COUNCIL DIRECTIVE 2002/11/EC

of 14 February 2002

amending Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine and repealing Directive 74/649/EEC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas:

- In the context of consolidating the internal market and (1) in the light of experience, various provisions of Directive 68/193/EEC (4) should be amended or repealed to remove all barriers to trade likely to prevent the free movement of vinepropagating material in the Community. To that end, any possibility for Member States to make unilateral derogations from the Directive should be removed.
- It should be made possible, on certain conditions, to (2) market propagating material produced by new production methods.
- (3) The Commission, assisted by the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry, should be able to lay down the conditions under which Member States may authorise the marketing of propagating material for trials, scientific purposes or selection work.
- In the light of the experience gained in other sectors (4) regarding the marketing of seed and propagating material, temporary trials should be organised, subject to certain conditions, to find better alternatives to certain provisions of the Directive.
- As a result of scientific and technical progress, it is now (5) possible to modify vine varieties genetically. It is therefore important that genetically modified vine varieties are not accepted unless all the appropriate measures have been taken to avoid any risk to human health or the environment.
- A specific environmental risk assessment should be (6)carried out equivalent to that provided for in 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) where vine variety propagating material is composed of genetically modified organisms. The Commission should submit to the European Parliament and the Council a proposal for a Regulation ensuring the equivalence of risk assessment and other relevant requirements, in particular those regarding risk management, labelling, any monitoring required, public information and a safeguard clause with those established by Directive 2001/18/EC. Pending the entry into force of that Regulation, the provisions of Directive 2001/18/EC should remain applicable.

- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (6) includes provisions on genetically modified food and food ingredients. In determining whether a genetically modified vine variety can be accepted on the market and in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients were subject to a safety assessment.
- To ensure that the movement of vine-propagating material is adequately monitored, it is appropriate that Member States should be able to require a document to accompany each lot.
- (9) It is desirable to ensure that genetic diversity is preserved. Appropriate biodiversity conservation measures to guarantee the conservation of existing varieties must be taken. The Commission should take into account not only the concept of variety but also that of genotype and of clone.
- The measures necessary for the implementation of Directive 68/193/EEC should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (7).
- Council Directive 74/649/EEC of 9 December 1974 on the marketing of material for the vegetative propagation of the vine produced in third countries (8) should be repealed,

OJ C 177 E, 27.6.2000, p. 77. OJ C 197, 12.7.2001, p. 24. OJ C 268, 19.9.2000, p. 42. OJ L 93, 17.4.1968, p. 15. Directive as last amended by the 1994

^(°) OJ L 106, 17.4.2001, p. 1. (°) OJ L 43, 14.2.1997, p. 1. (°) OJ L 184, 17.7.1999, p. 23. (°) OJ L 352, 28.12.1974, p. 45.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 68/193/EEC is hereby amended as follows:

- 1. Article 2(1) shall be replaced by the following:
 - '1. For the purposes of this Directive, the following definitions shall apply:
 - (A) Vines: plants of the genus Vitis (L.) intended for the production of grapes or for use as propagation material for such plants.
 - AA. Variety: a plant grouping within a single botanical tax on of the lowest known rank, which can be:
 - (a) defined by the expression of the characters resulting from a given genotype or combination of genotypes;
 - (b) distinguished from any other plant grouping by the expression of at least one of the said characters; and
 - (c) considered as an entity in view of its ability to be propagated unchanged.
 - AB. Clone: a clone is the vegetative progeny of a variety which is true to a vine stock chosen on account of varietal identity, its phenotypic characters and its state of health.
 - (B) Propagating material
 - (i) Young vine plants
 - (a) rooted cuttings: ungrafted pieces of rooted vine shoot or herbaceous shoot, intended for planting ungrafted or for use as rootstocks;
 - (b) rooted grafts: pieces of vine shoot or herbaceous shoot joined by grafting, the underground part of which is rooted.
 - (ii) Parts of young vine plants
 - (a) vine shoots: one-year shoots;
 - (b) herbaceous shoots: unlignified shoots;
 - (c) graftable rootstock cuttings: pieces of vine shoot or herbaceous shoot intended to form the underground part when preparing rooted grafts;
 - (d) top-graft cuttings: pieces of vine shoot or herbaceous shoot intended to form the part above ground when preparing rooted grafts or when grafting plants in situ;
 - (e) nursery cuttings: pieces of vine shoot or herbaceous shoot intended for the production of rooted cuttings.

