Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,190, 17 ta' Mejju, 2019

Taqsima B

L.N. 98 of 2019

PLANT QUARANTINE ACT (CAP. 433)

Control of *Xylella fastidiosa* (Wells et al.) Regulations, 2019

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, 2019.

(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:

Cap. 433

"the Act" means the Plant Quarantine Act;

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

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

"the Director" means the Director responsible for the Directorate;

"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;

"non-professional final user" means any person that does not

qualify as a professional operator;

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

(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 shall be carried out by the Directorate, or 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 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 by visual inspection, sampling and testing. 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. They shall also take into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website.

(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.

(3) The presence of the specified organism in areas other than demarcated areas, shall be screened by one molecular test, and in case of positive results, its presence shall be identified by carrying out, in line with international standards, at least one more positive molecular test. Those tests shall be listed in the Commission database of tests for the identification of the specified organism and its subspecies and target different parts of the genome.

The presence of the specified organism in demarcated areas shall be screened by one test, and in case of positive results, its presence shall be identified by carrying out, in line with international standards, at least one positive molecular test. Those tests shall be listed in the Commission database of tests for the identification of the specified organism and its subspecies.

(4) The Commission shall manage and update the database referred to in sub-regulation (3) and provide public access to it.

The tests listed in that database shall be divided into two categories, depending on their appropriateness for the identification of the specified organism and its subspecies in demarcated areas and in areas other than demarcated areas.

Contingency plans.

5. (1) The Directorate shall establish a plan setting out the actions to be taken in its territory in accordance with regulations 6 to 8, regulations 10 to 15 and regulation 22 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, on request, communicate its contingency plans to the Commission and shall inform all relevant professional operators through publication on the internet.

Establishment of demarcated areas.

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

By way of derogation from the first sub-paragraph, where the presence of one particular subspecies of the specified organism is confirmed, the Directorate may demarcate an area with regard to that subspecies only.

Where the presence of more than one subspecies of the specified organism is identified, the Directorate shall demarcate that area with regard to the specified organism and all of its possible subspecies.

Where the identification of the presence of a subspecies is pending, the Directorate shall demarcate that area with regard to the

specified organism and all of its possible subspecies.

The identification of the presence of the subspecies shall be based on the results of tests referred to in regulation 4(3).

(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 5km surrounding the infected zone. The buffer zone may be reduced to a width of no less than 1km if there is a high degree of confidence that the initial presence of the specified organism did not result in any spread, and if all of the following conditions have been fulfilled:

(i) all host plants, irrespective of their health status, have been immediately removed within a radius of 100m around the plant found infected;

(ii) no other plants have been found infected by the specified organism 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 technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website. Those tests shall be based on a sampling scheme able to identify with 99% reliability a level of presence of infected plants of 1% or above, and targeting symptomatic plants, as well as asymptomatic plants in the proximity of the symptomatic ones;

(iii) a delimiting survey has been carried out in a zone with a width of at least 5km surrounding the infected zone, concluding that the specified organism has not been found present in that zone. That survey shall be based on a grid split into 100m × 100m squares within a zone of a width of at least 1 km surrounding the infected zone, and a grid split into 1km × 1km squares within the rest of the buffer zone. In each of those squares, visual inspections

shall be carried out of the specified plants and symptomatic plants shall be sampled and tested, as well as asymptomatic plants in the proximity of the symptomatic ones;

(iv) no vectors carrying the specified organism have been detected in the infected zone 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. Those tests shall lead to the conclusion that natural spread of the specified organism is excluded.

When reducing the width of the buffer zone, the Directorate shall immediately notify the Commission and the other Member States of the justification for that reduction.

In the case of an infected zone for the purpose of containment measures as referred to in regulation 9(1), the buffer zone shall be of a width of at least 10km.

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) The Directorate shall keep and update a list of the demarcated areas established in Malta and shall publish that list and any updates. The Directorate shall notify the Commission of this list and any updates in accordance with Commission Implementing Decision 2014/917/EU.

