Application for renewal of consent for marketing approval under directive 2001/18/EC

Event; FLORIGENE®Moonaqua™

Decision authorisation number; C/NL/06/01
Number of consent; C/NL/06/01.abb2
Date of consent; July 14, 2009

Unique identifier; FLO-4Ø689-6

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Neither the application nor any of the supplementary files contains commercial-in-confidence information.

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A folder is also provided, containing copies of literature cited in supplementary file 7.

1. Introduction

Consent to market transgenic carnation event FLO-4Ø689-6 (Florigene®Moonaqua™) in the EU was granted by the NL competent authority on July 24 2009, following issue of a commission decision on March 16 2009. The marketing consent allows for import of cut flowers only and not cultivation in the EU. The purpose of this document is to formally request a renewal of the marketing application consent for this event. The renewal seeks a consent to market imported cut flowers only and not to extend the scope of the marketing approval to cultivation in the EU.

In accordance with article 17 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, this document is submitted to the competent authority which received the original notification no later than 9 months before the expiry of the consent (July 24 2019).

Aside from the specific requirements laid out in paragraph 2 of article 17 of directive 2001/18/EC, we are unaware of any guidelines for the renewal of events approved under directive 2001/18/EC. We are aware of the EFSA guidelines for renewal of applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 (EFSA, 2015a) and have included reference to an updated bioinformatic analysis as part of this renewal request for FLO-4Ø689-6 (Florigene®Moonaqua™).

1.1 Rationale for request for renewal

The rationale for the request for renewal is that we expect demand for Florigene®Moonaqua™ to be sustained or increased. Renewal is desired to maintain supply to EU based customers that require the product on a long-term basis.
As outlined elsewhere in this document, no information or observations have been collected on FLO-4Ø689-6 since it was granted marketing approval in the EU that suggests an increased risk of the product to human health or the environment**.**
FLO-4Ø689-6 (Florigene®Moonaqua™) is now an established carnation variety in the EU market, with a trend to increasing sales year by year (figure 1). Volumes imported into the EU, by month, are shown in figure 1.

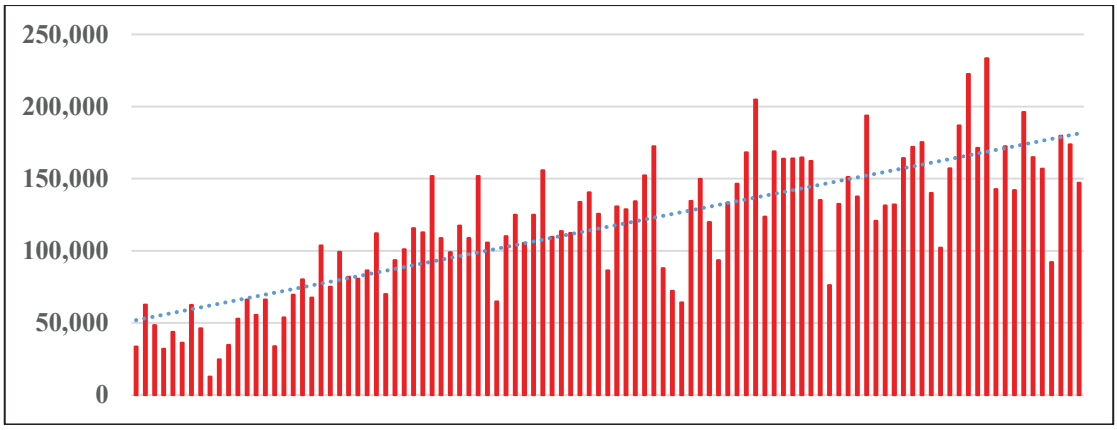

Figure 1. Monthly volume of flowers of transgenic carnation event Florigene®Moonaqua™ (FLO-4Ø689-6) imported into the EU from marketing approval to the end of March 2018. A linear trendline (dotted line) has been superimposed on the bar chart.

From marketing approval until the end of February 2018 11.9 million flowers of the variety have been imported into the EU, through a single Netherlands based importer. In the last full calendar year (2017) 2.04 million flowers were imported.

1.2 Related approvals

Event FLO-4Ø689-6

Table 1 lists the approvals for event FLO-4Ø689-6 that are registered with the Biosafety Clearing House. The event is also approved in Ecuador, USA and Canada.

Table 1. List of records in the Biosafety Clearing House database for event FLO-4Ø689-6.

Country	*Record ID
Australia	112183
Colombia	7108
European Union	103153
Japan	48206
Malaysia	104636
Netherlands	108637

**https://bch.cbd.int/database*

No approvals for cultivation or import of FLO-4Ø689-6 have been cancelled or rescinded since the EU marketing consent was issued in 2009.

Other transgenic carnation events in the EU

Five other transgenic carnation events have been approved in the EU, or are currently under review, since marketing approval was given for FLO-4Ø689-6. These are listed in table 2. For commercial reasons, two transgenic carnation events have been withdrawn from the EU market. These two events are; FLORIGENE®Moonshadow™ (FLO-11363-1) and FLORIGENE®Moondust™ (FLO-07442-4).

Table 2. Other transgenic carnation events which have been approved in the EU, or are currently under review

Event			Marketing consent date	Anthocyanidin (mg/g fresh weight petal)	
Tradename	Unique identifier	Dossier number		Delphinidin	Cyanidin
FLORIGENE® Moonaqua™	**FLO-4Ø689-6**	**C/NL/06/01**	**July 24 2009**	**0.07**	**0.02**
FLORIGENE® Moonlite™	FLO-4Ø644-6	C/NL/04/02	March 9 2017 (renewal)	**0.09**	**0.03**
FLORIGENE® Moonberry™	IFD-25958-3	C/NL/09/01	July 20 2015	0.54	0.10
FLORIGENE® Moonvelvet™	IFD-26407-2	C/NL/09/02	July 20 2015	2.87	0.37
FLORIGENE® Moontea™	SHD-27531-4	C/NL/13/01	March 1 2017	1.18	0.51
FLORIGENE® Moonvista™	FLO-4Ø685-2	C/NL/13/02	Application in process	1.8	0.02

The 5 other events in table 2 are closely related to FLO-4Ø689-6 because the modified phenotype is the same; expression of resistance to sulphonylurea type herbicides for selection *in vitro* and accumulation of delphinidin-based anthocyanins in flower petals (concentrations are shown in table 2) to confer novel flower colour. Scientific opinions provided by EFSA on dossiers C/NL/09/01, C/NL/09/02, C/NL/13/01 and C/NL/13/02 all conclude that there is no scientific reason to consider that the import, distribution and retailing in the EU of the transgenic carnation cut flowers for ornamental use will cause any adverse effects on human health or the environment (EFSA, 2014a, 2014b, 2015b, 2016).

2. Information required under paragraph 2, article 17 of directive 2001/18/EC

2.1 A copy of the consent to the placing on the market of the GMO

A copy of the consent to the placing on the market is provided in appendix 1.

2.2 A report on the results of the monitoring

Monitoring reports have been submitted on an annual basis from July 2010. Each report has covered the period July to June (the next report will be lodged in July 2018).
The supplementary file **1. Monitoring reports CNL0601 2010-2017.pdf** provides a single file with all monitoring reports for FLO-4Ø689-6 bookmarked by year for ease of navigation.
General monitoring has been used for FLO-4Ø689-6. In summary, the monitoring actions that have been carried out, and the observations that have been made are;

Questionnaire feedback from importer
These questionnaires have been provided by the importer at least once each year. The importer has reported every time that they were not aware of any illegal growing and that neither their staff nor consumers have reported any adverse effects of handling the flowers.

Expert monitoring group
An expert group, comprising breeders and research experts has been established. Each year members of the group have been asked to report on whether they have become aware of any illegal propagation of transgenic carnation in Europe, or of the incidence of any wild carnation populations. Responses from at least some of the group have been obtained each year including information on survey work carried out by botanical experts. There was no evidence of the establishment of transgenic carnation in the wild, or of introgression to wild *Dianthus* species in any survey, in any year. The survey work was largely confined to the Netherlands, Greece and the Swiss Alps but has recently been expanded. No reports of illegal propagation were made.

Mailing list
Herbaria, European botanical and plant conservation groups, national plant protection authorities, Italian phytosanitary agencies, national botanic survey networks, plant protection services, botanical gardens and individual scientists have been contacted by mail and email to request information on any reports of the identification of wild populations of carnation. In 2011, 2016 and 2017 brochures with descriptions of the transgenic varieties were included with the mail outs. From 2012, an emphasis was placed on Spain, Italy and France and communications have been made in the languages of these countries as well as English and Bulgarian. From 2010 to 2017 1,494 contacts were made. Some responses identified recent wild populations of *Dianthus caryophyllus*. In all cases where it was possible to confirm the

nature of the samples, collections were of the 5- petal unimproved *Dianthus caryophyllus*, **and not carnation.** Seed of wild *Dianthus caryophyllus* was also obtained, through a contact in France. Plants from these seed were grown to flowering over two seasons in Australia to understand the morphology and reproductive biology of wild *Dianthus caryophyllus* and to provide base line information on the wild species.

Literature review

Each year a literature search was undertaken to identify any new, or previously unidentified, scientific reports on any aspects of *Dianthus* biology or distribution in Europe. This was primarily undertaken to identify any reports of carnation in the wild. Since 2010 309 reports were identified and summarised in monitoring reports and though the information added to baseline knowledge of *Dianthus* biology, medicinal value and traditional uses **none of these reports identified carnation in the wild** nor evidence of introgression to wild *Dianthus* species. In 2015, the Office of the Gene Technology Regulator (Australia) updated their reference document "The Biology of *Dianthus caryophyllus* L. (carnation)"[1].

A publication of direct relevance to FLO-4Ø689-6 is Kim et al. (2010). In that study an event-specific qualitative and quantitative PCR assay was developed for the identification and quantification of Florigene®Moonaqua™ (this work was carried out independently of Suntory or Florigene). Zhu et al. (2011) confirmed the suitability of ANS as an endogenous control in PCR-based method for identification of transgenic carnation varieties. Chandler et al. (2013) reviewed the biosafety of transgenic carnation and included experimental data for Florigene®Moonaqua™ and Tanaka and Brugliera (2013) provided a detailed description of transgenic carnation varieties, including Florigene®Moonaqua™. Anderson and Walker (2013) studied the acceptability of transgenic carnation (including Florigene®Moonaqua™) in the floristry industry in the US.

Databases, keywords and syntaxes used for literature reviews

Literature searches described in this section and provided with monitoring reports were carried out using the following databases;

- AGRICOLA Article citation (NAL)
- Proquest
- Science Direct (Elsevier)
- SCOPUS (Elsevier)
- Web of science (ISI)
- Google Scholar

Search terms (words) were carnation, carnation biology, *Dianthus*, *Dianthus* biology, *Dianthus* fertilization, *Dianthus* gene, *Dianthus* genome, *Dianthus* medicinal, Europe flora, Europe plant survey, Europe plant checklist, Europe botany survey. These search terms were each used exactly as listed, with use of a filter of "since 2015" (as an example for the 2017 literature review).

For any relevant literature identified from google scholar, SCOPUS and Web of science databases the citation list within each paper was also reviewed as well as citing literature identified by the databases. Key citations in literature reviews from all previous monitoring reports were also searched in google scholar for citing literature, all which was then checked.

Compilation of cited literature

A compilation of all literature cited in monitoring reports between 2010 and 2017 is provided in the supplementary file **2. Cited literature compilation.pdf**. The file lists the references in each monitoring report, by year and provides a list of all cited literature, arranged alphabetically by author.

[1] *http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents*

Database review
From 2011, annual database and website review was added to the general monitoring process. 169 sites have been examined (most on an annual basis), all of which are European based floras, vegetation checklists and on-line herbaria. Sites are in multiple languages. None of these reports identified carnation populations in the wild, though useful information was gained on the location and form of wild *Dianthus caryophyllus* populations, largely in France. In all cases where it was possible to confirm the nature of the records, collections were of the 5- petal unimproved *Dianthus caryophyllus*, and not carnation.

Website
The Florigene website has been in place continuously since 2007 (http://www.florigene.com). No information on possible wild populations of Florigene®Moonaqua™ has been sent to the website during the period from the public, distributors or retailers.

Index Seminum
From 2016 a survey of European *Index Seminum* was carried out. 87 institutions were surveyed in 2016 and 108 in 2017 and 3 collections of wild type *D.caryophyllus* identified. No collections of carnation from the wild were identified.

2.3 Any other new information which has become available with regard to the risks of the product to human health and/or the environment

Additional information that has become available since the consent was issued is summarised in section 3. This information does not indicate a change in the risks of FLO-4Ø689-6 (Florigene®Moonaqua™) to human health and/or the environment.

2.4 As appropriate, a proposal for amending or complementing the conditions of the original consent, *inter alia* the conditions concerning future monitoring

Changes to the conditions of the original consent.
One amendment is requested;
The original consent application was lodged by Florigene Limited, Melbourne, Australia and this company was identified in the marketing application. Florigene Limited is no longer a registered company, having been purchased by Suntory Limited, Osaka, Japan. We request that the company named in the renewal of the marketing application be nominated as;

Suntory Flowers Limited
4-17-5 Shiba, Minato-ku,
Tokyo 108-0014 Japan

Future monitoring
We propose that a general monitoring scheme is continued with no changes.
The detection method for the event was approved by the JRC;
http://gmo-crl.jrc.ec.europa.eu/docs-valid-2001-18/CRL_Report_Flor_Moonaqua_v2.pdf
In section 3.1 we describe a correction to sequence that was made to locus 1. The correction has no effect on integrity or accuracy of the detection method.

3. Additional information

Additional information regarding the event that has become available since the consent to market was issued is summarised here. The information is not required as part of the

application for renewal and is provided here as evidence of no change in risk of the product to the environment or human health.

3.1 Sequencing of the event

In February 2017 we provided, on the request of the EU commission, the results of re-sequencing of event FLO-4Ø689-6[2]. The re-sequencing data was reviewed by the JRC. Event FLO-4Ø689-6 has three insertion loci and it was found that for loci 2 and 3 the sequences submitted to the EU in 2007 were identical to those obtained after re –sequencing in 2017. For loci 1, correction was required, by addition of one nucleotide to the sequence at base 12996 of the original sequence. The correction was in a linker sequence component of the transformation vector. The exact location of the correction is shown in yellow highlight in supplementary file **3. Moonaqua Locus 1 Alignments.pdf**. In the file **3. Moonaqua Locus 1 Alignments.pdf** the sequence provided to EFSA in 2007 is labelled Moonaqua Locus1 sequence and the re-sequence is labelled Moonaqua_Locus1_2017. The correction in sequence in locus 1 had no effect on the validated unique identification protocol for this event.

3.2 Bioinformatic analysis following sequence correction

Because of the introduction of an additional base in the sequence of locus 1 of event FLO-4Ø689-6 we carried out a complete bioinformatic analysis of the inserts and flanking regions in FLO-4Ø689-6, the results of which were provided to the EU in April 2017[3]. A full copy of that information (*Additional information; Genetically modified carnation event FLO-4Ø689-6 (C/NL/06/01), April 14 2017)* is included with this document as supplementary file **4. Bioinformatics information April 2017.pdf**. Bioinformatics analysis was made on all three loci in the event, using the corrected sequence for loci 1. All loci were analysed because;

- The bioinformatics analysis for event FLO-4Ø689-6 was last made in 2007.
- The information generated for the event at the time the application was made did not meet more recent information requirements[4].
- Now out of date databases were used at the time the original application was made.
- Only ORFs generated around the flanking sequences were analysed in 2007.

In the new analysis (supplementary file **4. Bioinformatics information April 2017.pdf**) all possible ORFs, from stop codon to stop codon and with no size limitation, were generated. The source sequence for ORF generation included 150 bp of genomic DNA either side of the insert. All ORFs and the inserted protein sequences were assessed for homology to known toxins and allergens. A carnation nuclear genome sequence database[5], not available in 2007, was used to look for possible insertion sites of the transgenic loci in event FLO-4Ø689-6 in the carnation genome.
In summary, the bioinformatic analysis showed;

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[2] Sequencing data was provided to the EU on Feb 18 2017 in a document entitled *Sequence analysis of the transgenes and their flanking regions in carnation GM-event FLO-40689-6 for complete and correct set of sequence data in accordance with "Guideline for the submission of DNA sequences and associated annotations within the framework of Directive 2001/18/EC and Regulation (EC) No 1829/2003 (2016)".*

[3] Document provided to the EU entitled *"Additional information; Genetically modified carnation event FLO-40689-6 (C/NL/06/01), April 14 2017"*

[4] *Reconsideration of the molecular characterisation criteria for marketing authorisation of GM crops COGEM Report CGM/140929-02; 160706-003 COGEM.pdf*

[5] http://carnation.kazusa.or.jp

1. Blastn and blastx results indicated that the insertions in loci 1 and 2 may be in protein encoding regions, though the function of the hypothetical proteins could not be identified from the information available in databases. Loci 3 was shown to be in a non-coding region of the carnation genome (supplementary file **4. Bioinformatics information April 2017.pdf**).
2. 2,186 putative ORFs were identified, 31 of which were generated across the gDNA/T-DNA junctions (supplementary file **4. Bioinformatics information April 2017.pdf**).
3. Analysis of the sequences of all ORFs using protein sequence databases indicated no biologically significant homology to toxins or allergens (supplementary file **4. Bioinformatics information April 2017.pdf**).
4. Analysis of the sequences of the three newly expressed proteins in FLO-4Ø689-6 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. Though included in supplementary file 4, details of this analysis are provided separately in supplementary file **5. Analysis of the sequences of newly expressed proteins for homology to toxins or allergens.pdf.**

The new information gathered because of the bioinformatics analysis does not indicate that the correction of one nucleotide in the sequence of one insert in the event has had an effect in terms of the potential production of novel toxin or allergen proteins, and so no change in potential risk of import of flowers of FLO-4Ø689-6 to the environment or human health.

3.3 Botanical surveys at production sites

FLO-4Ø689-6 flowers imported into the EU are produced at a single site in Ecuador and a single site in Colombia. At each site composting areas have been inspected regularly (table 3) for the possible establishment of wild populations of transgenic carnation, including FLO-4Ø689-6. Composting areas were selected as these were considered the most likely places in which a wild population might establish.

Table 3. Dates of visits to composting areas of FLO-4Ø689-6 production sites. The yellow cells indicate visits to Colombia only and the blue cells to Colombia and Ecuador. 24 inspections have been carried out in Colombia and 9 in Ecuador.

	Month											
	J	F	M	A	M	J	J	A	S	O	N	D
2009												
2010												
2011												
2012												
2013												
2014												
2015												
2016												
2017												
2018												

On no inspection has a wild population of carnation been identified. In Colombia the plants growing near carnation and rose compost heaps were identified in 2008. The dominant family at farm locations was the Asteraceae, followed by the Poaceae. The species found at the most sites in the farm environments were *Pennisetum clandestinum* (kikuyu grass), *Taraxacum*

officinale (dandelion) and *Poa annua* (annual bluegrass). No carnation (*Dianthus caryophyllus*) plants were found in any transect and the only Caryophyllaceae species found were *Arenaria lanuginosa* (Michx.) Rohrb., *Silene gallica* L., *Spergula arvensis* L. and *Stellaria media* (L.) Cirillo. Of these 4 species, only *Stellaria media* was identified at the composting area itself. The same dominant species have been found in the composting area in Colombia since 2008.
The lack of escapes at the site of production is consistent with the low probability of inadvertent spread of carnation because of vegetative spread. The observation supports the view that import of cut flowers of event FLO-4Ø689-6 does not pose a potential risk to the environment through establishment of wild populations.

3.4 Viable anther number and style length

Two or 3 times a year we have measured viable anther number and style length in flowers of FLO-4Ø689-6 produced in Colombia. These two characters have been measured because a significant increase in anther production or a significant decrease in style length might influence the assessment of gene flow potential.

Viable anther number
As was noted in the initial application for marketing approval, FLO-4Ø689-6 produced a low number of intact anthers when grown in the Netherlands or Australia. The event produces a very low number of viable anthers when grown in Colombia;

- Samples of 10 or 20 commercially harvested flowers have been assessed for the presence of anthers on 15 occasions since January 2012. No anthers were found in any sample.
- On October 14 2017 a sample population of 200 Colombia-grown, commercially harvested flowers of FLO-4Ø689-6 were dissected. None of the 200 flowers had viable anthers.
- On March 19 2018 a sample population of 198 Ecuador-grown, commercially harvested flowers of FLO-4Ø689-6 were dissected. None of the flowers had viable anthers.
- In a comparative trial (section 3.5) average anther number for FLO-4Ø689-6 was 0.5 (61% of flowers had no anthers).

The low anther number suggests no change in the potential for gene flow from imported cut flowers because of pollen flow.

