

COMMISSION DECISION

of 1 December 2004

concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted

(notified under document number C(2004) 4493)

(Text with EEA relevance)

(2004/842/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Whereas:

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed⁽¹⁾, and in particular Article 4a(2) thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed⁽²⁾, and in particular Article 4a(2) thereof,

Having regard to Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed⁽³⁾, and in particular Article 6(2) thereof,

Having regard to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed⁽⁴⁾, and in particular Article 23(2) thereof,

Having regard to Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes⁽⁵⁾, and in particular Article 6(2) thereof,

Having regard to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants⁽⁶⁾, and in particular Article 6(2) thereof,

- (1) Pursuant to Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/56/EC and 2002/57/EC, Member States may authorise producers of agricultural seed to place on the market seed belonging to a variety for which an application for entry in the catalogue of the Member State in question, as provided for in Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species⁽⁷⁾, has been lodged.
- (2) In addition, pursuant to Directive 2002/55/EC, Member States may authorise breeders or their representatives of vegetable seed to place on the market seed belonging to a variety for which an application for entry in a national catalogue of at least one Member State, as provided for in that Directive has been lodged.
- (3) To enable Member States to grant such authorisations it is necessary to lay down implementing rules for those Directives, covering in particular the purposes for and the conditions under which those authorisations may be granted, the labelling of the seed packages and in the case of agricultural seed, the quantities. It is also appropriate that in the case of a variety derived from a genetically modified organism, this genetically modified organism must be authorised for the placing on the market according to the Community legislation.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DECISION:

CHAPTER I

General provision*Article 1***Subject matter**

The purpose of this Decision is to lay down the rules whereby a Member State may grant an authorisation to place on the market:

⁽¹⁾ OJ L 125, 11.7.1966, p. 2298/66. Directive as last amended by Commission Directive 2004/55/EC (OJ L 114, 21.4.2004, p. 18).

⁽²⁾ OJ L 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2003/61/EC (OJ L 165, 3.7.2003, p. 23).

⁽³⁾ OJ L 193, 20.7.2002, p. 12. Directive as amended by Directive 2003/61/EC.

⁽⁴⁾ OJ L 193, 20.7.2002, p. 33. Directive as last amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 268, 18.10.2003, p. 1).

⁽⁵⁾ OJ L 193, 20.7.2002, p. 60. Directive as last amended by Directive 2003/61/EC.

⁽⁶⁾ OJ L 193, 20.7.2002, p. 74. Directive as last amended by Directive 2003/61/EC.

⁽⁷⁾ OJ L 193, 20.7.2002, p. 1. Directive as last amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

- (a) seed of varieties of agricultural plant species for which an application for entry in the national catalogue, provided for in Article 1(2) of Directive 2002/53/EC, has been submitted to the Member State in question, subject to compliance with Chapter II of this Decision; or
- (b) seed of varieties of vegetable species for which an application for entry in a national catalogue, provided for in Article 3(3) of Directive 2002/55/EC, has been submitted in at least one Member State and for which specific technical information has been submitted, subject to compliance with Chapter III of this Decision.

CHAPTER II

Agricultural plant species

Article 2

Authorisation

- For agricultural plant species covered by Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/56/EC and 2002/57/EC, Member States may authorise producers established in their own territory to place on the market seed belonging to a variety for which an application for entry in the national catalogue of varieties of agricultural plant species (the national catalogue) has been submitted to the Member State in question, subject to compliance with Articles 3 to 18 of this Decision.
- Member States shall ensure that when an authorisation has been granted in accordance with this Decision, the authorisation holder shall comply with any condition or restriction attached to such authorisation.

Article 3

Application

- The authorisation may be requested by the person who has duly submitted an application for entry of the varieties concerned in the catalogue of the Member State in question (hereafter called the applicant, which includes the representative of such a person, provided the representative has been officially delegated).
- The applicant shall submit the following information:
 - the envisaged tests and trials;
 - the name(s) of the Member State(s) in which those tests and trials are to be carried out;
 - a description of the variety;

- (d) the maintenance of the variety.

Article 4

Purpose

Authorisations shall only be granted for tests or trials carried out at agricultural enterprises to gather information on the cultivation or use of the variety.

Article 5

Technical conditions

1. Fodder plant seed shall comply with the conditions laid down in Annexes I and II to Directive 66/401/EEC for:

- certified seed (all species other than *Pisum sativum* and *Vicia faba*); or
- 'certified seed, second generation' (*Pisum sativum*, *Vicia faba*).

