Second renewal of the authorisation for import, distribution and retail of genetically modified carnation FLO-40689-6 (Moonaqua™)

COGEM advice CGM/260402-02

1. Introduction

COGEM has been requested to evaluate the environmental risks associated with the second renewal of the authorisation for import, distribution and retail of cut flowers of genetically modified (GM) carnation (*Dianthus caryophyllus*) FLO-40689-6 (also known as Florigene®Moonaqua™). The present application (C/NL/06/01_002), was filed by Suntory Flowers Ltd.

Consent to place Moonaqua™ on the market in Europe was granted in 2009.[1] Import authorisations remain valid for a period of 10 years. In 2018, the Netherlands Competent Authority proposed to consent to the renewal of placing on the market of FLO-40689-6 for another 10 years. The applicant now filed an application for the second renewal of the authorisation. COGEM previously advised positively on the import, distribution and retail in the EU of GM carnation Moonaqua™, FLO-40689-6 in 2007[2] and on renewal of the authorisation in 2018.[3] COGEM has also issued positive opinions on import, distribution and retail of similar GM carnations with altered flower colours (e.g., Moonvelvet™, Moonlite™, Moonberry™ and Moonvista™).[4,5,6,7,8,9,10,11,12,13]

1.1 Carnation

Carnation belongs to the species *Dianthus caryophyllus* of the widely cultivated genus *Dianthus*. Wild *Dianthus* species are found throughout Europe, the Balkan and the Mediterranean area.[14,15,16] In the Netherlands, several native Dianthus species occur and some Dianthus species that are commonly grown as garden plants have established themselves in the wild.[17,18]

Carnations have been cultured for hundreds of years to improve flower size and generate colour variants. Cultivated carnations are almost certainly hybrids between two or more *Dianthus* species, one of which is most likely *D. caryophyllus*. Cultivated carnation is highly domesticated; it is not propagated by seed, but vegetatively by cuttings and tissue culture. Carnation also does not spread vegetatively spontaneously, or produce vegetative organs like bulbs, stolons or rhizomes.[19] Carnation is semi-winter hardy, has no weedy characteristics and even after decades of cultivation has never shown to be able to establish itself in the wild.[20]

In nature, pollination of *D. caryophyllus* occurs exclusively by lepidopteran insects. *Dianthus* carnation pollen cannot be spread by wind. Any pollen produced is heavy, sticky and deeply buried in the flower.[21,22] Although the Netherlands has a large carnation handling industry, carnation pollen is not detected in the atmosphere.[23,24,25] Breeding has increased the number of petals present in carnation cultivars. As a result, the reproductive tissues of the flower have become enclosed, restricting access to insect pollinators.[14] There has never been any evidence of spontaneous hybridisation between carnation and wild *Dianthus* species, despite the fact that carnation has been cultivated worldwide for centuries.[14,26]

1.2 GM carnation FLO-40689-6

GM carnation FLO-40689-6 was developed by *Agrobacterium*-mediated transformation, and expresses the genes *f3'5'h* and *dfr* which result in an altered flower colour, and *SuRB* which provides tolerance to sulfonylurea herbicides and is used as marker trait in the selection of GM plants. For an overview and description of the introduced genes and traits in FLO-40689-6, see Table 1.

Table 1. *Description of the introduced genes and traits.*

Introduced genes	Encoded proteins	Regulatory elements	Traits
SuRB	Acetolactate synthase (ALS) enzyme derived from *Nicotiana tabacum*.[27]	Cauliflower mosaic virus 35S promoter, 5' untranslated region (ca. 60 bp) from the cDNA corresponding to the petunia gene encoding chlorophyll a/b binding protein. Terminator from *N. tabacum* SuRB gene.[2,28,29]	Confers tolerance to ALS inhibiting (sulfonylurea) herbicides which are used to select transformants.
f3'5'h	Flavonoid 3'5' hydroxylase (F3'5'H) enzyme derived from *Viola hortensis*.[30]	Promoter from snapdragon (*Antirrhinum majus*) chalcone synthase (CHS) gene, and terminator from the petunia D8 gene encoding a phospholipid transfer protein homologue.[2,28,29]	Modified flower colour.
dfr	Dihydroflavonol-4-reductase (DFR) derived from *Petunia × hybrida*.[31]	Own promoter and terminator of the petunia *dfr* gene.[2,28,29]	Modified flower colour.

2. Environmental risk assessment

The application for market authorisation of GM carnation FLO-40689-6 for import, distribution and retail of cut flowers contains reports of the annual monitoring reports, bioinformatic analyses, and other new information relating to FLO-40689-6 that has become available since the renewal for consent to market was issued in 2018. Bio-informatic analyses were performed using the translated protein sequences of the open reading frames (ORFs) bridging all T-DNA-genomic DNA junctions. In contrast to the previous application, longer flanking sequences were used. Potential protein sequence homology to allergens and toxins was assessed using up-to-date databases. In addition, translated protein sequences of the T-DNA coding regions of the transformation vector (pCGP1991) were assessed for potential homology to toxin-related proteins or allergens. No indications for potential environmental risks were identified.

The applicant supplied annual monitoring reports for FLO-40689-6 between July 2018 and June 2025. As part of yearly monitoring, the applicant obtains questionnaire feedback from the importer and expert monitoring groups, to obtain information on illegal propagation of GM carnation in Europe. Furthermore, they contacted individual scientists and several institutions (herbaria, plant protection services, conservation groups etc.) to request any reports on the identification of wild populations of carnation, *D. caryophyllus* or related *Dianthus* species. The monitoring plan was adapted once in November 2021, discontinuing the need for the so called 'mail out' component of the monitoring plan. COGEM previously advised positively on the discontinuation of the 'mail out' component, as the alternatives methods were deemed sufficient for timely observation.[32] This change was implemented in 2023. The applicant also inspected the composting areas of the production sites in Colombia and Ecuador and investigated whether GM carnation established at these areas. No evidence of the

establishment of FLO-40689-6 nor introgression of the transgenes into wild *Dianthus* species was obtained.

In addition, a literature and database search was performed as part of the monitoring process for FLO-40689-6, to identify reports of carnation in the wild. The literature and records evaluated by the applicant also did not contain any reports of carnations occurring in the wild or evidence of introgression of the transgenes to wild *Dianthus* species.

The genes introduced in FLO-40689-6 do not encode toxic or allergenic products. The authorisation of FLO-40689-6 is limited to import, distribution and retail and does not allow the use of the GM carnation as food. Therefore, retailers will not be allowed to sell the petals of the GM carnation for food purposes. Petals of carnation can sometimes be used in dishes and as garnishing.[33,34,35] Occasional consumption of flower petals is unlikely to lead to an adverse effect.

COGEM is not aware of any reports indicating that incidental consumption of FLO-40689-6 poses a risk to human health. In view of the above-mentioned considerations, COGEM is of the opinion that unauthorised incidental consumption of GM carnation FLO-40689-6 poses a negligible risk to human health.

3. Conclusion

No evidence was found to indicate a change in the outcome of the risk assessment carried out at the time of the marketing approval of FLO-40689-6. COGEM is of the opinion that a second renewal of the authorisation for import, distribution and retail of cut flowers of GM carnation FLO-40689-6 (Moonaqua™) poses a negligible risk to human health and the European environment.

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