Style length
Figure 2 shows average style length, measured in samples of 10 commercially harvested flowers on 15 occasions since January 2012

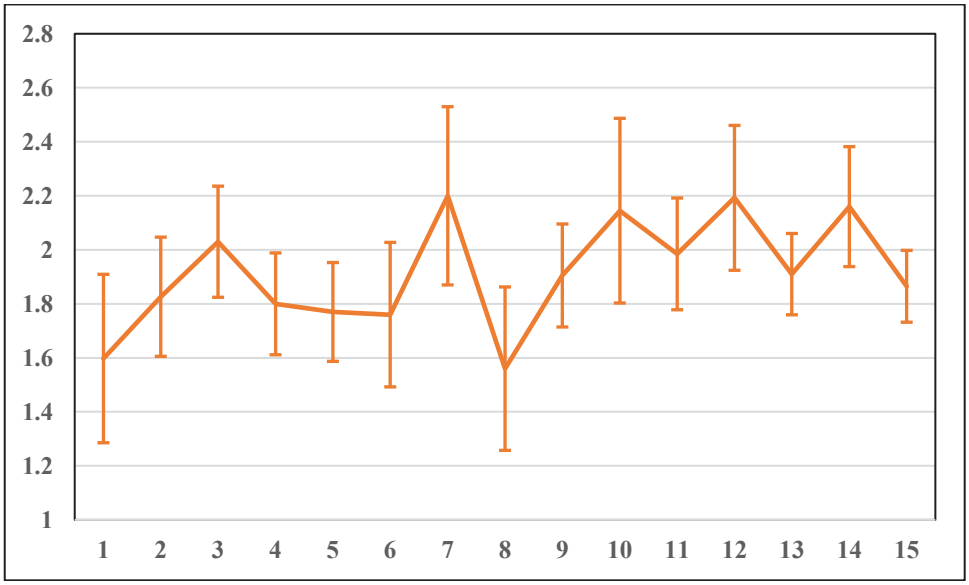

Figure 2. Average style length (cm) in flowers of FLO-4Ø689-6 measured on 15 occasions since January 2012. Each data point is the mean and standard deviation of 10 flowers.

As figure 2 shows, average style length is variable (we assume due to climatic differences at sampling date) but is consistent within a range of 1.6 – 2.2 cm, with no evident trend towards shorter length. The data suggests no change in the potential for gene flow from imported cut flowers because of shorter style length.

3.5 Comparison to parental variety

A comparison to the parental variety (the variety used for transformation) was included in the marketing application in 2007 and in support of the present application for renewal of marketing approval for event 4Ø689-6, a comparative trial of FLO-4Ø689-6 and Cream Cinderella (the parent variety) was planted in Colombia. This trial was designed over three replicate blocks (each character measured with 9, 10 or 12 replicates per block) to allow a two-way ANOVA separating the effect of planting location from variety. The trial was planted in May 2015 and harvested from late November to mid-December 2015. Results are summarised in table 4 and raw data is provided in the supplementary file **6. Trial data CNL0601.xlsx**.

Table 4. Summary of means, P-values and statistical significance (P<0.05) for 18 characters measured in a comparative trial of FLO-4Ø689-6 and its parental variety.

Character	Means		P-values		Statistical significance	
	Parent	FLO-4Ø689-6	Variety	Block	Variety	Block
Thickness of 5th node (mm)	9.0	8.4	0.000810	0.245717	Yes	No
Length of 5th node (mm)	105.9	105.4	0.822874	0.719004	No	No
Leaf length (mm)	64.1	67.6	0.079775	0.706793	No	No
Calyx diameter (mm)	22.1	19.7	0.000000	0.041663	Yes	Yes
Lobes per calyx	6	6	0.320963	0.373384	No	No
Style number	4.1	3.9	0.053132	0.146405	No	No
Style length (mm)	19	27	0.000000	0.286111	Yes	No
Calyx height (mm)	33.9	32.0	0.000038	0.144122	Yes	No
Plant height (cm)	118	113	0.000000	0.000179	Yes	Yes
Corolla height (mm)	29.4	27.9	0.097824	0.608235	No	No
Stamen number	5.0	6.2	0.000583	0.309477	Yes	No
Stamen length (mm)	16.4	18.9	0.000030	0.027989	Yes	Yes
Flower diameter (mm)	81.0	72.1	0.000000	0.484093	Yes	No
Petal number	57	37	0.000000	0.011944	Yes	Yes
Petal width (mm)	41	38	0.000000	0.013670	Yes	Yes
Stem length (cm)	95	88	0.000000	0.680364	Yes	No
Number of viable anthers	0.2	0.5	0.001255	0.210838	Yes	No
Total number anthers	3.6	5.1	0.000019	0.120647	Yes	No

There was a statistically significant effect of block for five characters but in all these cases the statistical effect of variety was highly statistically different (table 4). We therefore consider variation between blocks not to be an important factor.
Statistically significant differences noted between the parent and FLO-4Ø689-6 are highlighted in orange in the second last column on the left in table 4. In no case where there was a statistically significant difference could that difference suggest an increased risk of the FLO-4Ø689-6 to human health or the environment. In some cases, this is because the character which was different was biologically irrelevant to gene flow (for example node thickness, plant height and flower calyx diameter). It was noted in the original marketing application that FLO-4Ø689-6 is a small flowered variety and this was reflected in the trial results, showing FLO-4Ø689-6 to have a significantly lower plant height, stem length, flower size and petal count (table 4).
Of the characters that may be related to gene flow probability there were significant differences in;
Style length. FLO-4Ø689-6 had longer styles, which would reduce the probability of any theoretical fertilisation event. We noted there was no significant difference in style number, though the average was lower in FLO-4Ø689-6 (consistent with data from the trials in the marketing application).
Stamen number. Data from trials presented in the marketing application showed stamen number to be lower in FLO-4Ø689-6. In the Colombia trial stamen number was higher in FLO-4Ø689-6. This observation has no effect on the probability of gene flow, as stamens largely comprises filaments, with no anthers (table 4).
Number of viable anthers. In section 3.4 we noted that commercially harvested flowers sampled from Colombia or Ecuador did not have intact anthers. These are the flowers exported to the EU. In the trial situation (where flowers were open more fully) some anthers

were produced in both the parent and FLO-4Ø689-6 and the average number was statistically significantly higher in FO-4Ø689-6. In both the parent and FLO-4Ø689-6 most flowers did not have anthers (81% and 61% of flowers sampled respectively). Neither the presence of anthers nor the difference between transgenic and parent has any effect on the probability of gene flow, as we have established through repeat sampling that the exported flowers had zero anthers. Furthermore, the anthers produced in the trial did not release pollen.

3.6 Literature review

The initial application for FLO-4Ø689-6 was made in 2007 and since that time three more comprehensive and up to date literature reviews have been carried out for other lines of transgenic carnation. For cross reference, copies of the three literature reviews, which were carried out in 2013 and 2014, are provided in the supplementary file **7. Copies of recent literature reviews.pdf**. The literature reviews cover;

- An updated assessment of the probability of gene flow.
- An updated review of the biosafety of the ALS gene.
- A literature search on information relevant for the safety of GM carnation to humans, including the safety of delphinidin and potential allergenicity.

