SECTION D

Monitoring plan as required in Annex VII of Directive 2001/18/EC

Introduction

Transgenic carnation, and specifically the carnation line that is the subject of this proposal, now has a history of safe use. There is also sufficient history of 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 Moonlite* ™(123.2.38) 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 Moonlite* ™(123.2.38) 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. These two varieties are listed in the table below.

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

Our monitoring plan has therefore been developed on the basis of the above experience, and the environmental risk assessment shown in Section B, which indicated no hazard linked to the release of this product. As the flowers will not be grown in the EU, there is no requirement for monitoring of production locations within the EU.

Florigene are not required to undertake specific monitoring activity as a condition of approvals to grow and sell *Florigene Moonlite* ™(123.2.38) in Australia, Japan or South America.

Traceability

Information collected will be from general surveillance, rather than collection of specific data, or tracing products to end use. The nature of the floricultural business is such that there will be a reasonably accurate record of the flow of flowers to wholesale outlets. This information will be accessible to Florigene, and a database is maintained at Florigene of all individual exports to the EU.

- Florigene will maintain exact records of all exports to Europe – exact number of flowers, customer details, date and arrival airport will be recorded, and can be tallied to independent records of the freight forwarders, importers and airlines.
- Importers will record sales to wholesalers and supermarkets on a variety basis. This is done for them to evaluate the relative commercial success of specific products. The information could be used to identify date and customer name.
- Some wholesalers are very sophisticated and keep bar code systems that will allow the sale of the transgenic carnation to be traced by date, customer and volume. Not all wholesalers have such business systems. We would expect flowers supplied to supermarkets to be bar coded, providing a record of date and volume of sales by location. Florigene flowers sold to US supermarkets are bar coded in this way.
- We believe that it is impractical to monitor sales to the public.

We have developed a PCR based test that will allow the identification of the two lines that are described in this proposal, from vegetative and floral tissue, to support detailed investigation if necessary. This detection method is described in Section C of this application at page 10.

Monitoring

The following monitoring activities will be undertaken:

1. Importers will be asked to monitor their markets for any suppliers selling flowers that resemble the Florigene product. Samples will be collected for analysis if necessary.
2. On a six monthly basis our European importers will be asked in questionnaire format for feedback. The questionnaire is attached at the end of this document.
3. The Florigene website will provide a link at which European consumers will be invited to comment on Florigene products with all Florigene contact details. The names and locations of our importer customers will be listed on the website.
4. After release, Florigene will write to taxonomists and botanists with interests in *Dianthus* biology, asking them to alert us to any unusual hybrids that might find during survey work.

We will undertake to carry out molecular analysis and test for resistance to herbicides to eliminate the possibility of transgenic hybrid discovery, if these experts request it.

Whilst Florigene flowers are produced outside of the EU, the growers will continue to play a monitoring role. They are expected to provide Florigene feedback on:

- Any increase in disease susceptibility
- Any unusual increases in the incidence or type of pests
- Report any adverse reactions to handling the flowers
- Incidence of genetic off types

In addition Florigene staff visit the farms frequently, and personally inspect the areas where flowers are discarded, and the natural vegetation close to the growing areas, for any "escapes".

The Florigene office in Australia will collate all information from importers and any comments from consumers. We maintain sufficient resources to visit Europe to investigate any plausible observations that may warrant further investigation, from Australia, or from our Miami office. As we are importing flowers, and not growing in the EU, any situation that may arise where immediate corrective action is required can be implemented through suspension of exports. This is an unlikely scenario, based on the history of safe use of flowers from the GMHP. Florigene will submit an annual report to the Dutch competent authority, summarizing the results of our monitoring activity.

Our monitoring actions will be permanent, implemented as long as flowers are exported to the EU.

Questionnaire Number FLORIGENE TO COMPLETE

As part of the conditions for marketing approval of Florigene varieties in the EU. Florigene are required to monitor for any unexpected effects that may be associated with the import and consumption of our flowers. Your help in completing this questionnaire is very much appreciated. If you tick YES to any question a representative of Florigene will contact you as soon as possible for more details, including variety and circumstances.

Your feedback can be returned to us electronically to Florigene@florigene.com.au or by Fax to +61 3 9416 1761.

Your name WILL BE COMPLETED BY FLORIGENE

Your company WILL BE COMPLETED BY FLORIGENE

Today's date_____

Are you aware of any reports of illegal growing of Florigene varieties?

YES _____ **NO** _____

Has any of your staff or re-packers reported any adverse or unexpected response to handling Florigene flowers?

YES _____ **NO** _____

Have any of your customers reported to you any adverse or unexpected effects of handling Florigene flowers?

YES _____ **NO** _____

If there any other comments you wish to make, please type here;