

COMMISSION IMPLEMENTING DECISION (EU) 2015/692**of 24 April 2015****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 25958) genetically modified for flower colour***(notified under document C(2015) 2765)***(Only the Dutch text is authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 the Member State that received the notification for the placing on the market of that product, 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 25958) was submitted by Florigene Ltd, Melbourne, Australia, to the competent authority of the Netherlands in March 2009.
- (3) The notification covers import, distribution and retailing of cut flowers of carnation *Dianthus caryophyllus* L., line 25958 as for any other carnation.
- (4) In accordance with the procedure established by Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which concluded 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 25958) for ornamental use should be withheld, if specific conditions are fulfilled.
- (5) In its assessment report, the competent authority of the Netherlands also concluded that the general surveillance plan submitted by the applicant is sufficient taking into account the intended uses of the product.
- (6) The assessment report was submitted to the Commission and the competent authorities of the other Member States, some of which raised and maintained objections to the placing on the market of the product.
- (7) The opinion of the European Food Safety Authority (EFSA), published on 12 December 2014, concluded, from all evidence provided, that there is no scientific reason to consider that the placing on the market of the genetically modified carnation (*Dianthus caryophyllus* L., line 25958) for ornamental use will cause any adverse effects on human health or the environment ⁽²⁾. EFSA also found that the scope of the monitoring plan provided by the notifier is in line with the intended use of the carnation.
- (8) An examination of the full notification, additional information provided by the notifier, specific objections maintained by the Member States in the light of Directive 2001/18/EC, and 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 25958) will adversely affect human health or the environment in the context of its proposed ornamental use.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

⁽²⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on a notification (reference C/NL/09/01) for the placing on the market of the genetically modified carnation IFD-25958-3 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene. EFSA Journal 2014;12(12):3934, 19 pp. doi:10.2903/j.efsa.2014.3934.

- (9) A unique identifier has been assigned to the genetically modified carnation (*Dianthus caryophyllus* L., line 25958) for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽¹⁾ and Commission Regulation (EC) No 65/2004 ⁽²⁾.
- (10) 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.
- (11) The 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 25958 cannot be used for human or animal consumption nor for cultivation.
- (12) A detection method as required by Annex III B.D.12 of Directive 2001/18/EC, was verified and tested for the *Dianthus caryophyllus* L., line 25958 by the European Union Reference Laboratory in December 2012.
- (13) The Committee set up under Article 30(1) of Directive 2001/18/EC has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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/09/01).

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 AGLO, using the vector pCGP3366, and resulting in line 25958.

The product contains the following DNA in four cassettes:

(a) Cassette 1

The petunia *dfp* gene encoding dihydroflavonol 4-reductase (DFR), a key enzyme in the anthocyanin biosynthetic pathway, including its own promoter and terminator.

(b) Cassette 2

The promoter sequence from snapdragon chalcone synthase gene, flavonoid 3'5'-hydroxylase (*f3'5'h*) from *Viola hortensis* cDNA encoding F3'5'H, a key enzyme in the anthocyanin biosynthetic pathway, and the terminator from a petunia gene encoding a phospholipid transfer protein homologue.

⁽¹⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽²⁾ 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 (OJ L 10, 16.1.2004, p. 5).

(c) Cassette 3

The *Cauliflower mosaic virus* 35S promoter, a hairpin-forming construct consisting of a partial dihydroflavonol 4-reductase *dfR* sense and antisense fragment separated by a petunia *dfR* intron, targeted to specific, post-transcriptional down-regulation of endogenous carnation *dfR*, and the *CaMV* 35S terminator sequence.

These three cassettes were inserted into the plant genome to obtain the desired flower colour.

(d) Cassette 4

The *Cauliflower mosaic virus* 35S promoter, the 5' untranslated region of the petunia gene coding for chlorophyll a/b binding protein, the *SuRB (als)* gene coding for a mutant acetolactate synthase protein (ALS) derived from *Nicotiana tabacum* which confers tolerance to sulfonylurea, including its own terminator. This trait was used as a marker in the selection of transformants.

2. The consent shall cover progeny derived through vegetative reproduction of the genetically modified carnation (*Dianthus caryophyllus* L., line 25958).

Article 3

Conditions for placing on the market

The product may be placed on the market for ornamental use only and its cultivation is not allowed. The product may be placed on the market subject to the following conditions:

- (a) In accordance with Article 19(3)(b) of Directive 2001/18/EC, the period of validity of the consent shall be 10 years starting from the date on which the consent is issued;
- (b) The unique identifier of the product shall be IFD-25958-3;
- (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 single-laboratory validated by the EU Reference Laboratory is publicly available at <http://gmo-crl.jrc.ec.europa.eu/valid-2001-18.htm>;
- (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 EU 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 health or the environment arising from handling or use of the products, is put in place and implemented.

The monitoring plan is available at [Link: *plan published on the internet*].

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. 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 referred to in point (a) 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

Addressee

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 24 April 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission
