



> RIVM/SEC/BGGO, PO box 1, 3720 BA Bilthoven, The Netherlands.

Contact

Our ref.
C/NL/09/01_001.ar.1

Your ref

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Encl.

ASSESSMENT REPORT OF THE NETHERLANDS COMPETENT AUTHORITY IN ACCORDANCE WITH DIRECTIVE 2001/18/EC

RENEWAL OF NOTIFICATION C/NL/09/01

1. THE NOTIFICATION

The notification, submitted by Suntory Flowers Limited, Tokyo, Japan (formerly: Florigene), concerns renewal of placing on the market of imported cut flowers derived from genetically modified carnation (*Dianthus caryophyllus*) line IFD-25958-3 in accordance with Directive 2001/18/EC. The flowers of the carnation line have been modified with the *dfc* gene from petunia (*Petunia x hybrida*) and the *f3'5'h* gene from viola (*Viola* sp.), resulting in a modified flower colour (purple). Line IFD-25958-3 also contains a herbicide resistance gene (*suRB*) used to facilitate selection *in vitro*. The commercial name of the product is Florigene@Moonberry™.

2. SCOPE OF THE NOTIFICATION

This notification for renewal concerns import, distribution and retailing of line IFD-25958-3 in the cut flower market in the same way as any other carnation. This notification does not include cultivation or the use as feed or as food of line IFD-25958-3.

3. PROCEDURE

The original decision of the Netherlands competent authority to Florigene for import of line IFD-25958-3, under dossier number C/NL/09/01_000, was issued on July 9, 2015. According to article 17 of Directive 2001/18/EC the notifier shall submit a notification to the competent authority which received the original notification at the latest nine months before the expiry of the consent.

The dossier for renewal was received by the Netherlands competent authority on March 9, 2024. This dossier, under number C/NL/09/01_001, has been assessed with reference to Article 17 (2) of Directive 2001/18.

Scientific advice

Based on the dossier for renewal of March 9, 2024, the Dutch scientific advisory committee (COGEM) gave its advice on May 2, 2024 (CGM/240502-01) and concluded that the risks for human health and the European environment associated with import, distribution and retail of cut flowers of line IFD-25958-3 are negligible.

Confidentiality

The notification does not contain any information which the applicant regards as Confidential Business Information.

4. LIST OF DOCUMENTS

Based on article 17 (2) of Directive 2001/18/EC the following is required for a renewal of an existing market approval:

- a) A copy of the consent to the placing on the market of the GMO
- b) A report of the results from monitoring
- c) Any new information which has become available with regard to the risks of the product to human health and/or the environment
- d) As appropriate, a proposal for amending or complementing the conditions of the original consent, inter alia the conditions concerning future monitoring

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(a) A copy of the consent to the placing on the market of the GMO

A copy of the consent, issued by the Netherlands on July 09, 2015 is provided in the renewal application.

(b) A report of the results from monitoring

Reports of monitoring during 8 years (2015- 2023) are supplied. The eight reports listed in Table 1 have been consolidated into a single document, bookmarked for navigation between years (Monitoring reports CNL0901.pdf). Outcomes from the monitoring reports are provided in the document "Report on the results of the monitoring CNL0901". A summary of the information is given below.

✓ Annual or bi-annual questionnaires for feedback from the importer

These questionnaires have been provided by the importer each year. The importer has reported every year that he was not aware of any illegal growing and that neither the staff nor consumers have reported any adverse effects of handling the flowers.

✓ Expert monitoring group

Since 2016 members of an expert group of breeders and researchers have been asked, on a yearly basis, to report on whether they have become aware of any illegal propagation of transgenic carnation in Europe or the incidence of any wild carnation populations. Further details on locations are provided in the annual monitoring reports in the document "Monitoring reports CNL0901". There were no reports on the establishment of transgenic carnation in the wild or introgression to wild *Dianthus* species in any survey, in any year. No reports on illegal propagation were made.

✓ Mail out

Herbaria, European botanical and plant conservation groups, national plant protection authorities, national botanic survey networks, plant protection services, botanical gardens and individual scientists have been contacted by postal mail and email to request information on any reports of the identification of wild populations of carnation, *Dianthus caryophyllus* or related *Dianthus* species. Some responses provided information on observations of *D. caryophyllus*. In all cases, samples were of the wild type unimproved plants and not carnation.

Since IFD-25958-3 was placed on the market, the monitoring plan has been adapted once in November 2021. The amendment made was the discontinuation of the mail out component of the monitoring plan. This amendment was implemented in the 2023 monitoring report. Results of a final mail out in 2022 and to 40 herbaria in 2023 are summarized in the monitoring reports of the years 2022 and 2023. Supporting documents relating to the amendment of the monitoring plan are provided within this renewal application.

✓ Literature review

From 2016 a literature search was undertaken on an annual basis to identify any new, or previously unidentified, scientific reports on any aspects of *Dianthus* biology or distribution in Europe. None of these reports identified carnation in the environment or suggested introgression between carnation and wild *Dianthus* species.

✓ Database review

From 2016, an annual database and website review was added to the general monitoring process. The document "Monitoring reports CNL0901.pdf" provides details of the websites viewed and information gathered, including screenshots of some observations. Wild type *Dianthus caryophyllus*, whilst scarce compared to other *Dianthus* species, does occur in the natural environment in Europe and particularly in southern France.

✓ Website

The Florigene/Suntory website has been in place continuously since 2015. No information on possible wild populations of Florigene@Moonberry™ (IFD-25958-3) carnation has been conveyed through the website by the public, distributors or retailers.

