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Taqsima B

L.N. 315 of 2017

PLANT QUARANTINE ACT
(CAP. 433)

Control of *Xylella fastidiosa* (Wells et al.) Regulations, 2017

IN exercise of the powers conferred by article 32 of the Plant Quarantine Act, the Minister for the Environment, Sustainable Development and Climate Change has made the following regulations:-

Citation and scope.

1. (1) The title of these regulations is the Control of *Xylella fastidiosa* (Wells et al.) Regulations, 2017.

(2) These regulations provide the measures to be taken to control and contain *Xylella fastidiosa* and to prevent it from spreading and the implementation of 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.) and its amendments.

Interpretation.

2. In these regulations, unless the context otherwise requires:

"the Act" means the Plant Quarantine Act; Cap. 433.

"the Commission" means the Commission of the European Union;

"the Directorate" means the Directorate responsible for plant health;

"the Director" means the Director responsible for plant health;

"host plants" means plants for planting, other than seeds, belonging to the genera and species listed in the Commission database of host plants susceptible to *Xylella fastidiosa* in the Union territory, as having been found to be susceptible in the Union territory to the specified organism or, where a Member State has demarcated an area with regard to only one or more subspecies of the specified organism pursuant to the proviso to regulation 6(1), as having been found to be susceptible to that or those subspecies;

"the Minister" means the Minister responsible for agriculture;

"professional operator" means any person involved professionally in one or more of the following activities concerning plants:

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(a) planting;

(b) breeding;

(c) production, including growing, multiplying and maintaining;

(d) introduction into, and movement within, and out of the Union territory;

(e) making available on the market;

"the specified organism" means any subspecies of *Xylella fastidiosa* (Wells et al.);

"specified plants" means host plants and all plants for planting, other than seeds, belonging to the genera or species included in the list of plants known to be susceptible to the European and non-European isolates of the pest as published in the Government Gazette and the Directorate's website and which is updated accordingly from time to time;

"the Union" means the European Union.

Detection or suspected presence of the specified organism.

3. (1) Any person who suspects or becomes aware of the specified organism shall immediately inform the Directorate and provide it with all relevant information concerning the presence, or suspected presence, of the specified organism.

(2) The Directorate shall immediately record such information.

(3) Where the Directorate 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) The Directorate shall ensure that any person having under his control plants which may be infected with the specified organism is immediately informed of the suspected presence of the specified organism, of the possible consequences and risks and of the measures to be taken.

Surveys of the specified organism.

4. (1) The Directorate shall conduct annual surveys for the presence of the specified organism on the specified plants. Those surveys may be carried out under official supervision of the Directorate. They shall consist of visual examinations and, in the case of any suspicion of infection by the specified organism, collection of

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samples and testing. Those surveys shall be based on sound scientific and technical principles and shall be carried out at appropriate times of the year with regards to the possibility to detect the specified organism. Those surveys shall take account of the available scientific and technical evidence, the biology of specified organism and its vectors, the presence and biology of specified plants, and any other appropriate information concerning the presence of the specified organism.

(2) The Director may request the placement of traps for the monitoring of the presence of the vector and which shall be collected by the Directorate from time to time for such determination..

Contingency plans.

5. (1) The Directorate shall establish a plan setting out the actions to be taken in its territory in accordance with regulations 5 to 8 and regulations 10 to 14 in case of a confirmed or suspected presence of the specified organism (hereinafter "the contingency plan").

(2) The contingency plan shall also set out the following:

(a) the roles and responsibilities of the bodies involved in those actions and the single authority;

(b) one or more laboratories specifically approved for the testing of the specified organism;

(c) rules on the communication of those actions between the bodies involved, the single authority, the professional operators concerned and the public;

(d) protocols describing the methods of visual examinations, sampling and laboratory testing;

(e) rules on training of personnel of the bodies involved in those actions;

(f) minimum resources to be made available and proceedings to make available additional resources in case of a confirmed or suspected presence of the specified organism.

(3) The Directorate shall evaluate and review the contingency plans as necessary.

(4) The Directorate shall communicate the contingency plans to the Commission at its request.

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Establishment of demarcated areas.

