### EUROPEAN COMMUNITIES (INTRODUCTION AND MOVEMENT OF CERTAIN HARMFUL ORGANISMS, PLANTS, PLANT PRODUCTS AND OTHER OBJECTS FOR TRIAL OR SCIENTIFIC PURPOSES AND/OR FOR WORK ON VARIETAL SELECTIONS) REGULATIONS 1996

I, IVAN YATES, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Directive No. 95/44/EC(1) of 26 July 1995, hereby make the following Regulations: (1)O.J. No. L.184, 3-8-1995, p.34.

### REG 1

1. These Regulations may be cited as the European Communities (Introduction and Movement of Certain Harmful Organisms, Plants, Plant Products and other objects for trial or scientific purposes and/or for work on varietal selections) Regulations, 1996.

### REG 2

2. These Regulations shall come into force on the 10th day of May, 1996.

### REG 3

3. (1) In these Regulations:

"the activities" means any activity for trial or scientific purposes and/or for work on varietal selection which would involve the use of the material;

"Annex I" means Annex I in the Schedule to these Regulations;

"Annex II" means Annex II in the Schedule to these Regulations;

"Annex III" means Annex III in the Schedule to these Regulations;

"Authorised person" means a person appointed in writing by the Minister to be an authorised person for the purposes of these Regulations;

"The Council Directive" means Council Directive No. 77/93/EEC(2) of 21 December 1976 as amended;

(2) O.J. No. L.26, 31-1-1977, p.20.

"The Commission Directive" means Commission Directive No. 95/44/EC of 26 July 1995;

"The Minister" means the Minister for Agriculture, Food and Forestry; "The material" means the harmful organisms, plants, plant products and other objects the subject of subparagraph (e) of paragraph (7) of Article 3, paragraph (5) of Article 4, paragraph (5) of Article 5, or paragraph (3C) of Article 12 of the Council Directive other than potato breeding material or soil and growing medium being introduced from third countries, and intended for trial or scientific

purposes, the provisions for which are laid down in Commission

Decision 80/862/EEC(3), as amended, and Commission Decision 93/447/EEC(4), as amended, respectively.

(3) O.J. No. L.248, 19-9-1980, p.25.

(4) O.J. No. L.209, 20-8-1993, p.32.

"Member State" means a Member State of the European Communities; "Official release" means release approved by the official responsible body from the quarantine containment measures provided for in Annex III;

"the prohibition Regulations" means the European Communities (Introduction of Organisms Harmful to Plants or Plant Products) (Prohibition) Regulations, 1980 to 1996;

"Person responsible for the activities" means the person referred to in paragraph (a) of Regulation 5 of these Regulations;

"the responsible official body" means, for the purposes of these Regulations, the Minister for Agriculture, Food and Forestry; "third country" means a country which is not a member state of the European Communities;

(2) A word or expression that is used in any Council Directive or Commission Directive referred to in these Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council Directive or the Commission Directive as the case may be.

(3) In these Regulations, any reference to a Regulation shall be construed as a reference to a Regulation contained in these Regulations, unless it is indicated that reference to some other provision is intended, and any reference in a Regulation to a paragraph or sub-paragraph shall be construed as a reference to a paragraph or a sub-paragraph of that Regulation unless it is

indicated that some other provision is intended.

(4) These Regulations apply only to the introduction and movement for scientific purposes and/or for work on varietal selections of the harmful organisms, plants, plant products and other objects as listed in Annexes I to V inclusive to the Council Directive.

# REG 4

4. . A person shall not introduce the material into the State or move the material within the State unless

(a) such introduction and movement is intended solely for the activities referred to in these Regulations, and

(b) prior written application has been made to the Minister for the activities, and

(c) prior written approval for the activities and for the

introduction into the State has been granted by the Minister, and (d) such introduction and movement is in conformity with these Regulations.

### REG 5

5. The Application referred to in subparagraph (b) of Regulation 4 shall specify at least the following:

(a) the name and address of the person responsible for the activities,

(b) the scientific name or names of the material, including the harmful organism concerned, where appropriate,

(c) the type of material,

(d) the quantity of material,

(e) the place of origin of the material, with appropriate

documentary evidence for material to be introduced from a third country,

(f) the duration, nature and objectives of the activities envisaged, including at least, a summary of the work and a specification for trial for scientific purposes or work on varietal selections,

(g) the address and description of the specific site or sites for quarantine containment and, where appropriate for testing,

(h) the place of first storage or of first planting, as

appropriate, after the material has been officially released, where appropriate,

(i ) the proposed method of destruction or treatment of material on completion of the approved activities, where appropriate,

(j) the proposed point of entry into the Community for material to be introduced from a third country.

# REG 6

6. . (1) On receipt of the application referred to in Regulation 5, the Minister shall approve the activities provided that general conditions laid down in Annex 1 are satisfied.

(2) The approval referred to in paragraph (1) may be withdrawn by the Minister without notice in circumstances where the conditions laid down in Annex I cease to be met.

(3) In case such approval has been withdrawn in accordance with paragraph (2) the Minister may order the destruction of the material in such manner as he may specify at the expense of the person responsible for the activities.

# REG 7

7. . (1) Where approval for the activities has been granted under Regulation 6, or by another Member State under the Commission Directive, the Minister shall approve the introduction into or movement within the State of the material relevant to the approval provided that such material is accompanied at all times by a letter of authority conforming to the model set out in Annex II issued by the Minister where the activities have been approved by him or by the competent authority of the Member State where the activities were approved, as the case may be.

(2) The Minister may withdraw the approval referred to in paragraph (1) where he is satisfied that the conditions laid down wherein have not been complied with and may order the destruction of the material in such manner as he may specify at the expense of the person responsible for the activities.

#### REG 8

8. . In case the material referred to in Regulation 7 originates in another Member State, the letter of Authority referred in Regulation 7 shall be endorsed by that Member State and in cases where such material is also listed in part A of Annex V to the Council Directive, it shall also be accompanied by a plant passport provided for in Regulation 10 (3) (a) (i) of the prohibition Regulations with an endorsement to indicate that such material is being moved in accordance with the Commission Directive.

#### REG 9

9. In case the material referred to in Regulation 7 is being introduced from a third country, the letter of Authority referred to in Regulation 7 shall not issue unless appropriate documentary evidence of place of origin of such material has been produced by the person responsible for the activities and in cases where such material is also listed in part B of Annex V by a phytosanitary certificate provided for in Regulation 11(2) of the prohibition Regulations, with an endorsement to indicate the relevant harmful organism where appropriate and that such material is being imported in accordance with the Commission Directive.

#### **REG 10**

10. The person responsible for the activities shall

(1) notify the responsible official body in writing at least two days in advance of the proposed date of introduction of the material referred to in Regulation 7 giving full particulars of the proposed date and point of entry to the State,

(2) afford to an authorised person an opportunity of examining the material (and any packaging in which it is contained or any vehicle in which it is being transported) for the purposes of these Regulations at such time and in such manner as the authorised person may determine.

## **REG** 11

11. The material referred to in Regulation 7 shall be held under quarantine containment conditions at all times during introduction into and movement within the State and upon such introduction shall be directly and immediately moved to the site specified in the application under Regulation 5 where appropriate.

### **REG 12**

12. The person responsible for the activities approved under Regulation 6 shall immediately notify the responsible official body of—

(a) Any contamination of the material by harmful organisms listed in the Council Directive and any other harmful organism considered a risk to the Community, detected during the activities and/or(b) Any event resulting in the escape of such organisms into the environment.

## **REG 13**

13. A person shall not move within the State or introduce from the State into another Member State any material to which these Regulations relate without affording an authorised person, in such manner as the Minister shall direct, an opportunity of examining the material together with the packaging intended to be used in connection with such movement or introduction.

### **REG 14**

14. On cessation of the activities approved under Regulation 6:(a) The plants, plant products or other objects comprised in the material shall not enter into official release unless they have been subject to quarantine measures including testing carried out by scientifically trained staff in accordance with the provisions of Annex III and have been found free from any harmful organism unless the harmful organism is one which is known to occur in the Member States and is not listed in the Council Directive.

(b) Any plants, plant products or other objects comprised in the material which have not been found free from harmful organisms in accordance with sub-paragraph (a) and any other plants, plant products or other objects with which they may have been in contact or which may have become contaminated shall be destroyed or otherwise treated in such manner as may be prescribed by the responsible official body.

(c) All other material, including harmful organisms and contaminated material, and any other plants, plant products or other objects with which it has been in contact or which may have been contaminated shall be destroyed, sterilised or otherwise cleaned to the satisfaction of the responsible official body.

(d) The premises at which the activities have been undertaken shall be sterilised or otherwise cleaned to the satisfaction of the responsible official body.

**REG 15** 

15. (1) For the purpose of ensuring compliance with Article 2 of the Commission Directive, an authorised person may at all reasonable times—

(a) enter any premises/facilities where the approved activities are being carried out and monitor such activities,

(b) enter and inspect any premises, railway or other vehicle ship or vessel or aircraft,

(c) inspect the contents of any container in which there are reasonable grounds for believing that the material is moved, grown, produced, stored or offered for sale and

(d) examine, take samples and test any organism, plant, plant product or other object found in the course of the inspection, and (e) examine and take copies of any book or document or any other record in whatever form kept so found, or of extracts from any such records,

(f) examine any copy any data or data material (within the meaning in each case of the Data Protection Act, 1988) (No. 25 of 1988) found there, extract information from any such data and take extracts from any such material.

(2) The Minister shall furnish an authorised person with a certificate of appointment and, when exercising any power conferred by this Regulation, the authorised person shall, if requested by any person affected, produce the certificate to that person.

# **REG 16**

16. (1) Any person who contravenes Regulations 4, 10 or 11 of these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding  $\pounds1,000$  or to a term of imprisonment not exceeding 6 months or to both.

(2) Any person who fails to comply with the provisions of Regulations 12, 13 or 14 or who obstructs or interferes with an authorised person in the performance of his/her functions under these Regulations shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,000 or to a term of imprisonment not exceeding 6 months or to both. 17. An offence under these Regulations may be prosecuted by the Minister.

#### ANNEX I

1. For the purposes of Regulation 6 the following general conditions shall apply:

the nature and objectives of the activities for which the material is to be introduced or moved shall have been examined by the responsible official body and found to comply with the concept of trial or scientific purposes and for work on varietal selections provided for under the Council Directive.

the quarantine containment conditions of the premises and facilities at the site or sites at which the activities are to be undertaken shall have been inspected for compliance with the provisions laid down in point 2 and approved by the responsible official body, the responsible official body shall limit the quantity of material to an amount that is adequate for the approved activities and in any case the amount shall not exceed quantities which have been determined having regard to available quarantine containment facilities,

the scientific and technical qualifications of the personnel by whom the activities are to be undertaken, shall have been examined and approved by the responsible official body.

2. For the purposes of paragraph 1, the quarantine containment conditions of the premises and facilities at the site or sites at which the activities are to be undertaken shall be sufficient to ensure a safe handling of the material such that any harmful organisms of concern are contained and the risk of spreading such harmful organisms eliminated. For each activity specified in the application, the risk of spread of the harmful organisms held under quarantine containment conditions shall be determined by the responsible official body, having regard to the type of material and the activity envisaged, and to the biology of the harmful organisms, the means of their dispersal, the interaction with the environment and other relevant factors relating to the risk posed by the material concerned. As a result of the assessment of the risk the responsible official body shall consider and lay down as appropriate: (a) the following guarantine measures concerning the premises, facilities and working procedures:

physical isolation from all other plant/harmful organism material, including consideration of control of vegetation in surrounding areas, designation of a contact person responsible for the activities, restricted access to the premises and facilities, and to the surrounding area, as appropriate, to named personnel only, appropriate identification of the premises and facilities indicating the type of activities and the personnel responsible, maintenance of a register of the activities performed and a manual of operating procedures, including procedures in the event of escape of harmful organisms from containment,

appropriate security and alarm systems,

appropriate control measures to prevent the introduction into and the spread within the premises of harmful organisms,

controlled procedures for sampling and for transfer between premises and facilities, of the material,

controlled waste, soil and water disposal, as appropriate,

appropriate hygiene and disinfection procedures and facilities for personnel, structures and equipment,

appropriate measures and facilities for disposal of experimental material,

appropriate indexing (including testing facilities and procedures); and (b) further quarantine measures according to the specific biology and epidemiology of the type of material involved and the activities approved,

maintenance in facilities which separate chamber 'double door' access to personnel,

maintenance under negative air pressure,

maintenance in escape-proof containers with appropriate mesh size and other barriers e.g. water barrier for mites, closed soil containers for nematodes, electric insect traps,

maintenance in isolation from other harmful organisms and material, e.g. viruliferous plant food material, host material,

maintenance of material for breeding in breeding cages with manipulation devices,

no interbreeding of the harmful organisms with indigenous strains or species,

avoidance of continuous culture of the harmful organisms,

maintenance under conditions that strictly control the multiplication of the harmful organism, e.g. under an environmental regime such that diapause does not occur,

maintenance in such a way that no spread by propagules can occur, e.g. air streams should be avoided,

procedures to check the purity of cultures of the harmful organisms for freedom from parasites and other harmful organisms,

appropriate control programmes for the material to eliminate possible vectors,

for in vitro activities, handling of the material under sterile conditions: equipping the laboratory for the performance of aseptic procedures,

maintenance of harmful organisms spread by vectors under conditions such that there is no spread via the vector e.g. controlled mesh size, containment of soil,

seasonal isolation to ensure the activities are done during periods of low plant health risk.

## ANNEX II LETTER OF AUTHORITY

Name and address of consignor/Plant Protection organisation of the country of originLetter of Authority
for the introduction and/or movement of harmful organisms, plants,
plant products and other objects for trial or scientific purposes
and for work on varietal selections (issued under Directive
95/44/EC)2 Name and address of person responsible for the approved
activities3. Name of the responsible official body of the Member
State of issue4. Address and description of the specific site or
sites for quarantine containment5. Place of origin (documentary
evidence attached for material originating in a third country)7.
Declared point of entry for material introduced from a third
country6. Plant passport number: or Phytosanitary certificate number:8.
Scientific name(s) of the material including the harmful organisms
concerned9. Quantity of material10. Type of material

11. Additional declaration

This material is moved within/introduced into the Community under Directive 95/44/EC12. Additional information

13. Endorsement by the responsible official body of the Member State or origin of the material14. Stamp of the responsible official Place of endorsement: Place of Issue: Date: Date: Name and signature of authorised officer: Name and signature of authorised officer:

ANNEX III

QUARANTINE MEASURES INCLUDING TESTING ON PLANTS, PLANT PRODUCTS AND

OTHER OBJECTS INTENDED FOR RELEASE FROM QUARANTINE PART A

For certain plants, plant products and other objects listed in Annex III to the Council Directive.

SECTION I: Plants of Citrus L. Fortunella Swingle, Poncirus Raf: and their hybrids, other than fruit and seeds.

1. The plant material, as appropriate, shall be subjected to appropriate therapy procedures as laid down in FAO/IPGRI Technical

Guidelines.

2. The plant material, following the therapy procedures carried out in point 1. shall be subjected to indexing procedures in its entirety. All plant material including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex I. Plant material intended for approval for official release shall be held under conditions conducive to a normal cycle of vegetative growth and be subjected to visual inspection for signs and symptoms of harmful organisms including all relevant harmful organisms listed in the Council Directive, on arrival and subsequently, at appropriate times, during the period of the indexing procedures,

3. For the purposes of point 2. the plant material shall be indexed for harmful organisms (tested for and identified) according to the following procedures:

3. 1 The testing shall use appropriate laboratory methods and, where appropriate, indicator plants, including Citrus sinensis (L.) Osbeck, C. aurantifolia Christm. Swing. C. medica L., C. reticulata Blanco and Sesamum L., in order to detect at least the following harmful organisms:

(a) Citrus greening bacteriuim

(b) Citrus variegated chlorosis

(c) Citrus mosaic virus

(d) Citrus tristeza virus (all isolates)

(e) Citrus vein enation woody gall '

(f) Leprosis

(g) Naturally spreading psorosis

(h) Phoma tracheiphila (Petri) Kanchaveli & Gikashvili

( i ) Satsuma dwarf virus

(j) Spiroplasma citri Saglio et al

(k) Tatter leaf virus

(1) Witches' broom (MLO)

(m) Xanthomonas campestris (all strains pathogenic to Citrus).

3.2 For diseases such as Blight and Blight-like for which there are no short-term indexing procedures the plant material must be subjected upon arrival to shoot-tip grafting onto seeding stock grown under sterile culture as set out in FAO/IPGRI Technical Guidelines, and the resulting plants subjected to therapy procedures according to point 1.

4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms to harmful organisms have been observed shall be subjected to an investigation including testing where necessary, to determine as far as possible, the identity of the harmful organisms causing the signs and symptoms. SECTION II: Plants of Cydonia Mill, Malus Mill, Prunus L and Pyrus L and their hybrids and Fragaria L, intended for planting, other than seeds.

1. The plant material, as appropriate, shall be subjected to appropriate therapy procedures as laid down in FAO/IPGRI Technical Guidelines.

2. The plant material, following the therapy procedures carried out in point 1. shall be subjected to indexing procedures in its entirety. All plant material including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex 1. Plant material intended for approval for official release shall be held under conditions conducive to a normal for signs and symptoms of harmful organisms including all relevant harmful organisms listed in the Council Directive, on arrival and subsequently, at appropriate times, during the period of the indexing procedures:

3. For the purposes of point 2 the plant material shall be indexed for harmful organisms (tested for and identified) according to the following procedures;

3.1 In the case of Fragaria L., irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and, where appropriate, indicator plants, including Fragaria vesca, F: virginiana and Chenopodium spp. for the detection of at least the following harmful organisms:

(a) Arabis mosaic virus

(b) Raspberry ringspot virus

(c) Strawberry crinkle virus

(d) Strawberry latent 'C, virus

(e) Strawberry latent ringspot virus

(f) Strawberry mild yellow edge virus

(g) Strawberry vein banding virus

(h) Strawberry witches' broom mycoplasm

(i) Tomato black ring virus

(j) Tomato ringspot virus

(k) Colletotrichum acutatum Simmonds

(1) Phytophthora fragariae Hickman var fragariae Wilcox & Duncan

(m) Xanthomonas fragariae Kennedy & King.

3.2 In the case of Malus Mill:

(i) where the plant material originates from a country which is not known to be free of any of the following harmful organisms:

( a ) Apple proliferation mycoplasm; or

(b) Cherry rasp leaf visus (American).

the testing shall use appropriate laboratory methods and. where appropriate, indicator plants for the detection of the relevant harmful organisms, and

(ii) irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and. where appropriate, indicator plants for the detection of at least the following harmful organisms:

(a) Tobacco ringspot virus

(b) Tomato ringspot virus

(c) Erwinia amylovora (Burr.) Winsl. et al

3.3 In the case of Prunus L., as appropriate for each Prunus species:

(i) where the plant material originates from a country which is not known to be free of any of the following harmful organisms:

(a) Apricot chlorotic leafroll mycoplasm:

(b) Cherry rasp leaf virus (American): or

( c ) Pseudomonas syringae pv. persicae (Prunier et al.) Young et al,.

the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of the relevant harmful organisms: and

(ii) irrespective of the country of origin of the plant material,

the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of at least the following harmful organisms:

(a) Little cherry pathogen (non-European isolates)

(b) Peach mosaic virus (American)

(c) Peach phony rickettsia

(d) Peach rosette mosaic virus

- (e) Peach rosette mycoplasm
- (f) Peach X-disease mycoplasm
- (g) Peach yellows mycoplasm

(h) Plum line pattern virus (American)

(i) Plum pox virus

(j) Tomato ringspot virus

(k) Xanthomonas campestris pv. pruni (Smith) Dye.

3.4 In the case of Cydonia Mill. and Pyrus L. irrespective of the country of origin of the plant material, testing by appropriate laboratory methods, and, where appropriate, indicator plants, for detection of at least the following harmful organisms:

(a) Erwinia amylovora (Burr.) Winsl. et al.

(b) Pear decline mycoplasm.

4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms of harmful organisms have been observed shall be subject to an investigation including testing where necessary, to determine as far as possible, the identity of the harmful organisms causing the signs and symptoms. SECTION III: Plants of Vitis L, other than fruits

1. The plant material shall be subjected, as appropriate, to appropriate therapy procedures, as laid down in FAO/IPGRI Technical Guidelines.

2. The plant material, following the therapy procedures carried out in point I, shall be subjected to indexing procedures in its entirety. All plant material including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex I. Plant material intended for approval for official release shall be held under conditions conducive to a normal cycle of vegetative growth and shall be subjected to visual inspection for signs and symptoms of harmful organisms including those of Daktulosphaira vitifoliae (Fitch) and of all other relevant harmful organisms listed in the Council Directive, on arrival and subsequently, at appropriate times, during the period of the indexing procedures.

3. For the purposes of point 2 the plant material shall be indexed for harmful organisms (tested for and identified) according to the following procedures:

3.1 Where the plant material originates in a country which is not known to be free of the following harmful organisms:

(i) Ajinashika disease

The testing shall use an appropriate laboratory method. In the event of a negative result, the plant material shall be indexed on the vine variety Koshu and kept under observation during at least two cycles of vegetation.

(ii) Grapevine stunt virus

The testing shall use appropriate indicator plants, including the vine variety Campbell Early, and observation shall take place during one year.

(iii) Summer mottle

The testing shall use appropriate indicator plants, including the vine varieties Sideritis, Cabernet Franc and Mission.

3.2 Irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of at least the following harmful organisms:

(a) Blueberry leaf mottle virus

(b) Grapevine Flavescence doree MLO and other grapevine yellows

(c) Peach rosette mosaic virus

(d) Tobacco ringspot virus

(e) Tomato ringspot virus (strain 'yellow vein, and other strains)

(f) Xylella fastidiosa (Well & Raju)

(g) Xylophilus ampelinus (Panagopoulos) Willems et al.

4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms of harmful organisms have been observed shall be subjected to an investigation including testing where necessary, to determine as far as possible, the identity of the harmful organisms causing the signs and symptoms. PART B

For plants, plant products and other objects listed in Annexes II and IV to the Council Directive

1. The official quarantine measures shall include appropriate inspection or testing for the relevant harmful organisms listed in Annexes I and II to the Council Directive and shall be carried out in respect of the special requirements laid down in Annex IV to the Council Directive and shall be carried out in respect of the special requirements laid down in Annex IV to the Council Directive for specific harmful organisms, as appropriate. In respect of such special requirements the methods used for the quarantine measures shall be those laid down in Annex IV to the Council Directive or other equivalent officially approved measures.

2. The plants, plant products and other objects must be found free. according to the provisions of paragraph 1. from the relevant harmful organisms specified in Annexes I, II and IV to the Council Directive for the said plants, plant products and other objects.

GIVEN under my Official Seal, this 9th day of May, 1996. IVAN YATES, Minister for Agriculture, Food and Forestry.