The literature reviews were an important part of the risk assessment process which has concluded that the release of transgenic carnation modified for expression of delphinidin-related anthocyanins in flowers does not pose a risk to human health or the environment.

Literature review has also been carried out and reported on an annual basis as part of the monitoring process (refer to 2.2). On March 13 2018 a citation and academic literature database search was carried out to determine whether any recent scientific reports (since July 2017) have been published relating to the event specifically or to transgenic carnation in general. No such reports were identified.

3.7 Off types

Very occasionally, white or pink flowers are observed in production of Moonaqua. Collating all assessments since 2011, pink off types occurred at a frequency of 0.008% and white flowers at a frequency of 0.064%.

From 2011, it was noted in both Ecuador and Colombia production that line FLO-4Ø689-6 contained plants which produced purple flowers. Since early 2017, approximately 2.5% of production in Ecuador and Colombia has been this off-type. Though the off-type flowers are NOT exported to the EU a description of this off type is provided here as additional information.

Purple off type phenotype

The purple flowers have a changed anthocyanin profile and a changed flower morphology. The anthocyanin profile is primarily characterised by an approximately 30-fold increase in both delphinidin and cyanidin in the flowers of the purple off-type (table 5). This results in much darker coloured flowers (figure 3).

Table 5. Anthocyanin profiles of petals from FLO-4Ø689-6 and the purple off-type from this line.

Anthocyanin (µg/g petal)	FLO-4Ø689-6	Purple off type
Delphinidin	77	2,648
Cyanidin	23	658
Petunidin	0	11
Pelargonidin	4	60
Peonidin	0	0
Malvidin	0	1
Percentage delphinidin	74.0	78.4
Cyanidin/delphinidin	0.30	0.25
Increase in delphinidin	-	34
Increase in cyanidin	-	29

Figure 3. Comparison of FLO-4Ø689-6 (lower row) and purple off-type. Note the presence of pigment in the calyx of the purple off-type only (arrows).

The purple flowers are characterised by a higher petal number (table 6) and pigmentation in calyx (figure 3) and style and anthers (figure 4).

Table 6. Petal count of FLO-4Ø689-6 and the purple off-type from this line. Ten flowers of FLO-4Ø689-6 and the purple off-type were dissected at each of the four sites in March 2018.

Site	FLO-4Ø689-6	Purple off type
Ecuador sample 1	49 ±8	62 ±6
Ecuador sample 2	47 ±6	58 ±3
Colombia sample 1	43 ±6	51 ±6
Colombia sample 2	38 ±4	47 ±3

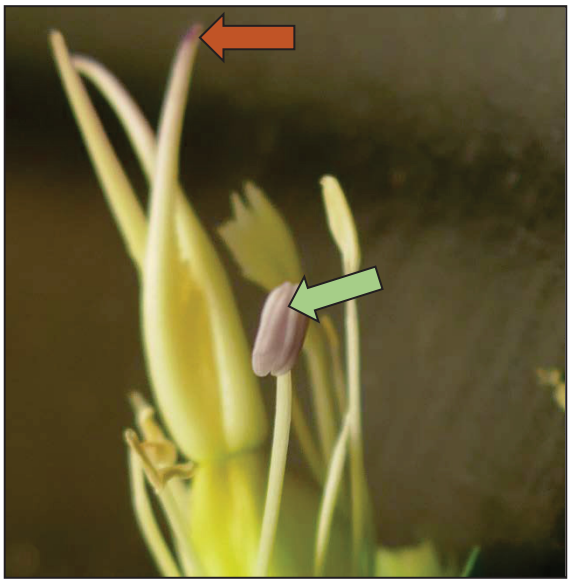

Figure 4. Dissected flower from the purple off-type found in FLO-4Ø689-6. Note the presence pigmentation in an anther (light green arrow) and style tip (orange arrow)

Origin of off-type

The presence of delphinidin in the purple off-type and the fact the unique identification test was positive for FLO-4Ø689-6 and its off-type (figure 5) shows the off-type is transgenic and that the introduced genes are still expressed.

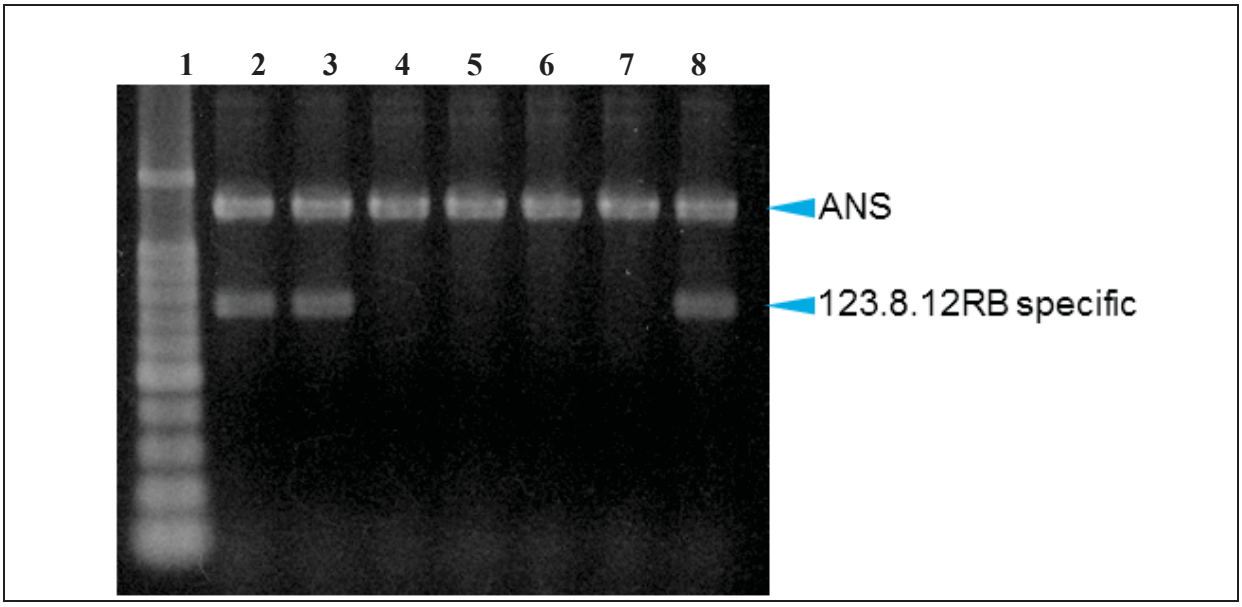

Figure 5. PCR test of purple off-type flower material, collected in Colombia (samples 2 and 3). Samples 4 to 7 are other transgenic carnation lines and sample 8 is tissue culture of FLO-4Ø689-6. The ANS primer is a positive internal control. The PCR protocol used was the unique identification method validated by the JRC (http://gmo-crl.jrc.ec.europa.eu/docs-valid-2001-18/CRL_Report_Flor_Moonaqua.pdf)

The higher concentration of anthocyanin in the off-types could be due to factors affecting expression or could be the result of nutritional or environmental factors affecting substrate availability.

