SECTION E

SNIF PART 2: Summary information format for products containing genetically modified higher plants (GMHPs)

GENERAL INFORMATION

E.1. Details of notification

(a)	**Member State of notification:** The Netherlands
(b)	**Notification number:** C/NL/06/01
(c)	**Name of the product (commercial and other names):** FLORIGENE Moonaqua™ (123.8.12)
(d)	**Date of acknowledgement of notification:** 13-10-2006

E.2. Notifier

(a)	**Name of notifier:**	Florigene Pty. Limited (Australia)
(b)	**Address of notifier:**	1 Park Drive, Bundoora, VIC 3083, Australia
(c)	**Is the notifier domestic manufacturer:** No	**Importer** Yes
(d)	**In case of an import the name and address of the manufacturer shall be given:** Florigene Pty. Limited, 1, Park Drive, Bundoora, VIC 3083, Australia.	
(e)	**Name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor;** Ms. Juliette Gray Suntory Ltd. Buchanan House 3 St. James's Square, London SW1Y4JU, U.K. Phone 44-20-7839-9370 Fax 44-20-7839-9379 e-mail juliette.gray@suntory-uk.co.uk	

E.3. General Description of the product

(a)	**Name of recipient or parental plant and the intended function of the genetic modification:** Recipient plant is *Dianthus caryophyllus L.* (UK carnation, NL anjer, ESP clavel). The product consists of a carnation variety in which the flowers have a modified flower colour as the result of genes enabling the biosynthesis of delphinidin pigment in the flowers. The flowers also carry an herbicide resistance gene to facilitate selection *in vitro*.
(b)	**Any specific form in which the product must not be placed on the market (seeds, cut-flower, vegetative parts, etc.) as a proposed condition of the authorization applied for:** None
(c)	**Intended use of the product and types of users:** The flower product will be sold in the cut flower market in the same way as other carnation flowers. Users include flower importers, flower auctioneers, flower wholesalers, retailers, and florists. Flowers will ultimately be sold to the general public.
(d)	**Any specific instructions and/or recommendations for use, storage and handling, including mandatory restrictions proposed as a condition of the authorization applied for:** There are no specific requirements.
(e)	**If, applicable, geographical areas within the EU to which the product is intended to be confined under the terms of the authorization applied for:** None
(f)	**Any type of environment to which the product is unsuited:** None
(g)	**Any proposed packaging requirements:** No specific packaging will be used for transport or marketing of the cut-flowers. The flowers will be handled according to general practice in handling carnations.
(h)	**Any proposed labeling requirements in addition to those required by law:** Product information, including written advice and associated labeling and information will be provided with the imported flowers. Proposed wording is; "These flowers are genetically modified to alter the flower colour and are for ornamental use only".
(i)	**Estimated potential demand:** The popularity of flower colour is highly sensitive to changes in consumer's taste. Currently, the estimated annual consumption in Europe is expected to be between 2.5 and 25 million flower stems.

(j) Unique identification codes(s) of the GMO(s):

Trade name	Florigene codes	Unique Identifier number
FLORIGENE Moonaqua™	123.8.12 (also 40689)	FLO-40689-6

E.4. Has the GMHP referred to in this product been notified under Part B of Directive 2001/18/EC and/or Directive 90/220/EEC?

Yes ☐	No ☑

If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC: The transformation experiment resulting in line FLORIGENE Moonaqua™ (123.8.12) was executed by Florigene Europe B.V. in the Netherlands. The plants were propagated and planted in trials in the Netherlands, at the premises of Florigene Europe B.V. under permit number BGGO 95/12-2 (SNIF B/NL/95-012/02).

FLORIGENE Moonshadow™, a carnation variety produced by use of the same transformation vector, has previous marketing approval in the EU (C/NL/97/13-1363A), under directive 90/220/EC.

E.5 (a) Is the product being simultaneously notified to another Member State?

Yes ☐	No ☑

(i) If no, refer to risk analysis data on the basis of the elements of Part B of Directive 2001/18/EC: An environmental risk assessment is provided with the application.

E.5 (b) Has the product been notified in a third country either previously or simultaneously?