6. (1) Where the presence of the specified organism is confirmed, the Directorate shall without delay demarcate an area, hereinafter referred to as a "demarcated area", in accordance with sub-regulation (2):

Provided that where the presence of one or more particular subspecies of the specified organism is confirmed, the Directorate may demarcate an area with regard to that or those subspecies only.

(2) The demarcated area shall consist of an infected zone and a buffer zone.

(a) The infected zone shall include all plants known to be infected by the specified organism, all plants showing symptoms indicating possible infection by that organism, and all other plants liable to be infected by that organism due to their close proximity to infected plants, or common source of production, if known, with infected plants, or plants grown from them.

(b) The buffer zone shall be of a width of at least 10km, surrounding the infected zone.

The exact delimitation of the zones shall be based on sound scientific principles, the biology of the specified organism and its vectors, the level of infection, the presence of the vectors and the distribution of specified plants in the area concerned.

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

(4) If the Directorate confirms the presence of the specified organism and is notified in accordance with EU legislation, it shall communicate the demarcated area to the Commission.

(5) Where, based on the surveys which the Directorate performs on the specified organism as in regulation 4 and on the monitoring referred to in regulation 8(7), the specified organism is not detected in a demarcated area for a period of five years, this demarcation may be lifted. In such cases, the Directorate shall notify the Commission and other Member States.

(6) Notwithstanding the provisions of sub-regulation (1), the Directorate may decide not to establish a demarcated area immediately where all of the following conditions are fulfilled:

(a) there is evidence that the specified organism was

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recently introduced into the area with the plants on which it was found;

(b) there is an indication that those plants were infected before their introduction into the area concerned;

(c) no vectors carrying the specified organism have been detected, on the basis of tests carried out in accordance with internationally validated testing methods, in the vicinity of those plants.

(7) In the case referred to in sub-regulation (6), the Directorate shall:

(a) carry out an annual survey for at least two years to determine whether any plants, other than those on which the specified organism was first found to be present, have been infected;

(b) on the basis of that survey, determine whether there is a need to establish a demarcated area;

(c) 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 paragraph (a) as soon as they become available.

Prohibition concerning the planting of host plants in infected zones.

7. (1) The planting of host plants in infected zones shall be prohibited, except in sites which are physically protected against the introduction of the specified organism by its vectors.

(2) Notwithstanding the provisions of sub-regulation (1), the Directorate may authorise, in accordance with the conditions laid down in regulation 20 of Plant Quarantine (Harmful Organisms) Regulations, the planting of the host plants for scientific purposes within the containment area referred to in regulation 9, outside the area referred to in regulation 9(2)(c).

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Eradication measures.

8. (1) The Directorate, having established the demarcated area referred to in regulation 6, shall take in that area the measures set out in this regulation.

(2) The Directorate shall, within a radius of 100m around the plants which have been tested and found to be infected by the specified organism, immediately remove:

(a) host plants, regardless of their health status;

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(b) plants known to be infected by the specified organism;

(c) plants showing symptoms indicating possible infection by the specified organism or suspected to be infected by that organism.

(3) The Directorate shall sample and test the specified plants within a radius of 100m around each of the infected plants, in accordance with the International Standard for Phytosanitary Measures ISPM No 31 - Methodologies of sampling of consignments.

(4) The Directorate shall carry out appropriate phytosanitary treatments prior to the removal of plants referred to in sub-regulation (2) against the vectors of the specified organism and plants that may host those vectors.

(5) The Directorate shall, *in situ*, or in a nearby location designated for this purpose within the infected zone, destroy the plants and parts of plants referred to in sub-regulation (2), in a manner ensuring that the specified organism is not spread.

(6) The Directorate shall carry out appropriate investigations to identify the origin of the infection and shall trace the specified 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 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.

(7) The Directorate shall monitor the presence of the specified organism by annual surveys at appropriate times and shall carry out visual inspections of the specified plants and sample and test symptomatic plants, as well as asymptomatic plants in the proximity of the symptomatic ones.

In buffer zones, the surveyed area shall be based on a grid split into 100m × 100m squares and visual inspections shall take place in each of those squares.

(8) The Directorate shall raise public awareness concerning the threat of the specified organism and concerning the measures adopted to prevent its introduction into and spread within the Union and shall set up road signs indicating the delimitation of the respective demarcated area.

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(9) The Directorate shall, where necessary, 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, irrespective of their location, public or private ownership or the person or entity responsible for them.

