (12) On 18 May 2018 the applicant wrote to the Commission to withdraw from the renewal application the representative uses concerning application by foliar spraying.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Taking into account the risk identified for birds and wild mammals from treated seeds the placing on the market and the use of seeds treated with plant protection products containing thiram should be prohibited.
- (15) The prohibition of placing on the market and use of treated seeds should apply as of 31 January 2020 in order to allow for a sufficient period of transition for the seed supply chain taking into account the limited availability of seeds that are not treated with products containing thiram.
- (16) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing thiram.
- (17) For plant protection products containing thiram, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 30 April 2019 for plant protection products used for foliar application and on 30 January 2020 for other plant protection products, including those used for seed treatment.
- (18) Commission Implementing Regulation (EU) 2018/524 ⁽²⁾ extended the expiry date of thiram to 30 April 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision is taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

⁽¹⁾ EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance thiram. *EFSA Journal* 2017;15(7):4700 [29 pp.]. doi:10.2903/j.efsa.2017.4700.

⁽²⁾ Commission Implementing Regulation (EU) 2018/524 of 28 March 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *Bacillus subtilis* (Cohn 1872) Strain QST 713, identical with strain AQ 713, clodinafop, clopyralid, cyprodinil, dichlorprop-P, fosetyl, mepanipyrim, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain: MA 342, pyrimethanil, quinoxifen, rimsulfuron, spinosad, thiacloprid, thiamethoxam, thiram, tolclofos-methyl, triclopyr, trinepaxap, triticonazole and ziram. (OJ L 88, 4.4.2018, p. 4).

- (19) This Regulation does not prevent the submission of a further application for the approval of thiram in accordance with Article 7 of Regulation (EC) No 1107/2009.
- (20) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance thiram is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 73, on thiram, is deleted.

Article 3

Prohibition of placing on the market of treated seeds

Seeds which have been treated with plant protection products containing thiram shall not be used or placed on the market.

Article 4

Transitional measures

Member States shall withdraw authorisations for plant protection products containing thiram as active substance by 30 January 2019 at the latest.

Article 5

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 30 April 2019 for plant protection products used for foliar application and on 30 January 2020 for other plant protection products, including those used for seed treatment, at the latest.

Article 6

Entry into force

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

Article 3 shall apply as of 31 January 2020.

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

Done at Brussels, 9 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1501**of 9 October 2018****concerning the non-renewal of approval of the active substance pymetrozine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2001/87/EC ⁽²⁾ included pymetrozine as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance pymetrozine, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2019.
- (4) An application for the renewal of the approval of pymetrozine was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 28 June 2013.
- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 28 August 2014 the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether pymetrozine can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that there is a high potential for the representative uses assessed to result in groundwater exposure above the parametric drinking water limit of 0,1 µg/l by the toxicologically relevant metabolite CGA371075 in all pertinent groundwater scenarios. The Authority further concluded that several other toxicologically relevant metabolites of pymetrozine are also predicted to occur above 0,1 µg/L in some or all pertinent

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2001/87/EC of 12 October 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include acibenzolar-s-methyl, cyclanilide, ferric phosphate, pymetrozine and pyraflufen-ethyl as active substances (OJ L 276, 19.10.2001, p. 17).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

⁽⁶⁾ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance pymetrozine. EFSA Journal 2014;12(9):3817, 102 pp. doi:10.2903/j.efsa.2014.3817.

groundwater scenarios for the representative uses evaluated. It also concluded that the toxicological profile of metabolites included in the plant residue definition for risk assessment could not be confirmed and that the assessment of the risk to aquatic organisms from exposure to metabolite M3MF could not be finalised for all representative uses considered based on the information available in the dossier.