2. Cereal seed shall comply with the conditions laid down in Annexes I and II to Directive 66/402/EEC for:

- certified seed (*Phalaris canariensis*, other than hybrids, *Secale cereale*, *Sorghum bicolor*, *Sorghum sudanense*, *Zea mays* and hybrids of *Avena sativa*, *Hordeum vulgare*, *Oryza sativa*, *Triticum aestivum*, *Triticum durum*, *Triticum spelta* and *x Triticosecale* other than self-pollinating varieties); or
- 'certified seed, second generation' (*Avena sativa*, *Hordeum vulgare*, *Oryza sativa*, *Triticum aestivum*, *Triticum durum*, *Triticum spelta* and self-pollinating varieties of *x Triticosecale*, other than hybrids in each case).

3. Beet seed shall comply with the conditions laid down in Annex I to Directive 2002/54/EC for certified seed.

4. Seed potatoes shall comply with the conditions laid down in Annexes I and II to Directive 2002/56/EC for certified seed potatoes.

5. Seed of oil and fibre plants shall comply with the conditions laid down in Annexes I and II to Directive 2002/57/EC for:

- certified seed (all species other than *Linum usitatissimum*);
- 'certified seed, second and third generation' (*Linum usitatissimum*).

*Article 6***Examination**

1. Compliance with the conditions referred to in Article 5 shall be assessed:

- (a) in the case of seed potatoes, by an official examination;
- (b) in the other case, by an official examination or an examination under official supervision.

2. For the assessment of compliance with the conditions concerning varietal identity and varietal purity, the description of the variety as supplied by the applicant, or where applicable the provisional description of the variety based on the results of the official examination of distinctness, stability and uniformity of the variety, as provided for in Article 7 of Directive 2002/53/EC, shall be used.

3. Examination shall be carried out in accordance with current international methods, in so far as such methods exist.

4. For the examination, samples shall be drawn officially or under official supervision or, in the case of seed potatoes, officially in accordance with appropriate methods.

5. Samples shall be drawn from homogeneous lots.

6. The maximum weight of a lot and the minimum weight of a sample are given in:

- (a) fodder plants: Annex III to Directive 66/401/EEC;
- (b) cereals: Annex III to Directive 66/402/EEC;
- (c) beet: Annex II to Directive 2002/54/EC;
- (d) oil and fibre plants: Annex III to Directive 2002/57/EC.

*Article 7***Quantities**

The quantities authorised for each variety shall not exceed the following percentages of seed of the same species utilised yearly in the Member State(s) for which the seed is intended:

- (a) in the case of durum wheat: 0,05 %;
- (b) in the case of field pea, field bean, oats, barley and wheat: 0,3 %;
- (c) in all other cases: 0,1 %.

However, if such quantities are not sufficient to sow 10 ha per Member State for which the seed is intended, the quantity needed for such an area may be authorised.

*Article 8***Packages and sealing**

Seed may be marketed only in closed packages or containers bearing a sealing device. Seed packages and containers shall be sealed officially or under official supervision in such a manner that they cannot be opened without damaging the sealing system or leaving evidence of tampering on either the official label provided for in Article 9 or on the package. In order to ensure sealing, the sealing system shall comprise at least either the official label or the affixing of an official seal.

In the case of seed potatoes, the packages shall be new and the container shall be clean.

*Article 9***Labelling**

1. The seed packages shall bear an official label in one of the official languages of the Community.

2. The label provided for in paragraph 1 shall include the following information:

- (a) the certification authority and Member State or their distinguishing abbreviation;
- (b) the lot reference number;
- (c) the month and year of sealing;
- (d) the species;
- (e) the denomination of the variety under which the seed is to be marketed (the breeder's reference, the proposed denomination or the approved denomination) and the official application number for listing the variety, if any;
- (f) the indication 'variety not yet officially listed';
- (g) the indication 'for tests and trials only';
- (h) where applicable, the words 'genetically modified variety';
- (i) size (only for seed potatoes);

(j) declared net or gross weight or declared number of pure seeds or, where applicable, clusters;

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

3. The label provided for in paragraph 1 shall be orange.

Article 10

Chemical treatment

Any chemical treatment shall be noted either on the official label provided for in Article 9, or on a supplier's label and on the package, or inside it, or on the container.

Article 11

Time period

Without prejudice to Articles 13 and 14, authorisations granted in accordance with the provisions of this Decision shall be valid for a period not exceeding one year and shall be renewable in accordance with Article 12.