(10) The Directorate shall take any other measure, which may contribute to the eradication of the specified organism, in accordance with ISPM No 9 - Guidelines for pest eradication programmes and applying an integrated approach in accordance with the principles set out in ISPM No 14 - The use of integrated measures in a systems approach for pest risk management.

(11) The Directorate shall apply appropriate agricultural practices for the management of the specified organism and its vectors.

Containment areas.

9. (1) Notwithstanding the provisions of regulation 8, only in the infected zone referred to in regulation 6(2), the Director may decide to apply containment measures, as set out in sub-regulations (2) to (7), hereinafter referred to as "containment areas".

(2) The Director shall immediately authorise the removal of at least all plants which have been found to be infected by the specified organism if they are situated in any of the following locations:

(a) in the proximity of the sites referred to in regulation 10(2);

(b) in the proximity of the sites of plants with particular cultural, social or scientific value;

(c) a location within the infected zone referred to in regulation 6(2), situated within a distance of 20km from the border of that infected zone with the rest of the Union territory.

All necessary precautions shall be taken to avoid spreading of the specified organism during and after removal.

(3) The Director shall order, within a radius of 100m around the plants referred to in sub-regulation (2) and which have been found to be infected by the specified organism, the sampling and testing of the host plants, in accordance with the International Standard for Phytosanitary Measures ISPM No. 31. That testing shall be carried out at regular intervals and at least, twice a year.

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(4) The Director shall order that appropriate phytosanitary treatments are applied prior to the removal of plants referred to in sub-regulation (2) against the vectors of the specified organism and plants that may host those vectors. Those treatments may include, as appropriate, removal of plants.

(5) The Director shall order that, *in situ* or in a nearby location designated for this purpose within the containment area, the plants and parts of plants referred to in sub-regulation (2) are destroyed in a manner ensuring that the specified organism is not spread.

(6) The Director shall order that appropriate agricultural practices are applied for the management of the specified organism and its vectors.

(7) The Directorate shall monitor the presence of the specified organism by annual surveys at appropriate times during the year in the areas situated within the distance of 20 km as referred to in paragraph (c) of sub-regulation (2). Those surveys shall be carried out in accordance with the provisions of regulation 8(7).

Movement of specified plants within the Union.

10. (1) This regulation shall apply to specified plants, other than plants which have been grown for the entire production cycle *in vitro*.

The movement out of the demarcated areas and from the infected zones into the respective buffer zones, of specified plants which have been grown for at least part of their life in a demarcated area established in accordance with regulation 6, shall be prohibited.

(2) Notwithstanding the provisions of sub-regulation (1), such movement can take place if the specified plants have been grown in a site where all of the following conditions are fulfilled:

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(a) it is registered in accordance with the Plant Quarantine (Harmful Organisms) Regulations;

(b) it is authorised by the Directorate as a site free from the specified organism and its vectors, taking into account the relevant International Standards for Phytosanitary Measures;

(c) it is physically protected against the introduction of the specified organism by its vectors;

(d) it is surrounded by a zone with a width of 200m which has been found by official visual inspection and, in the case of suspected presence of the specified organism, by sampling and testing, to be free from the specified organism,

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and is subject to appropriate phytosanitary treatments against the vectors of the specified organism; those treatments may include, as appropriate, removal of plants;

(e) it is subject to appropriate phytosanitary treatments to maintain freedom from vectors of the specified organism; those treatments may include, as appropriate, removal of plants;

(f) it is subjected annually, together with the zone referred to in paragraph (d), to at least two official inspections carried out at appropriate times;

(g) throughout the time of growth of the specified plants, neither symptoms of the specified organism nor its vectors were found in the site or, if suspect symptoms were observed, tests carried out confirmed the absence of the specified organism;

(h) throughout the time of growth of the specified plants, no symptoms of the specified organism were found in the zone referred to in paragraph (d) or, if suspect symptoms were observed, testing has been undertaken and absence of the specified organism has been confirmed.

