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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**as regards measures to prevent the introduction into and the spread within the Union of
Xylella fastidiosa (Wells *et al.*)**

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**as regards measures to prevent the introduction into and the spread within the Union of
Xylella fastidiosa (Wells *et al.*)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC¹, and in particular Article 28(1) and (2) thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2015/789² has been applied since May 2015 with the aim to prevent further spread within and introduction into the Union of *Xylella fastidiosa* (Wells *et al.*) ('the specified pest'). That Implementing Decision has been updated on several occasions to take into account the scientific and technical evidence made available at the time.
- (2) On 15 May 2019, the European Food Safety Authority ('the Authority') published a new Scientific Opinion³ on the risk to plant health posed by the specified pest in the Union territory, focusing on potential establishment, short- and long- range spread, the length of the asymptomatic period, the impact of the specified pest and an update on risk reduction options. On 15 May 2019, the Authority published a scientific report⁴ on the effectiveness of *in planta* control measures for the specified pest, confirming as previously stated that there are currently no control measures available to eliminate the specified pest from a diseased plant in open field conditions. On 25 June 2019, the Authority published a pest survey card⁵ on the specified pest providing further elements to ensure more targeted survey activities. On 28 April 2020, the Authority updated the database of plant species found infected by the specified pest worldwide⁶. Moreover, on 8 June 2020, the Authority published the Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*⁷ that will assist Member States to implement the confidence level, the design prevalence proposed and preparation of the survey activities to be carried out within and outside the demarcated areas, in the Union territory.

¹ OJ L 317, 23.11.2016, p. 4.

² Commission Implementing Decision (EU) 2015/789 of 18 May 2015 as regards measures to prevent the introduction into and the spread within the Union of *Xylella fastidiosa* (Wells *et al.*), OJ L 125, 21.5.2015, p. 36.

³ EFSA Journal 2019;17(5):5665, 200 pp. <https://doi.org/10.2903/j.efsa.2019.5665>

⁴ EFSA Journal 2019;17(5):5666, 17 pp. <https://doi.org/10.2903/j.efsa.2019.5666>

⁵ EFSA supporting publication 2019:EN-1667. 53 pp. doi:10.2903/sp.efsa.2019.EN-1667

⁶ EFSA Journal 2020;18(4):6114. <https://doi.org/10.2903/j.efsa.2020.6114>

⁷ EFSA supporting publication 2020:EN-1873. 76 pp. doi:10.2903/sp.efsa.2020.EN-1873

- (3) The recent scientific developments, the outcome of the audits carried out by the Commission in the Member States concerned and the experience gained during the implementation of Implementing Decision (EU) 2015/789 indicate the need to update those measures in order to ensure a more targeted approach for the control of the specified pest in the Union territory.
- (4) For the purpose of clarity, the definition of host plants should refer to all the plant species or genera found infected by the specified pest worldwide, while the definition of specified plants should only refer to those host plants which have been found infected by a particular subspecies of the specified pest. In this context, and in order to ensure a certain proportionality, some measures of this Decision should only apply to host plants and some others only to specified plants.
- (5) In order to ensure a better overview of the presence of the specified pest, Member States should intensify the annual surveys for that presence in line with the latest scientific and technical information.
- (6) In order to eradicate the specified pest and prevent its further spread in the rest of the Union, Member States should establish demarcated areas consisting of an infected zone and a buffer zone, and apply eradication measures. The width of the buffer zones should be proportionate to the level of risk and the spreading capacity of the vector.
- (7) However, in cases of isolated occurrences of the specified pest, the establishment of a demarcated area should not be required if the specified pest can be eliminated from those plants, recently introduced, where it was found to be present. This will be the most proportionate approach as long as the surveys carried out in the area concerned lead to the conclusion that the specified pest has not been established.
- (8) In certain areas of the Union, it is appropriate to conclude that the eradication of the specified pest is no longer possible. The Member States concerned should therefore be allowed to apply measures for the containment of that pest within those areas, instead of eradication. Those measures should be less stringent than the measures for eradication, but they should ensure a diligent survey approach and more precautionary actions in the respective buffer zones and at the outer part of the infected zones, in order to prevent the spread of the specified pest to the rest of the Union territory.
- (9) In order to ensure the immediate removal of the infected plants and prevent further spread of the specified pest in the rest of the Union territory, the monitoring of the demarcated areas should be carried out annually at the most appropriate time of the year.. The monitoring should also focus on vectors present in the demarcated area so as to determine the risk of further spreading by vectors and to evaluate the effectiveness of the phytosanitary control measures applied against all stages of the vector population.
- (10) Experience confirms, in line with the latest scientific evidences, that vector control, together with the immediate removal of the bacterial inoculum, is key to prevent further spread of the specified pest within the rest of the Union territory. Therefore, Member States should ensure proper implementation of the phytosanitary treatments, prior to the removal of the plants, as well as during the year, against all stages of the vector population. Those treatments should include efficient chemical, biological or mechanical treatments against the vectors, with preference to non-chemical solutions, wherever possible.
- (11) Plant species known to be susceptible to the subspecies of the specified pest detected in the demarcated area and which have been grown for at least part of their life in that

demarcated area, or which have been moved through such an area, are more likely to have been infected with the specified pest. Therefore, it is proportionate to establish special requirements for the movement within the Union only as regards specified plants. It is also proportionate to apply less stringent requirements for the movement of those plants within the infected zones, or from the infected zones to the buffer zones, than the requirements applied for their movement out of the demarcated areas.