- (9) Additionally, the Authority concluded that pymetrozine caused adverse effects on endocrine organs across different species and timelines. However, the scientific assessment for potential endocrine disruption properties of pymetrozine could not be finalised by the Authority based on the information available in the dossier.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 17(1) of Regulation (EU) No 1141/2010, on the draft review report. The applicant submitted its comments, which have been carefully examined.
- (11) However, despite the arguments put forward by the applicant, the concerns related to the substance could not be eliminated.
- (12) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance pymetrozine in accordance with Article 20(1)(b) of that Regulation.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Member States should be allowed sufficient time to withdraw authorisations for plant protection products containing pymetrozine.
- (15) For plant protection products containing pymetrozine, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 30 January 2020.
- (16) Commission Implementing Regulation (EU) 2018/917 ⁽¹⁾ extended the expiry date of pymetrozine to 30 June 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision is taken ahead of that extended expiry date, this Regulation should apply as soon as possible.
- (17) This Regulation does not prevent the submission of a further application for the approval of pymetrozine pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance pymetrozine is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 23, on pymetrozine, is deleted.

⁽¹⁾ Commission Implementing Regulation (EU) 2018/917 of 27 June 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthialdicarb, bifentazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobil, folpet, foramsulfuron, formetanate, Gliocladium catenulatum strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine and s-metolachlor (OJ L 163, 28.6.2018, p. 13).

*Article 3***Transitional measures**

Member States shall withdraw authorisations for plant protection products containing pymetrozine as active substance by 30 April 2019 at the latest.

*Article 4***Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 30 January 2020.

*Article 5***Entry into force**

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

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

Done at Brussels, 9 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

DECISIONS

COUNCIL DECISION (EU) 2018/1502

of 8 October 2018

appointing a member and an alternate member, proposed by the Kingdom of Spain, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Spanish Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ⁽¹⁾, (EU) 2015/190 ⁽²⁾ and (EU) 2015/994 ⁽³⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020. On 18 July 2016, by Council Decision (EU) 2016/1203 ⁽⁴⁾, Mr Francesc HOMS i MOLIST was replaced by Mr Jordi SOLÉ i FERRANDO as a member and Mr Roger ALBINYANA i SAIGÍ was replaced by Mr Amadeu ALTAFAJ i TARDIO as an alternate member. On 27 March 2017, by Council Decision (EU) 2017/602 ⁽⁵⁾, Mr Jordi SOLÉ i FERRANDO was replaced by Ms Maria BADIA i CUTCHET as a member.
- (2) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms Maria BADIA i CUTCHET.
- (3) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Amadeu ALTAFAJ i TARDIO,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

(a) as a member:

— Mr Ernest MARAGALL i MIRA, *Consejero de Asuntos Exteriores, Relaciones Institucionales y Transparencia de la Comunidad Autónoma de Cataluña*;

(b) as an alternate member:

— Ms Natàlia MAS GUIX, *Secretaria de Asuntos Exteriores y de la Unión Europea de la Comunidad Autónoma de Cataluña*.

⁽¹⁾ Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

⁽²⁾ Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

⁽³⁾ Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

⁽⁴⁾ Council Decision (EU) 2016/1203 of 18 July 2016 appointing a member and an alternate member, proposed by the Kingdom of Spain, of the Committee of the Regions (OJ L 198, 23.7.2016, p. 44).

⁽⁵⁾ Council Decision (EU) 2017/602 of 27 March 2017 appointing a member, proposed by the Kingdom of Spain, of the Committee of the Regions (OJ L 82, 29.3.2017, p. 8).

Article 2

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

Done at Brussels, 8 October 2018.

For the Council
The President
J. BOGNER-STRAUSS

COMMISSION IMPLEMENTING DECISION (EU) 2018/1503**of 8 October 2018****establishing measures to prevent the introduction into and the spread within the Union of *Aromia bungii* (Faldermann)***(notified under document C(2018) 6447)*

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 ⁽¹⁾, and in particular the third sentence of Article 16(3) thereof,

Whereas:

- (1) *Aromia bungii* (Faldermann) ('the specified organism') is not listed in Annex I or Annex II to Directive 2000/29/EC.
- (2) However, outbreaks of that organism have recently taken place for the first time in Italy and Germany. That organism has an unacceptable economic, environmental or social impact in the Union territory. Its introduction into, and presence in, the Union should therefore be prohibited and prevented. Specific measures should be adopted to that effect.
- (3) The European and Mediterranean Plant Protection Organisation (EPPO) adopted in 2014 a report on a Pest Risk Analysis for the specified organism ⁽²⁾. That report identified as likely pathways for the introduction of the specified organism any wood or wooden products of *Prunus* species, which are large enough to sustain the life cycle of the pest to adult emergence and which have not undergone treatment to kill the specified pest. It is therefore appropriate to establish specific measures for the introduction into, and movement within, the Union of plants for planting that have a stem or root collar diameter of 1 cm or more at their thickest point, other than seeds, of *Prunus* spp. ('specified plants'). Those measures should also apply to wood within the meaning of Article 2(2) of Directive 2000/29/EC ('specified wood') and wood packaging material, where it has been obtained in whole or part from *Prunus* spp. ('specified wood packaging material').
- (4) In the case of outbreak of the specified organism in Union territory, an area should be demarcated around the point of that outbreak, in order to adopt within that area effective eradication measures.
- (5) It is appropriate to take into account the economic and environmental impact of plant destruction. Under certain conditions, the establishment of a demarcated area should therefore not be required if the specified organism can be eliminated from the plants where it was found to be present and it can be ascertained that the specified organism cannot become established.
- (6) In specified circumstances, Member States should have the possibility to decide not to establish demarcated areas and to limit the measures to the destruction of the infested plants or plant products material, because this would be proportionate to the respective phytosanitary risk.
- (7) Specified plants and specified wood, which have been grown or been for at least part of their life in a demarcated area or which have been moved through such an area, or specified wood packaging material originating in demarcated areas, are more likely to have been infested with the specified organism. Therefore the movement of those plants, wood and wood packaging material should be subject to specific requirements, in order to prevent the further spread of the specified organism.
- (8) In order to ensure close monitoring of the movement of plants for planting originating in the demarcated areas, and to provide an effective overview of the sites where the phytosanitary risk due to the specified organism is high, the Commission and the Member States should have access to information concerning the production sites located in the demarcated areas.

⁽¹⁾ OJ L 169, 10.7.2000, p. 1.

⁽²⁾ EPPO (2014) *Pest risk analysis for *Aromia bungii**. EPPO, Paris. Available at http://www.eppo.int/QUARANTINE/Pest_Risk_Analysis/PRA_intro.htm

- (9) In order to ensure that specified plants and specified wood introduced into the Union from third countries are free from the specified organism, the requirements for their introduction from the third countries into the Union should be similar to those set out for movement of specified plants and specified wood from the demarcated areas to the rest of the Union territory.
- (10) 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

Definitions

For the purposes of this Decision, the following definitions shall apply:

- (a) 'specified organism' means *Aromia bungii* (Faldermann);
- (b) 'specified plants' means plants for planting, other than seeds, that have a stem or root collar diameter of 1 cm or more at their thickest point, of *Prunus* spp. with the exception of *Prunus laurocerasus* L.;
- (c) 'specified wood' means wood within the meaning of Article 2(2) of Directive 2000/29/EC where it has been obtained in whole or part from the following specified plants, as listed in Part II of Annex I to Council Regulation (EEC) No 2658/87 ⁽¹⁾:

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	Sawdust and wood waste and scrap, not agglomerated ⁽¹⁾
4403 12 00	Non-coniferous wood in the rough, treated with paint, stains, creosote or other preservatives, whether or not stripped of bark or sapwood, or roughly squared
ex 4404 20 00	Non-coniferous hoopwood; split poles; piles, pickets and stakes of wood, pointed but not sawn lengthwise; wooden sticks, roughly trimmed but not turned, bent or otherwise worked, suitable for the manufacture of walking sticks, umbrellas, tool handles or the like; chipwood and the like
4406	railway or tramway sleepers (cross-ties) of wood
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
4416 00 00	Casks, barrels, vats, tubs and other coopers' products and parts thereof, of wood, including staves
9406 10 00	Prefabricated buildings of wood

⁽¹⁾ Applied for wood waste and scrap, not agglomerated, of more than 2,5 cm thickness and width

- (d) 'specified wood packaging material' means packaging material obtained in whole or in part from the specified plants;
- (e) 'place of production' means any premises or collection of fields operated as a single production or farming unit, including production sites which are separately managed for phytosanitary purposes;

⁽¹⁾ 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).

- (f) 'professional operator' means any person involved professionally in one or more of the following activities concerning plants, plant products and wood packaging material:
- planting,
 - breeding,
 - production, including growing, multiplying and maintaining,
 - introduction into, and movement within, and out of the Union territory,
 - making available on the market.