Article 12

Renewal of authorisations

1. Without prejudice to Articles 13 and 14, authorisations referred to in Article 2 shall be renewable for periods not exceeding one year each.

2. The application shall be accompanied by the following documents:

- (a) a reference to the original authorisation;
- (b) any available information which supplements the information already provided on the description, the maintenance and/or the cultivation or use of the variety subject to the original authorisation;
- (c) evidence that evaluation for the entry into the catalogue of the variety concerned is still ongoing, if not otherwise available to the Member State.

Article 13

Cessation of validity

Authorisations shall cease to be valid if the application for entry in the national catalogue is withdrawn or rejected, or the variety is entered in the catalogue.

Article 14

Safeguard

Notwithstanding an authorisation granted under Article 2, a Member State may prohibit the use of the variety in all or in part of its territory or lays down appropriate conditions for cultivating the variety in accordance, in cases provided for in subparagraph (c), with the conditions for using the products resulting from such cultivation:

- (a) where it is established that the cultivation of the variety could be harmful from the point of view of plant health to the cultivation of other varieties or species; or
- (b) where official growing trials carried out in the applicant Member State show that the variety does not, in any part of its territory, produce results corresponding to those obtained from a comparable variety accepted in the territory of that Member State or, where it is well known that the variety is not suitable for cultivation in any part of its territory because of its type of maturity class; or
- (c) where it has valid reasons for considering that the variety presents a risk for human health or the environment.

Article 15

Reporting obligations

1. Following the grant of the authorisation, the authorising Member State may require the authorised person to report:

- (a) the results of the tests or trials carried out at agricultural enterprises to gather information on the cultivation or use of the variety;
- (b) the quantities of seed placed on the market during the authorised period and the Member State for which the seed was intended.

2. The information provided for in point (b) of paragraph 1 shall be treated as confidential.

Article 16

Maintenance checks

The authorising Member State may check maintenance of the variety.

Where maintenance takes place in a Member State other than the authorising Member State, the Member States shall assist each other administratively as regards the necessary checks.

A Member State may accept maintenance in a third country, provided that it has been decided under Article 22(1)(b) of Directive 2002/53/EC that the checks on practices for the maintenance afford the same assurances as those carried out by the Member States.

Article 17

Notification

Member States shall notify each other and the Commission of the following:

- (a) an application, as soon as this is received, or the rejection of an application for authorisation; and
- (b) the grant, renewal, revocation or withdrawal of an authorisation.

Article 18

Exchange of information

Member States shall use the existing computerised information exchange systems to facilitate the exchange of information as regards the connection with the application for acceptance of varieties into the national catalogues and the authorisation for seed of varieties not yet listed.

Article 19

Publication of a list of varieties

The Commission may, on the basis of the information supplied by the Member States, publish a list of varieties that have been authorised.

CHAPTER III

Vegetable species

Article 20

Authorisation

1. For vegetable species covered by Directive 2002/55/EC, Member States may authorise breeders established on their own territory to place on the market seed belonging to a variety for which an application for inclusion in a national catalogue of varieties of vegetable species (the national catalogue) has been submitted in at least one Member State and for which specific technical information has been submitted in the Member State(s) in question, subject to compliance with Articles 21 to 37 of this Decision.

2. Member States shall ensure that when an authorisation has been granted in accordance with this Decision, the authorisation holder shall comply with any condition or restrictions attached to such authorisation.

Article 21

Application

1. The authorisation may be requested by the person who has duly submitted an application for entry of the varieties concerned in the catalogue of at least one Member State (hereafter called 'the applicant' which includes the representative of such a person, provided that the representative has been officially delegated).

2. The applicant shall submit the following information:

- (a) a description of the variety;
- (b) the maintenance of the variety.

Article 22

Purpose

The authorisation shall only be granted for the purpose of gaining knowledge from practical experience during cultivation.

Article 23

Technical conditions

Vegetable seed shall comply with the conditions laid down in Annex II to Directive 2002/55/EC.

Article 24

Examination

1. Vegetable seed shall be subject to official post-control by check inspection to verify its varietal identity and varietal purity on the basis of the description of the variety as supplied by the applicant, or where available the provisional description of the variety based on the results of the official examination of distinctness, stability and uniformity of the variety as provided for in Article 7 of Directive 2002/55/EC.

2. Samples shall be drawn from homogeneous lots.

3. The maximum weight of a lot and the minimum weight of a sample are given in Annex III to Directive 2002/55/EC.

*Article 25***Genetically modified varieties**

In the case of a genetically modified variety, the authorisation may be granted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment. The genetically modified material must either be authorised under Directive 2001/18/EC of the European Parliament and of the Council ⁽¹⁾, or be authorised under Regulation (EC) No 1829/2003.

