Commission Implementing Decision (EU) 2019/1300 of 26 July 2019 as regards the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line FLO-40685-2) (notified under document C(2019) 5496) (Only the Dutch text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1300

of 26 July 2019

as regards the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line FLO-40685-2)

(notified under document C(2019) 5496)

(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.

(2) In October 2013, a notification concerning the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line FLO-40685-2) was submitted by Suntory Holdings Limited, Osaka, Japan, to the competent authority of the Netherlands.

(3) The notification covers import, distribution and retailing of cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2.

(4) In accordance with Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which concluded that there are no reasons on the basis of which consent for the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line FLO-40685-2) for ornamental use should be withheld, if specific conditions are fulfilled.

(5) The assessment report was submitted to the Commission and the competent authorities of the other Member States, some of which raised objections to the placing on the market of the product. One Member State maintained its objections.

(6) In its opinion of 10 March 2016, the European Food Safety Authority ('the Authority'), concluded that there is no scientific reason to consider that the import, distribution and retailing in the Union of carnation FLO-40685-2 cut flowers for ornamental use will cause any adverse effect on human health or the environment[(2)]. The Authority also found that the monitoring plan provided by the consent holder was acceptable in the light of the intended uses of the FLO-40685-2 carnation.

(7) An examination of the opinion of the Authority, which took into consideration the full notification, the assessment report drafted by the competent authority of the Netherlands, the Member States' objections and the additional information provided by the notifier in order to answer to the Member States' objections, discloses no reason to believe that the placing on the market of cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, will adversely affect human health or the environment in the context of its proposed ornamental use.

(8) A unique identifier should be assigned to the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council[(3)] and Commission Regulation (EC) No 65/2004[(4)].

(9) In light of the opinion of the 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) The labelling of the product should include information that cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, may not be used for human or animal consumption nor for cultivation.

(11) A detection method, as required in Annex III B.D.12 of Directive 2001/18/EC, was verified and tested for the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, in December 2016.

(12) 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

1 Written consent shall be granted by the competent authority of the Netherlands to the placing on the market of the genetically modified carnation *Dianthus caryophyllus* L., line

FLO-40685-2, notified by Suntory Holdings Limited, Osaka, Japan (Reference C/NL/13/02) and defined in Article 2.

2 The consent shall be given in writing and shall explicitly specify the requirements set out in Articles 3 and 4 and the unique identifier set out in Article 2(3).

3 The consent shall be limited to the placing on the market of cut flowers of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, as a product.

4 The consent shall cover progeny derived through vegetative reproduction of the genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2.

5 The period of validity of the consent shall be 10 years starting from the date on which the consent is issued.

Article 2

Product

1 The genetically modified organism to be placed on the market is a 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 pCGP1991, and resulting in line FLO-40685-2.

The genetically modified carnation contains the following DNA in three cassettes:

a Cassette 1

The petunia *dfr* 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 the *D8* petunia gene encoding a putative phospholipid transfer protein.

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

c Cassette 3

The *Cauliflower mosaic virus* 35S promoter, the 5′-untranslated region from the petunia gene encoding chlorophyll a/b binding protein, the *SuRB* (*als*) gene coding for a mutant acetolactate synthase (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 genetically modified carnation contains the insert, or part of it, in four loci:

— Locus 1: one copy of the T-DNA, containing the three cassettes and an incomplete copy of T-DNA containing only the *f3′5′h* cassette with the right T-DNA border. The two T-DNA copies are separated by a carnation genomic DNA region,

— Locus 2: one insert containing the *D8* terminator and the right T-DNA border,

— Locus 3: one complete and one incomplete copy of the *f3′5′h* cassette, both containing *D8* terminator sequences and the right T-DNA borders in a tail-to-tail orientation,

— Locus 4: an incomplete copy of the *als* cassette and the left T-DNA border.

3 The unique identifier of the genetically modified carnation shall be FLO-4Ø685-2.

Article 3

Conditions for placing on the market

The genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, may be placed on the market subject to the following conditions:

(a) the genetically modified carnation may only be used for ornamental purposes;

(b) the cultivation of the genetically modified carnation is not allowed;

(c) without prejudice to confidentiality requirements set out in Article 25 of Directive 2001/18/EC, the methodology for detecting and identifying the genetically modified carnation, including experimental data demonstrating the specificity of the methodology, as validated by the European Union Reference Laboratory is publicly available at http://gmo-crl.jrc.ec.europa.eu/valid-2001-18.htm;

(d) without prejudice to confidentiality requirements set out in Article 25 of Directive 2001/18/EC, the consent holder, whenever requested to do so, makes 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 Union 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’ appear either on a label or, for non-pre-packaged products, in a document accompanying the genetically modified carnations.

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 genetically modified carnation *Dianthus caryophyllus* L., line FLO-40685-2, 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 genetically modified carnation and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental propagation.

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 genetically modified carnation; 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, 26 July 2019.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

(**1**) OJ L 106, 17.4.2001, p. 1.

(**2**) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific opinion on a Part C notification (reference C/NL/13/02) from Suntory Holdings Limited for the import, distribution and retailing of carnation FLO-40685-2 cut flowers with modified petal colour for ornamental use. *EFSA Journal* 2016;14(4):4431, 18 pp. doi: 10.2903/j.efsa.2016.4431.

(**3**) 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).

(**4**) 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).