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

By way of derogation from the first sub-paragraph, where the Directorate has reduced the buffer zone to a width of no less than 1km pursuant to sub-regulation (2), the Directorate may lift that demarcated area after 12 months since its initial establishment, if both

of the following conditions are fulfilled:

(a) as result of the measures taken pursuant to sub-regulation (2), it is concluded with a high degree of confidence that the initial presence of the specified organism 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 technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website, using a sampling scheme able to identify with 99% reliability a level of presence of infected plants of 1% in accordance with international standards, and targeting symptomatic plants, as well as asymptomatic plants in the proximity of the symptomatic ones.

Where a demarcated area is lifted pursuant to the second sub-paragraph, 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 99% reliability a level of presence of infected plants of 1% or above in accordance with international standards and based on scientific and technical principles related to the potential spreading of the specified organism in the immediate surroundings, and targeting symptomatic plants, as well as asymptomatic plants in the proximity of the symptomatic ones.

When lifting the demarcated area after 12 months since its initial establishment, the Directorate shall immediately notify the Commission and the other Member States of the justification for that lifting.

(6) By way of derogation from 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 recently introduced into the area with the plants on which it was found, or that the specified organism has been found in a site with physical protection from the vectors of that organism;

(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) By way of derogation from sub-regulation (1), the Directorate may grant authorisations for the planting of the host plants within infected zones where containment measures pursuant to regulation 9 are applied, except in the 20km area referred to in regulation 9(7)(c). When granting those authorisations, the Directorate shall give preference to host plants belonging to varieties assessed as being resistant or tolerant to the specified organism.

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 the following sub-regulations (2) to(12).

(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;

(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) By way of derogation from sub-regulation (2)(a), the Directorate may decide that individual host 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 host plants concerned have been sampled and tested in accordance with regulation 4(3) and have been confirmed not to be infected by the specified organism;

(b) the individual host plants or the area concerned have been appropriately physically isolated from the vectors in such a way that those plants do not contribute to the further spread of the specified organism;

(c) appropriate agricultural practices for the management of the specified organism and its vectors have been applied.

Before a derogation is granted, the Directorate shall notify the Commission with the outcome of the sampling and testing referred to in sub-regulation (3)(a), the description of the measures referred to in sub-regulations (3)(b) and (3)(c) which are intended to be taken, the justification for them, and the location of the individual plants. The Commission shall publish the list and the location of the host plants for which such derogation is granted.

Each of those plants shall be officially inspected, during the flight season of the vector, for symptoms of the specified organism and for checking the appropriateness of the physical isolation. When symptoms are present, the plant shall be subject to sampling and testing for the presence of the specified organism.

(4) 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.

(5) 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. Those treatments may include, as appropriate, removal of plants.

(6) 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.

(7) 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.

(8) The Directorate shall monitor the presence of the specified organism by annual surveys, taking into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website. The Directorate 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 accordance with the respective provisions of regulation 4(1), (2) and (3).

In buffer zones, the surveyed area shall be based on a grid split into 100m × 100m squares within a zone of a width of at least 1km surrounding the infected zone, and a grid split into 1km × 1km squares within the rest of the buffer zone. In each of those squares, the Directorate 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.

(9) 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.

(10) 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.

(11) 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.

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

Containment measures.

9. (1) By way of derogation from regulation 8, only in an infected zone included in the list published in the Government Gazette and on the Directorate's website, and which is updated accordingly from time to time, the Director may decide to apply the containment measures, as set out in sub-regulations (2) to (7), hereinafter referred to as "containment area".

(2) The Director shall authorise the removal of all plants which have been found to be infected by the specified organism on the basis of the official surveys referred to in sub-regulation (7).

That removal shall take place immediately after the official identification of the presence of the specified organism. 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.

(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 official surveys taking into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website), at least in 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) within an infected zone included in the list published in the Gazette and on the Directorate's website, and which is updated accordingly from time to time, and situated within an area measuring at least 20km from the border of that infected zone with the rest of the Union territory.

Those surveys shall be based on a grid split into 100m × 100m squares. In each of those squares, the Member State concerned 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 accordance with the respective provisions of regulation 4(1), (2) and (3).

The Directorate shall immediately notify the Commission and the other Member States of any official identification of the presence of the specified organism in the locations referred to in paragraph (c).

