

Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 19,735, 3 ta' Marzu, 2017

Taqsimha B

L.N. 74 of 2017

**PLANT QUARANTINE ACT
(CAP. 433)**

**Fruit Trees Propagating Material (Amendment No. 2)
Regulations, 2017**

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

1. (1) The title of these regulations is the Fruit Trees Propagating Material (Amendment No. 2) Regulations, 2017, and these regulations shall be read and construed as one with the Fruit Trees Propagating Material Regulations, hereinafter referred to as "the principal regulations".

Citation and scope.

S.L. 433.08

(2) The scope of these regulations is to transpose Commission Implementing Directive 2014/97/EU as regards the registration of suppliers and of varieties and the common list of varieties.

2. Sub-regulations (5) and (6) of regulation 6 of the principal regulations shall be substituted by the following:

Amends regulation 6 of the principal regulations.

"(5) The requirements for the official registration referred to in sub-regulation (4) are provided in Schedule III, taking into account current scientific and technical knowledge and covering:

(a) the conditions of official registration, which may include in particular, distinctness, stability and sufficient uniformity;

(b) the characteristics which, as a minimum, the examinations of the various species must cover;

(c) the minimum requirements for carrying out the examinations;

(d) the maximum period of validity of the official registration of a variety.

(6) Rules on the system for the notification of varieties or species or interspecific hybrids to the responsible official bodies of the Member States and on a common list of varieties are provided in Schedule III."

Amends regulation 7 of the principal regulations.

3. Sub-regulation (5) of regulation 7 of the principal regulations shall be substituted by the following:

"(5) Detailed rules for the application of sub-regulation (1) are provided in Schedule III and the rules for the application of sub-regulation (2) may be established in accordance with the procedure of Article 19(2) of Council Directive 2008/90/EC."

Adds new schedule to the principal regulations.

4. Immediately after Schedule II to the principal regulations, there shall be added the following new schedule:

"SCHEDULE III

Registration of Suppliers

I. Register of suppliers

(1) The responsible official body shall keep and update a register of suppliers, as provided for in regulation 7(1) of these regulations. That register shall be referred to hereinafter as "the register of suppliers". In addition to suppliers registered in accordance with these regulations, that register shall include suppliers accredited in accordance with the provisions of regulation 10(1) of the Fruit Trees Propagation Material Regulations, 2010*. Where appropriate, the responsible official body shall make available the register of suppliers.

(2) The register of suppliers shall include the following information:

(a) the name, address and contact details of the supplier;

(b) the activities, within the meaning of the term "supplier" in regulation 3 of these regulations that are exercised by the supplier in Malta, the address of the premises involved and the main genera or species concerned; and

(c) the registration number or code.

(3) The responsible official body shall ensure that it removes a natural or legal person from the register of suppliers, if it is established that that person no longer exercises any activity within the meaning of term "supplier" in regulation 3 of these regulations.

II. Notification obligation of suppliers

* promulgated by Legal Notice 271 of 2004 and revoked by Legal Notice 223 of 2010.

(1) The responsible official body shall ensure that suppliers notify the information referred to in Section I point (2)(a) and (b). No notification shall, however, be required from suppliers accredited in accordance with regulation 10(1) of the Fruit Trees Propagation Material Regulations, 2010*.

(2) The responsible official body shall ensure that suppliers notify any change in their situation concerning the information referred to in Section I point (2)(a) and (b).

(3) The responsible official body shall ensure that suppliers are informed of their registration and of any modifications thereto within a time period to be laid down by national legislation.

Registration of Varieties

III. Variety register

(1) The responsible official body shall keep, update and publish a register of varieties (hereinafter "variety register"). In addition to varieties registered in accordance with these regulations, the variety register shall include varieties registered before 30 September 2012 in accordance with regulation 8(3) of the Fruit Trees Propagation Material Regulations, 2010** and varieties registered in accordance with the second sentence of regulation 6(4)(a) of these regulations.

(2) The variety register shall include the following information:

- (a) the denomination of the variety and synonyms;
- (b) the species the variety belongs to;
- (c) the indication "official description" or "officially recognised description", as appropriate;
- (d) the date of registration, or, where applicable, of renewal of registration;
- (e) the end of validity of registration.

(3) The responsible official body shall keep a file for each

* promulgated by Legal Notice 271 of 2004 and revoked by Legal Notice 223 of 2010.

** promulgated by Legal Notice 271 of 2004 and revoked by Legal Notice 223 of 2010.

variety it registers. That file shall contain a description of the variety and a summary of all the facts relevant to the registration of the variety.

IV. Conditions for registration of varieties

(1) The responsible official body shall ensure that a variety is registered as a variety with an official description if it fulfils the following requirements:

(a) it is distinct, uniform and stable within the meaning of point (2) of this Section;

(b) a sample of the variety is available; and

(c) as regards genetically modified varieties, the genetically modified organism of which the variety consists is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003.

(2) A variety shall be considered as:

(a) "distinct" where it is clearly distinguishable, by reference to the expression of the characteristics that result from a particular genotype or combination of genotypes, from any other variety commonly known at the date of the application referred to in Section V;

(b) "uniform" where, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any other characteristics used for the variety description;

(c) "stable" where the expression of the characteristics which are included in the examination for distinctness, as well as any other characteristics used for the variety description, remains unchanged after repeated propagation or, in the case of micro propagation at the end of each cycle.

V. Application for registration of a variety

(1) For registration of a variety as a variety with an official description, the responsible official body shall require to receive a written application.

(2) The application shall be accompanied by the following:

(a) the information required by the technical questionnaires set out at the time of application:

(i) in Annex II to the "Protocols for distinctness, uniformity and stability tests" of the Administrative Council of the Community Plant Variety Office (CPVO) for the relevant species for which such a protocol has been published; or, where no such protocols have been published,

(ii) in Section X of the "Test guidelines for the conduct of tests for distinctness, uniformity and stability" of the International Union for the Protection of new Varieties of Plants (UPOV) and the Annex to the Test guideline concerned for the relevant species for which such guidelines have been published; or, where no such guidelines have been published,

(iii) in national provisions;

(b) information on whether the variety is officially registered in another Member State, or is the subject of an application for such a registration in another Member State;

(c) a proposed denomination;

(d) in the case of a genetically modified variety, evidence that the genetically modified organism of which the variety consists is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003.

(3) The applicant may submit any of the following with its application:

(a) an official description established, in accordance with point (5) of Section VI, by a responsible official body of another Member State;

(b) any other relevant information.

VI. Examination of applications

(1) It shall be ensured that, where the responsible official body receives an application for registration of a variety as a variety with an official description, an examination of that variety is performed in accordance with points (2), (3) and (4) of this Section.

(2) Growing trials shall be carried out to establish an official

description of the variety. Where the applicant submits information in accordance with point (3)(a) of Section V and the responsible official body considers that this information shows that the conditions for registration provided for in Section IV are fulfilled, no growing trials shall, however, be carried out. Where growing trials are to be carried out, the responsible official body shall request a sample of the material of the variety.

(3) The growing trials referred to in point (2) of this Section shall be performed by:

(a) the responsible official body receiving the application; or

(b) the responsible official body of another Member State having agreed to perform those trials; or

(c) any legal person, in accordance with regulation 12(2) of these regulations.

Where point (c) applies and trials are carried out on the premises of private enterprises, the responsible official body shall ensure that no measures are applied that might interfere with the official examination.

(4) The growing trials shall be performed in accordance with the following provisions as regards trial design, growing conditions and characteristics of the variety to be covered as a minimum:

(a) the "Protocols for distinctness, uniformity and stability tests" of the Administrative Council of the Community Plant Variety Office (CPVO) applicable at the beginning of the technical examination; or, where no protocols have been published for the relevant species,

(b) the "Test guidelines for the conduct of tests for distinctness, uniformity and stability" of the International Union for the Protection of New Varieties of Plants (UPOV) applicable at the beginning of the technical examination; or, where no guidelines have been published for the relevant species,

(c) national provisions.

(5) If, based on the examination referred to in point (1) of this Section, the responsible official body concludes that the variety concerned fulfils the conditions of Section V it shall establish an official description and include that variety in the variety register.

VII. Period of validity of variety registration

(1) The maximum period of validity of the registration of a variety shall be 30 years.

In the case of genetically modified varieties, the validity of the registration shall be limited to the period for which the genetically modified organism of which the variety consists is authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003.

VIII. Renewal of variety registration

(1) The responsible official body shall ensure that the registration of a variety may be renewed for further maximum periods of 30 years, provided that material of that variety is still available.

In the case of a genetically modified variety, renewal shall, in addition, be subject to the condition that the respective genetically modified organism continues to be authorised for cultivation pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003. The renewal period shall be limited to the period of authorisation of the genetically modified organism concerned.

(2) For renewal of the registration, the responsible official body shall require to receive a written application. The application shall be accompanied by evidence showing that the conditions set out in point (1) of this Section are fulfilled. The responsible official body may, however, renew the registration of a variety for which no written application has been submitted, where it considers that renewal serves to preserve genetic diversity and sustainable production or serves another general interest.

IX. Removal of a variety from the variety register

(1) The responsible official body shall ensure that a variety is removed from the variety register if:

(a) the conditions for registration, as set out in Section IV, are no longer fulfilled;

(b) at the time of the application for registration or during examination, false or fraudulent particulars had been supplied concerning the facts on the basis of which the variety was registered.

X. Notifications

(1) The responsible official body shall notify to the responsible official bodies of the other Member States and the European Commission the information required to access the variety register of the Member State concerned.

(2) The responsible official body shall notify the European Commission as soon as possible of the inclusion of a variety in its variety register, and any other amendment to its variety register.

(3) The responsible official body shall, on request, make available to another Member State or the European Commission:

(a) the official or officially recognised description of varieties registered in the variety register of Malta;

(b) the results of examinations of applications for registration of varieties performed by Malta pursuant to Section VI;

(c) any other information available in respect of varieties included in the variety register of Malta or removed from that register;

(d) the list of varieties for which applications for registration are pending in Malta.

Common List of Varieties

XI. Common list

The European Commission shall, on the basis of the information received pursuant to point (2) of Section X, establish, regularly update and publish in an electronic format a common list of the varieties included in the variety registers of the Member States.