(3) Representative samples of each species of specified plants from each site have been subject to annual testing, at the most appropriate time, and the absence of the specified organism has been confirmed on the basis of tests carried out in accordance with internationally validated testing methods;

(4) As practically close to the time of movement as possible the lots of the specified plants were subjected to official visual inspection, sampling and molecular testing carried out in accordance with internationally validated testing methods, using a sampling scheme able to identify with 99% reliability a level of presence of infected plants of 1% or above and targeted especially at plants displaying suspect symptoms of the specified organism, in accordance with ISPM No 31.

(5) Notwithstanding the provisions of sub-regulations (1) and (4), the movement within the Union, within or out of demarcated areas, of dormant plants of *Vitis* intended for planting, other than seeds, may take place if both of the following conditions are fulfilled:

(a) the plants have been grown in a site registered in accordance with the Plant Quarantine (Harmful Organisms) Regulations; S.L. 433.03.

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(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 Directorate for that purpose, whereby the dormant plants are submerged for 45 minutes in water heated to 50 degrees Celsius, in accordance with the relevant EPPO standard (Hot water treatment of grapevine to control Grapevine flavescence dorée phytoplasma).

(6) Prior to movement, the lots of the specified plants were subjected to phytosanitary treatments against any of the vectors of the specified organism.

(7) Specified plants moving through or within demarcated areas shall be transported in closed containers or packaging, ensuring that infection with the specified organism or any of its vectors cannot occur.

(8) All plants referred to in sub-regulation (1) shall only be moved to and within the Union territory if they are accompanied by a plant passport prepared and issued in accordance with regulation 8 of the Plant Quarantine (Harmful Organisms) Regulations.

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(9) Host plants which have never been grown inside the demarcated areas shall only be moved within the Union if they are accompanied by a plant passport prepared and issued in accordance with the Standardization and Issue Procedures of Plant Passports Regulations:

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Provided that, without prejudice to Part A of Schedule V of the Plant Quarantine (Harmful Organisms) Regulations, no plant passport shall be required for the movement of host plants to any person, acting for purposes which are outside his trade, business or profession, and who acquires those plants for his own use.

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Movement within the Union of specified plants which have grown *in vitro*.

11. (1) Specified plants which have been grown for the entire production cycle *in vitro* and for at least part of their life in a demarcated area established in accordance with regulation 6, may only be moved out of the demarcated areas and from the infected zones into the respective buffer zones if the conditions set out in sub-regulations (2) to (5) are fulfilled.

(2) The specified plants referred to in sub-regulation (1) have been grown in a site where all of the following conditions are fulfilled:

(a) it is registered in accordance with the Plant Quarantine (Harmful Organisms) Regulations;

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(b) it is authorised by the Directorate as a site free from the specified organism and its vectors, taking into account the relevant International Standards for Phytosanitary Measures;

(c) it is physically protected against the introduction of the specified organism by its vectors;

(d) it is subjected annually to at least two official inspections carried out at appropriate times;

(e) throughout the time of growth of the specified plants, neither symptoms of the specified organism nor its vectors were found in the site or, if suspect symptoms were observed, tests carried out confirmed the absence of the specified organism.

(3) The specified plants referred to in sub-regulation (1) have been grown in a transparent container under sterile conditions and fulfil one of the following conditions:

(a) they have been grown from seeds;

(b) 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 organism and which have been tested and found free from the specified organism;

(c) they have been propagated, under sterile conditions, from mother plants which have been grown in a site fulfilling the conditions set out in sub-regulation (2) and which have been tested and found free from the specified organism.

(4) The specified plants referred to in sub-regulation (1) shall be transported in a transparent container under sterile conditions that precludes the possibility of infection by the specified organism through its vectors.

(5) They shall be accompanied by a plant passport prepared and issued in accordance with the Standardization and Issue Procedures of Plant Passports Regulations. S.L. 433.20

12. (1) Professional operators supplying specified plants which have been grown for at least part of their lives in a demarcated area, or which have been moved through such an area, shall keep a record of each lot supplied and of the professional operator who received it. Traceability.

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(2) Professional operators being supplied with specified plants which have been grown for at least part of their life in a demarcated area, or which have been moved through such an area, shall keep a record of each lot received and of the supplier.

(3) Professional operators shall keep the records referred to in sub-regulations (1) and (2) for a minimum period of three years from the date on which the respective lot was supplied to or by them.

