Summary of the 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[1]

(Question No EFSA-Q-2005-282)

Opinion adopted on 17 May 2006

SUMMARY

This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on the notification to import carnation Moonlite 123.2.38 variety, genetically modified (GM) for flower colour (Unique Identifier FLO-40644-4). The GM carnation also contains a gene conferring tolerance to sulfonylurea herbicides. Cut flowers of carnation Moonlite 123.2.38 are intended to be imported within the European Union for ornamental use only.

The present opinion is based on a question raised by the Commission related to a notification to place carnation Moonlite 123.2.38 on the market under Directive 2001/18/EC (Reference C/NL/04/02). The question followed a scientific assessment that was initially made by the competent authority of the Netherlands and evaluated subsequently by all other Member States. An assessment of the GM carnation Moonlite 123.2.38 was requested by the Commission because of questions raised by several Member States following the evaluations at the national level. When this is the case, the EU legislation requires that EFSA carries out a further assessment and provides an opinion. The GMO Panel was, therefore, asked to consider whether there is any scientific reason to believe that the placing on the market of the GM carnation Moonlite 123.2.38 for import is likely to cause any adverse effects on human health and the environment.

In delivering its opinion, the GMO Panel considered the notification, additional information provided by the applicant and the specific questions and concerns raised by the Member States. The carnation Moonlite 123.2.38 was assessed with reference to its intended use and the appropriate principles described in the 'Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed'. The scientific assessment included examination of the DNA inserted into the GM carnation using *Agrobacterium*-mediated transformation and the nature and safety of the new products intended to be produced by the GM variety. Furthermore, the potential environmental impact of carnation Moonlite 123.2.38, including a monitoring plan, was assessed in the context of the restricted intended use of carnation Moonlite 123.2.38.

The carnation Moonlite 123.2.38 has a modified flower colour, a shade of violet. The colour has been achieved by introducing into white carnation two genes of the anthocyanin biosynthesis

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pathway from petunia. These genes, encoding dihydroflavonol 4-reductase (*dfr*) and flavonoid 3'5' hydroxylase (*f3'5'h*), in combination with other genes of the anthocyanin biosynthesis pathway already present in the carnation, give rise to the anthocyanins delphinidin and cyanidin, the same compounds that give colour to blueberry, blackcurrant and red grape. Both anthocyanins are present in the petals of the GM carnations. Carnation Moonlite is also tolerant to sulfonylurea herbicides conferred by a mutated *SuRB (als)* gene used as marker trait in the selection of genetically modified plants but not for plant protection purposes. Another GM carnation variety, Florigene Moondust™, which is genetically modified with the same transformation vector, received the consent for placing on the market, including cultivation, within the EU in 1997.

The molecular analysis of the DNA inserts confirms that the three genes expressing the intended traits (violet flower colour encoded by *dfr* and *f3'5'h* genes and herbicide tolerance encoded by the mutated *SuRB (als)* gene) are present into carnation Moonlite 123.2.38. The carnation Moonlite 123.2.38 does not contain a functional antibiotic resistance marker gene. Bioinformatic analysis shows that two new open reading frames (ORFs) were created but that neither shows homologies to any toxic or allergenic proteins. Results of bioinformatic studies of the three newly expressed proteins in carnation Moonlite 123.2.38 did not indicate relevant homology with known toxins or allergens.

Given the intended use of carnation Moonlite 123.2.38 (excluding human or animal consumption and cultivation), the GMO Panel considers that the comparative analysis limited to the newly synthesised anthocyanins is sufficient for the risk assessment. The GMO Panel concludes that there is no indication of increased toxicity of the carnation Moonlite 123.2.38 compared to the recipient variety.

The carnation Moonlite 123.2.38 was assessed for imported cut flowers for ornamental use only. Scientific information on potential environmental effects associated with the cultivation of carnation Moonlite 123.2.38 was therefore not required. Carnation Moonlite 123.2.38 cut stems and flowers have very restricted viability, very low pollen emission and little or no viable seed. However, in the very unlikely event of accidental release into the environment, the GMO Panel considers that the carnation Moonlite 123.2.38 would not show enhanced fitness characteristics, except in the presence of sulfonylurea herbicides. The consequences of the potential transfer of the three genes would be negligible in terms of adverse effects on the environment. The GMO Panel concludes that there is no indication that GM carnation Moonlite 123.2.38 will have adverse effects on the environment in the context of the intended use.

The GMO Panel agrees with the applicant that the environmental risk assessment did not identify risks that require a case-specific monitoring plan. The GMO Panel also agrees with the general methods and approaches of the general surveillance plan.

In conclusion, the GMO Panel considers that the information available for carnation Moonlite 123.2.38 addresses the outstanding questions raised by the Member States and considers that, in the context of its intended use, carnation Moonlite 123.2.38 is unlikely to have adverse effects on human and animal health or the environment.

Key words: acetolactate synthase (SuRB/ALS), anthocyanin, carnation, C/NL/04/02, delphinidin, *Dianthus caryophyllus*, dihydroflavonol 4-reductase (DFR), Directive 2001/18/EC, environment, feed safety, flavonoid 3'5' hydroxylase (F3'5'H), Florigene, flower colour, GMO, health, herbicide tolerance, import, sulfonylurea, Unique Identifier FLO-40644-4.