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Copies of the papers cited are provided in the supplementary file **8. Copies of papers.pdf**

Appendix 1. Copy of marketing approval

Ministerie van Volkshuisvesting,
Ruimtelijke Ordening en
Milieubeheer

> Retouradres: Postbus 1, 3720 BA Bilthoven. RIVM/SEC, BGGO

Florigene
dr. S.F. Chandler
1 Park Drive
VIC 3083 Bundoora
Australië

Directoraat-Generaal Milieu
Directie Risicobeleid

RIVM/SEC/Bureau GGO
Anthonie van
Leeuwenhoeklaan 9
Postbus 1
3720 BA Bilthoven

Contactpersoon
Bureau GGO

Telefoon 030 - 274 2793
Fax 030 - 274 4401
bggo@rivm.nl
www.vrom.nl/ggo-vergunningverlening

Consent to placing on the market
Notification: C/NL/06/01

Datum	Kenmerk	Bijlagen
24-07-2009	C/NL/06/01.abb2	- C/NL/06/01.b. - C/NL/06/01.pub2
Uw brief	**Uw kenmerk**	**Afschrift aan**
11-10-2006		

Dear mr. Chandler,

In accordance with Article 18 of Council Directive 2001/18/EC of 17 April 2001, I herewith send you a consent to market genetically modified organisms.

Yours Sincerely,

dr. D.C.M. Glandorf
Bureau GGO

VROM 11

Directoraat-Generaal Milieubeheer
Directie Risicobeleid

Rijnstraat 8
Postbus 30945
2500 GX Den Haag
Interne postcode 645

www.vrom.nl

beschikking
DGM/RB C/NL/06/01

De Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer (hierna: VROM),

in overeenstemming met de Minister van Landbouw, Natuur en Voedselkwaliteit (hierna: LNV),

gelezen de aanvraag van Florigene Pty. Ltd., te Bundoora (voorheen Melbourne), Australië van 11 oktober 2006, met referentienummer C/NL/06/01, en de aanvullende informatie van 23 december 2006, om een vergunning als bedoeld in artikel 23 van het Besluit genetisch gemodificeerde organismen milieubeheer (hierna: Besluit ggo), en

gelet op de beschikking van de Commissie van de Europese Gemeenschappen (hierna: de Commissie) van 16 maart 2009, betreffende het in de handel brengen van een anjer (*Dianthus caryophyllus* L., lijn 123.8.12 (hierna: het product)), genetisch gemodificeerd met het oog op bloemkleur, overeenkomstig Richtlijn 2001/18/EG van het Europees Parlement en de Raad (2009/244/EG)[1], en

gelet op het Besluit ggo milieubeheer,

BESLUIT:

Artikel 1
Vergunning

1. De Minister van VROM, in overeenstemming met de Minister van LNV, verleent een vergunning, als bedoeld in artikel 23 van het Besluit ggo, aan Florigene Pty. Ltd., om het in artikel 2 gespecificeerde product, overeenkomstig deze beschikking in de handel te brengen.

2. Ingevolge artikel 32, eerste lid, van het Besluit ggo worden aan de vergunning de voorschriften verbonden zoals beschreven in de artikelen 3 en 4 van de beschikking van de Commissie (2009/244/EG).

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1 PB L 72 van 18.3.2009, blz. 18.

VROM 11

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Artikel 2
Product

1. De genetisch gemodificeerde organismen die als product in de handel worden gebracht (hierna: het product) zijn snijbloemen van een anjer (*Dianthus caryophyllus* L.) met een gewijzigde bloemkleur, afgeleid van de celcultuur van *Dianthus caryophyllus* L. en gemodificeerd met *Agrobacterium tumefaciens*, stam AGL0, met behulp van de vector pCGP1991, wat lijn 123.8.12 heeft opgeleverd.

   Het product bevat de volgende DNA-sequenties in drie cassettes:

   (a) Cassette 1
   Het *dfr*-gen van *Petunia* x *Hybrida* dat codeert voor dihydroflavonol-4-reductase (DFR), een sleutelenzym in de biosynthese van anthocyanines. Het *dfr*-gen staat onder controle van zijn eigen promoter en terminator.

   (b) Cassette 2

   De promotor van een leeuwenbekgen dat codeert voor chalconsynthase, cDNA voor flavonoïd-3'5'-hydroxylase (F3'5'H) van de petunia, een sleutelenzym in de biosynthese van anthocyanines, en de terminator van het petuniagen dat codeert voor een fosfolipide-transporteiwithomoloog.

   Gelijktijdige expressie van het *dfr*- en het *f3'5'h*-gen in anjers leidt tot een gewijzigde flavonoïdsynthese in de bloemen met als gevolg de vorming van het blauwe pigment delfinidine.

   (c) Cassette 3

   De 35S-promotor van het bloemkoolmozaïekvirus, een niet-vertaalde regio van het cDNA dat correspondeert met het petuniagen dat codeert voor bindingseiwit 5 van chlorofyl a/b en het van *Nicotiana tabacum* afgeleid gen *SuRB* (*als*) dat codeert voor een mutant acetolactaatsynthase-eiwit (ALS), dat tolerantie voor sulfonylureum geeft, met inbegrip van de terminator daarvan.

   Dit gen is gebruikt voor in vitro selectie.

2. De vergunning geldt voor nakomelingen die zijn verkregen door vegetatieve vermeerdering van de genetisch gemodificeerde anjer (*Dianthus caryophyllus* L., lijn 123.8.12).

Artikel 3
Voorschriften voor het in de handel brengen

Het product mag alleen als sierbloemen worden gebruikt en de teelt ervan is niet toegestaan. Het product mag met inachtneming van de volgende voorwaarden in de handel worden gebracht:

(a) de vergunning heeft een geldigheidsduur van tien jaar, ingaande op de datum waarop de vergunning wordt verleend;

(b) de eenduidige identificatiecode van het product is FLO-4Ø689-6;

(c) de houder van de vergunning stelt op verzoek positieve en negatieve controlemonsters van het product of het genetisch materiaal daarvan of referentiematerialen ter beschikking aan de bevoegde instanties en de inspectiediensten van de lidstaten en de communautaire controlelaboratoria;

(e) op een etiket of in een bij het product gevoegd document worden de woorden "Dit product is een genetisch gemodificeerd organisme" of "Dit product is een genetisch gemodificeerde anjer" en de woorden "niet voor consumptie door mens en dier of voor de teelt" vermeld.

Artikel 4
Monitoring

1. Gedurende de gehele geldigheidsduur van de vergunning ziet de houder van de vergunning erop toe dat het in de aanvraag opgenomen monitoringplan, dat bestaat uit een algemeen plan van toezicht en tot doel heeft na te gaan of de behandeling of het gebruik van het product eventueel nadelige effecten heeft op de gezondheid van mens en dier of op het milieu, wordt uitgevoerd.

2. De houder van de vergunning stelt de exploitanten en gebruikers rechtstreeks in kennis van de veiligheid en de algemene kenmerken van het product en de voorwaarden ten aanzien van de monitoring, inclusief de beheersmaatregelen die in het geval van accidentele teelt moeten worden genomen.

3. De houder van de vergunning dient bij de Commissie en de bevoegde instanties van de lidstaten jaarlijks een verslag in over de resultaten van alle monitoringactiviteiten. Het eerste jaarverslag wordt ingediend één jaar nadat de definitieve toestemming is verleend.

4. het in de aanvraag opgenomen monitoringplan wordt in het licht van de resultaten van de monitoringactiviteiten door de houder van de vergunning, indien nodig en voor zover de Commissie en de Minister van VROM hiermee instemmen, en/of door de Minister van VROM, voorzover de Commissie hiermee instemt, herzien. Voorstellen voor de herziening van een monitoringplan worden ingediend bij de Minister van VROM.

5. De houder van de vergunning dient bij machte te zijn om aan de Commissie en de bevoegde instanties van de lidstaten het bewijs te leveren:

   (a) dat de bestaande monitoringnetwerken, met inbegrip van de nationale botanische toezichtsnetwerken en gewasbeschermingsdiensten, zoals gespecificeerd in het in de aanvraag opgenomen monitoringplan, de informatie verzamelen die relevant is voor de monitoring van het product, en

   (b) dat de onder a) genoemde bestaande monitoringnetwerken hebben toegezegd deze informatie vóór de in lid 3 vastgestelde datum voor de indiening van de monitoringverslagen bij de Commissie en de bevoegde instanties van de lidstaten aan de houder van de vergunning beschikbaar te stellen.

Artikel 5
Inwerkingtreding

Deze beschikking treedt in werking overeenkomstig artikel 20.3 van de Wet milieubeheer.

→

DE GEVOLGDE PROCEDURE

(1) Florigene Pty. Ltd. heeft op 11 oktober 2006 bij de Minister van VROM een aanvraag ingediend om een vergunning als bedoeld in artikel 23 van het Besluit ggo, voor het in de handel brengen van een genetisch gemodificeerde anjer (*Dianthus caryophyllus* L., lijn 123.8.12).

(2) Florigene Pty. Ltd. heeft, op verzoek van de Minister van VROM, op 23 december 2006 aanvullende informatie ingediend.

(3) De aanvraag en de aanvullende informatie zijn getoetst aan de vereisten van artikel 28 van het Besluit ggo en voldoen daaraan.

(4) De aanvraag is behandeld conform paragraaf 3.3 van het Besluit ggo en deel C van Richtlijn 2001/18/EG van het Europees Parlement en de Raad van 12 maart 2001, inzake de doelbewuste introductie van genetisch gemodificeerde organismen in het milieu en tot intrekking van Richtlijn 90/220/EG van de Raad (hierna:de richtlijn).

(5) Ingevolge artikel 29 van het Besluit ggo is een beoordelingsrapport opgesteld. Het beoordelingsrapport vermeldt dat het product onder voorwaarden in de handel kan worden gebracht. Dit beoordelingsrapport en een afschrift van de aanvraag zijn op 2 maart 2007 naar Florigene Pty. Ltd. en de Commissie gezonden.

(6) Conform artikel 14, tweede lid, van de richtlijn is het beoordelingsrapport op 28 maart 2007 door de Commissie doorgezonden aan de lidstaten van de Europese Gemeenschap (hierna: de lidstaten).

(7) Conform de standaardprocedure als bedoeld in artikel 15 van de richtlijn kon een bevoegde instantie of de Commissie binnen 60 dagen na de verspreiding van het beoordelingsrapport om nadere informatie verzoeken, opmerkingen maken, of met redenen omklede bezwaren maken tegen het in de handel brengen van het betrokken product. Er zijn opmerkingen, bezwaren en verzoeken om informatie van een aantal lidstaten ontvangen. De Minister van VROM heeft vervolgens 45 dagen de tijd gehad om te proberen tot overeenstemming te komen met de Commissie en de lidstaten. Dit is niet voor alle bezwaren gelukt.

(8) Ingevolge artikel 28 van de richtlijn heeft de Commissie advies gevraagd over de aanvraag aan de Europese Autoriteit voor voedselveiligheid (hierna: EFSA).

(9) De EFSA is in haar op 12 maart 2008 vastgestelde (en op 26 maart 2008 gepubliceerde) advies op grond van alle ingediende gegevens tot de conclusie gekomen dat het onwaarschijnlijk is dat het product in de context van het voorgestelde gebruik als sierbloemen nadelige effecten op de gezondheid van mens of dier of op het milieu zal hebben. De EFSA concludeerde tevens dat de reikwijdte van het door de houder van de vergunning ingediende monitoringplan in overeenstemming is met het voorgenomen gebruik van het product.

(10) Uit onderzoek van alle de ingediende bezwaren, de bij de aanvraag ingediende informatie en het advies van de EFSA zijn geen redenen naar voren gekomen om aan te nemen dat het in de handel brengen van het product in de context van het voorgestelde gebruik als sierbloemen nadelige effecten op de gezondheid van mens of dier of op het milieu zal hebben.

(11) De Commissie heeft derhalve ingevolge artikel 19 van de richtlijn een positief ontwerpbesluit, betreffende het in de handel brengen van *Dianthus caryophyllus*, lijn 123.8.12, opgesteld. Het ontwerpbesluit is op 15 september 2008 besproken en ter stemming gebracht in het comité, bedoeld in artikel 30 van de richtlijn. De stemming leidde noch tot een gekwalificeerde meerderheid voor of tegen het ontwerpbesluit.

(12) Ingevolge de artikelen 5 en 7 van Besluit 1999/468/EG is het ontwerpbesluit voor de Landbouwraad van 19 januari 2009 geagendeerd. De stemming tijdens de Landbouwraad leidde wederom niet tot een gekwalificeerde meerderheid voor of tegen het ontwerpbesluit.

(13) Ingevolge Besluit 1999/468/EG stelt de Commissie in een dergelijk geval het besluit zoals dat is voorgelegd aan de Landbouwraad vast. Op 16 maart 2009 is de positieve beschikking van de Commissie met nr. 2009/244/EG gepubliceerd in het publicatieblad van de Europese Unie (PB L 72/18-20).

(14) Deze beschikking van de Commissie is gericht aan het Koninkrijk der Nederlanden, en geeft opdracht aan de daarvoor bevoegde instanties in Nederland om, overeenkomstig de in de beschikking genoemde voorwaarden, vergunning te verlenen aan Florigene Pty. Ltd. voor het in de handel brengen van het product. De beschikking vermeldt welke voorschriften op basis van artikel 19, derde lid, van de richtlijn aan de vergunning moeten worden verbonden.

(15) Conform de voorwaarde genoemd in artikel 3, onderdeel c, van de Beschikking van de Commissie met nr. 2009/244/EG is de methodologie voor de detectie en identificatie van het product, met inbegrip van experimentele gegevens die de intralaboratoriumvalidatie van de specificiteit van de methodologie door het communautair referentielaboratorium aantonen, publiek beschikbaar op http://gmo-crl.jrc.ec.europa.eu.

(16) Ingevolge de Wet milieubeheer en het Besluit ggo is de Minister van VROM, in overeenstemming met de Minister van LNV, bevoegd vergunning te verlenen voor het in de handel brengen van het product.