Yes ☑	No ☐

(i) If yes, specify: FLORIGENE Moonaqua™ (123.8.12) has previous approval for production in Ecuador, and Colombia and for importation into Canada and the USA.

E.6. Has the same GMHP been previously notified for marketing in the Community?

Yes ☐	No ☑
(i) If yes, give notification number and Member State:	

E.7. Measures suggested by the notifier to take in case of unintended release or misuse as well as measures for disposal and treatment

None.

NATURE OF THE GMHP CONTAINED IN THE PRODUCT INFORMATION RELATING TO THE RECIPIENT OR (WHERE APPROPRIATE) PARENTAL PLANTS

E.8. Complete name

(a)	**Family name:**	Caryophyllaceae
(b)	**Genus:**	*Dianthus*
(c)	**Species:**	*caryophyllus*
(d)	**Subspecies:**	Not applicable
(e)	**Cultivar/breeding line:**	Recipient variety FE123
(f)	**Common name:**	Carnation

E.9 (a) Information concerning reproduction

(i) **Mode(s) of reproduction:** The cultivated carnation is vegetatively propagated and to produce plants for cut flower production cuttings are taken from vegetative 'mother plants' which are continually pruned to produce a high number of vegetative cuttings from axillary buds. These cuttings are rooted in conditions of high humidity, after treatment with rooting powder.

Rooted plants may be planted in soil or grown hydroponically, and are kept for 1-2 years.

Flowers are produced in flushes, beginning 3-5 months after rooted cuttings are planted.

Picking of <u>all</u> flowers is essential and flowers must be harvested in tight bud (or closed bud for spray types) for distribution and marketing.

Carnation is not reproduced by seed, and seed cannot form during cultivation. Carnation pollen can only be dispersed by lepidopteran insects such as moths. Pollen is not wind dispersed.

(ii)	**Specific factors affecting reproduction, if any:** Imported cut-flowers have no capacity for gene dispersal by seed formation or pollen dispersal.
(iii)	**Generation time:** Cultivated carnation is grown for 1 to 2 years. The application is for import of cut-flowers only.

E.9 (b) Sexual compatibility with other cultivated or wild plant species

Carnations are double-flowered cultivars and in the general trade and botanical and horticultural literature carnation cultivars are considered to belong to the species *Dianthus caryophyllus.* The common name for *Dianthus caryophyllus* is carnation. However, the exact taxonomic and breeding history of carnation is not known and it is almost certain that carnation is a hybrid involving two or more *Dianthus* species, one of which is *Dianthus caryophyllus*

Whilst there are wild *Dianthus* species in Europe, there is no compatibility between these plants and imported carnation flowers. There is no potential for hybridization. No report exists of spontaneous hybridization between carnation cultivated in Europe and either wild *Dianthus* types or species of other genera.

E.10. Survivability

(a)	**Ability to form structures for survival or dormancy:** The survival structures carnation can produce are seeds and pollen, though it is impossible for imported carnation flowers to form seed.
(b)	**Specific factors affecting survivability, if any:** Imported carnation flowers will not survive more than 3 weeks in the hands of the consumer. During this time seed set is impossible. Discarded carnation flowers have no vegetative propagation ability.

E.11. Dissemination

(a)	**Ways and extent of dissemination:** Genetic material from cultivated carnation plants could theoretically be disseminated through seed or insect pollination or vegetative propagation. None of these avenues are realistic avenues for gene dispersal in the case of the carnation flowers imported into Europe.
(b)	**Specific factors affecting dissemination, if any:** Not applicable.

E.12. Geographical distribution of the plant

The carnation is a cultivated plant and is not found in the wild, but is grown worldwide. In Europe, main production countries are Italy, Spain and the Netherlands. Carnation flowers are imported into the EU from Africa, South America and the middle East. Wild. *Dianthus caryophyllus* is very rare and can only be found in specific coastal regions of Corsica, Sardinia, France and Italy.

E.13. In the case of plant species not normally grown in the Member States(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts

Carnation is cultivated and has no natural habiitat. Carnation flowers are routinely imported into the EU from Africa, South America and the middle East, and are also widely grown in Europe. Several billion carnation flowers are distributed within the EU per annum.