*Article 26***Supplier**

The persons responsible for affixing the label or printing or stamping notice on the packages shall:

- (a) inform the Member State of the dates when their activities begin and end;
- (b) keep records of all lots of seed and make them available to the Member States for not less than three years;
- (c) draw samples from each lot intended for marketing and make them available to Member States for not less than two years.

The operations referred to in points (b) and (c) shall be subject to official checks carried out on a random basis.

*Article 27***Packages and sealing**

Seed may be marketed only in closed packages bearing a sealing device. Seed packages shall be sealed in such a manner that they cannot be opened without damaging the sealing device or leaving evidence of tampering either on the label provided for in Article 28 or on the package.

*Article 28***Labelling**

1. The seed packages shall bear a supplier's label or a printed or stamped notice in one of the official languages of the Community.
2. The label provided for in paragraph 1 shall include the following information:
 - (a) the lot reference number;
 - (b) the month and year of sealing;
 - (c) the species;

⁽¹⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

(d) the denomination of the variety under which the seed is to be marketed (the breeder's reference, the proposed denomination or the approved denomination) and the official application number for listing the variety, if any;

(e) the indication 'variety not yet officially listed';

(f) where applicable, the words 'genetically modified variety';

(g) declared net or gross weight or declared number of pure seeds or, where applicable, clusters;

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

3. The label provided for in paragraph 1 shall be orange.

*Article 29***Chemical treatment**

Any chemical treatment shall be noted either on the label provided for in Article 28 and on the package or inside it.

*Article 30***Time period**

Without prejudice to Articles 32 and 33, authorisations granted in accordance with the provisions of this Decision shall be valid for a period not exceeding one year and shall be renewable in accordance with Article 31.

*Article 31***Renewal of authorisations**

1. Without prejudice to Articles 32 and 33, authorisations referred to in Article 20 shall be renewable, maximum twice for a period not exceeding one year each.
2. The application shall be accompanied by the following documents:
 - (a) a reference to the original authorisation;
 - (b) any available information which supplements the information already provided on the description, the maintenance and/or the knowledge from practical experience during the cultivation of the variety subject to the original authorisation;

- (c) evidence that the evaluation for the entry into the catalogue of the variety concerned is still ongoing, if not otherwise available to the Member State.

Article 32

Cessation of validity

Authorisations shall cease to be valid, if the application for entry in the national catalogue is withdrawn or rejected, or the variety is entered in the catalogue.

Article 33

Safeguard

Notwithstanding an authorisation granted under Article 20 a Member State may be authorised to prohibit the use of the variety in all or in part of its territory or to lay down appropriate conditions for cultivating the variety in accordance, in cases provided for in paragraph (b), with the conditions for using the products resulting from such cultivation:

- (a) where it is established that the cultivation of the variety could be harmful from the point of view of plant health to the cultivation of other varieties or species; or
- (b) where it has valid reasons for considering that the variety presents a risk for human health or the environment.

Article 34

Reporting obligations

1. Following the grant of the authorisation, the authorising Member State may require the authorised person to report:

- (a) the knowledge gained from practical experience during cultivation;
- (b) the quantities of seed placed on the market during the authorised period and the Member State for which the seed was intended.

2. The information provided for in point (b) of paragraph 1 shall be treated as confidential.

Article 35

Maintenance checks

The authorising Member State may check maintenance of the variety.

Where maintenance takes place in a Member State other than the authorising Member State, the Member States shall assist each other administratively as regards the necessary checks.

A Member State may accept maintenance in a third country, provided that it has been decided under Article 37(1)(b) of Directive 2002/55/EC that the checks on practices for the maintenance afford the same assurances as those carried out by the Member States.

Article 36

Notification

Member States shall notify each other and the Commission of the following:

- (a) an application, as soon as this is received, or the rejection of an application for authorisation; and
- (b) the grant, renewal, revocation or withdrawal of an authorisation.

Article 37

Exchange of information

Member States shall use the existing computerised information exchange systems to facilitate the exchange of information as regards the connection with the application for acceptance of varieties into the national catalogues and the authorisation for seed of varieties not yet listed.

Article 38

Publication of a list of varieties

The Commission may, on the basis of the information supplied by the Member States, publish a list of varieties that have been authorised.

CHAPTER IV

Article 39

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 1 December 2004.

For the Commission

Markos KYPRIANOU

Member of the Commission