- (C) Stock nurseries: nurseries for the production of rootstock cuttings for grafting, nursery cuttings or topgraft cuttings.
- (D) Cutting nurseries: nurseries for the cultivation of rooted cuttings or rooted grafts.
- DA. Initial propagating material: propagating material
 - (a) which has been produced under the responsibility
 of the grower according to accepted practices for
 the maintenance of the identity of the variety and,
 where applicable, of the clone, and for the
 prevention of diseases;
 - (b) which is intended for the production of basic propagating material or certified propagating material;
 - (c) which satisfies the conditions laid down in Annexes I and II for basic propagating material. These Annexes may be amended in accordance with the procedure laid down in Article 17(2) in order to set additional or more stringent conditions for the certification of initial propagating material;
 - (d) which has been found by official examination to satisfy the above conditions.
- (E) Basic propagating material: propagating material
 - (a) which has been produced under the responsibility of the grower according to accepted practices for the maintenance of the identity of the variety and, where applicable, of the clone, and for the prevention of diseases and which is obtained by vegetative propagation directly from initial propagating material;
 - (b) which is intended for the production of certified propagating material;
 - (c) which satisfies the conditions laid down in Annexes I and II for basic propagating material; and
 - (d) which has been found by official examination to satisfy the above conditions.
- (F) Certified material: propagation material
 - (a) which is obtained directly from basic propagating material or initial propagating material;
 - (b) which is intended for:
 - the production of young plants or parts of plants for use in the production of grapes, or
 - the production of grapes;
 - (c) which satisfies the conditions laid down in Annexes I and II for certified material; and
 - (d) which has been found by official examination to satisfy the abovementioned conditions.

- (G) Standard material: propagation material
 - (a) which has varietal identity and purity;
 - (b) which is intended for:
 - the production of young plants or parts of plants for use in the production of grapes, or
 - the production of grapes;
 - (c) which satisfies the conditions laid down in Annexes I and II for standard material; and
 - (d) which has been found by official examination to satisfy the abovementioned conditions.
- (H) Official measures: measures taken
 - (a) by State authorities; or
 - (b) by any legal person whether governed by public or by private law, acting under the responsibility of the State; or
 - (c) in the case of ancillary activities which are also subject to State control, by any natural person duly sworn for that purpose,

provided that the persons mentioned under (b) and (c) derive no private gain from such measures.

(I) Marketing:

the sale, holding with a view to sale, offer for sale and any disposal, supply or transfer aimed at commercial exploitation of propagating material to third parties, whether or not for a consideration.

Trade in propagating material not aimed at commercial exploitation of the variety, such as the following operations, shall not be regarded as marketing:

- (a) the supply of propagating material to official testing and inspection bodies;
- (b) the supply of propagating material to providers of services for processing or packaging, provided that the provider of services does not acquire title to propagating material thus supplied.

The rules for the application of these provisions shall be adopted in accordance with the procedure laid down in Article 17(3).';

2. Article 3 shall be replaced by the following:

'Article 3

- 1. The Member States shall require that vine propagating material may not be placed on the market unless:
- (a) it has been officially certified as "initial propagating material", "basic propagating material" or "certified propagating material" or, in the case of propagating material not intended for use as rootstocks, it is officially checked standard material, and

- (b) it satisfies the conditions laid down in Annex II.
- 2. By derogation from paragraph 1, Member States may, as a transitional measure until 1 January 2005, allow the marketing in their own territory of standard material intended for use as rootstocks and taken from parent plants in existence on 23 February 2002.
- 3. Notwithstanding paragraph 1, Member States may authorise producers on their own territory to place on the market appropriate quantities of propagating material:
- (a) intended for trials or for scientific purposes;
- (b) for selection work;
- (c) intended to help preserve genetic diversity.

The conditions under which Member States may grant such authorisation may be determined in accordance with the procedure laid down in Article 17(2).

In the case of genetically modified material, such authorisation may be granted only if all appropriate measures have been taken to avoid risks to human health and the environment. For the environmental risk assessment and other checks to be carried out in this respect, Article 5ba shall apply accordingly.