E.14. Potentially significant interactions of the plant with other organisms in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms

The product is imported cut flowers, and the receiving environment is the commercial environment of airports, warehouses, trucks and shops, and the home. The product will not be grown in Europe. Discarded flowers will be dead, or soon die, have no ability to survive after use and will not enter human or animal food chains.

Carnation has been used safely by humans for ornamental purposes for centuries. The modification in the GMHP (production of delphinidin) is novel for carnation, but there are many flowers and other ornamental species that produce delphinidin. Delphinidin is also present in many common foods.

Direct tests of potential toxicity indicate no potential for harm to plant, animal or human health.

There is now a long history of safe use of the products. Carnation is not reported to be a poisonous plant, and there is no evidence that the transgenic line has, or could, cause an adverse reaction.

E.15. Phenotypic and genetic traits

The product consists of imported flowers from carnation plants that have a modified flower colour and are herbicide resistant.

Phenotype

Flower colour is generally the result of the relative concentration and type of two pigment types - carotenoids and flavonoids. Carotenoids are responsible for yellow through orange colours however most plants do not contain carotenoid pigments. Anthocyanins are flavonoid based coloured pigments. There are three groups of anthocyanins, the delphinidins that generally produce blue flower colour, cyanidins that produce red or pink flower colour, and pelargonidins that produce orange or brick red flower colour. Non-genetically modified carnations lack the part of the anthocyanin biosynthetic pathway that is responsible for the production of delphinidin, as they lack a gene encoding the enzyme flavonoid 3'5' hydroxylase that converts dihydrokaempferol (DHK) to dihydroquercetin (DHQ) and then to dihydromyricetin (DHM). In the genetically modified carnations commercialized by Florigene a gene encoding DFR has also been introduced as the particular non-genetically modified starting material used lacked both F3'H and DFR activity. The enzyme DFR can use either DHK, DHQ or DHM as substrate. Delphinidin is thus produced as a result of the combined expression of the introduced genes DFR and F3'5'H together with endogenous genes in the anthocyanin biosynthetic pathway. The production of delphinidin results in a change in flower colour.

Genotype

Three genes have been transferred;

- The **petunia DFR gene**, coding for dihydroflavonol 4-reductase (DFR), derived from *Petunia* X *hybrida*. The petunia DFR enzyme is only capable of using dihydroquercetin and dihydromyricetin as substrate, not dihydrokaempferol. This ensures that most or all of the anthocyanidin produced is delphinidin. A constitutive promoter drives the petunia *DFR-A* cDNA derived gene.
- the **pansy F3'5'H gene,** coding for flavonoid 3' 5' hydroxylase (F3'5'H), derived from *Viola sp.* F3'5'H acts by converting the dihydroflavonols dihydrokaempferol and/or dihydroquercetin into the dihydroflavonol dihydromyricetin. The cDNA for F3'5'H encodes the enzyme F3'5'H allowing transgenic plants normally lacking this enzyme to produce violet or blue delphinidin derived pigments.
- ***ALS gene (SuRB),*** coding for a mutant acetolactate synthase protein (ALS), derived from *Nicotiana tabacum.* Expression of the mutation confers resistance to sulfonylurea herbicides.

INFORMATION RELATING TO THE GENETIC MODIFICATION

E.16. Description of the methods used for the genetic modification

Genetic material was inserted into carnation by *Agrobacterium*-mediated transformation using the disarmed *Agrobacterium tumefaciens* strain AGL0 carrying the transformation vector pCGP1991, developed by Florigene Pty. Limited, Bundoora, Australia.

E.17. Nature and source of the vector used

The transformation vector pCGP1991, developed by Florigene Pty. Limited, Bundoora, Australia.

