

SECTION D

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

Type of monitoring plan

The monitoring plan described in the submission is based on general surveillance. After approval SHD-27531-4 will be included with the GM carnation lines already approved in Europe in an annual general monitoring report. We believe general monitoring is a realistic approach and it has already been established for the genetically modified carnation lines already approved in Europe. Once purchased by an end consumer, the imported flowers could be used anywhere in the EU and case-specific monitoring is impractical as it is not possible to track the final distribution of all imported flowers. As no potentially adverse effects have been identified for the GM product described in this application, we believe case-specific monitoring is not appropriate for SHD-27531-4 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.

In reviewing previous applications in Europe for marketing of GM carnation, the GMO panel of EFSA concluded that case-specific monitoring for marketing of colour-modified, genetically-modified carnation was not appropriate and was not required (EFSA, 2006, 2014a, 2014b).

Monitoring at production sites

Though specific monitoring activity is not required as a condition of approvals to grow and sell SHD-27531-4 in USA or South America, we monitor the production site areas in South America for the presence of wild populations of GM carnation, particularly in the area where the waste from the carnation production is recycled. We will continue to do this; Suntory 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.

Growers are also 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 off types (flowers with unexpected colour)

Traceability

Information collected will be from general surveillance, but 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 and a database is maintained of all exports to the EU.

- Suntory will maintain exact records of all exports to Europe – number of flowers, customer details, shipment date and arrival airport will be recorded. This information 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.

A PCR based test has been developed that will allow the specific identification of the line that is

described in this proposal to support detailed investigation if necessary. This detection method is described in Attachment C1 of the application for C/NL/13/01 and has been validated by the Joint Research Centre.

Monitoring methods

Importer feedback

Importers will be asked to monitor their markets for any suppliers selling flowers that resemble the SHD-27531-4. Samples will be collected for analysis if necessary. On a six monthly basis our European importers will be asked for feedback in questionnaire format. The questionnaire is attached at the end of this document.

Consumer feedback

The Florigene web site has a regulatory link in German, English and French at which consumers are provided contact details through which to comment on Florigene products. The names and locations of our importer customers are listed on the website.

Expert monitoring group

Suntory has engaged the services of breeders and botanists with interests in *Dianthus* biology. We have asked them to alert us to any unusual hybrids that might find during their routine 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. The experts group comprises Europe-based carnation breeders and Europe-based academics with expertise in *Dianthus* biology, ecology and taxonomy.

Binding agreements/contracts have not been made with the experts as we feel this would discourage participation in the monitoring activity. Participation of the academic experts is supported by an annual honorarium, for which we would expect a brief annual statement on their survey work applicable to the monitoring. The breeders will not be paid. Active participation will be encouraged through contact by phone and email. It is envisaged that the surveys carried out by the contact group would be part of any survey work normally undertaken by the experts, rather than a specific expedition mounted to seek theoretical hybrids. The monitoring parameters will comprise an indication of the locations surveyed, area surveyed and if any *Dianthus* species are identified. Through the contact Suntory will keep with the experts we expect to be advised of the location and timing of surveys and will advise them of known carnation growing areas. Our expectation is that at least one of the primary designated experts would participate in such a survey each year. If not, Suntory will provide support to carry out a survey during one of the summer months in the carnation growing region of southern Spain in the vicinity of Chipiona, Andalusia. This region has been chosen because of the high density of carnation plants, grown in relatively open conditions, in a region of Europe where several *Dianthus* species do occur. 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.

Mailing list

Suntory has compiled a mailing list of herbaria, national botanic survey networks, plant protection services and botanic gardens in Europe and we will write to these institutions to notify them of the importation of the product into Europe and alert them to take this into account when reviewing any *Dianthus* collections that may come into their possession. A copy of the mailing list is provided at Attachment D1.

Literature review and database review

The scientific literature and on-line European floral databases are reviewed on an annual basis for new reports of *Dianthus* collection, ecology and biology.

Annual report

In July each year Suntory will provide an annual report to the Dutch CA and the EU Commission describing the outcome of the monitoring activity. The report will include;

- Number of flowers imported into Europe in each week of the year by variety, importer and importer location
- List of surveys carried out by expert groups with date, location and area surveyed

- All reports of putative *Dianthus* hybrids identified
- All reports of any wild carnation populations
- Response to mail out to herbaria, national botanic survey networks, plant protection services and botanical gardens
- Results of literature and database review

References

EFSA, 2006. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/NL/04/02) for the placing on the market of the genetically modified carnation Moonlite 123.2.38 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene. *The EFSA Journal* 362, 1-19, 2006.

EFSA, 2014a. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on a notification (reference C/NL/09/01) for the placing on the market of the genetically modified carnation IFD-25958-3 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene. *EFSA Journal* 2014;12(12):3934, 19 pp. doi:10.2903/j.efsa.2014.3934

EFSA, 2014b. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on a notification (reference C/NL/09/02) for the placing on the market of the genetically modified carnation IFD-26407-2 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene. *EFSA Journal* 2014;12(12):3935, 18 pp. doi:10.2903/j.efsa.2014.3935

Questionnaire

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.

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;