



Final Health and Environmental Risk Assessment of Genetically Modified Carnation Moonvelvet IFD26407-2

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Authors' contributions

This work was carried out in collaboration between 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 IFD-26407-2 with product name Moonvelvet™, expresses three introduced traits. The cytb5 gene and the f3'5'h (Hf1) gene from *Petunia x hybrida*, coding for cytochrome b5 (CYTB5) and flavonoid 3',5'-hydroxylase (F3'5'H), respectively, lead to the biosynthesis of anthocyanin pigments, which confer the desired violet/blue colour to the flowers. A mutated als gene (SuRB) from *Nicotiana tabacum* has also been inserted, coding for an acetolactate synthase (ALS) variant protein and thereby conferring tolerance to the

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active, ALS-inhibiting, herbicidal substances chlorimuron, thifensulfuron and sulfonylureas, used to facilitate the selection of GM shoots during genetic transformation. Bioinformatic analyses of the inserted DNA and flanking sequences in carnation Moonvelvet IFD-26407-2 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 *cytb5* and *f3'5'h* (*Hf1*) genes, have been shown over several generations of carnation Moonvelvet IFD-26407-2. Data reported from several field trials show that carnation Moonvelvet IFD-26407-2 petals contain higher levels of the anthocyanins delphinidin and cyanidin, and lower levels of pelargonidin compared to the non-GM (conventional) carnation counterpart Cerise Westpearl (CW). Other morphological traits were reported and along with differing petal colour, carnation Moonvelvet IFD-26407-2 differed significantly in 10 traits compared to conventional carnation counterpart CW. Aqueous extracts from leaves or petals showed no mutagenic activity *in vitro*. ALS, CYTB5, and F3'5'H proteins do not show sequence resemblance to known toxins or IgE-dependent allergens, nor have they been reported to be toxic to animals or 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 Moonvelvet IFD-26407-2 represents an environmental risk in Norway.

Considering that carnation Moonvelvet IFD-26407-2 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 pelargonidin in its petals is sufficient for the risk assessment. The reported morphological differences between Moonvelvet IFD-26407-2 and its conventional carnation counterpart Cerise Westpearl (CW) do not raise safety concerns. It is unlikely that either the CYTB5, F3'5'H or ALS proteins, or the delphinidin or cyanidin pigments, will introduce a toxic or allergenic potential in Moonvelvet IFD-26407-2.

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 Moonvelvet IFD-26407-2 is as safe as its conventional counterpart CW.

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 Moonvelvet IFD-26407-2 will have any adverse effects on the biotic or abiotic environment in Norway.

Keywords: *GMO; carnation (Dianthus caryophyllus L.); Moonvelvet; 26407; anthocyanin; petal colour; cytb5; 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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