



Final Health and Environmental Risk Assessment of Genetically Modified Carnation Moonlite 123.2.38

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Authors' contributions

This work was carried out in collaboration among all authors. The opinion has been assessed and approved by the Panel on Genetically Modified Organisms of VKM. All authors read and approved the final manuscript.

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ABSTRACT

Genetically modified carnation (*Dianthus caryophyllus* L.) line 123.2.38 with product name Moonlite™, expresses three introduced traits. The *df*r and *f3'5'h* (*Hf1*) genes from *Petunia x hybrida* coding for dihydroflavonol 4-reductase (DFR) and flavonoid 3',5'-hydroxylase (F3'5'H), respectively, lead to the biosynthesis of anthocyanin pigments, which confer the desired violet colour to the flowers. A mutated *als* gene from *Nicotiana tabacum* has also been inserted, coding for an acetolactate synthase (ALS) variant protein and thereby conferring tolerance to the active, ALS-inhibiting, herbicidal substances chlorimuron, thifensulfuron and sulfonylureas, used to facilitate the selection of GM shoots during genetic transformation. Bioinformatics analyses of the

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inserted DNA and flanking sequences in carnation 123.2.38 have not indicated a potential production of putative harmful proteins or polypeptides caused by the genetic modification. Genomic stability of the functional insert and consistent expression of the *dfr* and *f3'5'h* (*Hf1*) genes, have been shown over several generations of carnation 123.2.38. Data reported from several field trials show that carnation 123.2.38 petals contain higher levels of the anthocyanins delphinidin and cyanidin compared to the non-GM (conventional) carnation counterpart 123. Other morphological traits were reported and along with differing petal colour, carnation Moonlite 123.2.38 differed significantly in one trait compared to conventional carnation counterpart 123. An acute toxicity study in mice and two in vitro studies, both employing aqueous extracts from leaves or petals, showed no adverse effects. DFR, F3'5'H and ALS proteins do not show sequence resemblance to known toxins or IgE-dependent allergens, nor have they been reported to cause IgE-mediated allergic reactions. The anthocyanins delphinidin and cyanidin are present in numerous foods and are also approved food additives. Carnations are cultivated in Norway, but since 1) the intended uses includes import of cut flowers for ornamental use only, 2) the spread and viability of pollen from the cut flowers is low, 3) seed formation in cut flowers is unlikely to occur, and 4) spread of inserted genes to target or non-target organisms is either unlikely to occur or is not of biological relevance, the VKM GMO Panel does not consider that carnation 123.2.38 represents an environmental risk in Norway.

Considering that carnation Moonlite 123.2.38 is not intended for cultivation or use as food or feed, the VKM GMO Panel considers that comparative analysis of the newly synthesised anthocyanin pigments delphinidin, cyanidin and petunidin in its petals is sufficient for the risk assessment. The reported morphological differences between Moonlite 123.2.38 and its conventional carnation counterpart 123 do not raise safety concerns. It is unlikely that the DFR, F3'5'H or ALS proteins, or the delphinidin or cyanidin pigments, will introduce a toxic or allergenic potential in Moonlite 123.2.38.

Based on current knowledge and information supplied by the applicant, and considering the intended uses, which exclude cultivation and use as food and feed, the VKM GMO Panel concludes that Moonlite 123.2.38 is as safe as its conventional counterpart 123.

Based on the current knowledge and considering its import, distribution and intended use as cut ornamental flowers, the VKM GMO Panel concludes that it is unlikely that carnation Moonlite 123.2.38 will have any adverse effects on the biotic or abiotic environment in Norway.

Keywords: *GMO; carnation (Dianthus caryophyllus L.); Moonlite; 123.2.38; anthocyanin; petal colour; dfr; f3'5'h; als; SuRB; health safety; environmental risk evaluation; Regulation (EC) No 1829/2003; VKM; risk assessment; Norwegian Scientific Committee for Food Safety; Norwegian Food Safety Authority/Norwegian Environment Agency.*

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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