Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections (Codified version)

COMMISSION DIRECTIVE 2008/61/EC

of 17 June 2008

establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community[(1)], and in particular Articles 3(8), 4(5), 5(5) and 13b(4) thereof,

Whereas:

(1) Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections[(2)] has been substantially amended[(3)]. In the interests of clarity and rationality the said Directive should be codified.

(2) Under the provisions of Directive 2000/29/EC, harmful organisms listed in its Annexes I and II, whether singly or associated with the relevant plants or plant products listed in Annex II to that Directive, may not be introduced into and spread by movement within the Community or certain protected zones thereof.

(3) Under Directive 2000/29/EC, plants, plant products and other objects listed in its Annex III may not be introduced into the Community or into certain protected zones thereof.

(4) Plants, plant products and other objects listed in Annex IV to Directive 2000/29/EC may not be introduced into or moved within the Community or certain protected zones thereof unless the relevant special requirements indicated in that Annex are met.

(5) Plants, plant products and other objects listed in Annex V, Part B to Directive 2000/29/EC coming from third countries may not be introduced into the Community unless they comply with the standards and requirements laid down in that Directive and are

accompanied by an official phytosanitary certificate ensuring such compliance and are, moreover, inspected on an official basis for compliance with these provisions.

(6) However, Articles 3(8), 4(5), 5(5) and 13b(4) of Directive 2000/29/EC provide for those rules not to apply to the introduction and movement of such harmful organisms, plants, plant products and other objects, for trial or scientific purposes and for work on varietal selections, under conditions which shall be determined at Community level.

(7) Therefore, it is necessary to determine the conditions which must be satisfied in the case of such introductions or movements, in order to ensure that there is no risk of harmful organisms spreading.

(8) The conditions laid down for material under Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein[(4)] and under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[(5)], and other more specific Community provisions regarding endangered species of wild fauna and flora and genetically modified organisms, are not affected by this Directive.

(9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health.

(10) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1 Member States shall ensure that for any activity for trial or scientific purposes and for work on varietal selections, hereinafter referred to as ‘the activities’, which would involve the use of harmful organisms, plants, plant products and other objects pursuant to Article 3(8), 4(5), 5(5) or 13b(4) of Directive 2000/29/EC, hereinafter referred to as ‘the material’, an application shall be submitted to the responsible official bodies prior to the introduction into, or movement within, any Member State or relevant protected zones thereof, of any such material.

2 The application referred to in paragraph 1, 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 resumé of the work and a specification for trial or 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.

Article 2

1 Member States, on receipt of the application referred to in Article 1, shall approve the activities concerned, if it is established that the general conditions laid down in Annex I are satisfied.

Member States shall withdraw the said approval at any time if it is established that the conditions laid down in Annex I cease to be met.

2 Following the approval of the activities referred to in paragraph 1, Member States shall approve the introduction into or movement within the Member State or relevant protected zones of the material referred to in the application, provided that such material is accompanied in all cases by a letter of authority for such introduction or movement of harmful organisms, plants, plant products and other objects for trial or scientific purposes and for work on varietal selections, hereinafter referred to as a 'letter of authority', conforming to the model set out in Annex II and issued by the responsible official body of the Member State in which the activities are to be undertaken, and

a in the case of material originating in the Community:

(i) where the place of origin is in another Member State, the accompanying letter of authority shall be officially endorsed by the Member State of origin for movement of the material under quarantine containment conditions; and

(ii) for those plants, plant products and other objects listed in Annex V, Part A to Directive 2000/29/EC, the material shall also be accompanied by a plant passport issued in accordance with Article 10 of Directive 2000/29/EC, on the basis of the examination carried out pursuant to Article 6 of that Directive for compliance with the provisions laid down therein, other than those relating to any harmful organism in respect of which the activities have been approved under the first subparagraph of paragraph 1 of this Article. The plant passport shall contain the following statement: 'This material is moved under Directive 2008/61/EC'.

In cases where the address of the specific site or sites for quarantine containment is located in another Member State, the Member State responsible for issuing the plant passport shall issue a plant passport only on the basis of information regarding the approval referred to in the first subparagraph of paragraph 1 of this Article received officially from the Member State responsible for the approval of the activities, and on the assurance that quarantine containment conditions shall be applied during movement of the material; and

b in the case of material introduced from a third country:

(i) Member States shall ensure that the letter of authority is issued on the basis of appropriate documentary evidence as regards the place of origin of the material; and

(ii) for plants, plant products and other objects listed in Annex V, Part B to Directive 2000/29/EC the material shall also be accompanied wherever possible by a phytosanitary certificate issued in the country of origin in accordance with Article 13(1) of Directive 2000/29/EC, on the basis of the examination carried out pursuant to Article 6 of that Directive for compliance with the provisions laid down therein, other than those relating to any harmful organism in respect of which the activities have been approved under the first subparagraph of paragraph 1 of this Article.