- (12) With the aim of facilitating trade while protecting plant health, and taking into account the nature of the specified pest, host plants originating in a third country where that pest is not present should, when introduced into the Union, be accompanied by a phytosanitary certificate including an additional declaration stating that that country is free from the specified pest.
- (13) In order to ensure that host plants introduced into the Union from areas of third countries where the specified pest is known to be present, are free from the specified pest, the requirements for their introduction into the Union should be similar to those set out for movement of specified plants originating in demarcated areas.
- (14) In light of the latest scientific and technical evidence, survey activities carried out by third countries to confirm the absence of the specified pest in areas of their territory or in production sites authorised for export to the Union should be also intensified.
- (15) Rules should be established concerning official checks on movements of the specified plants out of the demarcated areas to the rest of the Union territory, and the introduction into the Union of host plants from third countries. Those rules should be proportionate, effective and take into account the provisions of Regulation (EU) 2017/625 of the European Parliament and of the Council⁸, which became applicable on 14 December 2019.
- (16) Implementing Decision (EU) 2015/789 should therefore be repealed.
- (17) As regards survey activities carried out in areas of the Union territory where the pest is known not to occur, as well as in areas or production sites of third countries, it is appropriate to allow sufficient time to Member States and third countries to design those activities so that they provide the level of statistical confidence required. The requirements relating to those survey activities should therefore apply from 1 January 2022.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food, and Feed,

⁸ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1.

HAS ADOPTED THIS REGULATION:

CHAPTER I DEFINITIONS

Article 1

Definitions

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

- (a) 'specified pest' means *Xylella fastidiosa* (Wells *et al.*) and any of its subspecies;
- (b) 'host plants' means all plants for planting, other than seeds, belonging to the genera or species listed in Annex I;
- (c) 'specified plants' means host plants for planting, other than seeds, belonging to the genera or species listed in Annex II and known to be susceptible to the specific subspecies of the specified pest.

CHAPTER II ANNUAL SURVEYS FOR THE PRESENCE OF THE SPECIFIED PEST AND CONTINGENCY PLANS

Article 2

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

1. Member States shall conduct annual surveys of the host plants for the detection of the specified pest in their territory.
2. Those surveys shall be carried out by the competent authorities, or under the official supervision of the competent authorities.
3. Those surveys shall be performed on the basis of the level of risk. They shall take place in open air, including cropping fields, orchards, vineyards, as well as nurseries, garden centres and/or trading centres, natural areas and other relevant locations.
4. Those surveys shall consist in the collection of samples and testing of plants for planting. Taking into account the European Food Safety Authority's (Authority) Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme used shall be able to identify within the Member State concerned, with at least 80% of confidence, a level of presence of infected plants of 1%.
5. Those surveys shall be carried out at appropriate times of the year with regard to the possibility to detect the specified pest, taking into account the biology of that pest and its vectors, the presence and biology of host plants, and the scientific and technical information referred to in the Authority's Pest Survey Card on *Xylella fastidiosa*.
6. The presence of the specified pest shall be monitored by one of the molecular tests listed in Annex IV. In case of positive results detected in areas other than the demarcated areas, the presence of the specified pest shall be confirmed on the same plant extract by one more positive molecular test listed in that Annex, targeting different parts of the genome.

7. The identification of the subspecies of the specified pest shall be carried out on each plant species that is found infected by the specified pest in the demarcated area concerned. That identification shall be carried out by using the molecular tests listed in Section B of Annex IV.
8. Member States shall report the results of the surveys referred to in paragraph 1 in accordance with Article 22(3) of Regulation (EU) 2016/2031.

Article 3
Contingency plans

1. Each Member State shall establish a contingency plan. That contingency plan shall set out the actions to be taken in its territory concerning:
 - (a) the eradication of the specified pest, as set out in Articles 7 to 11;
 - (b) the movements of specified plants within the Union, as set out in Articles 19 to 26;
 - (c) the official checks to be carried out on movements of specified plants within the Union and of host plants into the Union, as set out in Articles 31 and 32.Each Member State shall update its contingency plan, as appropriate, by 31 December of each year. Contingency plans established under Implementing Decision (EU) 2015/789 shall be updated by 31 December 2020.
2. In addition to the elements referred to in Article 25(2) of Regulation (EU) 2016/2031, the contingency plan shall include all of the following elements:
 - (a) the minimum resources to be made available and the procedures for making those additional resources available in case of a confirmed or suspected presence of the specified pest;
 - (b) rules detailing the procedures for identifying the owners of the plants to be removed, for notifying the order of removal and for accessing private properties.

CHAPTER III
DEMARCATED AREAS

Article 4
Establishment of demarcated areas

1. Where the presence of the specified pest is officially confirmed, the Member State concerned shall without delay establish a demarcated area.

Where only the presence of one or more particular subspecies of the specified pest is confirmed, the Member State concerned may demarcate an area with regard to those subspecies only.

Where the confirmation of the presence of a subspecies is pending, the Member State concerned shall demarcate that area with regard to the specified pest and all of its possible subspecies.
2. The demarcated area shall consist of an infected zone and a buffer zone.

The infected zone shall have a radius of at least 50 m around the plant found infected by the specified pest.

The buffer zone shall be of the following width:

- (a) at least 2,5 km in the case of an infected zone established for the purpose of taking the eradication measures referred to in Articles 7 to 11;
 - (b) at least 5 km in the case of an infected zone established for the purpose of taking the containment measures referred to in Articles 12 to 17.
3. The Commission shall update and publish a list of the demarcated areas established by Member States, as notified pursuant to Article 18(6) of Regulation (EU) 2016/2031.