E.18. Size, source of the vector used

Position (nt)	Genetic element	Origin	Function
27119-563 (27432)	LB	*Ti* plasmid *A. tumefaciens* Octopine strain	Defines junction between T-DNA and plant genomic DNA. Utilized in transfer of insert to the plant.
564-571	polylinker	pBluescript/pUC, E. coli	Residual sequences from vectors used in assembling transformation vector.
571-770	35S promoter	Cauliflower Mosaic Virus	Constitutive promoter in plants*.
771-829	*Cab 5'utr*	*Petunia* X *hybrida*	Chlorophyll a/b binding protein cDNA 5' untranslated region (utr)
830-4596	*SuRB* (ALS)	Tobacco, *Nicotiana tabacum*	Encodes Acetolactate Synthase. Chlorsulfuron-resistance gene with terminator. Chlorsulfuron is only used during the tissue culture process8.
4597-4861	polylinker	*pBluescript/pUC series E. coli vectors*	Residual pBluescript and/or pUC series vector DNA used for making the construct. Cloning & ligation sites.
4862-9819	DFR genomic clone	*Petunia* X *hybrida*	Encodes the dihydroflavonol reductase protein with its own promoter and terminator; a key enzyme in the anthocyanin biosysnthesis pathway. The gene is comprised of 6 exons and 5 introns (see map)*.
9820-9846	polylinker	pBluescript/pUC series *E. coli* vectors	Residual pBluescript and/or pUC series vector DNA used for making the construct. Cloning & ligation sites.
9847-11018	CHS promoter	*Antirrhinum majus*	Flavonoid pathway promoter from a gene encoding chalcone synthase.
11019-11042	polylinker	pBluescript/pUC series *E. coli* vectors	Residual pBluescript and/or pUC series vector DNA used for making the construct. Cloning & ligation sites.
11043-12839	F3'5'H cDNA	*Viola* sp.	Encodes the flavonoid 3'5'hydroxylase protein. A key enzyme in the anthocyanin biosynthesis pathway leading to the biosynthesis of delphinidin*.
12840-12852	polylinker	pBluescript/pUC series *E. coli* vectors	Residual pBluescript and/or pUC series vector DNA used for making the construct. Cloning & ligation sites.
12853-13664	'D8' terminator	*Petunia* X *hybrida*	Terminator sequence from petunia 'D8', a gene encoding a phospolipid transfer homologue.
13665-13846	polylinker	pBluescript/pUC series *E. coli* vectors	Residual pBluescript and/or pUC series vector DNA used for making the construct. Cloning & ligation sites.
13847-15693	RB	*Ti* plasmid *A.tumefaciens* Octopine strain	Defines junction between T-DNA and plant genomic DNA. Utilized in transfer of insert to the plant*.

Position (nt)	Genetic element	Origin	Function
15694-15703	polylinker	pBluescript/pUC series *E. coli* vectors	Residual pBluescript and/or pUC series vector DNA used for making the construct. Cloning & ligation sites.
15704-23618	pVS1 replicon	*Pseudomonas aeruginos*	For replication in *A. tumefaciens*. This is a broad spectrum replicon, which allows plasmid replication in a wide range of bacteria. Includes flanking sequences either side of origin of replication*.
23619-25591	Tetracycline resistance gene complex	*Escherichia coli*	Used for the selection of bacteria carrying the transformation vector. This DNA has a known function and encodes a membrane associated protein that prevents tetracycline from entering bacterial cells.
25592-27120	Modified pACYC184 replicon	*Escherichia coli*	This low copy replicon allows replication in *E. coli* only. Includes flanking sequences either side of origin of replication*.

INFORMATION RELATING TO THE GMHP

E.19 Description of the trait(s) and characteristics, which have been introduced or modified

Flowers of the genetically modified carnation product of this application produce delphinidin whilst carnations which are not modified do not. The production of delphinidins results in a change in flower colour. The flower products of this application are a shade of light mauve, compared to the cream-white flowers of the line from which the transgenic line was derived.

E.20 Information on the sequences actually inserted/deleted/modified

(a) Size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP:

The T-DNA is 27,432 base pairs. The size and structure of the inserts have been analyzed by Southern blot analysis and T-DNA between the left and right borders of pCGP1991 remains in the GMHP. Through Southern Blot analysis it has been shown that no DNA from outside the T-DNA borders is present in the GMHP and that the introduced DNA is present as three loci.

No carrier (*Agrobacterium*) remains in the GMHP.

(b) In the case of deletion, size and function of the deleted region(s):

Not applicable.

(c) Location of the insert in the plant cells (integrated in the chromosome, chloroplast, mitochondrion, or maintained in a non-intergrated form) and method for its determination:

The insert is integrated into the plant chromosome.