The certificate shall, under 'Additional declaration', contain the following indication: 'This material is imported under Directive 2008/61/EC'. The relevant harmful organism or organisms shall also be specified, where appropriate.

In all cases Member States shall ensure that the material is held under quarantine containment conditions during the said introduction or movement, and is moved directly and immediately to the site or sites specified in the application.

3 The responsible official body shall monitor the approved activities and shall ensure that:

a the quarantine containment conditions and other general conditions specified in accordance with Annex I are complied with throughout the duration of the activities, by examination of the premises and activities at appropriate times;

b the following procedures are applied according to the type of approved activities:

(i) for plants, plant products or other objects intended for release from quarantine:

— the plants, plant products or other objects shall not be released without approval by the responsible official body, hereinafter referred to as 'official release'. Prior to official release, the plants, plant products or other objects shall have been subject to quarantine measures, including testing, and must have been found free by such measures from any harmful organism, unless it is identified as one which is known to occur in the Community and is not listed in Directive 2000/29/EC,

— the quarantine measures, including testing, shall be carried out by scientifically trained staff of that body or of any officially approved body, and shall be carried out in accordance with the provisions laid down in Annex III to this Directive for the plants, plant products and other objects specified,

— any plants, plant products or other objects which have not been found free, by such measures, from harmful organisms as specified in the first indent, and any other plants, plant products or other objects with which they have been in contact or which may have become contaminated shall be destroyed or subjected to an appropriate treatment or quarantine measure aimed at eradicating the relevant harmful organisms; the provisions of (ii), second indent shall apply accordingly;

(ii) for all other material (including harmful organisms), at the end of the duration of the approved activities, and for all material found to be contaminated during the activities:

— the material (including the harmful organisms and any contaminated material) and any other plants, plant products or other objects

with which it has been in contact or which may have become contaminated shall be destroyed, sterilised or otherwise treated in a manner to be specified by the responsible official body, and

— the premises and facilities at which the activities in question have been undertaken shall be sterilised or otherwise cleaned, as necessary, in a manner to be specified by the responsible official body;

c any contamination of the material by harmful organisms listed in Directive 2000/29/EC and any other harmful organism considered a risk to the Community by the responsible official body and detected during the activity shall be notified immediately to the responsible official body by the person responsible for the activities, along with notification of any event resulting in the escape of such organisms into the environment.

4 Member States shall ensure that for activities utilising plants, plant products and other objects listed in Annex III to Directive 2000/29/EC and not covered by Part A, Sections I, II and III of Annex III to this Directive, appropriate quarantine measures, including testing, shall be carried out. These quarantine measures shall be notified to the Commission and to the other Member States. The details of such quarantine measures shall be completed and inserted in Annex III to this Directive once the necessary technical information is available.

Article 3

1 Before 1 September each year, Member States shall send to the Commission and to the other Member States a list, with quantities, of the introductions and movements of material approved under this Directive during the preceding period of one year ending on 30 June, and of any contamination by harmful organisms of such material, which has been confirmed under the quarantine measures, including testing, carried out under Annex III during the same period.

2 Member States shall cooperate administratively through the authorities established or designated pursuant to Article 1(4) of Directive 2000/29/EC, with regard to the provision of details of the quarantine containment conditions and measures imposed for activities approved under this Directive.

Article 4

Member States shall immediately communicate to the Commission all provisions of national law which they adopt in the field covered by this Directive. The Commission shall inform the other Member States thereof.

Article 5

Directive 95/44/EC, as amended by the Directive listed in Annex IV, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V.

Article 6

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 17 June 2008.

For the Commission

The President

José Manuel BARROSO

ANNEX I

1. For the purposes of Article 2(1) of this Directive 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 Directive 2000/29/EC,

— 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 point 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 quarantine 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 with 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

Model Letter 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

EUROPEAN COMMUNITIES LETTER OF AUTHORITY

<table>
<tr><td>1. Name and address of consignor/plant protection organisation of the coutry of origin</td><td colspan="2" rowspan="2">Letter 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 2008/61/EC)</td></tr>
<tr><td rowspan="2">2. Name and address of person responsible for the approved activities</td></tr>
<tr><td colspan="2">3. Name of the responsible official body of the Member State of issue</td></tr>
<tr><td rowspan="2">4. Address and description of the specific site or sites for quarantine containment</td><td colspan="2">5. Place of origin (documentary evidence attached for material originating in a third country)</td></tr>
<tr><td colspan="2" rowspan="2">6. Plant passport number:

or Phytosanitary certificate number:</td></tr>
<tr><td>7. Declared point of entry for material introduced from a third country</td></tr>
<tr><td colspan="2">8. Scientific name(s) of the material, including the harmful organisms concerned</td><td>9. Quantity of material</td></tr>
<tr><td colspan="3">10. Type of material</td></tr>
<tr><td colspan="3">11. Additional declaration

This material is [introduced into]/[moved within] (1) the Community under Directive 2008/61/EC

(1) delete if not applicable</td></tr>
<tr><td colspan="3">12. Additional information</td></tr>
<tr><td>13. Endorsement by the responsible official body of the Member State of origin of the material

Place of endorsement:

Date:

Name and signature of authorised officer:</td><td colspan="2">14. Stamp of the responsible official body of issue

Place of issue:

Date:

Name and signature of authorised officer:</td></tr>
</table>

Original dimensions reduced by 10 %.

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 Directive 2000/29/EC

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 pursuant to 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 Directive 2000/29/EC, 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. aurantiifolia* Christm. Swing, *C. medica* L., *C. reticulata* Blanco and *Sesamum* L., in order to detect at least the following harmful organisms:

(a) Citrus greening bacterium

(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

(l) 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 seedling 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 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.

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 pursuant to 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 Directive 2000/29/EC, 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

(l) *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 virus (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 pursuant to 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 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 Directive 2000/29/EC, 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 dorée 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.

Section IV:

Plants of stolon- or tuber-forming species of *Solanum* L. or their hybrids, intended for planting

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

2. Each unit of the plant material, following the therapy procedures carried out pursuant to point 1, shall be subjected to indexing procedures. 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 Directive 2000/29/EC and potato yellow vein disease, on arrival and subsequently, at regular intervals until senescence, during the period of the indexing procedures.

3. The indexing procedures referred to in point 2 shall follow the technical provisions set out in point 5, in order to detect at least the following harmful organisms:

— *Bacteria*

(a) *Clavibacter michiganensis* (Smith) Davis *et al.* ssp. *sepedonicus* (Spieckermann et Kotthoff) Davis *et al.*;

(b) *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*

— *Viruses and virus-like organisms*

(a) Andean potato latent virus,

(b) Potato black ringspot virus,

(c) Potato spindle tuber viroid,

(d) Potato yellowing alfamovirus,

(e) Potato virus T,

(f) Andean potato mottle virus,

(g) Common potato viruses A, M, S, V, X and Y (including Y^o, Y^n and Y^c) and potato leaf roll virus.

However, in the case of true seed of potato, the indexing procedures shall be carried out in order to detect at least the viruses and virus-like organisms listed above at (a) to (e).

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.

5. The technical provisions referred to in point 3 shall be as follows:

— *Bacteria*

1. For tubers, test the heel end of each tuber. The standard sample size shall be 200 tubers. However, the procedure can be applied for samples with less than 200 tubers.

2. For young plants and cuttings, including micro-plants, test the lower sections of the stem and, where appropriate, the roots, for each unit of the plant material.

3. For testing of progeny tubers, or of stem bases for non-tuber forming species, one normal cycle of vegetative growth after the testing referred to in points 1 and 2, is recommended.

4. For the material referred to in point 1, the testing method for *Clavibacter michiganensis* (Smith) Davis *et al.* ssp. *sepedonicus* (Spieckermann et Kotthoff) Davis *et al.* shall be the Community method set out in Annex I to Council Directive 93/85/EEC[(6)]. For the material referred to in point 2, this testing method could be applied.

5. For the material referred to in point 1, the testing method for *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* shall be the test scheme set out in Annex II to Council Directive 98/57/EC[(7)]. For the material referred to in point 2, this testing method could be applied.

— *Viruses and virus-like organisms, other than potato spindle tuber viroid*

1. The minimum testing for vegetative material (tubers, young plants and cuttings, including micro-plants) shall include a serological test done at or near flowering for each of the specified list of harmful organisms other than

potato spindle tuber viroid, and followed by a biological test of material testing negative in the serological test. For Potato leaf roll virus, two serological tests shall be done.

2. The minimum testing for true seed shall be a serological test or a biological test if no serological test is available. Retesting of a proportion of negative samples and testing of borderline results by another method is highly recommended.

