



ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Advice on a notification for marketing of carnation “Florigene Moonlite”

- Notifier:** Florigene Ltd.
- Notification Reference:** C/NL/04/02
- Product:** A GM carnation line genetically modified for petal colour and herbicide tolerance. This line (123-2-38) is modified with *hfl* and *dfr* genes, which confer the ability to produce a violet pigment in the petals and the *SuRB (ALS)* gene, which confers tolerance to the sulfonylurea herbicides.
- Scope:** For import of cut carnation flowers containing event 123-2-38 into the European Community. The scope of this notification does not include cultivation or use as food or feed.
- Date:** 18 August 2006

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, Ministers of the Welsh Assembly Government and the Department of Environment (Northern Ireland).

Final advice: ACRE has not altered its previous advice in concluding that the import and distribution of cut flowers from GM carnation line 123-2-38 does not pose an increased risk to human health or the environment compared with non-GM carnation varieties.

ACRE did not request further information from the notifier after previous assessments of this notification. ACRE has however, considered the further information provided by the notifier in response to requests from other Member States and the EFSA GMO panel, none of which alters our previous advice (please see below).



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- Notification Reference:** C/NL/04/02
- Product:** A GM carnation line genetically modified for petal colour and herbicide tolerance. This line (123-2-38) is modified with *hfl* and *dfr* genes, which confer the ability to produce a violet pigment in the petals and the *SuRB (ALS)* gene, which confers tolerance to the sulfonylurea herbicides.
- Scope:** For import of cut carnation flowers containing event 123-2-38 into the European Community. The scope of this notification does not include cultivation or use as food or feed.
- Date:** 24 October 2005

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, Ministers of the Welsh Assembly Government and the Department of Environment (Northern Ireland).

Secondary advice: ACRE has not altered its previous advice in concluding that the import and distribution of cut flowers from GM carnation line 123-2-38 does not pose an increased risk to human health or the environment compared with non-GM carnation varieties.

ACRE did not request further information from the notifier after the initial assessment period of this notification. ACRE has however, considered the further information provided by the notifier in response to requests from other Member States, none of which alters our previous advice (please see below).



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Advice on a notification for marketing of carnation “Florigene Moonlite”

- Notifier:** Florigene Ltd.
- Notification Reference:** C/NL/04/02
- Product:** A GM carnation line genetically modified for petal colour and herbicide tolerance. This line (123-2-38) is modified with *hfl* and *dfr* genes, which confer the ability to produce a violet pigment in the petals and the *SuRB (ALS)* gene, which confers tolerance to the sulfonylurea herbicides.
- Scope:** For import of cut carnation flowers containing event 123-2-38 and progeny derived by conventional breeding into the European Community. The scope of this notification does not include cultivation or use as food or feed.
- Date:** 14 April, 2005

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, Ministers of the Welsh Assembly Government and the Department of Environment (Northern Ireland).

Primary advice: ACRE agrees with the lead competent authority’s (Netherlands) assessment of notification C/NL/04/02 and concludes that the import and distribution of cut flowers from GM carnation line 123-2-38 does not pose an increased risk to human health or the environment compared with non-GM carnation varieties. ACRE considers that the dossier provides sufficient information to assess the impact of this organism on human health and the environment and that the post-market monitoring plan is proportionate to the risk assessment.

Comment

The scope of the notification is for import, distribution and retailing and does not include cultivation or the use as food or as feed of carnation line 123-2-38. ACRE considered the molecular characterisation of 123-2-38 carnation, the potential environmental impacts of imports of cut flowers resulting from gene flow and the potential impacts on human health resulting from any changes in toxicity and allergenicity and on the plan for post-market monitoring.

Molecular characterisation

The carnation line 123-2-38 “Florigene MoonliteTM” described in this notification contains *hfl* and *dfr* genes, which confer a violet colouring to the petals of these

plants and the *SuRB* (also known as *ALS*) gene which confers tolerance to sulfonylurea herbicides.

The PCR detection method provided in this notification is considered to be event specific. The stability of the phenotype of this carnation line has been demonstrated through at least four years of continuous vegetative propagation. Evidence from PCR tests supports the conclusion that a complete copy of the *tetA* gene which confers resistance to tetracycline (present on the backbone of the vectors) is absent from 123-2-38 carnation.

The borders and flanking sequences of the T-DNA inserts are not fully characterised, and sequence analysis to determine whether new open reading frames (ORFs) were formed due to these insertions were not performed. Since carnation is very rarely consumed as a food, information on putative new ORFs is not required by ACRE, and instead toxicity tests were carried out (see below). The information provided is proportionate to this notification.

The results of Southern hybridizations support the notifier's conclusions that 123-2-38 carnation could be a periclinal chimera, with the inserted T-DNAs contained only within the L1 layer of tissue. Cells from this tissue layer do not produce germ cells in the flowers and therefore it is not possible for the plants to produce pollen containing transgenic material unless sporting occurs. The anthers are also developmentally abnormal, and produce very little pollen. This greatly reduces the risk of gene flow from pollen in these plants.

Environmental exposure

The inserted genes for altered flower colour are locally expressed within the petals of the flower, and the enzymes produced from the transcription of the genes use compounds naturally produced by the carnation as a substrate to produce delphinidin. Delphinidin is a compound that occurs naturally in many foodstuffs and there is evidence that it has a low toxicity. Incidental ingestion of GM carnation could arise through inclusion of the petals in salad garnishes. The notifier has investigated whether the transgenic proteins synthesised from the inserted DNA in 123-2-38 carnation have the potential to be allergenic or toxic. In the absence of sequence data for the DNA in the flanking regions of the insert the notifier has instead provided results of three different toxicity tests which provide a direct indication that no toxic compounds are produced by these plants. No reports of adverse reactions have been submitted by workers handling plants in areas where they are cultivated. ACRE is content that this risk has been satisfactorily addressed.

ACRE agrees with the notifier that the risk of gene flow or potential weediness from these plants is very low. Cut carnation flowers are not able to produce seed and have low male fertility. Exposure to insect pollinators is likely to be negligible in the display environment and a barrier is presented by the petals of the double inflorescence and the chimerical nature of the plant will further reduce the possibility of transgene release. However propagation by leaf and stem cuttings from cut flowers allows the possibility of clonal propagation either in glasshouses or in gardens. There is no evidence of gene flow occurring from garden cultivated carnations into related species or of these plants becoming invasive or weedy.

Post-market monitoring

ACRE agrees with the Dutch competent authority that the post-market monitoring plan for 123-2-38 carnation is proportionate to the environmental risk assessment. As the scope of this notification is for import and distribution of cut flowers, the general

surveillance plan addresses the availability of illegal products, unexpected adverse effects on human health consequent to handling and displaying this product and gene flow to wild related species.

The notifier/consent holder will submit general surveillance reports of 123-2-38 carnation imports on an annual basis, to the Dutch competent authority. If risks associated with either the cultivation or import of these flowers are identified, immediate suspension of exports will be implemented. ACRE agrees that this approach is appropriate.