(d) Copy number and genetic stability of the insert: The T-DNA is present at three integration loci, as summarized in the table below.

Estimated copy numbers of probes that span the region within the T-DNA in transgenic tissue of the line FLORIGENE Moonaqua™(123.8.12)

Probe	Estimated Copy Number FLORIGENE Moonaqua™(123.8.12)		
	Locus 1	**Locus 2**	**Locus 3**
LB	1	0	0
SuRB	1	0	0
F3'5'H	1	1	1
gDFR	1	0	0
RB	1	2	0

FLORIGENE Moonaqua™ (123.8.12) has been vegetatively propagated since 1999. Since 2000 plants have been in continuous commercial production in Ecuador and Colombia. Measured by flower colour, the line is genetically stable.

(e) In case of modification other than insertion or deletion, describe function of the modified genetic material before and after modification as well as direct changes in expression of genes as a result of the modification: Not applicable.

E.21 Information on the expression of the insert

(a) Information on the expression of the insert and methods used for its characterization:

Expression of the insert has been determined by the presence of delphinidin-type pigments using TLC and HPLC techniques. Flowers of the product contain approximately 0.1 mg delphinidin per gram fresh weight, determined by HPLC.

Northern analysis of expression of three introduced genes was carried out in FLORIGENE Moonaqua™™™ (123.8.12) and the parental line it was derived from (FE 123). The *Su*RB(ALS) gene is under the direction of a CaMV 35S promoter which generates transcript in numerous plant tissues including the petal. A strong hybridization signal indicates the introduced ALS mRNA is present in petal tissue.The petunia DFR gene used is under the direction of its own promoter which is relatively weak and typically strongest early in flower development in petunia. The pansy F3'5'H gene is under the control of an *Antirrhinum* CHS promoter which typically directs expression through most stages of flower development.

The parental line FE123 has no closely homologous ALS gene, is a DFR mutant and has no F3'5'H gene. Hence controls show no detectable transcript for all the probes used.

(b) **Parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc):** Flowers of the genetically modified carnation product produce delphinidin whilst carnations which are not modified do not. The production of delphinidin results in a change in flower colour. Transgenic flowers are light mauve, compared to the cream-white flowers of the control line. Delphinidin production has not been observed in other tissues of the transgenic flowers and plants, such as stems, nodes, leaves and roots. Production of delphinidin is confined to the petals as result of the use of floral specific promoters for some genes and because the biochemical pathway leading to anthocyanin biosynthesis is induced to coincide with flower development.

E.22 Information on how the GMHP differs from the recipient plant in:

(a) **Mode(s) and/or rate of reproduction:** There no avenue of reproduction from imported cut flowers of either recipient or GMHP.

(b) **Dissemination:** There are three theoretical avenues of gene dispersal from an imported carnation flower;

1. Vegetative spread of the imported cut flowers, leading to the formation of wild clonal populations.
2. Formation and dispersal of seed from the imported cut flower as a result of self fertilization or fertilization with pollen from an external source.
3. Formation of seed by a recipient plant, fertilized by pollen dispersed from the imported cut flower.

The probability of gene dispersal from a carnation flower, of recipient or GM origin, is negligible to nil.

(c) **Survivability:** Imported flowers of the GMHP have no greater ability to survive than flowers from any other carnation variety, including the recipient.

(d) **Other differences:** The primary difference between FLORIGENE Moonaqua™ (123.8.12) and the recipient plant is in the colour of the flowers, because of the production of delphinidin in the GMHP. The transgenic line FLORIGENE Moonaqua™ (123.8.12) produces smaller flowers than the parental line it is derived from, and these flowers have a much reduced number of anthers, styles and stamens. The styles and stamens are also significantly shorter in the transgenic line.

E.23 Potential for transfer of genetic material from the GMHP to other organisms

There is an extremely low risk of gene dispersal for imported carnation flowers. The imported flowers from the GMHP have no enhanced ability to transfer genetic material.