Paragraph (c) above shall not apply in the case of islands which are entirely containment areas and are situated more than 10km to the nearest Union land territory.

Movement of specified plants within the Union.

10. (1) This regulation shall only apply to the movement of specified plants other than:

(a) plants which have been grown for the entire production cycle *in vitro*; or

(b) plants belonging to varieties of specified plants which are non-susceptible to the respective strain of the sub-species of the specified organism as included in the list published in the Government Gazette and on the Directorate's website and which is updated accordingly from time to time.

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) By way of derogation to 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:

(a) it is registered in accordance with the Plant Quarantine (Harmful Organisms) Regulations; S.L. 433.03

(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 100m which has been subject to official inspections twice per year and where all the plants found to be infected with the specified organism or to have symptoms, have been immediately removed and appropriate phytosanitary treatments against the vectors of the specified organism have been applied before that removal;

(e) it is subject to phytosanitary treatments at appropriate times of the year 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, taking into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website;

(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) By way of derogation from 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:

S.L. 433.03

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

(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) Specified plants which have been grown for at least part of their life in a demarcated area 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.

S.L. 433.03

(9) Host plants which have never been grown inside the demarcated areas shall only be moved within the Union if the

following conditions have been fulfilled:

(a) they have been grown in a site that is subject to annual official inspection, and, in the case of symptoms of the specified organism, sampling, taking into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website, as well as testing in line with international standards for the presence of the specified organism;

(b) they are accompanied by a plant passport prepared and issued in accordance with regulation 8 of the Plant Quarantine (Harmful Organisms) Regulations: S.L. 433.03

However, 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, shall only be moved within the Union if they have been grown in a site that is subject to annual official inspection and sampling, taking into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website, as well as testing in line with international standards for the presence of the specified organism, confirming the absence of the specified organism, using a sampling scheme able to identify with 99% reliability the level of presence of infected plants of 5%. In addition, and prior to its first movement out of its production site, each lot of plants for planting of Polygala myrtifolia L. which is to be moved within the Union shall be subjected to official visual inspection and sampling, as close to the time of that movement as possible, taking into account the technical guidelines for the survey of *Xylella fastidiosa* provided on the Commission website, as well as testing in line with international standards for the presence of the specified organism, confirming the absence of the specified organism, using a sampling scheme able to identify with 99% reliability a level of presence of infected plants of 5%. By way of derogation from the first sub-paragraph of article 4(3), the presence of the specified organism shall be screened by one test, and in case of positive results, its presence shall be identified by carrying out, in line with international standards, at least one positive molecular test. Those tests shall be listed in the Commission database of tests for the identification of the specified organism and its subspecies.

Without prejudice to Part A of Schedule V to the Plant Quarantine (Harmful Organisms) Regulations, no plant passport shall be required for the movement of the host plants referred to in this paragraph to any person acting for purposes which are outside his trade, business or profession, and who acquires those S.L.433.03

plants for his own use.

S.L.433.08

(10) Without prejudice to sub-regulation (9), pre-basic mother plants as defined in regulation 3 of the Fruit Trees Propagating Material Regulations or pre-basic material as defined in regulation 3 of the Fruit Trees Propagating Material Regulations which belong to the species *Juglans regia* L., *Olea europaea* L., *Prunus amygdalus* Batsch, *P. amygdalus* × *P. persica*, *P. armeniaca* L., *P. avium* (L.) L., *P. cerasus* L., *P. domestica* L., *P. domestica* × *P. salicina*, *P. dulcis* (Mill.) D.A. Webb, *P. persica* (L.) Batsch, and *P. salicina* Lindley and which have been grown outside the demarcated areas and spent at least part of their life outside insect proof facilities, shall only be moved within the Union if they are accompanied by a plant passport prepared and issued in accordance with regulation 8 of the Plant Quarantine (Harmful Organisms) Regulations and if the following conditions have been fulfilled:

(a) they are subject to the authorisation provided for in Commission Implementing Decision (EU) 2017/167;

(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 organism carried out in accordance with international standards.