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The results from monitoring do not indicate any risk for human health and the environment of the import of cut flowers of line IFD-25958-3.

(c) Any new information which has become available with regards to the risks of the product to human health and/or the environment

A summary of all new information that was generated or found since the consent was issued in 2015, is described below.

Regulatory decisions and opinions on the event

The Norwegian Environment Agency published details of the assessment and recommendations concerning the placing on the market of IFD-25958-3 (Andreassen et al., 2021). Furthermore, The Australian government regulatory body made a determination to include dealings with IFD-25958-3 onto the GMO Register, effective 17 July 2020. The new information does not suggest any new risk of the product to the environment or human health.

Scientific literature adding to baseline knowledge

The outcome of the literature review carried out since IFD-25958-3 was imported into the EU has provided new evidence to substantiate the assertion that release of transgenic carnation modified for expression of delphinidin-related anthocyanins in flowers does not pose a risk to human health or the environment.

Information on the phenotypic stability of event IFD-25958-3

To assess the stability of the phenotype of IFD-25958-3, the characteristics petal number, bud count, intact anther number, style number and style length were measured on an annual to biannual basis since IFD-25958-3 flowers were imported into the EU. Though there is variation between sample dates no significant differences were found in the chosen characteristics for measuring morphological stability of the flowers of IFD-25958-3. In addition, the stability of the modified flower colour phenotype has been measured. The incidence of flower colour "off -type" was collected on a weekly basis by the post-harvest facility in Colombia. No completely off-type flowers were identified in the period. On an annual basis, rejection rate because of colour variation ranged from 0% in 2017 to 0.10% in 2023. These off-types are not exported to the EU. The stability of the modified flower colour suggests no change in the stability of expression of the introduced genes.

Information on flanking sequences of IFD-25958-3

Southern and sequencing analysis demonstrates that the transgenic carnation event IFD-25958-3 contains a single, intact, T-DNA insert (Nakamura et al., 2020). Longer flanking genomic DNA sequence of IFD-25958-3 has been obtained since the consent to marketing was provided for IFD-25958-3 (Bioinformatic analysis of flanking sequences C/NL/09/01 and associated files).

✓ Disruption of endogenous genes

BLASTn and (t)BLASTx results indicated a possibility that the left border of the insert is inserted into a coding region though the function of the hypothetical proteins could not be identified from information available in databases. Bioinformatic analysis did not provide evidence of which linkage group the insert might be located and did not clearly indicate a gene in which the insert might be inserted.

✓ ORF analysis

Novel ORFs (equal or greater than 25 amino acids length) were identified using two ORF generators across the genomic DNA/T-DNA junctions. Analysis of the sequences of all ORFs using protein sequence databases indicated no biologically significant homology to toxins or allergens (RFI response_CNLO901_001_230524.pdf).

Updated bioinformatic analysis of the inserted genes in IFD-25958-3

Analysis of the sequences of the three newly expressed proteins in IFD-25958-3 using protein sequence databases indicated no biologically significant homology to toxins or allergens. The three newly expressed proteins are ubiquitous, well characterized proteins and are not known to be allergens (Bioinformatic analysis of inserted genes CNLO901.pdf).

(d) As appropriate, a proposal for amending or complementing the conditions of the original consent, inter alia the conditions concerning future monitoring

The following information is supplied:

Changes to the conditions of the original consent:

✓ Change of company name

The consent for placing on the market for Florigene®Moonberry™ as issued to Florigene Limited, Melbourne. This company has been purchased by Suntory Limited, Osaka, Japan. The company requests therefore that the consent for renewal will be in the name of Suntory Flowers Limited.

Future monitoring

✓ No changes are foreseen in the general monitoring scheme.

5. ADVICE OF THE NETHERLANDS COMPETENT AUTHORITY FOR DIRECTIVE 2001/18/EC

Based on the notification for renewal and the above mentioned considerations, the Netherlands competent authority concludes that no reasons have emerged on the basis of which consent to the proposed renewal of placing on the market should be withheld.

The Netherlands Competent Authority therefore proposes to consent to the renewal of placing on the market of the product as described below, for which a notification has been submitted on March 9, 2024 registered under number C/NL/09/01_001 under explicit specification of:

- a) The consent will be granted to Suntory Flowers Ltd, Tokyo, Japan and concerns renewal of the placing on the market under part C of 2001/18/EC of the product consisting of carnation genetically modified with the *dfr*, *f3'5'h* and *SuRB* genes, with the unique identification code IFD-25958-3 and product name Florigene® Moonberry™, for the purpose of import, distribution and retailing. This consent excludes cultivation and excludes the use as feed or as food of line IFD-25958-3.

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- b) The consent will be valid for a period of 10 years after approval.
- c) The company should ensure that the following information is transmitted in writing to the importer receiving the product:
 - The statement that "These flowers are genetically modified to alter the flower colour and are only produced for use as an ornamental product";
 - The unique identifier is IFD-25958-3 .
- d) The consent holder is required to supply reference material of line IFD-25958-3 for detection purposes at any time to the competent authority.
- e) The consent holder should carry out monitoring according to the general surveillance plan of the notification and report on the results of the general surveillance every year, during the period the consent is valid.
- f) 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.

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6 juni 2024,
DE MINISTER VAN INFRASTRUCTUUR EN WATERSTAAT,

namens deze,

de directeur Omgevingsveiligheid en Milieurisico's,



Mr. Judith Elsinghorst