L.N. 22 of 2011

PLANT QUARANTINE ACT
(CAP. 433)

Seeds of Vegetable Landraces and Varieties Regulations, 2011

IN exercise of the powers conferred by article 32 of the Plant Quarantine Act, the Minister for Resources and Rural Affairs after consulting the Plant Health Directorate has made the following regulations:-

Title, scope and commencement.

1. (1) The title of these regulations is the Seeds of Vegetable Landraces and Varieties Regulations, 2011.

(2) The scope of these regulations is to transpose Commission Directive 2009/145/EC providing for certain derogations for the acceptance for inclusion of vegetable landraces and varieties in national catalogues of varieties of vegetable species as provided for in the Seeds of Agricultural Plants and Vegetables Regulations, 2010 to ensure the sustainable use of such plant genetic resources through growing. Such derogation shall apply to the following:

L.N. 331 of 2010.

(a) vegetable landraces and varieties which have been traditionally grown in particular localities and regions hereinafter referred to as "conservation in situ" and are threatened by genetic erosion hereinafter referred to as "conservation varieties"; and

(b) vegetable varieties with no intrinsic value for commercial crop production but solely developed for growing under particular pedological or agro-technical conditions hereinafter referred to as "varieties developed for growing under particular conditions",

and consequently for marketing of seeds of such vegetable landraces and varieties.

(3) These regulations shall be deemed to have come into force on the 31st December, 2010.

Interpretation. Cap. 433.

2. (1) Unless otherwise stated in these regulations, the definitions in the Act and those contained in the Seeds of Agricultural Plants and Vegetables Regulations, 2010 shall continue to apply.

(2) For the purpose of these regulations and unless the context otherwise requires, the following definitions shall apply:

"the Act" means the Plant Quarantine Act;

"the applicant" means any person, farmer or breeder who submits an application to the Directorate whereby he may be granted an authorisation in accordance with these regulations;

"authorisation" means any permit, licence, decision or concession granted by the Directorate to the applicant in terms of these regulations;

"certified seed" shall have the same meaning as that provided for under the Seeds of Agricultural Plants and Vegetables Regulations, 2010;

"conservation in situ" means the conservation of genetic material in its natural surroundings and, in the case of cultivated plant species, in the farmed environment where they have developed their distinctive properties;

"conservation varieties" means vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion;

"the Commission" means the European Commission;

"the Community" means the European Community as established by the Treaty of the European Union;

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

"genetic erosion" means the loss of genetic diversity between and within populations or varieties of the same species over time, or reduction of the genetic basis of a species due to human intervention or environmental change;

"landrace" means a set of populations or clones of a plant species which are naturally adapted to the environmental conditions of their region;

"Member State" means a state which is a member of the European Union;

"person" means any natural or legal person;

"standard seed" shall have the same meaning as that provided under the Seeds of Agricultural Plants and Vegetables Regulations, 2010.

"varieties developed for growing under particular conditions" means varieties with no intrinsic value for commercial crop production but solely developed for growing under particular pedological or agro-technical conditions.

Applicability.

3. These regulations shall apply in particular to ensure that any seeds of vegetable landraces and varieties produced and placed on the market in Malta meets specified quality standards and shall apply without prejudice to the Seeds of Agricultural Plants and Vegetables Regulations, 2010.

Acceptance for inclusion of conservation varieties in national catalogues.

4. (1) Conservation varieties may be accepted for inclusion in national catalogues subject to the requirements provided for in regulations 5 and 6 of these regulations.

(2) Such varieties shall be accepted:

(a) as a variety the seeds of which may either be certified as "certified seed of a conservation variety" or verified as "standard seed of a conservation variety". Such a variety shall enter the Common Catalogue of varieties of vegetable species as a "conservation variety the seeds of which shall be certified in accordance with regulation 11 of these regulations or verified in accordance with regulation 12 of these regulations";

(b) as a variety the seeds of which may only be verified as "standard seed of a conservation variety". Such a variety shall enter the Common Catalogue of varieties of vegetable species as a "conservation variety the seeds of which shall be verified in accordance with regulation 12 of these regulations".

Substantive requirements for acceptance of a landrace or variety as a conservation variety.

5. (1) In order to be accepted as a conservation variety, as referred to in sub-regulation (2) of regulation 2 hereof, a landrace or variety shall present an interest for the conservation of plant genetic resources.

(2) The Directorate may adopt its own provisions as regards distinctness, stability and uniformity of conservation varieties by way of derogation from paragraphs (a) and (b) of sub-regulation (1) of regulation 3 of the Examination of Varieties of Vegetable Species Regulations, 2007. In such cases, the Directorate shall ensure that for the purpose of distinctness and stability, at least the characteristics referred to in the following shall apply:

LN 87 of 2007.

(a) the technical questionnaires associated with the test protocols of the Community Plant Variety Office (CPVO) listed in Schedule I to the Examination of Varieties of Vegetable Species Regulations, 2007, which apply to those species; or

(b) the technical questionnaires of the guidelines of the International Union for the Protection of New Varieties of Plants (UPOV) listed in Schedule II to the Examination of Varieties of Vegetable Species Regulations, 2007, which apply to those species.

(3) The provisions contained under the Examination of Varieties of Vegetable Species Regulations, 2007 shall apply with regard to the assessment of uniformity. However, if the uniformity level is established on the basis of off-types, a population standard of 10% and an acceptance probability of at least 90 % shall apply.

Procedural requirements for the acceptance of conservation varieties.

6. Without prejudice to the first sentence of sub-regulation (4) of regulation 6 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010, no official examination shall be required if a decision is taken by the Directorate regarding the acceptance of conservation varieties based on the following information:

(a) the description of the conservation variety and its denomination;

(b) the results of unofficial tests;

(c) knowledge gained from practical experience during cultivation, reproduction and use, as notified by the applicant to the Directorate;

(d) other information in particular that obtained from the plant genetic resources authorities or from other organisations or entities recognised as such by the Directorate.

Exception to the acceptance of a conservation variety.

7. A conservation variety shall not be accepted for inclusion in the national catalogue of varieties of vegetable species if:

(a) it is already listed in the Common Catalogue of varieties of vegetable species as a variety other than a conservation variety; or

(b) it was deleted from such catalogue during the years 2008 to 2010 or within the two years immediately following the expiry period of the acceptance granted under sub-regulation (11) of regulation 6 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010; or

(c) it is protected by a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 on Community plant variety rights or by a national plant variety right, or where an application for such a right is pending.

Denominations of conservation varieties.

8. (1) With respect to denominations of conservation varieties known prior to 25th May 2000, the Directorate may permit derogations from the provisions of Commission Regulation (EC) No 637/2009 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species except where such derogations would violate prior rights of a third party protected under Article 2 of that Regulation.

(2) Notwithstanding sub-regulation (6) of regulation 6 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010 providing that a variety shall be known by the same name in all Member States at the time of acceptance, the Directorate may accept more than one name for a variety if the names concerned are historically known.

Region of origin of conservation varieties.

9. (1) When a conservation variety is accepted, the locality or localities, the region or regions, in which the variety has historically been grown and to which it is naturally adapted shall be

identified, and hereinafter these shall be referred to as the "region of origin". Information available from plant genetic resources authorities or from other organisations or entities recognised as such shall be taken into account. If the region of origin is located in Malta and in other Member States, it shall be identified by all Member States concerned by means of a common accord.

(2) The Directorate or the other competent authorities of other Member States, as the case may be, identifying the region of origin shall notify such identification to the Commission.

Maintenance of conservation varieties.

10. The Directorate shall ensure that a conservation variety shall be maintained in its region of origin.

Certification of seeds.

11. By way of derogation from the certification requirements provided for in sub-regulations (1) of regulation 7 and regulation 9 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010, the Directorate may provide that the seed of a conservation variety may be certified as certified seed of a conservation variety if it meets the following requirements:

(a) the seed originates from seeds produced according to well defined practices for the maintenance of the conservation variety;

(b) the seed shall comply with the requirements for certification of certified seed provided for in sub-regulation (5) of regulation 3 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010 except with the requirements in respect of minimum varietal purity and the requirements concerning official examination or examination under official supervision; and

(c) the seed shall have sufficient varietal purity.

Verification of seeds of a conservation variety.

12. By way of derogation from the certification requirements provided for in sub-regulation (1) of regulation 7and regulation 9 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010, the Directorate may provide that seeds of a conservation variety be verified as standard seeds of a conservation variety if it meets the following requirements:

(a) the seed shall comply with the requirements for the marketing of "standard seed" provided for in the Seeds of Agricultural Plants and Vegetables Regulations, 2010

other than those requirements set out in respect of minimum varietal purity; and

(b) the seed shall have sufficient varietal purity.

Seed testing of a conservation variety.

13. (1) The Directorate shall ensure that tests are carried out in order to verify that seeds of a conservation variety comply with the certification requirements provided for in regulation 11 and 12 of these regulations.

(2) The tests referred to in sub-regulation (1) hereof shall be carried out in accordance with current international methods, or in the absence of such, in accordance with any appropriate methods.

(3) Samples taken for the tests referred to in sub-regulation (1) hereof shall be drawn from homogeneous lots. The rules on lot weight and sample weight provided for in Schedule IV to the Seeds of Agricultural Plants and Vegetables Regulations, 2010 shall be applied.

Region of seed production of a conservation variety.

14. (1) The Directorate shall ensure that seeds of a conservation variety may only be produced in the region of origin. If the seed cannot be produced in that region, owing to a specific environmental problem, additional regions for seed production may be approved by the Directorate taking into account information from plant genetic resources authorities or from other organisations or entities recognised as such by the Directorate. However, seed produced in such additional regions shall be used exclusively in the region of origin.

(2) The Directorate shall notify the Commission and the other Member States on the additional regions which it intends to approve for seed production pursuant to sub-regulation (1) hereof.

Marketing of seeds.

15. (1) Seeds of a conservation variety may only be marketed if the following conditions are satisfied:

(a) they shall have been produced in their region of origin or in a region referred to in regulation 14 of these regulations; and

(b) marketing shall take place in their region of origin.

(2) By way of derogation from sub-regulation (1)(b) hereof, additional regions may be approved by the Directorate in Malta for the marketing of seeds of a conservation variety provided that those regions are comparable to the region of origin as regards the natural and semi-natural habitats of such variety. If the Directorate approves such additional regions, it shall ensure that the amount of seed necessary for the production of at least the quantity of seed referred to in regulation 16 hereof is reserved to conserve the variety in its region of origin. The Directorate shall inform the Commission and the other Member States of the approval of such additional regions.

(3) If the Directorate approves additional regions for seed production in accordance with regulation 14 hereof, it shall not use the derogation provided for in sub-regulation (2) of this regulation.

Quantitative restrictions for conservation varieties.

16. For each conservation variety, the quantity of seed marketed per year shall not exceed the quantity necessary for producing vegetables in terms of the number of hectares set out for the respective species in Schedule I to these regulations.

Application of quantitative restrictions.

17. (1) Before the commencement of each production season, producers shall notify the Directorate of the size and location of the area for the seed production.

(2) If, based on the notifications referred to in sub-regulation (1) hereof, the quantities referred to in regulation 16 of these regulations are likely to be exceeded, the Directorate shall allocate to each producer concerned the quantity which may be marketed in the respective production season.

Sealing of packages of conservation varieties.

18. (1) The Directorate shall ensure that seeds of conservation varieties shall be marketed only in closed packages bearing a sealing device.

(2) Seed packages shall be sealed by the supplier in such a manner that they cannot be opened without damaging the sealing system or leaving evidence of tampering with the supplier's label, or with the package.

(3) In order to ensure sealing in accordance with sub-regulation (2) hereof, the sealing system shall at least include the label or the affixing of a seal.

Labelling of packages of conservation varieties.

19. Packages or containers of seeds of conservation varieties shall bear a supplier's label or a printed or stamped notice which shall include the following information:

(a) the words "EC rules and standards";

(b) the name and address of the person responsible for affixing the labels or the identification mark of such person;

(c) the year of sealing expressed as: "sealed in (year)", or the year of the last sampling taken for the purposes of the last testing of germination expressed as: "sampled in (year)";

(d) the species;

(e) the denomination of the conservation variety;

(f) the words "certified seed of a conservation variety" or "standard seed of a conservation variety";

(g) the region of origin;

(h) where the region of seed production is different from the region of origin, the indication of the region of seed production;

(i) the reference number of the lot given by the person responsible for affixing the labels;

(j) the declared net or gross weight, or declared number of seeds; and

(k) where the weight is indicated, and granulated pesticides, pelleting substances or other solid additives are used, the nature of the chemical treatment or additive and the approximate ratio between the weight of clusters or pure seeds and the total weight.

Official post control for conservation varieties.

20. (1) The Directorate shall ensure that seed of a conservation variety marketed under these regulations is subject to official post control by means of inspections carried out randomly in order to verify its varietal identity and varietal purity.

(2) The official post control referred to in sub-regulation (1) hereof shall be carried out in accordance with current

international methods, or, in the absence of such, in accordance with any appropriate methods.

Monitoring of conservation varieties.

21. The Directorate shall ensure by means of official monitoring carried out during production and marketing, that the seeds of conservation varieties comply with these regulations, particularly taking into account the variety, the location of the seed production and quantities.

Acceptance of varieties developed for growing under particular conditions.

22. (1) Varieties developed for growing under particular conditions may be accepted for inclusion in the national catalogues subject to the requirements provided for in regulations 23 and 24 of these regulations.

(2) A variety developed for growing under particular conditions shall be accepted as a variety the seeds of which may only be verified as "standard seed of a variety developed for growing under particular conditions". Such a variety shall be entered into the Common Catalogue of varieties of vegetable species as a "variety developed for growing under particular conditions the seeds of which shall be verified in accordance with regulation 27 of these regulations".

Substantive requirements for the acceptance of a variety developed for growing under particular conditions.

23. (1) In order to be accepted as a variety developed for growing under particular conditions, as referred to in sub-regulation (2) of regulation 2 of these regulations, a variety shall be with no intrinsic value for commercial crop production but developed for growing under particular conditions.

(2) A variety shall be considered as having been developed for growing under particular conditions if it has been developed for growing under particular agro-technical, climatic or pedological conditions.

(3) The Directorate may adopt its own provisions as regards distinctness, stability and uniformity of varieties developed for growing under particular conditions by way of derogation from sub-regulation (1) (a) and (b) of regulation 3 of the Examination of Varieties of Vegetable Species Regulations, 2007. In such cases, the Directorate shall ensure that for the determination of distinctness and stability, at least the characteristics referred to in the following shall apply:

(a) the technical questionnaires associated with the test protocols of the Community Plant Variety Office (CPVO)

listed in Schedule I to the Examination of Varieties of Vegetable Species Regulations, 2007, which apply to those species, or

(b) the technical questionnaires of the guidelines of the International Union for the Protection of New Varieties of Plants (UPOV) listed in Schedule II to the Examination of Varieties of Vegetable Species Regulations, 2007, which apply to those species.

(4) For the assessment of uniformity, the provisions of the Examination of Varieties of Vegetable Species Regulations, 2007 shall apply. However, if the uniformity level is established on the basis of off-types, a population standard of 10% and an acceptance probability of at least 90 % shall be applied.

Procedural requirements of varieties developed for growing under particular conditions.

24. Without prejudice to sub-regulation (4) of regulation 6 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010, no official examination shall be required if a decision is taken by the Directorate regarding the acceptance of varieties developed for growing under particular conditions based on the following information:

(a) the description of the variety developed for growing under particular conditions and its denomination;

(b) the results of unofficial tests;

(c) knowledge gained from practical experience during cultivation, reproduction and use, as notified by the applicant to the Directorate concerned;

(d) other information in particular that obtained from the plant genetic resources authorities or from other organisations or entities recognised as such by the Directorate.

Exception to the acceptance of varieties developed for growing under particular conditions.

25. A variety developed for growing under particular conditions shall not be accepted for inclusion in the national catalogue of varieties of vegetable species if:

(a) it is already listed in the Common Catalogue of varieties of vegetable species as a variety other than a variety developed for growing under particular conditions; or

(b) it was deleted from such catalogue during the years 2008 to 2010 or within the two years immediately following the expiry period of the acceptance granted under sub-regulation (11) of regulation 6 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010; or

(c) it is protected by a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 on Community plant variety rights or by a national plant variety right, or an application for such a right is pending.

Denominations of varieties developed for growing under particular conditions.

26. (1) With respect to denominations of varieties developed for growing under particular conditions known prior to 25th May 2000, the Directorate may permit derogations from the provisions of Commission Regulation (EC) No 637/2009 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species, except where such derogations would violate prior rights of a third party protected under Article 2 of that Regulation.

(2) Notwithstanding sub-regulation (6) of regulation 6 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010 providing that a variety shall be known by the same name in all Member States at the time of acceptance, the Directorate may accept more than one name for a variety if the names concerned are historically known.

Verification of seeds of varieties developed for growing under particular conditions.

27. By way of derogation from the certification requirements provided for in sub-regulation (1) of regulation 7 and regulation 9 of the Seeds of Agricultural Plants and Vegetables Regulations, 2010, the Directorate may provide that seed of a variety developed for growing under particular conditions be verified as standard seed of a variety developed for growing under particular conditions if it meets the following requirements:

(a) the seed shall comply with the requirements for the marketing of "standard seed" provided for in the Seeds of Agricultural Plants and Vegetables Regulations, 2010 other than those requirements set out in respect of minimum varietal purity; and

(b) the seed shall have sufficient varietal purity.

Seed testing of varieties developed for growing under particular conditions.

28. (1) The Directorate shall ensure that tests are carried out in order to verify that seeds of varieties developed for growing under particular conditions comply with the certification requirements provided for in regulation 27 hereof.

(2) The tests referred to in sub-regulation (1) hereof shall be carried out in accordance with current international methods, or in the absence of such, in accordance with any appropriate methods.

Quantitative restrictions for varieties developed for growing under particular conditions.

29. For each variety developed for growing under particular conditions, the quantity of seeds marketed in small packages shall not exceed the maximum net weight set out for the respective species in Schedule II to these regulations.

Sealing of packages of varieties developed for growing under particular conditions.

30. (1) The Directorate shall ensure that seeds of varieties developed for growing under particular conditions shall be marketed only in closed packages bearing a sealing device.

(2) Seed packages shall be sealed by the supplier in such a manner that they cannot be opened without damaging the sealing system or leaving evidence of tampering with the supplier's label, or with the package.

(3) In order to ensure sealing in accordance with sub-regulation (2) hereof, the sealing system shall at least include the label or the affixing of a seal.

Labeling of packages of varieties developed for growing under particular conditions.

31. Packages of seeds of varieties developed for growing under particular conditions shall bear a supplier's label or a printed or stamped notice which shall include the following information:

(a) the words "EC rules and standards";

(b) the name and address of the person responsible for affixing the labels or the identification mark of such person;

(c) the year of sealing expressed as: "sealed in (year)", or the year of the last sampling taken for the purposes of the last testing of germination expressed as: "sampled in (year)";

(d) the species;

(e) the denomination of the variety;

(f) the words "variety developed for growing under particular conditions";

(g) the reference number of the lot given by the person responsible for affixing the labels;

(h) the declared net or gross weight, or declared number of seeds; and

(i) where the weight is indicated, and granulated pesticides, pelleting substances or other solid additives are used, the nature of the chemical treatment or additive and the approximate ratio between the weight of clusters or pure seeds and the total weight.

Official post control of varieties developed for growing under particular conditions.

32. (1) The Directorate shall ensure that seed of a variety developed for growing under particular conditions is subject to official post control by means of inspections carried out randomly in order to verify its varietal identity and varietal purity.

(2) The official post control referred to in sub-regulation (1) hereof shall be carried out in accordance with current international methods, or in the absence of such, in accordance with any appropriate methods.

Monitoring of varieties developed for growing under particular conditions.

33. The Directorate shall ensure by means of official monitoring carried out during production and marketing that the seeds of varieties developed for growing under particular conditions comply with these regulations, particularly taking into account the variety and quantities.

Schedule I

Regulation 16

Quantitative restrictions for the marketing of seed of conservation varieties

Botanical name	Maximum number of hectares per Member State for production of vegetables per conservation variety
Allium cepa L. — Cepa group *Brassica oleracea* L. *Brassica rapa* L. *Capsicum annuum* L. *Cichorium intybus* L. *Cucumis melo* L. *Cucurbita maxima* Duchesne *Cynara cardunculus* L. *Daucus carota* L. *Lactuca sativa* L. *Lycopersicon esculentum* Mill. *Phaseolus vulgaris* L. *Pisum sativum* L. (partim) *Vicia faba* L. (partim)	40
Allium cepa L. — Aggregatum group	20

Allium porrum L. *Allium sativum* L. *Beta vulgaris* L. *Citrullus lanatus* (Thunb.) Matsum. et Nakai *Cucumis sativus* L. *Cucurbita pepo* L. *Foeniculum vulgare* Mill. *Solanum melongena* L. *Spinacia oleracea* L.	
Allium fistulosum L. *Allium schoenoprasum* L. *Anthriscus cerefolium* (L.) Hoffm. *Apium graveolens* L. *Asparagus officinalis* L. *Cichorium endivia* L. *Petroselinum crispum* (Mill.) Nyman ex A. W. Hill *Phaseolus coccineus* L. *Raphanus sativus* L. *Rheum rhabarbarum* L. *Scorzonera hispanica* L. *Valerianella locusta* (L.) Laterr. *Zea mays* L. (partim)	10

Schedule II

Regulation 29

Maximum net weight per package

Botanical name	Maximum net weight per package expressed in grams
Phaseolus coccineus L. *Phaseolus vulgaris* L. *Pisum sativum* L. (partim) *Vicia faba* L. (partim) *Spinacia oleracea* L. *Zea mays* L. (partim)	250
Allium cepa L. (Cepa group, Aggregatum group) *Allium fistulosum* L. *Allium porrum* L. *Allium sativum* L. *Anthriscus cerefolium* (L.) Hoffm. *Beta vulgaris* L. *Brassica rapa* L. *Cucumis sativus* L. *Cucurbita maxima* Duchesne	25

Cucurbita pepo L. *Daucus carota* L. *Lactuca sativa* L. *Petroselinum crispum* (Mill.) Nyman ex A. W. Hill *Raphanus sativus* L. *Scorzonera hispanica* L. *Valerianella locusta* (L.) Laterr.	
Allium schoenoprasum L. *Apium graveolens* L. *Asparagus officinalis* L. *Brassica oleracea* L. (all) *Capsicum annuum* L. *Cichorium endivia* L. *Cichorium intybus* L. *Citrullus lanatus* (Thunb.) Matsum. et Nakai *Cucumis melo* L. *Cynara cardunculus* L. *Lycopersicon esculentum* Mill. *Foeniculum vulgare* Mill. *Rheum rhabarbarum* L. *Solanum melongena* L.	5

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 riċiklata — *Printed at the Government Printing Press on recycled paper*

Prezz/*Price*
€0.84