(4) The professional operators referred to in sub-regulations (1) and (2) shall inform the Directorate forty-eight hours prior to the arrival of the plant material in Malta, by means of the EU Plant Movement Notification form available on the Directorate's website, of each lot supplied or received by them. That information shall include the origin, consigner, consignee, place of destination, individual serial, week or batch number of the plant passport and identity and quantity of the lot concerned.

(5) The Directorate receiving information pursuant to sub-regulation (4) shall immediately inform the responsible official body of the place of destination of the lot concerned.

(6) The professional operators being supplied from Union territories with specified plants which have been grown in non-demarcated areas, or which have not been moved in such areas shall also inform the Directorate by means of the EU Plant Movement Notification form available on the Directorate's website forty-eight hours prior to the arrival of the plant material in Malta.

(7) The professional operator being supplied with specified plants referred to in sub-regulation (6) shall keep a record of each lot received and, or supplied to other professional operator/s. The records shall include the notification form, all invoices and accompanying documents (delivery notes or receipts), plant passports in accordance with the Standardization and Issue Procedures of Plant Passports Regulations where applicable.

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(8) The Directorate shall, upon request, make available the information referred to in sub-regulation (4) to the Commission.

Official checks on movements of specified plants.

13. (1) The Directorate shall carry out regular official checks on specified plants being moved out of a demarcated area, or from an infected zone to a buffer zone. Such checks shall be performed at least in:

(a) the points where the specified plants are moved from infected zones into buffer zones;

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(b) the points where the specified plants are moved from buffer zones into non-demarcated areas;

(c) the place of destination of the specified plants in the buffer zone;

(d) the place of destination in the non-demarcated areas.

(2) The checks as referred to in sub-regulation (1) shall include a documentary check, and an identity check of the specified plants.

The checks as referred to in sub-regulation (1) shall be carried out irrespective of the location of the specified plants, ownership or the person or entity responsible for them.

(3) The intensity of the checks referred to in sub-regulation (2) shall be based on the risk that the plants carry the specified organism or the known or potential vectors, taking into account the provenance of the lots, the degree of susceptibility of the plants, and the compliance by the professional operator responsible for the movement with these regulations and with any other measure taken to contain or eradicate the specified organism or any other factor considered relevant by the Directorate.

List of authorised sites.

14. The Director shall establish and update a list of all sites authorised in accordance with regulation 10(2). The Director shall submit that list to the Commission. On the basis of the information received from the Member States, the Commission shall establish and update a list of all sites authorised in the Member States. The Commission shall transmit that list to any Member State.

Measures in case of non-compliance with regulation 10.

15. Where the checks referred to in regulation 13(2) show that the conditions laid down in regulation 10 are not satisfied, the Director 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 organism, and any vectors carried by that plant, during and after removal.

Prohibition of the introduction of plants for planting, other than seeds, of *Coffea* originating in Costa Rica or Honduras.

16. The introduction into the Maltese territory of plants for planting, other than seeds, of *Coffea* originating in Costa Rica or Honduras shall be prohibited. Plants for planting, other than seeds, of *Coffea* originating in Costa Rica or Honduras which have been introduced into the Maltese territory before the coming into force of these regulations shall only be moved within the Maltese territory and the Union by professional operators after they have informed the Directorate.

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Introduction into the Maltese territory and the Union of specified plants originating in a third country where the specified organism is not present.

17. Specified plants originating in a third country where the specified organism is not present may be introduced into the Maltese territory and the Union if 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 organism is not present in the country;

(b) the specified plants are accompanied by a phytosanitary certificate, as referred to in regulation 15 of the Plant Quarantine (Harmful Organisms) Regulations, stating under the rubric 'Additional Declaration' that the specified organism is not present in the country;

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(c) the professional operators being supplied with these specified plants shall also inform the Directorate by means of the Third Countries Notification Form available on the Directorate's website forty-eight hours prior to the arrival of the plant material in Malta;

(d) on entry into the Maltese territory the specified plants have been checked by the Directorate in accordance with regulation 19(2) and neither presence nor symptoms of the specified organism have been found.