S.L.433.03

Without prejudice to Part A of Schedule V to the Plant Quarantine (Harmful Organisms) Regulations, no plant passport shall be required for the movement of the pre-basic mother plants and pre-basic material referred to in this paragraph to any person acting for purposes which are outside his trade, business or profession, and who acquires those plants for its own use.

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:

S.L. 433.03

(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 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 regulation 8 of the Plant Quarantine (Harmful Organisms) Regulations. S.L. 433.03

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.

(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) Sub-regulations (1) and (2) shall also apply to the supply of plants for planting of *Coffea, Lavandula dentata* L.*, Nerium oleander* L., *Olea europaea* L., *Polygala myrtifolia* L. and *Prunus dulcis* (Mill.) D.A. Webb which have never been grown within a demarcated area.

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

(5) The professional operators referred to in sub-regulations (1) and (2) shall declare the introduction of plant material forty-eight (48) hours prior to its arrival in Malta, through the Supplementary Declaration System of Malta (Intrastat) and information on each lot 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.

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

(7) 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 declare the introduction of plant material through the Supplementary Declaration System of Malta (Intrastat), forty-eight hours (48) prior to their arrival in Malta.

(8) The professional operator being supplied with specified plants referred to in sub-regulation (7) shall keep a record of each lot received and, or supplied to other professional operator/s. The records shall include the supplementary declaration form, all invoices and accompanying documents (delivery notes or receipts), plant passports in accordance with regulation 8 of the Plant Quarantine (Harmful Organisms) Regulations where applicable.

S.L. 433.03

(9) The non-professional final user being supplied with specified plants shall also inform the Directorate by means of the EU-Plant Notification Form (For General Public) available on the Directorate's website forty-eight hours (48) prior to the arrival of the plant material in Malta irrespective of origin, location and growing areas.

(10) The Directorate shall, upon request, make available the information referred to in sub-regulation (5) 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;

(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/s *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/s, 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 and non-professional final users, after they have informed the Directorate.

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;

S.L. 433.03

(c) 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 shall only be introduced into the Union if they have been grown in a site that is subject to annual official inspection, with sampling and testing carried out at the appropriate times on those plants for the presence of the specified organism and in accordance with international standards, confirming the absence of the specified organism, using a sampling scheme able to identify with 99% reliability the level of presence of infected plants of 5%. In addition, and prior to its first movement out of its production site and as close to the time of that movement as possible, each lot of plants for planting of Polygala myrtifolia L. shall be subjected to official visual inspection and sampling, as well as testing in line with international standards for the presence of the specified organism, confirming the absence of the specified organism, using a sampling scheme able to identify with 99% reliability a level of presence of infected plants of 5%;

(d) the professional operators and the non-professional final user 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 (48) prior to the arrival of the plant material in Malta;

(e) 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.

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:

S.L. 433.03

(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 (48) prior to the arrival of the plant material in Malta;

(d) the non-professional final user 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 (48) prior to the arrival of the plant material in Malta;

(e) 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.

(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 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.

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 100m which has been subject to official inspections twice per year and where all of the plants found to be infected with the specified organism or to have symptoms have been immediately removed, and appropriate phytosanitary treatments against the vectors of the specified organism have been applied before that removal;

(d) at appropriate times throughout the year, it is subject to phytosanitary treatments 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 during the flight season of the vector;

(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 paragraph (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 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. 433.03

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 Plant Quarantine (Harmful Organisms) 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(b), 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 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 shall apply 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 there under, 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. (1) The Directorate shall make information available to the general public, travellers, professional and international transport 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. This shall include posters or brochures and on the respective website of the Directorate.

(2) (a) Seaports, airports and international transport operators shall make information available to travellers concerning

prohibitions, requirements and exemptions referred to in regulations 10 to 12 and 16 to 18 as regards the introduction of specified plants into the Maltese territory.

They shall provide that information in the form of posters or brochures and, where applicable, on their internet sites.

(b) Postal services and professional operators involved in sales through distance contracts shall also make available to their clients that information concerning such specified plants at least through the internet.

23. The Control of *Xylella fastidiosa* (Wells et al.) Regulations are hereby repealed. Repeal. S.L. 433.29.

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Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta FSC — ***Printed at the Government Printing Press on FSC certified paper***

Prezz/*Price*
€1.26