E.24 Information on any harmful effects on human health and the environment, arising from the genetic modification

Carnation has been used safely by humans for ornamental purposes for centuries. The modification in the GMHP (production of delphinidin) is novel for carnation, but there are many flowers and other ornamental species that produce delphinidin. Delphinidin is also present in many common foods. Carnation is not reported to be a poisonous plant, or to cause allergic reactions, and there is no evidence that the transgenic line has, or could, cause an adverse reaction. There is now an extensive history of safe use of the product overseas. Carnation is not used as a food but there is a slight possibility that some home consumers may decide to eat flower petals, or garnish foods with flower petals. In the event that this did occur we do not believe the transgenic carnation poses any health risk because the novel products in the GMHP are found naturally in many foods. Open reading frame analysis of introduced regions of DNA reveals that the deduced amino acid sequences of the transgenic carnation lines in this application appear not to be homologous to any known toxic or allergenic proteins. Direct tests of potential toxicity indicate no potential for harm to plant, animal or human health.

There is no potential for gene dispersal. The settings in which the imported flowers will be used, the relatively small number of flowers imported, their dispersal across Europe, and the short longevity of the flowers are all factors that preclude any direct or indirect effect on the environment.

E.25 Information on the safety of the GMHP to animal health, where the GMHP is intended to be used in animal feedstuffs, if different from that of the recipient/parental organism(s)

Not applicable. The product is not intended to be used as animal feed.

E.26 Mechanism of interaction between the GMHP and target organisms (if applicable), if different from that of the recipient/parental organism(s)

Not applicable. There are no target organisms.

E.27 Potentially significant interactions with non-target organisms, if different from the recipient or parental organism(s)

The flowers from the GMPH are intended to be used for human consumption as an ornamental product, in the same way as other carnation flowers. There are no changes in this interaction as a result of the genetic modification.

E.28 Description of detection and identification techniques for the GMHP, to distinguish it from the recipient or parental organism(s)

The GMHP can be distinguished using DNA based identification methods, such as Southern analysis and PCR. A PCR based identification technique has also been developed that will allow the product to be distinguished from other transgenic carnation lines.

Flower colour can be used to distinguish the product from the recipient plant, and biochemical tests such as thin layer chromatography may be used to determine that delphinidin is produced. The product, but no non GM carnation variety, is able to produce delphinidin.

INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GMHP

E.29 Potential environmental impact from the release or the placing on the market of GMOs (Annex II, D2 of Directive 2001/18/EC), if different from a similar release or placing on the market of the recipient or parental organism(s)

There is no environmental impact from the placing on the market of the GMHP which would be different to that of placing flowers from the recipient plant on the market. Carnation flowers from many varieties, including the recipient, are a commodity in the EU, and several billion non-GM carnation flowers are consumed per annum in the community. There is no evidence the products would have any adverse

effects;

- An analysis of the biology of carnation shows no potential for gene dispersal as a result of import of cut-flowers. The flowers are not invasive and there is no opportunity for the cut-flowers to become "weeds". Carnation is not a weed in Europe and despite hundreds of years of cultivation, and plantings in parks and gardens, it has not become a weed, or escaped from cultivation, anywhere in the world. No hybrid between carnation and any other *Dianthus* species has ever been recorded in the wild.
- FLORIGENE Moonaqua™ (123.8.12) has a history of safe use outside the EU.
- Field trial results show substantial equivalence between FLORIGENE Moonaqua™ (123.8.12) and the recipient plant, aside from a significantly reduced production of anthers, stamens and styles in the transgenic line.
- There is no evidence that carnation flowers in general, and the transgenic line that is the subject of this application specifically, have any pathogenic, phyto-toxic, toxic or allergenic properties.

The transgenic carnation variety FLORIGENE Moonshadow™ has already been approved for commercial production within the EU (C/NL/97/13-1363A). This variety was developed with the same transformation vector as FLORIGENE Moonaqua™ (123.8.12).

E.30 Potential environmental impact of the interaction between the GMHP and target organisms (if applicable), if different from that of the recipient or parental organism(s)

Not applicable. There are no target organisms.

E.31 Possible environmental impact resulting from potential interactions with non-target organisms, if different from that of the recipient or parental organism(s)

(a) **Effects on biodiversity in the area of cultivation:** Not applicable. The products are cut flowers and will not be cultivated.

(b) **Effects on biodiversity in other habitats:** Not applicable. The imported cut flowers have no means to become established in any habitat.