Article 5

Derogations for the establishment of demarcated areas

1. By way of derogation from Article 4, the buffer zone surrounding the infected zone established for the purpose of eradication may be reduced to a width of no less than 1 km, where there is a high degree of confidence that the initial presence of the specified pest did not result in its spread and where all of the following conditions have been fulfilled:
 - (a) all specified plants located in the infected zone, irrespective of their health status, have been immediately sampled and removed;
 - (b) no other plants have been found infected by the specified pest in the infected zone since the eradication measures have been taken, on the basis of official tests carried out at least once during the course of the year, taking into account the Authority's Pest Survey Card on *Xylella fastidiosa*;
 - (c) a survey has been carried out at least once during the first year following the identification of the specified pest in a zone with a width of at least 2,5 km surrounding the infected zone, which shows that the specified pest has not been found present in that zone. The Member State concerned shall sample and test the host plants located in that area. For that purpose, they shall use a sampling scheme able to identify with at least 90% confidence a level of presence of infected plants of 1%, taking into account that the zone of a width of at least 400 m surrounding the infected plants has a higher level of risk compared to the other part of that area;
 - (d) no vectors carrying the specified pest have been detected in the infected zone and its immediate vicinity since the eradication measures have been taken, on the basis of tests carried out twice during the flight season of the vector, and in accordance with International Standards for Phytosanitary Measures. Those tests shall lead to the conclusion that the natural spread of the specified pest is excluded.
2. When reducing the width of the buffer zone pursuant to paragraph 1, the Member State concerned shall immediately notify the Commission and the other Member States of the justification for that reduction.
3. By way of derogation from Article 4, the Member State concerned may decide not to establish a demarcated area immediately, where all of the following conditions are fulfilled:

- (a) there is evidence that the specified pest was recently introduced into the area with the plants on which it was found, or that the specified pest has been found in a site with physical protection from the vectors of that pest;
 - (b) the results of inspection activities indicate that those plants were infected before their introduction into the area concerned;
 - (c) no vectors carrying the specified pest have been detected, on the basis of tests carried out in the vicinity of those plants.
4. In the case referred to in paragraph 3, the Member State concerned shall:
- (a) carry out, in the area where the presence of the specified pest was first confirmed, an annual survey for at least two years to determine whether any other plants have been infected and whether any further measures should be taken;
 - (b) notify to the Commission and the other Member States the justification for not establishing a demarcated area, and the outcome of the survey referred to in point (a) as soon as it becomes available.

Article 6

Lifting of the demarcated areas

1. Where, based on the surveys referred to in Article 10, the specified pest has not been detected in a demarcated area for a period of four years, this demarcation may be lifted. In such cases, the Member State concerned shall notify the Commission and other Member States.
2. By way of derogation from paragraph 1, in the case where the Member State concerned has reduced the buffer zone to a width of no less than 1 km in accordance with Article 5(1), the Member State may lift the demarcated area after 12 months since its initial establishment, where both of the following conditions are fulfilled:
 - (a) as a result of the measures taken pursuant to Article 5(1), it is concluded with a high degree of confidence that the initial presence of the specified pest was an isolated case and no further spread occurred in the respective demarcated area;
 - (b) as practically close to the time of lifting, official tests have been carried out within the demarcated area, taking into account the Authority's Pest Survey Card on *Xylella fastidiosa* and using a sampling scheme able to identify with at least 95% confidence a level of presence of infected plants of 1%.
3. Where a demarcated area is lifted pursuant to paragraph 2, the specified plants located in the previously established demarcated area shall be subject to intensive surveys during the following two years. That survey shall be carried out using a sampling scheme able to identify with at least 80% confidence a level of presence of infected plants of 1%.
4. When lifting the demarcated area after 12 months since its initial identification, the Member State concerned shall immediately notify the Commission and the other Member States of the justification for that lifting.

CHAPTER IV ERADICATION MEASURES

Article 7

Removal of plants

1. The Member State concerned shall immediately remove from the infected zone:
 - (a) plants known to be infected by the specified pest;
 - (b) plants showing symptoms indicating possible infection by that pest or suspected to be infected by that pest;
 - (c) plants which belong to the same species as that of the infected plant, regardless of their health status;
 - (d) plants of other species than that of the infected plant, which have been found infected in other parts of the demarcated area;
 - (e) specified plants, other than the ones referred to in points (c) and (d), which have not been immediately subjected to sampling and molecular testing and have not been found free from the specified pest.
2. When removing the plants referred to in paragraph 1, the Member State concerned shall take all necessary precautions into account, and shall organise the removal on the basis of the level of risk posed by those plants
3. By way of derogation from points (b), (c) and (d) of paragraph 1, Member States may decide that individual specified plants officially designated as plants with historic value do not need to be removed, provided that all of the following conditions have been fulfilled:
 - (a) the specified plants concerned are subject to annual inspection, sampling and testing by one of the molecular tests listed in Annex IV and it is confirmed that they are not infected by the specified pest;
 - (b) the individual specified plants or the area concerned are subject to appropriate phytosanitary treatments against all stages of the vector population of the specified pest. Those treatments may include chemical, biological or mechanical methods, taking into account the local conditions.

Article 8

Measures against the vectors of the specified pest

1. The Member State concerned shall apply appropriate phytosanitary treatments, in the infected zone, against all stages of the vector population of the specified pest. It shall apply those treatments prior to and during the removal of the plants referred to in Article 7(1). Those treatments shall include efficient chemical, biological or mechanical treatments against the vectors, taking into account the local conditions.
2. The Member State concerned apply agricultural practices for the control of all stages of the vector population of the specified pest in the infected zone and in the buffer zone. It shall apply those practices at the most appropriate time of the year, regardless of the removal of the plants concerned. Those practices shall include efficient chemical, biological or mechanical treatments against the vectors, as appropriate, taking into account the local conditions.

Article 9
Destruction of plants

1. The Member State concerned shall destroy the plants and parts of plants referred to in Article 7(1), in a manner ensuring that the specified pest is not spread, *in situ* or in a nearby location designated for this purpose within the infected zone or, provided that those plants or parts of plants are covered by net against the vectors, at the shortest distance from that location.
2. The Member State concerned may decide, on the basis of the risk level, to limit the destruction to the branches and foliage only and subject the related wood to phytosanitary treatment as referred to in Article 8(1). The root system of those plants shall be either removed or devitalised, with an appropriate phytosanitary treatment to avoid resprouting.