3. The serological and biological testing referred to in points 1 and 2 shall be done on glasshouse grown plants, sampled from at least two positions on every stem, including a young fully expanded leaflet at the top of each stem and an older leaflet from a midway position; each stem shall be sampled because of possible non-systemic infection. In the case of the serological testing, no bulking of leaflets from separate plants shall be done, unless the bulking rate has been validated for the method of use; leaflets from each stem may however be bulked to make up the sample from each plant. In the case of the biological testing, the maximum bulking is up to five plants with inoculation of a minimum of duplicate indicator plants.

4. The appropriate indicator plants to be used for the biological testing referred to in points 1 and 2 shall be those listed by the European and Mediterranean Plant Protection Organization (EPPO), or other officially approved indicator plants, which have been shown to detect the viruses.

5. Only material which has been directly tested shall be released from quarantine. Where eye indexing has been done, only the progeny of the tested eye may be released. The tuber should not be released because of possible problems with non-systemic infection.

— *Potato spindle tuber viroid*

1. For all material, glasshouse grown plants shall be tested, as soon as they are well established but prior to flowering and pollen production. Testing on tuber sprouts/*in vitro* plants/small seedlings shall only be regarded as a preliminary test.

2. Samples shall be taken from a fully expanded leaflet at the top of each stem of the plant.

3. All material for testing shall be grown at temperatures not less than 18 °C (preferably at temperatures higher than 20 °C) and with at least a 16-hour photo-period.

4. Testing shall be by radioactive or non-radioactive labelled cDNA or RNA-probes, return-PAGE (with silver staining) or RT-PCR.

5. The maximum bulking rate for probes and return-PAGE is 5. Use of this or higher bulking rates must be validated.

PART B

For plants, plant products and other objects listed in Annexes II and IV to Directive 2000/29/EC

1. The official quarantine measures shall include appropriate inspection or testing for the relevant harmful organisms listed in Annexes I and II to Directive 2000/29/EC and shall be carried out in respect of the special requirements laid down in Annex IV to Directive 2000/29/EC 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 Directive 2000/29/EC or other equivalent officially approved measures.

2. The plants, plant products and other objects must be found free, according to the provisions of point 1, from the relevant harmful organisms specified in Annexes I, II and IV to Directive 2000/29/EC for those plants, plant products and other objects.

ANNEX IV

PART A

REPEALED DIRECTIVE WITH ITS AMENDMENT

(referred to in Article 5)

Commission Directive 95/44/EC	(OJ L 184, 3.8.1995, p. 34)
Commission Directive 97/46/EC	(OJ L 204, 31.7.1997, p. 43)

PART B

LIST OF TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW

(referred to in Article 5)

Directive	**Time-limit for transposition**
95/44/EC	1 February 1996
97/46/EC	1 January 1998

ANNEX V

CORRELATION TABLE

Directive 95/44/EC	**This Directive**
Article 1(1)	Article 1(1)
Article 1(2), introductory sentence	Article 1(2), introductory sentence

Article 1(2), first indent	Article 1(2)(a)
Article 1(2), second indent	Article 1(2)(b)
Article 1(2), third indent	Article 1(2)(c)
Article 1(2), fourth indent	Article 1(2)(d)
Article 1(2), fifth indent	Article 1(2)(e)
Article 1(2), sixth indent	Article 1(2)(f)
Article 1(2), seventh indent	Article 1(2)(g)
Article 1(2), eighth indent	Article 1(2)(h)
Article 1(2), ninth indent	Article 1(2)(i)
Article 1(2), tenth indent	Article 1(2)(j)
Articles 2 and 3	Articles 2 and 3
Article 4(1)	—
Article 4(2)	Article 4
—	Article 5
Article 5	Article 6
Article 6	Article 7
Annexes I, II and III	Annexes I, II and III
—	Annex IV
—	Annex V

(**1**) OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2007/41/EC (OJ L 169, 29.6.2007, p. 51).

(**2**) OJ L 184, 3.8.1995, p. 34. Directive as amended by Directive 97/46/EC (OJ L 204, 31.7.1997, p. 43).

(**3**) See Annex IV, Part A.

(**4**) OJ L 61, 3.3.1997, p. 1. Regulation as last amended by Commission Regulation (EC) No 318/2008 (OJ L 95, 8.4.2008, p. 3).

(**5**) OJ L 106, 17.4.2001, p. 1. Directive as last amended by Directive 2008/27/EC (OJ L 81, 20.3.2008, p. 45).

(**6**) OJ L 259, 18.10.1993, p. 1. Directive as amended by Commission Directive 2006/56/EC (OJ L 182, 4.7.2006, p. 1).

(**7**) OJ L 235, 21.8.1998, p. 1. Directive as amended by Commission Directive 2006/63/EC (OJ L 206, 27.7.2006, p. 36).