COMMISSION DIRECTIVE 97/46/EC

of 25 July 1997

amending Directive 95/44/EC 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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 77/93/EEC of 21 December 1976 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], as last amended by Commission Directive 97/14/EC [2], and in particular Articles 3 (7) (e), 4 (5), 5 (5) and 12 (3c) thereof,

Whereas pursuant to the provisions of Directive 77/93/EEC, 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 the said Directive, may not be introduced into and spread by movement within the Community or certain protected zones thereof;

Whereas pursuant to Directive 77/93/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;

Whereas, also, plants, plant products and other objects listed in Annex IV to the said Directive, may not be introduced into or moved within the Community or certain protected zones thereof unless the relevant special requirements indicated in the said Annex are met;

Whereas plants, plant products and other objects listed in Annex V Part B to the Directive 77/93/EC coming from third countries may not be introduced into the Community unless they comply with the standards and requirements laid down in the said 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;

Whereas, however, Articles 3 (7) (e), 4 (5), 5 (5) and 12 (3c) of the said Directive 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, subject to certain conditions which shall be determined at Community level;

Whereas Commission Directive 95/44/EC [3] laid down the conditions which must be satisfied in cases of such introductions or movements, in order to ensure that there is no risk of harmful organisms spreading;

Whereas in the Member States there is a need to import plants of stolon- or tuber-forming species of *Solanum* L. or their hybrids, intended for planting, for work on varietal selection, or for gene conservation or scientific research purposes;

Whereas Commission Decision 80/862/EEC [4], as last amended by Decision 96/713/EC [5], laid down the conditions which must be satisfied in the case of introductions or movements of the said plants, in order to ensure that there is no risk of harmful organism spreading;

Whereas Decision 80/862/EEC, as amended, expires on 31 December 1997 and it is therefore appropriate to incorporate the conditions laid down in that Decision into this Directive;

Whereas it is necessary to determine the conditions which must be satisfied in the case of introductions or movements of the said plants, in order to ensure that there is no risk of harmful organism spreading;

Whereas these conditions have to take into account new developments in the testing methods for diseases of potato and new information on organisms harmful to potato, for which a test is necessary in order to detect their presence;

[1] OJ No L 26, 31. 1. 1977, p. 20.
[2] OJ No L 87, 2. 4. 1997, p. 17.
[3] OJ No L 184, 3. 8. 1995, p. 34.
[4] OJ No L 248, 19. 9. 1980, p. 25.
[5] OJ No L 326, 17. 12. 1996, p. 70.

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 95/44/EC is hereby amended as follows:

(1) Article 1 (1) is replaced by the following:

'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 (7) (e), 4 (5), 5 (5) or 12 (3c) of Directive 77/93/EEC, 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) in Annex III, Part A the following text shall be added:

'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 in 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 77/93/EEC 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) *Pseudomonas solanacearum* (Smith) Smith.

— 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 conveniently 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. The 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 point 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 (1). For the material referred to in point 2, this testing method could be applied.

(1) OJ No L 259, 18. 10. 1993, p. 1.

5. For the material referred to in point 1, the testing method for *Pseudomonas solanacearum* (Smith) Smith shall be the interim test scheme set out in the Annex to the Commission decision to be taken in order to replace the quarantine procedure No 26 for *Pseudomonas solanacearum* (Smith) Smith as established by the European and Mediterranean Plant Protection Organization (EPPO). 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 testings 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 labeled 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.'

Article 2

1. Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive on 1 January 1998. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall immedialety 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1997.

For the Commission

Franz FISCHLER

Member of the Commission