Article 10
Annual surveillance of the demarcated area

In the entire demarcated area, the Member State concerned shall monitor, at the most appropriate times, the presence of the specified pest by annual surveys, in accordance with Article 2(5) and (6), and taking into account the information referred to in the Authority's Pest Survey Card on *Xylella fastidiosa*.

In the infected zones, the Member State concerned shall sample and test the host plants, including the specified plants which have not been removed pursuant to Article 7(1). For that purpose, and taking into account the Authority's Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme shall be able to identify with at least 90% confidence a level of presence of infected plants of 0,5%.

In buffer zones, the Member State concerned shall sample and test the host plants, as well as other plants showing symptoms indicating possible infection or suspected to be infected by that pest. For that purpose, and taking into account the Authority's Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme shall be able to identify with at least 90 % confidence a level of presence of infected plants of 1%, taking into account that the first 400 m surrounding the infected zones has a higher risk.

The Member State concerned shall also monitor the presence of the specified pest in the vectors located in the demarcated area in order to determine the risk of further spreading posed by vectors and to evaluate the effectiveness of the phytosanitary control measures applied in accordance with Article 8.

Article 11
Other relevant measures for the eradication of the specified pest

1. The Member State concerned shall take any other measure which may contribute to the eradication of the specified pest, in accordance with International Standard for Phytosanitary Measure ("ISPM") No 9⁹ and applying an integrated approach in accordance with the principles set out in ISPM No 14¹⁰.

⁹ Guidelines for pest eradication programmes — Reference Standard ISPM No 9 by the Secretariat of the International Plant Protection Convention, Rome. Published 15 December 2011.

¹⁰ The use of integrated measures in a systems approach for pest risk management — Reference Standard ISPM No 14 by the Secretariat of the International Plant Protection Convention, Rome. Published 8 January 2014.

2. The Member State concerned shall take measures addressing any particularity or complication that could reasonably be expected to prevent, hinder or delay eradication, in particular those related to the accessibility and adequate destruction of all plants that are infected or suspected of infection, or of their location, public or private ownership or the person or entity responsible for them.
3. The Member State concerned shall carry out appropriate investigations to identify the origin of the infection. It shall trace the host plants associated with the case of infection concerned, including those which were moved before a demarcated area was established. The results of such investigations shall be communicated to the Commission and the Member States in which those plants concerned originate, to the Member States through which those plants have moved and to the Member States where those plants have moved into.

CHAPTER V CONTAINMENT MEASURES

Article 12

General provisions

The competent authority of the Member State concerned may decide to apply the containment measures set out in Articles 13 to 17, instead of eradication measures, in an infected zone listed in Annex III.

Article 13

Removal of plants in an infected zone listed in Annex III

1. The Member State concerned shall remove all plants which have been found to be infected by the specified pest on the basis of the monitoring referred to in Article 15(2).

That removal shall take place immediately after the official identification of the presence of the specified pest or, if the specified pest is detected outside the flight season of the vector, that removal shall take place before the next flight season of the vector. All necessary precautions shall be taken to avoid spreading of the specified pest and its vectors during and after removal.
2. By way of derogation from paragraph 1, the Member State concerned may decide, for scientific purposes, not to remove plants which have been found to be infected by the specified pest in the sites of plants with particular cultural and social value, referred to in Article 15(2)(b).

Article 14

Measures against the vectors of the specified pest in the infected zones listed in Annex III

1. The Member State concerned shall apply appropriate phytosanitary treatments against all stages of the vector population of the specified pest on the plants referred to in Article 13(1) prior to their removal and around the plants referred to in Article 13(2). Those treatments shall include efficient chemical, biological or mechanical treatments against the vectors, taking into account the local conditions.

2. In the areas referred to in points (a) and (b) of Article 15(2), the Member State concerned shall apply agricultural practices for the control of all stages of the vector population of the specified pest at the most appropriate time of each year. Those practices shall include efficient chemical, biological or mechanical treatments against the vectors, taking into account the local conditions.

Article 15

Annual surveillance of the infected zones listed in Annex III

1. The Member State concerned shall, at least in the parts of the infected zone referred to in paragraph 2, immediately sample and test, within a radius of 50 m around the plants which have been found to be infected by the specified pest, the following plants:
 - (a) all specified plants which belong to the species of the specified plants which have been found infected in the same demarcated area; and
 - (b) all other plants showing symptoms indicating possible infection by that pest or suspected to be infected by that pest.
2. The Member State concerned shall monitor, at the most appropriate times, the presence of the specified pest by annual surveys, taking into account the information referred to in the Authority's Pest Survey Card on *Xylella fastidiosa*. That monitoring shall take place at least in the following parts of the infected zone listed in Annex III:
 - (a) within an area measuring at least 5 km from the border of the infected zone with the buffer zone;
 - (b) in the proximity of the sites of plants with particular cultural and scientific value located outside the area referred to in point (a) and designated accordingly by the Member State.

In those parts of the infected zone, the Member State concerned shall carry out sampling and testing of the species of host plants found infected in the demarcated area, in accordance with Article 2(6). For that purpose, taking into account the Authority's Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme shall be able to identify with at least 90% confidence a level of presence of infected plants of 0,7%. It shall also sample and test the vector population for the presence of the specified pest.
3. Point (a) of paragraph 2 shall not apply in the case of islands which are entirely under containment measures and are situated more than 5 km to the nearest Union land territory.
4. In buffer zones, the Member State concerned shall sample and test the host plants, as well as other plants showing symptoms indicating possible infection by that pest or suspected to be infected by that pest. For that purpose, taking into account the Authority's Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme shall be able to identify with at least 90 % confidence a level of presence of infected plants of 1%, taking into account that the first 400 m adjacent to the infected zones pose a higher risk.
5. The Member State shall monitor the presence of the specified pests in vectors in the parts of the infected zone referred to in paragraph 2 and in the buffer zone in order to determine the risk of further spreading posed by vectors and to evaluate the

effectiveness of the phytosanitary control measures applied in accordance with Article 14.

