



Final Health and Environmental Risk Assessment of Genetically Modified Carnation Moonberry IFD25958-3

**Åshild Andreassen^{1*}, Nana Yaa Ohene Asare², Anne Marie Bakke²,
Merethe Aasmo Finne², Anne Marthe Jevnaker², Olavi Junntila²,
Ville Erling Sipinen², Rose Vikse¹, Per Brandtzæg², Knut Helkås Dalen²,
Knut Tomas Dalen³, Richard Meadow⁴, Kåre M. Nielsen^{5,6}, Monica Sanden⁷
and Hilde-Gunn Opsahl-Sorteberg⁴**

¹Norwegian Scientific Committee for Food Safety (VKM), Norwegian Institute of Public Health (FHI), Norway.

²Norwegian Scientific Committee for Food Safety (VKM), Norway.

³Norwegian Scientific Committee for Food Safety (VKM), University of Oslo, Norway.

⁴Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Life Sciences, Norway.

⁵Norwegian Scientific Committee for Food Safety (VKM), Norway.

⁶Norwegian Scientific Committee for Food Safety (VKM), Oslo and Akershus University College of Applied Sciences, Norway.

⁷Norwegian Scientific Committee for Food Safety (VKM), Institute of Marine Research, Norway.

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.

Article Information

DOI: 10.9734/EJNFS/2021/v13i130358

Grey Literature

Received 22 December 2020

Accepted 28 February 2021

Published 06 March 2021

ABSTRACT

Genetically modified carnation (*Dianthus caryophyllus* L.) line IFD-25958-3 with product name Moonberry™, expresses three introduced traits. The *df*r gene from *Petunia x hybrida* and the *f3'5'h* gene from *Viola hortensis*, 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/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

*Corresponding author: Email: tron.gifstad@vkm.no;

conferring tolerance to the active, ALS-inhibiting, herbicidal substances chlorimuron, thifensulfuron and sulfonylureas, used to facilitate the selection of GM shoots during genetic transformation. Of note, carnation Moonberry IFD25958-3 contained a hairpin RNA interference (RNAi) gene, which down-regulates endogenous *dfr*. Bioinformatics analyses of the inserted DNA and flanking sequences in carnation Moonberry IFD-25958-3 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* genes, have been shown over several generations of carnation Moonberry IFD-25958-3. Data reported from several field trials show that carnation Moonberry IFD-25958-3 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 Moonberry IFD-25958-3 differed significantly in nine traits compared to conventional carnation counterpart CW. Aqueous extracts from leaves or petals showed no mutagenic activity *in vitro*. ALS, DFR, 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 Moonberry IFD-25958-3 represents an environmental risk in Norway.

Considering that carnation Moonberry IFD-25958-3 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 Moonberry IFD-25958-3 and its conventional carnation counterpart Cerise Westpearl (CW) 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 Moonberry IFD-25958-3.

Based on current knowledge and information supplied by the applicant, and considering the intended use, which excludes cultivation and use as food and feed, the VKM GMO Panel concludes that Moonberry IFD-25958-3 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 Moonberry IFD-25958-3 will have any adverse effects on the biotic or abiotic environment in Norway.

Keywords: *GMO; carnation (Dianthus caryophyllus L.); Moonberry; 25958; 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.*

Available: <https://vkm.no/download/18.2994e95b15cc54507161468a/1498136952603/f998b47edd.pdf>

ISBN: 978-82-8259-172-0

NOTE:

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.

Competence of VKM experts: Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives

for their employers or third party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

Suggested citation: VKM (2015) Final health and environmental risk assessment of genetically modified carnation Moonberry IFD-25958-3. Opinion of the Panel on Genetically Modified Organisms of the Norwegian Scientific Committee for Food Safety, ISBN: 978-82-8259-172-0, Oslo, Norway.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

© 2021 Andreassen et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.