Ministry of Infrastructure and Water Management

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

RENEWAL OF NOTIFICATION C/NL/13/01

Directorate-General for the Environment and International Affairs
Directorate of Environmental Safety and Risks

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Our ref.
C/NL/13/01/00_001

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 SHD-27531-4 in accordance with Directive 2001/18/EC. The flowers of the carnation line have been modified with the *dfr* gene from petunia (*Petunia x hybrida*) and the *f3'5'h* gene from viola (*Viola* sp.), resulting in a modified flower colour (purple). Line SHD-27531-4 also contains a herbicide resistance gene (s*uRB*) used to facilitate selection *in vitro*. The commercial name of the product is Florigene®Moontea™.

2. SCOPE OF THE NOTIFICATION

This notification for renewal concerns import, distribution and retailing of line SHD-27531-4 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 SHD-27531-4.

3. PROCEDURE

The original decision of the Netherlands competent authority to Florigene for import of line SHD-27531-4, under dossier number C/NL/13/01/00, was issued on February 2, 2017.
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 January 21, 2026. This dossier, under number C/NL/13/01/00_001, has been assessed with reference to Article 17 (2) of Directive 2001/18.

Scientific advice
Based on the dossier for renewal of January 21, 2026, the Dutch scientific advisory committee (COGEM) gave its advice on April 2,2026 (CGM/260402-03) and concluded that the risks for human health and the European environment associated with import, distribution and retail of cut flowers of line SHD-27531-4 are negligible.

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

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4. LIST OF DOCUMENTS

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

1) A copy of the consent to the placing on the market of the GMO;
2) A report of the results from monitoring;
3) Any new information which has become available with regards to the risks of the product to human health and/or the environment;
4) As appropriate, a proposal for amending or complementing the conditions of the original consent, inter alia the conditions concerning future monitoring.

(a) A copy of the consent to the placing on the market of the GMO
A copy of the consent for renewal (C/NL/13/01), issued by the Netherlands on February 2, 2017 is provided in the renewal application.

(b) A report of the results from monitoring
Reports of monitoring during 9 years (2016- 2025) are supplied. The nine reports have been consolidated into a single document, bookmarked for navigation between years (Monitoring reports CNL1301.pdf). Outcomes from the monitoring reports are provided in the document “Report on the results of the monitoring CNL1301”. 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 CNL1301.pdf”.
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 SHD-27531-4 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 CNL1301.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 and Italy.

- ✓ Website

The Florigene/Suntory website has been in place continuously since 2016. No information on possible wild populations of Florigene®Moontea™ (SHD-27531-4) 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 SHD-27531-4.

(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 2017, is described below.

Scientific literature adding to baseline knowledge
The outcome of the literature review carried out since SHD-27531-4 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 SHD-27531-4
To assess the stability of the phenotype of SHD-27531-4, the characteristics petal number, intact anther number, style number and style length were measured on an annual to biannual basis since SHD-27531-4 flowers were imported into the EU. Furthermore, flower morphology of SHD-27531-4 grown in Colombia was also assessed July 2025 (Flower morphology report FLN CNL1301.pdf). Though there is variation between sample dates no significant differences were found in the chosen characteristics for measuring morphological stability of the flowers of SHD-27531-4. 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. On an annual basis, rejection rate because of colour variation ranged from 0.008% in 2017 to 1.54% in 2019.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 SHD-27531-4
Southern and sequencing analysis demonstrates that the transgenic carnation event SHD-27531-4 contains a single, intact, T-DNA insert (Nakamura *et al*., 2020). Longer flanking genomic DNA sequence of SHD-27531-4 has been obtained since the

consent to marketing was provided for SHD-27531-4. Each of the genomic DNA (gDNA) sequences flanking the T-DNA integration in SHD-27531-4 were subjected to Blastn and (t)Blastx. Details of the analysis undertaken is provided in the file "Bioinformatic analysis of flanking sequences CNL1301.pdf".

- ✓ Disruption of endogenous genes

Blastn and (t)Blastx results indicated a possibility that 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 has provided evidence the transgene insert in this event is in linkage group LG08 and may have been inserted within a genomic DNA region encoding a short-chain dehydrogenase; specifically, the Dca 8018.1 carnation gene.

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- ✓ ORF analysis

In total 7 ORFs bridging the T-DNA and adjacent genomic DNA have been (re)-assessed for homology to toxin and allergen proteins using multiple allergen databases and cross matching of BLAST outputs against a set of toxin-related protein sequences obtained from the UniProtKB/Swiss-Prot database. These analysis indicated no biologically significant homology to toxins or allergens (Bioinformatic analysis of ORFs for homology to allergen and toxin proteins CNL1301.pdf).

- ✓ Inserted genes

Analysis of the sequences of the three newly expressed proteins in SHD-27531-4 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 pCGP1991.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®Moontea™ 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 January 21, 2026 registered under number C/NL/13/01/00_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 SHD-27531-4 and product name Florigene® Moontea™, for the purpose of import, distribution and retailing. This consent

excludes cultivation and excludes the use as feed or as food of line SHD-27531-4.

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 and final users receiving the product:
   - On a label or in a document 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 be stated.

d) The consent holder is required to supply reference material of line SHD-27531-4 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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