Article 16

Destruction of plants

1. The Member State concerned shall, in situ or in a nearby location designated for this purpose within the infected zone listed in Annex III, destroy plants and parts of plants which have been found to be infected by the specified pest, in a manner ensuring that the specified pest is not spread.
2. The Member State concerned may decide to limit the destruction to branches and foliage only and subject the related wood to appropriate phytosanitary treatments in accordance with Article 14(1), where it concludes that those plants do not pose any risk for further spreading of the specified pest. The root system of those plants shall be either removed or devitalised with an appropriate phytosanitary treatment to avoid resprouting.

Article 17

Other relevant measures for the containment of the specified pest

The Member State concerned shall take measures addressing any particularity or complication that could reasonably be expected to prevent, hinder or delay containment, in particular those related to the accessibility and adequate destruction of all plants that are infected or suspected of infection, or of their location, public or private ownership or the person or entity responsible for them.

CHAPTER VI

PLANTING OF SPECIFIED PLANTS IN INFECTED ZONES

Article 18

Authorisation concerning the planting of specified plants in infected zones

The planting of specified plants in infected zones may only be authorised by the Member State concerned in one of the following cases:

- (a) those specified plants are grown in insect-proof sites of production free from the specified pest and its vectors;
- (b) those specified plants preferably belong to varieties assessed as being resistant or tolerant to the specified pest and are planted in the infected zones listed in Annex III, but outside the area referred to in Article 15(2)(a);
- (c) those specified plants belong to the same species of plants which have been tested and found free from the specified pest on the basis of the survey activities carried out for at least the past two years in accordance with Article 10 and are planted in the infected zones established for the purpose of eradication.

CHAPTER VII

MOVEMENT WITHIN THE UNION OF SPECIFIED PLANTS

Article 19

Movement out of a demarcated area, and from the respective infected zones into the

buffer zones, of specified plants which have been grown in authorised production sites located in that demarcated area

The movement out of a demarcated area, and from the respective infected zones into the buffer zones, of specified plants which have been grown in a production site located in that demarcated area, may only be allowed where all of the following conditions are fulfilled:

- (a) the specified plants have been grown during their entire production cycle in a site that has been authorised in accordance with Article 24 or have been present in such a site for at least the last three years;
- (b) throughout the time of growth of the specified plants, neither the presence of the specified pest nor that of its vectors were found in the site;
- (c) the specified plants are subject to phytosanitary treatments against all stages of the vector population at appropriate times of the year to maintain freedom from vectors of the specified pest. Those treatments shall include, as appropriate, efficient chemical, biological or mechanical methods, taking into account the local conditions.
- (d) the specified plants are transported through or within the demarcated area in closed containers or packaging, ensuring that infection with the specified pest or any of its vectors cannot occur.
- (e) As close as possible to the time of movement, the specified plants have been subjected to molecular testing for the presence of the specified pest on the basis of a test listed in Annex IV, using a sampling scheme able to identify with at least 80% confidence a level of presence of infected plants of 1%.

Article 20

Movement out of a demarcated area, and from the respective infected zones into the buffer zones, of specified plants which have never been found infected in that demarcated area

The movement out of a demarcated area, and from the respective infected zone into the buffer zones, of specified plants which have never been found infected in that demarcated area, may only be allowed where all of the following conditions are fulfilled:

- (a) the specified plants have been grown in a site that belongs to a professional operator registered in accordance with Article 65 of Regulation (EU) 2016/2031;
- (b) the specified plants belong to species of plants which have been grown for at least part of their life in a demarcated area and have been subjected, during three years from the establishment of the demarcated area, to survey activities as referred to in Articles 10 and 15 and never found to be infected with the specified pest;
- (c) the species of the specified plants referred to in point (b) are published in the Commission database of host plants which are not known to be infected in that specific demarcated area;
- (d) the specified plants are subject to phytosanitary treatments against all stages of the vector population at appropriate times of the year to maintain freedom from vectors of the specified pest. Those treatments shall include, as appropriate, efficient chemical, biological or mechanical methods based on local conditions;
- (e) as practically close to the time of movement as possible, the lots of the specified plants were subjected to official inspection and molecular testing, using a sampling

scheme able to identify with at least 95 % confidence a level of presence of infected plants of 1%;

- (f) as practically close to the time of movement as possible, the lots of the specified plants were subjected to phytosanitary treatments against any of the vectors of the specified pest.

Article 21

Movement out of a demarcated area, and from the respective infected zones into the buffer zones, of specified plants which have been grown for the entire production cycle *in vitro* in that demarcated area

The movement out of a demarcated area, and from the respective infected zones into the buffer zones, of specified plants which have been grown for the entire production cycle *in vitro* in that demarcated area, may only be allowed where all of the following conditions are fulfilled:

- (a) the specified plants have been grown for their entire production cycle in a site that has been authorised in accordance with Article 24;
- (b) the specified plants have been grown in a transparent container under sterile conditions and fulfil one of the following conditions:
- (i) they have been grown from seeds;
 - (ii) they have been propagated, under sterile conditions, from mother plants which have spent their entire lives in an area of the Union territory free from the specified pest and which have been tested and found free from the specified pest;
 - (iii) they have been propagated, under sterile conditions, from mother plants which have been grown in a site fulfilling the conditions laid down in Article 19 and which have been tested and found free from the specified pest using a sampling scheme able to identify with at least 95 % confidence a level of presence of infected plants of 1%;
- (c) the specified plants are transported through or within demarcated areas in a container under sterile conditions that precludes the possibility of infection by the specified pest through its vectors.

Article 22

Movement out of a demarcated area, and from the respective infected zones into the buffer zones, of dormant plants of *Vitis* which have been grown for part of their life in that demarcated area

Movement out of a demarcated area, and from the respective infected zones into the buffer zones, of dormant plants of *Vitis* intended for planting, other than seeds, which have been grown for part of their life in that demarcated area and are listed as specified plants for that demarcated area, may only be allowed where all of the following conditions are fulfilled:

- (a) the plants have been grown in a site that belongs to an operator registered in accordance with Article 65 of Regulation (EU) 2016/2031;
- (b) as practically close to the time of movement as possible, the plants have undergone an appropriate thermotherapy treatment in a treatment facility authorised and

supervised by the competent authority for that purpose, whereby the dormant plants are submerged for 45 minutes in water heated to 50 °C.

Article 23

Movement within the infected zones and within the buffer zones of specified plants which have been grown for part of their life in a demarcated area

The movement within the infected zones and within the buffer zones of specified plants which have been grown for at least part of their life in a demarcated area may only be allowed where all of the following conditions are fulfilled:

- (a) the specified plants have been grown in a site that belongs to an operator registered in accordance with Article 65 of Regulation (EU) 2016/2031;
- (b) that site is subject to annual sampling and testing for the presence of the specified pest, taking into account the information set out in the Authority's Pest Survey Card on *Xylella fastidiosa*;
- (c) the results of the annual official inspection and of the testing of a representative sample confirm the absence of the specified pest;
- (d) the specified plants are subject to phytosanitary treatments against all stages of the vector population at appropriate times of the year to maintain freedom from vectors of the specified pest. Those treatments shall include, as appropriate, efficient chemical, biological or mechanical methods, taking into account the local conditions;
- (e) the professional operators shall ask the person receiving those plants to sign a declaration that those plants are not going to be moved out of those zones.

Article 24

Authorisation of production sites

1. The competent authority may only authorise a production site for the purposes of Articles 19 and 21 where it fulfils all of the following conditions:
 - (a) it is registered in accordance with Article 65 of Regulation (EU) 2016/2031;
 - (b) it has been authorised by the competent authority as a site physically protected against the specified pest and its vectors;
 - (c) it has been subjected annually to at least two official inspections, at the most appropriate time.
2. Where, during the annual official inspections, the competent authorities detect the presence of the specified pest, as well as damages to the physical protection referred to in point (b) of paragraph 1, they shall immediately revoke the authorisation of the site and temporarily suspend the movement of the specified plants out of the demarcated areas concerned, and from the respective infected zones into the buffer zones.
3. Each Member State shall establish and update a list of all sites authorised in accordance with paragraph 1.

It shall transmit that list to the Commission and the other Member States immediately after establishing or updating that list.

Article 25

Movement within the Union of specified plants which have never been grown inside a demarcated area

1. Specified plants which have never been grown inside a demarcated areas may only be moved within the Union where they have been grown in a site that fulfils the following conditions:
 - (a) it belongs to a professional operator registered in accordance with Article 65 of Regulation (EU) 2016/2031 and is subject to annual official inspection;
 - (b) it is subject, as appropriate for the level of risk, to sampling and testing for the presence of the specified pest, using a test listed in Annex IV and taking into account the information set out in the Authority's Pest Survey Card on *Xylella fastidiosa*.
2. By way of derogation from paragraph 1, plants for planting, other than seeds, of *Coffea*, *Lavandula dentata* L., *Nerium oleander* L., *Olea europaea* L., *Polygala myrtifolia* L. and *Prunus dulcis* (Mill.) D.A. Webb, may only be moved for the first time within the Union where the following conditions are fulfilled:
 - (a) they have been grown in a site that is subject to annual official inspection;
 - (b) that site is subject to sampling and testing for the presence of the specified pest, taking into account the information set out in the Authority Pest Survey Card on *Xylella fastidiosa* and using a sampling scheme able to identify with at least 80 % confidence a level of presence of infected plants of 1%,
 - (c) the results of the annual official inspection and of the sampling and testing confirm the absence of the specified pest.

Article 26

Movement within the Union of pre-basic mother plants or pre-basic material, which have been grown outside a demarcated area

Pre-basic mother plants as defined in Article 1(3) of Commission Implementing Directive 2014/98/EU¹¹ or pre-basic material as defined in Article 2(5) of Council Directive 2008/90/EC¹² which belong to the species *Juglans regia* L., *Olea europaea* L., *Prunus amygdalus* Batsch, *P. amygdalus* x *P. persica*, *P. armeniaca* L., *P. avium* (L.) L., *P. cerasus* L., *P. domestica* L., *P. domestica* x *P. salicina*, *P. dulcis* (Mill.) D.A. Webb, *P. persica* (L.) Batsch, and *P. salicina* Lindley and which have been grown outside a demarcated area and spent at least part of their life outside insect-proof facilities, may only be moved within the Union where they are accompanied by a plant passport and the following conditions have been fulfilled:

- (a) they have been certified in accordance with Article 1 of Commission Implementing Decision (EU) 2017/925¹³;

¹¹ Commission Implementing Directive 2014/98/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections, OJ L 298, 16.10.2014, p. 22.

¹² Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production, OJ L 267, 8.10.2008, p. 8.

¹³ Commission Implementing Decision (EU) 2017/925 of 29 May 2017 temporarily authorising certain Member States to certify pre-basic material of certain species of fruit plants, produced in the field under non-insect proof conditions, and repealing Implementing Decision (EU) 2017/167, OJ L 140, 31.5.2017, p.7.