KENNISGEVING EN BEZWAAR

Dit besluit wordt bekend gemaakt door kennisgeving ervan in de Staatscourant en in de Volkskrant.
Op grond van artikel 20.1 Wet milieubeheer juncto artikel 7:1 van de Algemene wet bestuursrecht kan door belanghebbenden binnen zes weken na de datum van verzending van dit besluit een bezwaarschrift worden ingediend. Het bezwaarschrift moet zijn gemotiveerd, gedagtekend en voorzien van naam, adres en woonplaats van de indiener. Het bezwaarschrift moet worden ingediend bij de Minister van VROM, p/a Bureau Genetisch Gemodificeerde Organismen, Postbus 1, 3720 BA Bilthoven.
Tevens kan de indiener van het bezwaarschrift gedurende de termijn dat bezwaar kan worden gemaakt een verzoek tot het treffen van een voorlopige voorziening als bedoeld in artikel 8:81 van de Algemene wet bestuursrecht indienen bij de voorzitter van de Afdeling bestuursrechtspraak van de Raad van State, Postbus 20019, 2500 EA Den Haag. Tijdens de Europese besluitvormingsprocedure kon het publiek opmerkingen maken bij de Commissie met betrekking tot de samenvatting van het dossier als bedoeld in artikel 13, 2e lid onder h van de Richtlijn.

Den Haag, 20-07-2009

De Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer,

dr. Jacqueline Cramer

→

Kennisgeving Besluit genetisch gemodificeerde organismen milieubeheer

Introductie in het milieu door het in de handel brengen van genetisch gemodificeerde organismen.

Beschikking op de vergunningaanvraag van Florigene Pty. Ltd.

Op 20 juli 2009 is door De Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer, in overeenstemming met de Minister van Landbouw, Natuur en Voedselkwaliteit, vergunning verleend, met kenmerk DGM/RB C/NL/06/01, voor het in de handel brengen van genetisch gemodificeerde organismen krachtens artikel 23 van het Besluit genetisch gemodificeerde organismen milieubeheer (hierna: Besluit ggo) aan Florigene Pty. Ltd., gevestigd in Bundoora, in Australië. De beschikking is op 24 juli 2009 aan Florigene Pty. Ltd. verzonden.
Op 11 oktober 2006 had Florigene Pty.Ltd. een daartoe strekkende aanvraag ingediend. De genetisch gemodificeerde organismen die als product of in een product in de handel worden gebracht ten behoeve van import zijn snijbloemen van een anjer (*Dianthus caryophyllus* L.) met een gewijzigde bloemkleur, afgeleid van een celcultuurlijn van *Dianthus caryophyllus* L. en gemodificeerd met *Agrobacterium tumefaciens*, stam AGLO, met behulp van de vector pCGP1991, waaruit lijn 123.8.12 is ontstaan.

Procedure

Voor de behandeling van de aanvraag van Florigene Pty. Ltd. is de procedure doorlopen als beschreven in paragraaf 3.3 van het Besluit ggo en deel C van de Richtlijn 2001/18/EG van het Europees Parlement en de Raad van de Europese Unie van 12 maart 2001 inzake de doelbewuste introductie van genetisch gemodificeerde organismen in het milieu.
Op 18 maart 2009 is de positieve beschikking van de Europese Commissie met nr. 2009/244/EG gepubliceerd in het publicatieblad van de Europese Unie (PB L 72/18 - 20). Deze beschikking is gericht aan De Minister van VROM en de Minister van LNV om vergunning te verlenen aan Florigene Pty. Ltd. om *Dianthus caryophyllus*, lijn 123.8.12, in de handel te brengen.

Inzage beschikking

De beschikking en de overige relevante stukken liggen vanaf 25-7-2009 op werkdagen ter inzage bij het Ministerie van VROM, afdeling Documentaire Informatie (C01 70), Rijnstraat 8 te Den Haag. De stukken kunnen daar ingezien worden van (maandag t/m vrijdag van 8.30 tot 17.00 uur) na afspraak via telefoon of mail (tel. 070-3393156, mail secretariaat.risicobeleid@minvrom.nl). De bezoeker dient zich te melden bij de receptie.
Deze kennisgeving, de beschikking en de bijbehorende stukken zijn ook beschikbaar op de internetpagina www.vrom.nl/ggo-vergunningverlening.

Bezwaar

Op grond van de Algemene wet bestuursrecht kan door belanghebbenden binnen zes weken na de datum van bekendmaking van dit besluit een bezwaarschrift worden ingediend. Het bezwaarschrift moet zijn gemotiveerd, gedagtekend en voorzien van naam, adres en woonplaats van de indiener. Het bezwaarschrift moet worden ingediend bij De Minister van VROM, p/a Bureau Genetisch Gemodificeerde Organismen, Postbus 1, 3720 BA Bilthoven. Bezwaarschriften per e-mail worden niet geaccepteerd.
Tevens kan de indiener van het bezwaarschrift gedurende de termijn dat bezwaar kan worden gemaakt een verzoek tot het treffen van een voorlopige voorziening als bedoeld in artikel 8:81 van de Algemene wet bestuursrecht indienen bij de voorzitter van de Afdeling bestuursrechtspraak van de Raad van State, Postbus 20019, 2500 EA Den Haag.

→

Kennisgeving Besluit genetisch gemodificeerde organismen milieubeheer

Introductie in het milieu door het in de handel brengen van genetisch gemodificeerde organismen.

Beschikking op de vergunningaanvraag van Florigene Pty. Ltd.

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Inzage beschikking
De beschikking en de overige relevante stukken liggen vanaf 25-7-2009 op werkdagen ter inzage bij het Ministerie van VROM, afdeling Documentaire Informatie (C01 70), Rijnstraat 8 te Den Haag. De stukken kunnen daar ingezien worden van (maandag t/m vrijdag van 8.30 tot 17.00 uur) na afspraak via telefoon of mail (tel. 070-3393156, mail secretariaat.risicobeleid@minvrom.nl). De bezoeker dient zich te melden bij de receptie.
Deze kennisgeving, de beschikking en de bijbehorende stukken zijn ook beschikbaar op de internetpagina www.vrom.nl/ggo-vergunningverlening.

Bezwaar
Op grond van de Algemene wet bestuursrecht kan door belanghebbenden binnen zes weken na de datum van bekendmaking van dit besluit een bezwaarschrift worden ingediend. Het bezwaarschrift moet zijn gemotiveerd, gedagtekend en voorzien van naam, adres en woonplaats van de indiener. Het bezwaarschrift moet worden ingediend bij De Minister van VROM, p/a Bureau Genetisch Gemodificeerde Organismen, Postbus 1, 3720 BA Bilthoven. Bezwaarschriften per e-mail worden niet geaccepteerd.
Tevens kan de indiener van het bezwaarschrift gedurende de termijn dat bezwaar kan worden gemaakt een verzoek tot het treffen van een voorlopige voorziening als bedoeld in artikel 8:81 van de Algemene wet bestuursrecht indienen bij de voorzitter van de Afdeling bestuursrechtspraak van de Raad van State, Postbus 20019, 2500 EA Den Haag.