

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)

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.

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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.

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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;
 - 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.

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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.

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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.

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- (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](#)).

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