Article 2

Prohibition of the introduction into, or spread within, the Union territory of the specified organism

The introduction into, or spread within, the Union territory of the specified organism shall be prohibited.

Article 3

Detection or suspected presence of the specified organism

1. Any person who suspects or becomes aware of the presence of the specified organism shall immediately inform the responsible official body and provide it with all relevant information concerning the presence, or suspected presence, of the specified organism.
2. The responsible official body shall immediately record such information.
3. Where the responsible official body has been informed of a presence, or suspected presence, of the specified organism, it shall take all necessary measures to confirm that presence, or the suspected presence.
4. Member States shall ensure that any person having under its control plants which may be infested with the specified organism, is immediately informed of the presence or the suspected presence of the specified organism, of the possible consequences and risks and of the measures to be taken.

Article 4

Surveys of the specified organism in the territories of the Member States

Member States shall conduct annual surveys for the presence of the specified organism in their territory.

Those surveys shall be carried out by the responsible official body, or under official supervision of the responsible official body. They shall consist of visual examinations and, in the case of any suspicion of infestation by the specified organism, collection of samples for pest identification. Those surveys shall take account of the available scientific and technical evidence, the biology of the specified organism, the presence and biology of susceptible plants, and any other appropriate information concerning the presence of the specified organism.

Article 5

Establishment of demarcated areas

1. Where the presence of the specified organism is confirmed, the Member State concerned shall without delay demarcate an area ('demarcated area') in accordance with paragraph 2.
2. The demarcated area shall consist of an infested zone and a buffer zone.

The infested zone is the zone where the presence of the specified organism has been confirmed, and which contains:

- (a) all plants known to be infested by the pest concerned;

- (b) all plants showing signs or symptoms indicating possible infestation by that pest;
- (c) all other plants liable to have been or become contaminated or infested by that pest, including plants liable to be infested due to their susceptibility to that pest and their close proximity to infested plants or common source of production, if known, with infested plants, or plants grown from them.

The buffer zone shall be of a width of at least 2 km surrounding the infested zone.

The exact delimitation of the infested zone and buffer zone shall be based on sound scientific principles, the biology of the specified organism, the level of infestation and the distribution of specified plants and specified wood in the area concerned.

In cases where the responsible official body concludes that eradication of the specified organism is possible in accordance with Article 6(1), taking into account the circumstances of the outbreak, the results of a specific investigation or the immediate application of eradication measures, the radius of the buffer zone may be reduced to not less than 1 km beyond the boundary of the infested zone.

3. If the presence of the specified organism is confirmed in the buffer zone, the delimitation of the infested zone and buffer zone shall immediately be reviewed and changed accordingly.

4. Where, based on the surveys referred to in Article 4 and paragraph 6(b) of this Article, the specified organism is not detected in a demarcated area for a period of four consecutive years, that demarcation may be lifted. In such cases, the Member State concerned shall notify the Commission and other Member States.

5. Member States need not establish demarcated areas, as provided for in paragraph 1, if one of the following conditions is satisfied:

- (a) there is evidence that the specified organism has been introduced into the area with plants, wood or wood packaging material that were infested before their introduction into the area concerned; and it is ascertained that there is no establishment of the specified organism and that the spread and breeding of the specified organism is not possible due to its biology;
- (b) there is evidence that the presence of the specified organism is an isolated finding, immediately associated with a specified plant, wood or wood packaging material, which is not expected to lead to establishment, and
it is ascertained that there is no establishment of the specified organism and that the spread and breeding of the specified organism is not possible due to its biology.

For the purposes of point (b), the results of a specific investigation and eradication measures shall be taken into account. Such measures may consist of precautionary felling and disposal of specified plants and plant products and of destruction and disposal of wood packaging material, after they have been examined.

6. Where one of the conditions set out in paragraph 5 is satisfied, Member States shall take the following measures:

- (a) immediate measures to ensure the prompt eradication of the specified organism and to exclude the possibility of its spread;
- (b) regular and intensive surveillance during the period covering at least one life cycle of the specified organism and one additional year including surveillance of at least four consecutive years, in a radius of at least 1 km around the infested plants, wood or wood packaging material, or the place where the specified organism was found;
- (c) the destruction of any infested plant material, wood or wood packaging material;
- (d) the investigation of the origin of the infestation by the tracing of plants or of wood, or wood packaging material as far as possible and the examination thereof for any sign of infestation;
- (e) activities to raise public awareness concerning the threat of that organism;
- (f) any other measure, which may contribute to the eradication of the specified organism, taking account of international standard for phytosanitary measures ('ISPM') No 9 and applying an integrated approach according to the principles set out in ISPM No 14.

For the purposes of point (d), the examination shall include targeted destructive sampling.

The measures referred to in points (a) to (f) shall be presented in the form of a report in accordance with Article 10(1)(a).

Article 6

Eradication and containment measures

1. The Member State which establishes the demarcated area referred to in Article 5 shall adopt the following measures in that area:

- (a) the immediate felling of infested plants and plants with symptoms caused by the specified organism, and the complete removal of their roots if larval galleries are observed below the root collar of the infested plant;
- (b) the felling of all specified plants within a radius of 100 m around infested plants and the examination of those specified plants for any sign of infestation;
- (c) removal, examination and safe disposal of plants felled in accordance with points (a) and (b) and of their roots where necessary, as well as examination of and disposal of other plant products and wood packaging material;
- (d) prohibition of any movement of potentially infested material out of the demarcated area;
- (e) investigation of the origin of the infestation by the tracing of plants, wood and wood packaging material concerned, as far as possible, and the examination thereof for any sign of infestation;
- (f) replacement of specified plants by other plant species, where appropriate;
- (g) prohibition of planting of new specified plants in the open air in the area referred to in point (b) of this paragraph, except for the places of production referred to in Article 7(1);
- (h) intensive surveillance for the presence of the specified organism on *Prunus* spp. species with specific focus on the buffer zone, which shall include at least one inspection per year.
- (i) activities to raise public awareness concerning the threat of that organism and the measures adopted to prevent its introduction into and spread within the Union, including the conditions regarding movement of specified plants, specified wood and specified wood packaging material from the demarcated area;
- (j) where necessary, specific measures to address any particularity or complication that could reasonably be expected to prevent, hinder or delay eradication, in particular those related to the accessibility and adequate eradication of all plants that are infested or suspected of infestation, irrespective of their location, public or private ownership or the person or entity responsible for them;
- (k) any other measure, which may contribute to the eradication of the specified organism, taking account of ISPM No 9 and applying an integrated approach according to the principles set out in ISPM No 14.

For the purposes of point (a), where the infested plants were found outside the flying period of the specified organism the felling and removal shall be carried out before the start of the next flying period.

By way of derogation from point (b), where a responsible official body concludes that felling is inappropriate for individual trees, due to their particular social, cultural or environmental value, the Member State which has established the demarcated area shall ensure that those specified plants which are not to be felled are subject to an individual and regular examination for any sign of infestation and that measures equivalent to felling are taken to prevent any possible spread of the specified organism from those plants. The report referred to in Article 10 shall set out the reasons for that conclusion and a description of the measures.

For the purposes of point (c), all necessary precautions shall be taken to avoid spreading of the specified organism during and after felling.

For the purposes of point (e), where the examination shows that the specified plants are infested, those plants shall be felled.

For the purposes of point (h), where appropriate, targeted destructive sampling shall be carried out by the responsible official body and the number of samples shall be indicated in the report referred to in Article 10(1).

The measures referred to in points (a) to (k) shall be presented in the form of a report in accordance with Article 10(1).

2. Where, for a period of more than four consecutive years, the results of the surveys referred to in Article 4 have confirmed the presence of the specified organism in an area, and in case there is evidence that the specified organism can no longer be eradicated, Member States may limit the measures to the containment of the specified organism within that area.

In that case, the radius of the buffer zone shall be increased to no less than 4 km.

