COMMISSION DECISION

of 23 May 2007

concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (*Dianthus caryophyllus* L., line 123.2.38) genetically modified for flower colour

(notified under document number C(2007) 2120)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(2007/364/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of a Member State, in accordance with the procedure laid down in that Directive.

(2) A notification concerning the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line 123.2.38) was submitted by Florigene Ltd, Melbourne, Australia, to the competent authority of the Netherlands in September 2004.

(3) The notification covers import, distribution and retailing of *Dianthus caryophyllus* L., line 123.2.38 as for any other carnation.

(4) In accordance with the procedure provided for in Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which was submitted to the Commission and the competent authorities of the other Member States. That assessment report concludes that no reasons have emerged on the basis of which consent for the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 123.2.38) for ornamental use should be withheld, if specific conditions are fulfilled.

(5) The competent authorities of certain Member States raised objections to the placing on the market of the product.

(6) The opinion adopted on 17 May 2006 (published 27 June 2006) by the European Food Safety Authority (EFSA), concluded, from all evidence provided, that cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 123.2.38) are unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed ornamental use. EFSA also found that the scope of the monitoring plan provided by the consent holder is in line with the intended use of the carnation.

(7) An examination of each of the objections in the light of Directive 2001/18/EC, of the information submitted in the notification and of the opinion of EFSA, discloses no reason to believe that the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 123.2.38) will adversely affect human or animal health or the environment in the context of its proposed ornamental use.

(8) A unique identifier has been assigned to the genetically modified carnation (*Dianthus caryophyllus* L., line 123.2.38) for the purposes of Regulation (EC) No 1830/2003 and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms [2].

[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).

[2] OJ L 10, 16.1.2004, p. 5.

(9) In light of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended use with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.

(10) Proposed labelling, on a label or in an accompanying document, should include wording to inform operators and final users that the cut flowers of *Dianthus caryophyllus* L., line 123.2.38 can not be used for human or animal consumption nor for cultivation.

(11) The measures provided for in this Decision are not in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC and the Commission therefore submitted to the Council a proposal relating to these measures. Since on the expiry of the period laid down in Article 30(2) of Directive 2001/18/EC, the Council had neither adopted the proposed measures nor indicated its opposition to them, in accordance with Article 5(6) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1], the measures should be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

Consent

Written consent shall be granted by the competent authority of the Netherlands to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Florigene Ltd, Melbourne, Australia (Reference C/NL/04/02).

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

Article 2

Product

1. The genetically modified organisms to be placed on the market as product, hereinafter 'the product', are cut flowers of carnation (*Dianthus caryophyllus* L.), with modified flower colour, derived from a *Dianthus caryophyllus* L. cell culture, and transformed with *Agrobacterium tumefaciens*, strain AGL0, using the vector pcGP1470, and resulting in line 123.2.38.

The product contains the following DNA in three cassettes:

(a) Cassette 1

The promoter from a snapdragon gene encoding chalcone synthase, petunia flavonoid 3'5' hydroxylase (F3'5'H) cDNA, the terminator from the petunia gene encoding a phospholipid transfer protein homologue;

(b) Cassette 2

The constitutive promoter Mac, the petunia dihydroflavonol 4 reductase (DFR) cDNA, the terminator from the *Agrobacterium tumefaciens* gene encoding mannopine synthase (Mas);

Simultaneous expression of both genes in carnation results in a modified flavonoid synthesis in flowers, and subsequent formation of the blue pigment delphinidin.

(c) Cassette 3

The cauliflower mosaic virus 35S promoter, a non-translated region from the cDNA corresponding to the petunia gene encoding chlorophyll a/b binding protein 5, the *SuRB (als)* gene coding for a mutant acetolactate synthase protein (ALS), which confers tolerance to sulfonylurea, derived from *Nicotiana tabacum*, including its terminator.

This gene was used for *in vitro* selection.

2. The consent shall cover progeny derived through vegetative reproduction of the genetically modified carnation (*Dianthus caryophyllus* L., line 123.2.38).

Article 3

Conditions for placing on the market

The product may be put to ornamental use only, with the exception of cultivation, and may be placed on the market subject to the following conditions:

(a) the period of validity of the consent shall be 10 years starting from the date on which the consent is issued;

[1] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(b) the unique identifier of the product shall be FLO-4Ø644-4;

(c) without prejudice to Article 25 of Directive 2001/18/EC, the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology, as verified by the Community Reference Laboratory, shall be made available to the competent authorities and to inspection services of Member States as well as to the Community control laboratories.

(d) without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall, whenever requested to do so, make positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and to inspection services of Member States as well as to the Community control laboratories;

(e) the words 'This product is a genetically modified organism' or 'This product is a genetically modified carnation', and the words 'not for human or animal consumption nor for cultivation' shall appear either on a label or in a document accompanying the product.

Article 4

Monitoring

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan to check for any adverse effects on human and animal health or the environment arising from handling or use of the products, is put in place and implemented.

2. The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental cultivation.

3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.

4. Without prejudice to Article 20 of Directive 2001/18/EC the monitoring plan as notified shall be revised by the consent holder, where appropriate and subject to the agreement of the Commission and the competent authority of the Member State which received the original notification, and/or by the competent authority of the Member State which received the original notification, subject to the agreement of the Commission, in the light of the results of the monitoring activities. Proposals for a revised monitoring plan shall be submitted to the competent authorities of the Member States.

5. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

(a) that the existing monitoring networks, including national botanic survey networks and plant protection services, as specified in the monitoring plan contained in the notification, gather the information relevant for the monitoring of the products; and

(b) that these existing monitoring networks have agreed to make available that information to the consent holder before the date of submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

Article 5

Applicability

This Decision shall apply from the date on which the detection method specific to the carnation (*Dianthus caryophyllus* L., line 123.2.38) referred to in Article 3(c) of this Decision, is verified by the Community Reference Laboratory.

Article 6

Addressee

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 23 May 2007.

For the Commission

Stavros DIMAS

Member of the Commission