Introduction into the Maltese territory and the Union of specified plants originating in a third country where the specified organism is known to be present.
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18. (1) Specified plants originating in a third country where the specified organism is known to be present may be introduced into the Union and the Maltese territory where the following conditions are fulfilled:

(a) they are accompanied by a phytosanitary certificate, as referred to in regulation 15 of the Plant Quarantine (Harmful Organisms) Regulations;

(b) they comply with the provisions of sub-regulation (2) or sub-regulations (3) and (5);

(c) the professional operators being supplied with these specified plants shall also inform the Directorate by means of the Third Countries Notification Form available on the Directorate's website forty-eight hours prior to the arrival of the plant material in Malta.

(d) on entry into the Union and the Maltese territory they have been checked by the Directorate in accordance to regulation 19 and neither presence nor symptoms of the specified organism have been found.

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(2) Where specified plants originate in an area free from the specified organism, as established by the national plant protection organisation concerned in accordance with relevant International Standards for Phytosanitary Measures, the following conditions shall be fulfilled:

(a) the national plant protection organisation of the third country concerned has communicated in writing to the Commission the name of that area;

(b) the name of that area is stated in the phytosanitary certificate under the rubric 'place of origin'.

(3) Where specified plants, other than plants which have been grown for the entire production cycle *in vitro* originate in an area where the specified organism is known to be present, the phytosanitary certificate shall state under the rubric 'Additional Declaration' that:

(a) the specified plants have been produced in one or more sites fulfilling the conditions set out in sub-regulation (5);

(b) the national plant protection organisation of the third country concerned has communicated in writing to the Commission the list of those sites, including their location within the country;

(c) phytosanitary treatments against the vectors of the specified organism are applied in the site and its zone as referred to in sub-regulation (5)(c);

(d) representative samples of each species of specified plants from each site have been subject to annual testing, at the most appropriate time, and the absence of the specified organism has been confirmed on the basis of tests carried out in accordance with internationally validated testing methods;

(e) the specified plants have been transported in closed containers or packaging, ensuring that infection with the specified organism or any of its known vectors cannot occur;

(f) as practically close to the time of export as possible, the lots of the specified plants were subjected to official visual inspection, sampling and molecular testing, carried out in accordance with internationally validated testing methods, confirming the absence of the specified organism, using a sampling scheme able to identify with 99% reliability a level of

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presence of infected plants of 1% or above and targeted especially at plants displaying suspect symptoms of the specified organism;

(g) immediately prior to export, the lots of the specified plants were subjected to phytosanitary treatments against any of the known vectors of the specified organism.

In addition, the phytosanitary certificate referred to in sub-regulation (1)(a) shall indicate under the rubric 'Place of origin' the identification of the site referred to in paragraph (a).

(4) Where specified plants, which have been grown for the entire production cycle *in vitro*, originate in an area where the specified organism is known to be present, the phytosanitary certificate shall state under the rubric 'Additional Declaration' that:

(a) the specified plants have been produced in one or more sites fulfilling the conditions set out in sub-regulation (6);

(b) the national plant protection organisation of the third country concerned has communicated in writing to the Commission the list of those sites, including their location within the country;

(c) the specified plants have been transported under sterile conditions in a transparent container that precludes the possibility of infection by the specified organism through its vectors;

(d) the specified 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 organism and which have been tested and found free from the specified organism;

(iii) they have been propagated, under sterile conditions, from mother plants which have been grown in a site fulfilling the conditions of sub-regulation (5) and which have been tested and found free from the specified organism.

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In addition, the phytosanitary certificate referred to in sub-regulation (1)(a) shall indicate under the rubric 'Place of origin' the site referred to in paragraph (a) of sub-regulation (4).

(5) The site referred to in sub-regulation (3)(a) shall fulfil the following conditions:

(a) it is authorised by the national plant protection organisation as free from the specified organism and its vectors, in accordance with the relevant International Standards for Phytosanitary Measures;

(b) it is physically protected against the introduction of the specified organism by its vectors;

(c) it is surrounded by a zone with a width of 200m which has been found by official visual inspection, and, in case of suspicion of the presence of the specified organism, by sampling and testing, to be free from the specified organism, and is subject to appropriate phytosanitary treatments against the vectors of the specified organism; those treatments may include, as appropriate, removal of plants;

(d) it is subject to phytosanitary treatments that aim to maintain freedom from vectors of the specified organism; those treatments may include, as appropriate, removal of plants;

(e) it is subjected annually, together with the zone referred to in paragraph (c), to at least two official inspections carried out at appropriate times;

(f) throughout the production time of the specified plants, neither symptoms of the specified organism nor its vectors were found in the site, or, if suspect symptoms were observed, testing has been undertaken and absence of the specified organism has been confirmed;

(g) throughout the production time of the specified plants, no symptoms of the specified organism were found in the zone referred to in sub-regulation (4)(c) or, if suspect symptoms were observed, testing has been undertaken and absence of the specified organism has been confirmed.