Such measures shall include at least the following:

- (a) immediate felling of infested plants and plants with symptoms caused by the specified organism, and the complete removal of their roots if larval galleries are observed below the root collar of the infested plant;
- (b) removal, examination and disposal of plants felled and of their roots, taking all necessary precautions to avoid spreading of the specified organism after felling;
- (c) prohibition of any movement of potentially infested material out of the demarcated area;
- (d) where appropriate, replacement of specified plants by other plants;
- (e) prohibition of planting of new specified plants in the open air in the infested zone as referred to in Article 5, except for the places of production referred to in Article 7(1);
- (f) intensive surveillance for the presence of the specified organism on *Prunus* spp. species with specific focus on the buffer zone, which shall include at least one inspection per year;
- (g) activities to raise public awareness concerning the threat of the specified organism and the measures adopted to prevent its introduction into and spread within the Union, including the conditions regarding movement of specified plants and specified wood from the demarcated area;
- (h) where necessary, specific measures to address any particularity or complication that could reasonably be expected to prevent, hinder or delay containment, in particular those related to the accessibility and adequate eradication of all plants that are infested or suspected of infestation, irrespective of their location, public or private ownership or the person or entity responsible for them;
- (i) any other measure which may contribute to the containment of the specified organism.

For the purposes of point (a), where the infested plants were found outside the flying period of the specified organism the felling and removal shall be carried out before the start of the next flying period.

For the purposes of point (f), where appropriate, targeted destructive sampling shall be carried out by the responsible official body and the number of samples shall be indicated in the report referred to in Article 10(1).

The measures referred to in points (a) to (i) shall be presented in the form of a report in accordance with Article 10(1).

Article 7

Movement of specified plants within the Union

1. Specified plants originating ⁽¹⁾ in a demarcated area may be moved within the Union only if they are accompanied by a plant passport prepared and issued in accordance with Commission Directive 92/105/EEC ⁽²⁾ and have been grown during a period of at least two years prior to movement or, in the case of plants which are younger than two years, have been grown throughout their life, in a place of production which fulfils the requirements set out in paragraphs 2 to 5.
2. The place of production shall be registered in accordance with Commission Directive 92/90/EEC ⁽³⁾.
3. The place of production shall have been subjected annually to at least two meticulous official inspections carried out at appropriate times and shall show no sign of infestation by the specified organism. The inspection shall include targeted destructive sampling of the stems and branches of plants in case of an increased level of suspicion concerning the presence of the specified organism.
4. The place of production:
 - (i) shall have complete physical protection against the introduction of the specified organism; or

⁽¹⁾ Glossary of Phytosanitary Terms — Reference Standard ISPM No 5 and Phytosanitary certificates — Reference Standard ISPM No 12 by the Secretariat of the International Plant Protection Convention, Rome, 2013.

⁽²⁾ Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement (OJ L 4, 8.1.1993, p. 22).

⁽³⁾ Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration (OJ L 344, 26.11.1992, p. 38).

- (ii) shall have been subjected to appropriate preventive treatments and targeted destructive sampling shall have been carried out on each lot of specified plants prior to movement at the level set out in the table below; the place of production shall be subjected annually to official surveys within a radius of at least 1 km around the site at appropriate times and shall show no signs of infestation.

Number of plants in lot	Level of destructive sampling (number of plants to be destroyed)
1–4 500	10 % of lot size
> 4 500	450

5. Rootstocks which meet the requirements of paragraphs 1 to 4 may be grafted with scions which have not been grown in accordance with those requirements, but which are no more than 1 cm in diameter at their thickest point.

6. Specified plants not originating in demarcated areas, but introduced into a place of production in such areas, may be moved within the Union on condition that this place of production complies with the requirements set out in paragraphs 2, 3 and 4 and only if the plants are accompanied by a plant passport prepared and issued in accordance with Directive 92/105/EEC.

7. Specified plants imported from third countries where the specified organism is known to be present, in accordance with Article 11, may be moved within the Union only if they are accompanied by a plant passport prepared and issued in accordance with Directive 92/105/EEC.

Article 8

Movement within the Union of specified wood

1. The movement within the Union of specified wood originating in a demarcated area or specified wood retaining all or part of its surface introduced into a demarcated area shall be prohibited.