- (b) within the shortest possible time prior to their movement, they have been subjected to visual inspection, sampling and molecular testing for the presence of the specified pest carried out in accordance with International Standards for Phytosanitary Measures.

Article 27

Plant passports

The plants referred to in Articles 19 to 26 shall only be moved within the Union if accompanied by a plant passport, subject to the requirements of Articles 78 to 95 of Regulation (EU) 2016/2031.

In the case of the specified plants referred to in Article 23, the following additional conditions shall apply:

- (a) in the case where they move within the infected zones only, the indication “Infected Zone – XYLEFA” shall be included next to the traceability code referred to in point (e) of Part A of Annex VII to Regulation (EU) 2016/2031;
- (b) in the case where they move within the buffer zone, or from the buffer zone into the infected zone, the indication “Buffer Zone and Infected Zone – XYLEFA” shall be included next to the traceability referred to in point (e) of Part A of Annex VII to Regulation (EU) 2016/2031.

CHAPTER VIII

INTRODUCTION INTO THE UNION OF HOST PLANTS

Article 28

Introduction into the Union of host plants originating in a third country where the specified pest is known not to be present

Host plants originating in a third country where the specified pest is known not to be present, may only be introduced into the Union where the following conditions are fulfilled:

- (a) the national plant protection organisation of the third country concerned has communicated in writing to the Commission that the specified pest is known not to be present in the country on the basis of official inspection, sampling and molecular testing, using a test listed in Annex IV, and in accordance with relevant International Standards for Phytosanitary Measures. Taking into account the Authority’s Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme used are able to identify with at least 80% confidence a level of presence of infected plants at national level of 1%;
- (b) the host plants are accompanied by a phytosanitary certificate stating under the rubric ‘Additional Declaration’ that the specified pest is not present in the country;
- (c) host plants have been grown in a site that is subject to annual official inspection and, as appropriate for the level of risk, with sampling and testing, listed in Annex IV, carried out at the appropriate times on those plants for the presence of the specified pest;
- (d) plants for planting, other than seeds, of *Coffea*, *Lavandula dentata* L., *Nerium oleander* L., *Olea europaea* L., *Polygala myrtifolia* L. and *Prunus dulcis* (Mill.) D.A. Webb, have been grown in a site that is subject to annual official inspection, with sampling and testing, listed in Annex IV, carried out at the appropriate times on

those plants for the presence of the specified pest, using a sampling scheme able to identify with at least 80 % confidence a level of presence of infected plants of 1%.

- (e) on entry into the Union, the host plants have been checked by the competent authority in accordance with Article 33 and the presence of the specified pest has not been found.

Article 29

Introduction into the Union of host plants originating in a pest free area of an infected country

Host plants originating in a third country where the specified pest is known to be present may only be introduced into the Union where all of the following conditions are fulfilled:

- (a) the host plants originate in an area which has been declared to be free from the specified pest, by the national plant protection organisation concerned in accordance with the relevant International Standards for Phytosanitary Measures and on the basis of official surveys based on sampling and testing, using a test listed in Annex IV. Taking into account the Authority's Guidelines for statistically sound and risk-based surveys of *Xylella fastidiosa*, the survey design and sampling scheme used are able to identify with at least 80% confidence a level of presence of infected plants of 1%;
- (b) the national plant protection organisation of the third country concerned has communicated in writing to the Commission the name of that area;
- (c) the host plants are accompanied by a phytosanitary certificate stating under the rubric 'place of origin' that the host plants concerned have spent their entire life in the area referred to in point (a), with specific reference to the name of that area;
- (d) host plants have been grown in a site that is subject to annual official inspection and, as appropriate for the level of risk, with sampling and testing, listed in Annex IV, carried out at the appropriate times on those plants for the presence of the specified pest;
- (e) plants for planting, other than seeds, of *Coffea*, *Lavandula dentata* L., *Nerium oleander* L., *Olea europaea* L., *Polygala myrtifolia* L. and *Prunus dulcis* (Mill.) D.A. Webb, have been grown in a site that is subject to annual official inspection, with sampling and testing, listed in Annex IV, carried out at the appropriate times on those plants for the presence of the specified pest, using a sampling scheme able to identify with at least 80 % confidence a level of presence of infected plants of 1%.
- (f) on entry into the Union, the host plants have been checked by the competent authority in accordance with Article 33 and the presence of the specified pest has not been found.

Article 30

Introduction into the Union of host plants originating in a pest free production site of an infected country

1. Host plants originating in a third country where the specified pest is known to be present may only be introduced into the Union where the following conditions are fulfilled:
 - (a) the host plants originate in a production site that has been authorised as pest free by the national plant protection organisation in accordance with Article 31;

- (b) the national plant protection organisation of the third country concerned has communicated in writing to the Commission the list of pest free production sites, including their location within the country;
- (c) the host plants are accompanied by a phytosanitary certificate stating the following:
 - (i) under the rubric ‘additional declaration’, that the host plants have been produced for their entire production cycle in one or more sites authorised as pest free by the national plant protection organisation in accordance with Article 31 and that the host plants have been transported in closed containers or packaging, ensuring that infection with the specified pest or any of its known vectors cannot occur;
 - (ii) under the rubric ‘place of origin’, the name or code of the pest free production site(s).
- (d) on entry into the Union, the host plants have been checked by the competent authority in accordance with Article 33 and the presence of the specified pest has not been found.