(6) The site referred to in sub-regulation (4)(a) shall fulfil the following conditions:

(a) it is authorised by the national plant protection

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organisation as free from the specified organism and its vectors, in accordance with the relevant International Standards for Phytosanitary Measures;

(b) it is physically protected against the introduction of the specified organism by its vectors;

(c) it is subjected annually to at least two official inspections carried out at appropriate times;

(d) throughout the production time of the specified plants, neither symptoms of the specified organism nor its vectors were found in the site, or, if suspect symptoms were observed, testing has been undertaken and absence of the specified organism has been confirmed.

Official checks at introduction into the Union and the Maltese territory.

S.L. 433.17

19. (1) All consignments of specified plants introduced into the Union and the Maltese territory from a third country shall be officially checked at the point of entry into the Union and the Maltese territory or at the place of destination established in accordance with the Identity and Plant Health Checks of Plants, Plant Products or other Objects carried out at a place other than Point of Entry into the European Community Regulations and, as applicable, pursuant to sub-regulations (2) or (3), and sub-regulation (4).

(2) In the case of specified plants originating in a third country where the specified organism is not present or in an area referred to in regulation 17(2), the Directorate shall carry out the following checks:

(a) a visual inspection; and

(b) in the case of suspicion of the presence of the specified organism, sampling and testing of the lot of the specified plants to confirm the absence of the specified organism or its symptoms.

(3) In the case of specified plants originating in an area where the specified organism is known to be present, the Directorate shall carry out the following checks:

(a) a visual inspection; and

(b) sampling and testing of the lot of the specified plants to confirm the absence of the pest or its symptoms.

(4) The samples referred to in sub-regulations (2)(b) and (3)(b) shall be of a size that allows identifying with 99% reliability a

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level of infected plants of 1% or above, taking account of ISPM No 31.

The first sub-paragraph shall not apply to specified plants which have been grown for the entire production cycle *in vitro* and are transported in transparent containers under sterile conditions.

Responsibilities of the legal entities.

20. (1) Any entity, governing body, local council or any other legally constituted body, which manages and, or administers or is responsible for any areas and, or territories on which any susceptible plants are found, shall be obliged to follow the guidelines issued by the Directorate and which the Director may, from time to time, deem necessary to issue.

(2) Failure by such entity, governing body, local council or any other legally constituted body to abide by the Directorate's instructions shall entitle the Director to gain access to any premises and, or property and to take any action which is deemed necessary in terms of these regulations. All expenses incurred by the Directorate in exercising such action shall be borne solely by the entity, governing body, local council or any other legally constituted body on whose property or premises the plants are found.

Powers of the Director.

21. (1) The Director shall revoke the measures taken to control the specified organism or to prevent it from spreading only if the Director is satisfied that it is no longer present and no further risks exist.

S.L. 594.64
S.L. 549.44

(2) These regulations are without prejudice to the Trees and Woodlands Protection Regulations and to the Flora, Fauna and Natural Habitats Protection Regulations.

(3) Nothing in these regulations shall be construed as contravening the provisions of the Act and regulations made thereunder, and, or relative European Union Regulations, Directives and Decisions in particular, but not exclusive of, Commission Implementing Decision (EU) 2015/789 of the 18 May 2015 regarding measures to prevent the introduction into and the spread within the Union of *Xylella fastidiosa* (Wells et al.) and its amendments.

(4) Without prejudice to the provisions of these regulations, the Director is empowered to issue additional and stricter legally binding guidelines, as may be required, and which are conducive to preventing the spread of the specified organism and its further entry into Malta.

Awareness campaigns.

22. The Directorate shall make information available to the general public, travellers, professional and international transport

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operators concerning the threat of the specified organism for the Union territory. The information shall be made publicly available, in the form of targeted awareness campaigns on the respective websites of the Directorate or other websites designated by those bodies.

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