2. By way of derogation from paragraph 1, specified wood other than in the form of chips, particles, shavings, wood waste and scrap originating in a demarcated area and specified wood retaining all or part of its surface, may only be moved within the Union if it is accompanied by a plant passport prepared and issued in accordance with Directive 92/105/EEC. That plant passport shall be issued only if that wood fulfils one of the following requirements:

(a) it is debarked and 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 (including at its core). The heat treatment shall be evidenced by a mark 'HT' put on the wood or on any wrapping in accordance with current usage;

(b) it has undergone appropriate ionising radiation to achieve a minimum absorbed dose of 1kGy throughout the wood.

3. By way of derogation from paragraph 1, specified wood in the form of chips, particles, shavings, wood waste and scrap, originating in a demarcated area, may only be moved within the Union if it is accompanied by a plant passport prepared and issued in accordance with Directive 92/105/EEC and fulfils one of the following conditions:

(a) it is debarked and it 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 (including at its core);

(b) it has been processed into pieces of not more than 2,5 cm thickness and width.

4. In the case of paragraphs 2 and 3, if no treatment or processing facilities are available within the demarcated area, the specified wood may only be moved within the Union under official control, and under closed conditions, so as to ensure that the specified organism cannot spread, to the nearest facility outside the demarcated area for the purposes of immediate treatment or processing in accordance with paragraphs 2 or 3.

Waste material resulting from the treatment or processing carried out under paragraphs 2 and 3 shall be disposed of in such a manner as to ensure that the specified organism cannot spread outside the demarcated area.

The responsible official body shall carry out intensive surveillance at appropriate times for the presence of the specified organism through inspections on *Prunus* spp. species within at least 1 km of that treatment or processing facility.

Article 9

Movement within the Union of specified wood packaging material

1. The movement within the Union of specified wood packaging material originating in a demarcated area shall be prohibited.
2. By way of derogation from paragraph 1, movement of specified wood packaging material, originating in a demarcated area may only take place if the specified wood packaging material fulfils all of the following conditions:
 - (a) it has been subject to one of the approved treatments specified in Annex I to FAO International Standard for Phytosanitary Measures No 15 ⁽¹⁾ on Regulation of wood packaging material in international trade;
 - (b) it displays a mark as specified in Annex II to FAO International Standard for Phytosanitary Measures No 15, indicating that the specified wood packaging material has been subjected to an approved phytosanitary treatment in accordance with this Standard.
3. If no treatment facilities are available within the demarcated area, the specified wood packaging material may only be moved under official control and closed conditions, in such a manner as to ensure that the specified organism cannot spread, to the nearest treatment facility outside the demarcated area for the purposes of immediate treatment and marking in accordance with paragraph 2.

Waste material resulting from treatment in accordance with the first subparagraph shall be disposed of in such a manner as to ensure that the specified organism cannot spread outside a demarcated area.

The responsible official body shall carry out intensive surveillance at appropriate times for the presence of the specified organism through inspections on *Prunus* spp. species, within a radius of at least 1 km of the treatment facility.

Article 10

Reporting on surveys and measures

1. Member States shall, by 30 April of each year, communicate to the Commission and to the other Member States:
 - (a) a report on the surveys carried out during the previous calendar year, and measures taken or intended to be taken in that year pursuant to Articles 4 to 6, as well as on the results of those surveys and measures;
 - (b) an up-to-date list of all demarcated areas established under Article 5, including information on their description and location with maps showing their delimitation;
 - (c) in cases where, pursuant to Article 5(5), Member States have decided not to establish a demarcated area, supporting data and reasons.
2. Where justified by the development of the respective phytosanitary risk, Member States shall adapt the respective surveys and measures. They shall immediately communicate that adaptation to the Commission and the other Member States.

Article 11

Introduction into the Union of specified plants originating from a third country where the specified organism is known to be present

Specified plants originating from third countries, where the specified organism is known to be present, shall be accompanied by the certificate referred to in Article 13(1)(ii) of Directive 2000/29/EC. That certificate shall contain one of the following statements under the entry 'Additional Declaration':

- (a) that the plants have been grown throughout their life in a place of production which is registered and supervised by the national plant protection organisation in the country of origin and situated in an area, established by that organisation, in accordance with relevant International Standards for Phytosanitary Measures, as known to be free from the specified organism;
- (b) that the plants 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 the specified organism, in accordance with the International Standards for Phytosanitary Measures, and that the following conditions are fulfilled:
 - (i) the place of production is registered and supervised by the national plant protection organisation in the country of origin;

⁽¹⁾ Glossary of Phytosanitary Terms — Reference Standard ISPM No 15 by the Secretariat of the International Plant Protection Convention, Rome, 2013.

- (ii) the place of production has been subjected annually to at least two meticulous official inspections for any sign of the specified organism carried out at appropriate times, and no signs of the organism have been found;
- (iii) the place of production is with complete physical protection against the introduction of the specified organism, or has been subjected to appropriate preventive treatment and surrounded by a buffer zone with a radius of at least 4 km where official surveys for the presence or signs of the specified organism are carried out annually at appropriate times;
- (iv) where the presence or signs of the specified organism have been found, eradication measures have been immediately taken to restore the pest freedom of the buffer zone;
- (v) immediately prior to export, consignments of the plants have been subjected to a meticulous official inspection for the presence of the specified organism, in particular in stems and branches of those plants. That inspection has included targeted destructive sampling. Where consignments include plants originating in sites which at the time of their production were located in a buffer zone, where presence or signs of the specified organism had been found, destructive sampling of the plants of that consignment has been carried out at the level set out in the following table:

Number of plants in lot	Level of destructive sampling (number of plants to be destroyed)
1–4 500	10 % of lot size
> 4 500	450

- (c) that the plants have been grown from rootstocks which fulfil the requirements of point (b), grafted with scions which meet the following requirements:
 - (i) at the time of export, the grafted scions are no more than 1 cm in diameter at their thickest point;
 - (ii) the grafted plants have been inspected in accordance with point (b)(ii).

For the purposes of point (a), the name of the area shall be mentioned under the entry 'place of origin'.

Article 12

Introduction into the Union of specified wood originating from a third country where the specified organism is known to be present

1. Specified wood, other than in the form of chips, particles, shavings, wood waste and scrap, originating from third countries, where the specified organism is known to be present, shall be accompanied by the certificate referred to in Article 13(1)(ii) of Directive 2000/29/EC. That certificate shall contain one of the following statements under the entry 'Additional Declaration':

- (a) the wood originates in areas, established by the national plant protection organisation in the country of origin, in accordance with relevant International Standards for Phytosanitary Measures, as known to be free from the specified organism;
- (b) the wood is debarked and 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, including at its core;
- (c) the wood has undergone appropriate ionising radiation to achieve a minimum absorbed dose of 1kGy throughout the wood.

The name of the area referred to in point (a) shall be mentioned under the entry 'place of origin'

For the purposes of point (b), the heat treatment shall be evidenced by a mark 'HT' put on the wood or on any wrapping, in accordance with current usage.

2. Specified wood in the form of chips, particles, shavings, wood waste and scrap originating from third countries, where the specified organism is known to be present, shall be accompanied by the certificate referred to in Article 13(1)(ii) of Directive 2000/29/EC. That certificate shall contain one of the following statements under the entry 'Additional Declaration':

- (a) the wood originates from areas, established by the national plant protection organisation in the country of origin, in accordance with relevant International Standards for Phytosanitary Measures, as known to be free from the specified organism;

- (b) the wood is debarked and 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, including at its core;
- (c) the wood has been processed into pieces of not more than 2,5 cm thickness and width.

For the purposes of point (a), the name of the area shall be mentioned under the entry 'place of origin'

Article 13

Official checks at introduction into the Union of specified plants and specified wood originating from a country where the specified organism is known to be present

1. All consignments of specified plants and specified wood introduced into the Union from a third country, where the specified organism is known to be present, shall be subject to a meticulous official check at the point of entry into the Union or at the place of destination established in accordance with Article 1 of Commission Directive 2004/103/EC ⁽¹⁾.
2. The inspection methods applied shall ensure the detection of any sign of the specified organism, in particular in stems and branches of the plants. That inspection shall include, where appropriate, targeted destructive sampling.

Article 14

Compliance

Member States shall repeal or amend the measures which they have adopted to protect themselves against the introduction and spread of the specified organism in order to comply with this Decision. They shall immediately inform the Commission of those measures.

Article 15

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 8 October 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks (OJ L 313, 12.10.2004, p. 16).