2. Host plants which originate in a third country where the specified pest is known to be present and have been grown for the entire production cycle *in vitro*, may only be introduced into the Union where the following conditions are fulfilled:

- (a) the host plants meet one of the following conditions:
 - (i) they have been grown from seeds;
 - (ii) they have been propagated, under sterile conditions, from mother plants which have spent their entire lives in an area free from the specified pest and which have been tested and found free from the specified pest;
 - (iii) they have been propagated, under sterile conditions, from mother plants which have been grown in a site fulfilling the conditions of Article 26 and which have been tested and found free from the specified pest.
- (b) the host plants have been grown in a production site that has been authorised as pest free by the national plant protection organisation in accordance with Article 31;
- (c) the national plant protection organisation of the third country concerned has communicated in writing to the Commission the list of pest free production sites, including their location within the country.;
- (d) the host plants are accompanied by a phytosanitary certificate stating the following:
 - (i) under the rubric ‘additional declaration’, that the host plants have been produced *in vitro* for their entire production cycle in one or more sites authorised as pest free by the national plant protection organisation in accordance with Article 30 and that the host plants have been transported in closed containers or packaging, ensuring that infection with the specified pest or any of its known vectors cannot occur;
 - (ii) under the rubric ‘place of origin’, the name or code of the pest free production site.

Article 31

Authorisation of production sites as pest free

1. A production site may only be authorised as pest free where all of the following conditions are fulfilled:
 - (a) the production site has been declared by the national plant protection organisation as an insect-proof site free from the specified pest and its vectors, in accordance with the relevant International Standards for Phytosanitary Measures;
 - (b) the production site has undergone phytosanitary treatments against all stages of the vector population at appropriate times of the year to maintain freedom from vectors of the specified pest. Those treatments shall include efficient chemical, biological or mechanical methods based on local conditions;
 - (c) the production site is subjected annually to at least two official inspections, at the most appropriate time;
 - (d) as close as possible to the time of movement, the host plants originating in the production site have been subjected to molecular testing for the presence of the specified pest on the basis of a test listed in Annex IV and using a sampling scheme able to identify with at least 90% confidence a level of presence of infected plants of 1%.

Where during the annual official inspections, the competent authorities detect the presence of the specified pest, as well as damages hindering the insect-proof conditions of the pest free production site, they shall immediately revoke the authorisation of the site and temporarily suspend the movement of the host plants. They shall immediately inform the Commission thereof.

CHAPTER IX OFFICIAL CHECKS ON MOVEMENT OF SPECIFIED PLANTS WITHIN, AND OF HOST PLANTS INTO, THE UNION

Article 32

Official checks on movements of specified plants within the Union

1. Member States shall carry out systematic official checks on specified plants being moved out of a demarcated area, or from an infected zone to a buffer zone.
2. Such checks shall be performed at least in the locations, including roads, airports and ports, where the host plants are moved from infected zones into buffer zones or other parts of the Union territory.

Those checks shall include a documentary check, and an identity check of the specified plants.
4. Those checks shall be carried out irrespective of the declared origin of the specified plants, ownership or the person or entity responsible for them.
5. Where those checks show that the conditions laid down in Articles 19 to 23 are not satisfied, the Member State which carried them out shall immediately destroy the non-compliant plant *in situ* or in a nearby location. That action shall be carried out

taking all necessary precautions to avoid spreading of the specified pest, and any vectors carried by that plant, during and after removal.

Article 33

Official checks at introduction into the Union

1. All consignments of host plants introduced into the Union from a third country shall be officially checked at the point of entry into the Union or at the place of destination established in accordance with Commission Directive 2004/103/EC¹⁴.
2. In case of host plants originating in areas where the specified pest is known to occur, the competent authority shall carry out an inspection, consisting of sampling and testing of the lot of the specified plants to confirm the absence of the specified pest, using a sampling scheme able to identify with at least 80% confidence, a level of infected plants of 1%, taking account of ISPM No 31.
3. Paragraph 2 shall not apply to host plants which have been grown for the entire production cycle *in vitro* and are transported in transparent containers under sterile conditions.

CHAPTER X COMMUNICATION ACTIVITIES

Article 34

Awareness campaigns

1. Member States shall make information available to the general public, travellers, professional and international transport operators concerning the threat of the specified pest for the Union territory. They shall make that information publicly available, in the form of targeted awareness campaigns on the respective websites of the competent authority or other websites designated by those bodies.
2. Within the demarcated areas, the Member State concerned shall raise public awareness concerning the threat of the specified pest and the measures adopted to prevent its introduction into and spread within the Union. It shall ensure that the general public, travellers and relevant operators are aware of the delimitation of the demarcated area, the infected zone and the buffer zone. The Member State concerned shall also inform relevant operators about the measures to take against the vector as laid down in Articles 8 and 14.

CHAPTER XI FINAL PROVISIONS

Article 35

Reporting on measures by Member States

1. Member States shall, by 30 April of each year, transmit to the Commission and to the other Member States a report on the measures taken during the preceding year, pursuant to Articles 2, 4, 5, 7 to 18 and 32, as applicable, and on the results of those measures.

¹⁴

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.

2. Member States shall, by 31 December of each year, transmit to the Commission and the other Member States a plan setting out the measures to be taken pursuant to Articles 2, 4, 5, 7 to 18 and 32, as applicable, in the following year. That plan shall set out the scheduled time period of each measure, the deadlines for implementing the measures and the allocated budget for all measures.
3. Where justified by the development of the respective phytosanitary risk, Member States shall adapt the respective measures and accordingly update the plan referred to paragraph 2. They shall immediately communicate that update to the Commission and the other Member States.
4. The Member State concerned shall immediately notify the Commission and the other Member States of any official identification of the presence of the specified pest in the locations referred to in Article 15(2)(a).

Article 36
Compliance

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

Article 37
Repeal

Implementing Decision (EU) 2015/789 is repealed.

Article 38
Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*. However, the second sentence of Article 2(4), the second sentence of Article 28(a) and the second sentence of Article 29(b) shall apply from 1 January 2023.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN