

SECTION D

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

Type of monitoring plan

The proposed monitoring plan is based on general surveillance. As no potentially adverse effects have been identified for the GM product we believe case-specific monitoring is not appropriate for FLO-4Ø644-6 as the guideline parameters that are recommended for case specific monitoring do not apply. For example;

- Because there is no avenue for gene dispersal it is not possible to document the spread, persistence and accumulation of transgenes and recombinant proteins.
- There are no apparent organisms, food chains or habitats that are affected by conventional carnation flower imports, which could therefore be the subject of specific attention for transgenic carnation.
- It is not possible to quantify a baseline environment in the absence of the imported carnation flowers in the floral trade distribution environment and household environment.

As the flowers will not be grown in the EU, there is no requirement for monitoring of production locations within the EU.

Components of the monitoring plan

The components of the monitoring plan are;

Importer questionnaire. On a bi-annual basis the importers will be asked to complete a questionnaire, an example of which is shown at Figure 1.

Consumer feedback. The Florigene website has a regulatory link (<http://www.florigene.com/product/regulatory.html>) in German, French and English. Consumers are provided contact details through which comments may be made on the transgenic carnation products.

Survey reports. Each year Suntory engages the services of botanists with interests in *Dianthus* biology. In the past 6 years two experts were contacted. The experts are asked to alert Suntory to any wild populations or unusual *Dianthus* hybrids they find during their routine survey work. If a likely hybrid is found, molecular analysis will be carried out to eliminate the possibility of hybridization with transgenic carnation. A PCR based detection method has been developed and validated by the JRC (JRC, 2007). This will allow the specific identification of the line that is described in this proposal to support detailed investigation if necessary. Participation by each expert is supported by an annual honorarium of less than 1000 EURO, for which Suntory receive a written annual report of activity. The reports cover the locations surveyed, area surveyed and species identified.

Institutional mail out. Suntory has a mailing list of herbaria, national botanical survey networks, plant protection services and botanical gardens in Europe. These are contacted each year to seek information on any *Dianthus* collections or samples which come into their institutions. Communication will be in at least four languages (English, French, Italian, Spanish), as required by the institution.

Literature review. Each year, the scientific literature is reviewed for new reports on *Dianthus* taxonomy, botany and vegetation.

Web site, database and personal communication review. Each year, web sites and data bases are reviewed for new reports on *Dianthus* taxonomy, botany and vegetation. These are complemented with any personal communications on the same subjects that are generated from the mail out.

Monitoring at production sites

Though Suntory are not required to undertake specific monitoring activity as a condition of approvals to grow and sell FLO-4Ø644-6 in South America, we will continue to monitor the production site areas in Colombia and Ecuador for the presence of escapes of carnation from cultivation, particularly in the area where the waste from the carnation production is recycled. Growers are expected to provide 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
- Any incidence of genetic off types

Traceability

A database will be maintained of all individual imports of the GM product into the EU. Suntory will maintain exact records of all exports to Europe – exact number of flowers will be recorded along with customer details, date and arrival airport. This data can be tallied to independent records of the freight forwarders, importers and airlines. Importers record sales to wholesalers on a variety basis. Once purchased by an end consumer, the imported flowers could be used anywhere in the EU and it is not possible to track the final distribution of all flowers.

Annual reporting

It is planned that line FLO-4Ø644-6 will be reported separately but that the monitoring work will be directed to all transgenic carnation varieties marketed in the EU i.e. monitoring activity will be for transgenic carnation *per.se*.

The annual report includes details of annual imports into the EU by variety and the proportion of transgenic varieties as a percentage of all imports.

Monitoring reports will be lodged in July each year.

References

JRC, 2007. http://gmo-crl.jrc.ec.europa.eu/docs-valid-2001-18/CRL_Report_Flor_Moonlite_v2.pdf

Figure 1. Example copy of questionnaire to be issued to importers. The example shown is the most recent questionnaire to have been issued, for other transgenic carnation varieties. The format will be modified to include FLO-40644-6. The questionnaire is in two parts.

Questionnaire

Questionnaire	Number FLORIGENE TO COMPLETE
<p>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 schandler@florigene.com.au</p>	
Your name	WILL BE COMPLETED BY FLORIGENE
Your company	WILL BE COMPLETED BY FLORIGENE

PART ONE

(Please tick appropriate box)

Are you aware of any reports of illegal growing of Florigene varieties?		Yes	No
	Florigene®Moonaqua™		
	Florigene®Moonlite™		
	Florigene®Moonberry™		
	Florigene®Moonvelvet™		

Has any of your staff or re-packers reported any adverse or unexpected response to handling Florigene flowers?		Yes	No
	Florigene®Moonaqua™		
	Florigene®Moonlite™		
	Florigene®Moonberry™		
	Florigene®Moonvelvet™		

Have any of your customers reported to you any adverse or unexpected effects of handling Florigene flowers?		Yes	No
	Florigene®Moonaqua™		
	Florigene®Moonlite™		
	Florigene®Moonberry™		
	Florigene®Moonvelvet™		

If there any comments you wish to make on PART 1, please make them here;

PART TWO

Please provide an estimation of the number of staff who have handled the flowers during import or re-packing in the last 6 months	
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Please provide an estimation of the number of customers you have supplied the flowers to in the last 6 months	
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If there any other comments you wish to make, please make them here;

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Signature _____

Date _____