- 4. In the case of propagating material produced by means of *in vitro* propagation techniques, the following provisions may be adopted in accordance with the procedure laid down in Article 17(2):
- (a) derogation from specific provisions of this Directive;
- (b) conditions applicable to such propagating material;
- (c) designations that may be used for such propagating material;
- (d) conditions to guarantee that the varietal authenticity has first been verified.
- 5. The Commission, acting in accordance with the procedure laid down in Article 17(3), may require that, after specified dates, propagating material other than for use as rootstocks may be placed on the market only if it has been officially certified as "initial propagating material", "basic propagating material" or "certified propagating material":
- (a) throughout the Community, in the case of certain vine varieties for which the Community's needs can be covered, taking into account their genetic diversity, if necessary under an established programme, by propagating material officially certified as "initial propagating material", "basic propagating material" or "certified propagating material", and

- (b) in the case of propagating material of varieties other than those referred to in (a), if intended for use in the territory of Member States which have already required, in accordance with this Directive, that "standard material" may no longer be marketed.";
- 3. the following subparagraph shall be added to Article 4:

'This provision shall not apply, in the case of grafting, to propagating material produced in another Member State or in a third country recognised as equivalent in accordance with Article 15(2).';

4. Article 5 shall be replaced by the following:

'Article 5

- 1. Each Member State shall establish a catalogue of the vine varieties officially accepted for certification and for checking as standard propagating material in its territory. The catalogue shall be open to public inspection. The catalogue shall determine the principal morphological and physiological characters by which the varieties can be distinguished from one another. For those varieties already accepted as at 31 December 1971, reference may be made to the description in the official ampelographic publications.
- 2. Member States shall ensure that varieties and clones accepted into the catalogues of the other Member States are also accepted for certification and for the checking of standard propagating material in their own territory, without prejudice to Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine (*), with regard to the rules for the classification of vine varieties.
- 3. Each Member State shall also establish, if appropriate, a list of clones officially accepted for certification in its territory.

Member States shall ensure that clones accepted for certification in another Member State are also accepted for certification in their own territory.

(*) OJ L 179, 17.7.1999, p. 1.';

5. Article 5b shall be replaced by the following:

'Article 5b

1. A variety shall be deemed to be distinct if it is clearly distinguishable, by reference to the expression of the characteristics resulting from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge in the Community.

A variety shall be deemed to be a matter of common knowledge in the Community if, on the date on which application is duly made for its acceptance, it either is entered in the catalogue of the Member State in question or of another Member State or is the subject of an application for acceptance in the Member State in ques-

tion or in another Member State, unless the conditions referred to in the first sentence of this paragraph are no longer met in all the Member States concerned before a decision is made regarding the application for acceptance of the new variety being assessed.

- 2. A variety shall be deemed to be stable if the expression of the characters which are included in the examination for distinctness, as well as any others used for the variety description, remains unchanged after repeated propagation.
- 3. A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characters which are included in the examination for distinctness, as well as any others used for describing the variety.';
- 6. the following Article shall be inserted:

'Article 5ba

- 1. In the case of a genetically modified variety within the meaning of points 1 and 2 of Article 2 of 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 (*), the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment.
- 2. With regard to genetically modified varieties within the meaning of paragraph 1:
- (a) a specific environmental risk assessment equivalent to the assessment provided for in Directive 2001/18/EC and in accordance with the principles set out in Annex II and on the basis of the information specified in Annex III of that Directive shall be carried out;
- (b) the procedures intended to ensure the equivalence of the specific risk assessment and other relevant requirements, in particular those regarding risk management, labelling, and any monitoring required, public information and a safeguard clause with those established by Directive 2001/18/EC shall be introduced, on a proposal from the Commission, by a Regulation of the European Parliament and of the Council. Pending the entry into force of that Regulation, genetically modified varieties shall be accepted for inclusion in a national catalogue only when they have been accepted for marketing in accordance with Directive 2001/18/EC;
- (c) Articles 13 to 24 of Directive 2001/18/EC shall no longer apply to genetically modified varieties of vine authorised in conformity with the Regulation referred to in point (b).

- 3. Where products derived from vine propagating material are intended to be used as a food or food ingredient falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (**), it must be ensured prior to the acceptance of genetically modified varieties of vine that the foods or food ingredients derived therefrom do not:
- (a) present a danger for the consumer;
- (b) mislead the consumer;
- (c) differ from the foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

Where products derived from one of the varieties referred to in this Directive is intended for use as a food or food ingredient covered by Regulation (EC) No 258/97, the variety shall be accepted only if the food or food ingredient has already been authorised in accordance with that Regulation.