(c) **Effects on pollinators:** Not applicable. Imported cut flowers are very unlikely to come into contact with pollinators in the environment in which they will be used.

(d) Effects on endangered species: Not applicable. The imported cut flowers have no means to become established, and will be consumed in the human household environment in the same way as other carnation flowers.

INFORMATION RELATING TO PREVIOUS RELEASES

E.32 History of previous releases notified under Part B of the Directive 2001/18/EC and under Part B of Directive 90/220/EEC by the same notifier

(a) Notification number: The variety FLORIGENE Moonaqua™ (123.8.12) has not been notified. However, similar products have been approved under Part B of directive 90/220/EEC and two varieties of these approved GM carnation have been imported into the EU;

Trade name	Plasmid	OECD ID No. (Unique Identifier)	EU approval & registration No.
FLORIGENE Moondust™	pCGP1470	FLO-07442-4	C/NL/96/14-11
FLORIGENE Moonshadow™	pCGP1991	FLO-11363-1	C/NL/97/13-1363A

(b) Conclusions of post-release monitoring: Production sites overseas have been monitored for escapes from cultivation of the GMHP and none have been found. There have been no reports from growers and consumers of the product relating to harmful effects on human health.

(c) Results of the release in respect to any risk to human health and the environment (submitted to the competent authority according to Article of Directive 2001/18/EC):

The product has been released in Colombia, Canada, USA and Australia. There have been no reports from growers and consumers of the product relating to harmful effects on human health.

E.33 History of previous releases carried out inside or outside the Community by the same notifier

(a) Inside the community:

The transformation experiments resulting in lines FLORIGENE Moonaqua™ (123.8.12) were executed by Florigene Europe B.V. in the Netherlands. In 1998 the first plants flowered under a contained use permit. Trials were carried out in the summers of 1999 and 2000 under permit number BGGO 95/12-02.

(b) Outside the community:

USA

FLORIGENE Moonaqua™ (123.8.12) has been sold in the USA since July 2001.

Canada

Flowers from FLORIGENE Moonaqua™ (123.8.12) have been imported into Canada in small numbers since August 2002.

Colombia

A resolution permitting commercial release was issued in May 2000. Production of FLORIGENE Moonaqua™ (123.8.12) began in mid-2000 and first flowers were exported from June 2001.

INFORMATION RELATING TO THE MONITORING PLAN- IDENTIFIED TRAITS, CHARACTERISTICS AND UNCERTAINTIES RELATED TO THE GMO OR ITS INTERACTION WITH THE ENVIRONMENTAL THAT SHOULD BE ADDRESSED IN THE POST –COMMERCIALIZATION MONITORING PLAN

E.34 Information relating to the monitoring plan- identified traits, characteristics and uncertainties related to the GMO or its interaction with the environmental that should be addressed in the post – commercialization monitoring plan

Transgenic carnation, and specifically the carnation line that is the subject of this proposal, now has sufficient history of safe use to support the fact that the biology of the crop precludes gene dispersal and dissemination from transgenic carnation at either production locations or after import of flowers.

- In trials and a period of commercial production in Europe, no observations were made to suggest that GMHP behaved any differently to non-genetically modified carnation.
- Transgenic carnation flowers have been imported into the EU on a virtually weekly basis for the past 18 months. We have received no reports from the users of these flowers to suggest any features or characteristics that would require further monitoring.
- Several hundred thousand plants of FLORIGENE Moonaqua™ (123.8.12) have been grown in South America since 2000, and several million flowers produced. Surveys of the production

sites have found no evidence of dissemination from outside of the cultivation area and there have been no adverse effect reports from any of the workers handling the plants or flowers.

- Several million flowers of FLORIGENE Moonaqua™ (123.8.12) have been exported to the USA and Japan with no reports of adverse effects on distributors or end users.
- There is experience of growing and selling two similar transgenic carnation varieties within the EU, without any reports of adverse effects.

A general monitoring plan has therefore been proposed for this product. The environmental risk assessment indicates no risks associated with the import of the GMHP and that issues associated with imports are the same as non GM carnation flowers. As the flowers will not be grown in the EU, there is no requirement for monitoring of production locations within the EU.
Information collected will be from general surveillance, rather than collection of specific data, or tracing products to end use.