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(*) OJ L 106, 17.4.2001, p. 1. (**) OJ L 43, 14.2.1997, p. 1.';
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7. Article 5c shall be replaced by the following:

'Article 5c

Member States shall ensure that varieties and, where applicable, clones coming from other Member States are subject to the same requirements as those which apply to domestic varieties or clones, in particular as regards the acceptance procedure.';

- 8. Article 5e(2) shall be replaced by the following:
 - '2. All applications or withdrawals of applications for acceptance of a variety, entries in a catalogue of varieties and amendments made to it shall immediately be communicated to the other Member States and to the Commission. On the basis of the notifications from the Member States, the Commission shall publish a common catalogue of varieties.';
- 9. the following Article shall be inserted:

'Article 5f

Member States shall ensure that genetically modified varieties which have been accepted are clearly indicated as such in the catalogue of varieties. They shall further ensure that any person marketing such a variety clearly indicates in their vine sales catalogue that the variety is genetically modified and states the purpose of the modification.';

10. the following Article shall be inserted:

'Article 5g

- 1. Member States shall require that varieties and, where applicable, clones accepted into the catalogue are maintained by selection for conservation.
- 2. Maintenance must always be verifiable on the basis of records made by those responsible for maintenance of a variety and, where applicable, of a clone.
- 3. Samples may be requested from those responsible for maintenance of a variety. Where necessary, samples may be taken officially.
- 4. Where maintenance is carried out in a Member State other than that in which the variety was accepted, the Member States in question shall assist each other administratively as regards control.';
- 11. Article 7 shall be replaced by the following:

'Article 7

Member States shall provide that, while growing and during lifting, or removal from the parent vine, packaging, storage and transportation, propagation material be kept in separate batches and be marked with the variety and, where applicable, in the case of original propagating materials, basic material and certified material, with the clone.';

- 12. Article 8(2) shall be replaced by the following:
 - '2. By way of derogation from paragraph 1 as regards packaging, sealing and marking, the Commission shall determine, in accordance with the procedure laid down in Article 17(2), the provisions applicable to the sale of small quantities to final consumers and also to market vines in pots, crates or boxes.';
- 13. Article 9 shall be replaced by the following:

'Article 9

Member States shall require packages and bundles of propagating material to be sealed officially or under official supervision in such a manner that they cannot be opened without damaging the seal or without the official label referred to in Article 10(1) or, in the case of packaging, the packaging showing signs of tampering. To ensure proper sealing, the sealing device must comprise at least either the official label or an official seal. A decision may be taken in accordance with the procedure laid down in Article 17(2) as to whether a specific sealing device meets the requirements of this Article. Further sealing may take place only officially or under official supervision.';

14. Article 10 shall be replaced by the following:

'Article 10

1. The Member States shall require that an official label in one of the official languages of the Community, conforming to the specification in Annex IV, be affixed on the outside of packages and bundles of propagating

material by means of the sealing device. The colour of the label shall be white with a diagonal violet stripe for initial material, white for basic material, blue for certified material and dark yellow for standard material.

- 2. However, Member States may authorise producers in their territory to market more than one package or bundle of grafted or rooted vines with the same characteristics, using a single label conforming to the specification in Annex IV. In such cases, the packages or bundles shall be attached together in such a way that the attachment is damaged on separation and can no longer be put back. The label shall be affixed by means of the attachment. No resealing shall be authorised.
- 3. Without prejudice to Article 23(2) of Regulation (EC) No 1493/1999, Member States may require that each delivery of material produced within their territories also be accompanied by a uniform document featuring the following particulars inter alia: the nature of the goods, the variety and, where applicable, the clone, the category, quantity, consignor and recipient. The conditions to be set regarding this accompanying document shall be established according to the procedure provided for under Article 17(3) of this Directive.
- 4. The official label provided for under paragraph 1 may also include the phytosanitary accompanying documents, provided for in Commission Directive 92/105/EEC (*), which establishes a degree of standardisation for plant passports. However, all of the conditions applicable to the official labelling and plant passports are defined and must be recognised as equivalent.
- 5. Member States shall prescribe that the official labels must be preserved by the recipient of the material for the vegetative propagation of the vine for at least one year and made available to the official control authority.
- 6. By 23 February 2004, the Commission shall draw up a report, together with proposals, if appropriate, on the movement of material for the propagation of the vine and in particular on the use of official labels and the accompanying documents introduced by the Member States.

(*) OJ L 4, 8.1.1993, p. 22.';

15. the following Article shall be inserted:

'Article 10a

In the case of propagating material of a variety which has been genetically modified, any label and document, official or otherwise, which is affixed to or accompanies the batch of material under this Directive shall clearly indicate that the variety has been genetically modified and shall name the genetically modified organisms.';

- 16. Article 11(2) shall be replaced by the following:
 - '2. Without prejudice to the free movement of material within the Community, Member States shall take all necessary measures to ensure that the competent authorities are supplied with the following particulars during the marketing of propagating material imported from a third country:
 - (a) species (botanical name);
 - (b) variety and, where applicable, clone; in the case of rooted grafts, such information shall apply both to the rootstock and to the top-graft cutting;
 - (c) category;
 - (d) nature of propagating material:
 - (e) country of production and official control authority;
 - (f) country of despatch, if different from the country of production;
 - (g) importer;
 - (h) quantity of material.

The manner in which these particulars are to be presented may be determined in accordance with the procedure laid down in Article 17(2).';

17. Article 12 shall be replaced by the following:

'Article 12

Member States shall ensure that propagating material marketed in accordance with this Directive, under either compulsory or optional rules, is not subjected to any marketing restrictions as regards its characteristics, examination arrangements, marking and sealing other than those laid down in this Directive.';

18. Article 12a shall be replaced by the following:

'Article 12a

Member States shall ensure that propagating material of vine varieties and, where applicable, clones, which have been officially accepted in one of the Member States for certification and for checking as standard propagating material in accordance with this Directive, are not subjected to any marketing restrictions in their territory based on variety, and, where applicable, clone, without prejudice to Regulation (EC) No 1493/1999.;

- 19. Article 14(1) shall be replaced by the following:
 - '1. In order to eliminate any temporary difficulties in the supply of propagating material in the Community that cannot be overcome in any other way, a decision may be taken in accordance with the procedure laid down in Article 17(2) that Member States should authorise, for a specified period, the marketing throughout the Community's territory of such quantity of propagating material of a category satisfying less stringent requirements as is needed to overcome the difficulties.';

20. the following Article shall be inserted:

'Article 14a

For the purpose of seeking better alternatives to certain provisions of this Directive, it may be decided, in accordance with the procedure laid down in Article 17(3), to organise temporary experiments under specified conditions at Community level.';

- 21. Article 15(2) shall be replaced by the following:
 - '2. (a) On a Commission proposal the Council, acting by qualified majority, shall determine whether material for the vegetative propagation of the vine produced in a third country offers, as regards the conditions for its acceptance and the measures taken to ensure its production with a view to its marketing, the same guarantees as material produced in the Community and meets the requirements of this Directive.
 - (b) Furthermore, the Council shall determine the types of material and the categories of material for the vegetative propagation of the vine that may be admitted to marketing within the territory of the Community under point (a).
 - (c) Until the Council has taken a decision pursuant to point (a) and without prejudice 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 (*), the Member States may be authorised to take such decisions in accordance with the procedure laid down in Article 17(2). When doing so, they shall ensure that the material to be imported offers guarantees equivalent in every respect to those offered by material for the vegetative propagation of the vine produced in the Community in accordance with this Directive. Such imported material shall in particular be accompanied by a document setting out the particulars prescribed in Article 11(2).

(*) OJ L 169, 10.7.2000, p. 1.';

22. the following Articles shall be inserted:

'Article 16a

The measures necessary for the implementation of this Directive with regard to the matters contained in the provisions referred to below shall be adopted in accord-

ance with the management procedure laid down in Article 17(2):

Article 2(1)(DA)(c), Article 3(3), Article 8(2), Article
 9, Article 11(2), Article 14(1) and Article 15(2)(c).

Article 16b

The measures necessary for the implementation of this Directive with regard to the matters contained in the provisions referred to below shall be adopted in accordance with the regulatory procedure laid down in Article 17(3):

- Article 2(1)(I), Article 3(5), Article 10(3) and Article 14a':
- 23. Article 17 shall be replaced by the following:

'Article 17

- 1. The Commission shall be assisted by the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry (hereinafter referred to as the "committee").
- 2. Where reference is made to this paragraph, Articles 4 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (*) shall apply.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at one month.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be two months.

- 4. The committee shall adopt its rules of procedure.
- (*) OJ L 184, 17.7.1999, p. 23.';
- 24. References to Article 17 appearing in Article 5d(2), Article 14(3), Article 16, Article 17a and Article 18a shall be deemed to be references to Article 17(2).

Article 2

Directive 74/649/EEC shall be repealed.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 23 February 2003. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 14 February 2002.

For the Council
The President
P. del CASTILLO