Advisory Committee on Releases to the Environment

Advice on a notification for the marketing of a GM carnation SHD-27531-4

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to UK ministers and ministers in the Devolved Administrations

Details of notification

Notifier:	Suntory Holdings Ltd.
Notification reference:	C/NL/13/01
Product:	A GM carnation line genetically modified for petal colour and herbicide tolerance. This line (SHD-27531-4) is modified to contain *F3'5'H* and *DFR* proteins, which confer the ability to produce a violet pigment and a mutated ALS protein, which confers tolerance to sulfonylurea herbicides.
Scope:	To import, distribute and retail cut carnation flowers containing event SHD-27531-4 into the EU. The scope of this notification does not include cultivation or use as food or feed.

60 day assessment period advice

ACRE agrees with the lead competent authority's (Netherlands) assessment of notification C/NL/13/011 and concludes that the import and distribution of cut flowers from GM carnation line SHD-27531-4 does not pose an increased risk to human health or the environment as compared with non-GM carnation varieties. ACRE considers that the notification 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 assessment.

Comment

This notification is to import, distribute and retail one line of a GM carnation (SHD-27531-4) onto the EU cut flower market. The scope of the notification does not include cultivation or use as food or as feed.

[1] The Dutch assessment report on notification C/NL/13/01 is available at: http://gmoinfo.jrc.ec.europa.eu/gmc_browse.aspx

ACRE has considered the molecular characterisation of SHD-27531-4 carnation and the risks associated with importing and retailing cut flowers, including the potential impacts on human health. We have considered the suitability of the plan for post-market monitoring in the light of the risks posed by this GMO.

ACRE is familiar with the transgenes/ GM traits associated with SHD-27531-4 carnation as we have considered them in a previous notification to market a GM carnation in accordance with Directive 2001/18/EC (please refer to notification C/NL/06/01). Our conclusions on the risks posed to human health and the environment are consistent. These were reached after a case-specific assessment of each GMO.

Molecular characterisation

The non-GM parental line of this GM carnation line has white flowers. It was modified with two enzymes in the anthocyanin biosynthetic pathway *i.e.* dihydroflavonol-4-reductase (DFR) and flavonoid 3'5'- hydroxylase (F3'5'H). The *DFR* gene is a genomic clone derived from Petunia x hybrida and it is under the control of its own regulatory elements. The *F3'5'H* gene is a copy DNA derived from Viola species and is under the control of the antirrhinum CHS promoter. Simultaneous expression of the proteins encoded by these genes in the carnation results in modified flavonoid synthesis and formation of the violet pigment delphinidin.

In addition, SHD-27531-4 carnation has been modified to contain a mutated version of the enzyme acetolactate synthase (ALS). The gene encoding this enzyme is derived from *Nicotiana tabacum* (cultivated tobacco) and is under the control of the 35S cauliflower mosaic virus promoter. There are two unlinked *ALS* genes in tobacco, *SuRA* and *SuRB*. This GM carnation contains a version of the *SuRB* gene (i.e. *S4-Hra*) that has been mutated to confer resistance to sulfonylurea herbicides. This trait was used to select for transformed plants during the genetic transformation process.

ACRE considers that the notifier has submitted good quality, detailed molecular data. The notifier has used Southern hybridisations and DNA sequence analysis to characterise the transformation event. The results support the notifier's conclusion that SHD-27531-4 carnation has a single insertion locus, which contains a complete copy of the transferred DNA (T-DNA). This DNA was introduced into the carnation using an Agrobacterium vector. The notifier has demonstrated (using a number of different probes spanning the backbone of the Agrobacterium vector) that no backbone DNA (including the tetA antibiotic resistance marker gene) from the Agrobacterium is present in the GMO.

The notifier has analysed 150 base pairs of DNA flanking the insertion locus to search for newly created, chimeric open reading frames (ORFs). The notifier also searched databases of known allergens and toxins with the deduced amino acid sequences of the inserted genes (i.e. *DFR, F3'5'H and ALS*). ACRE is content that, in addition to the information provided on toxicity and allergenicity elsewhere in the notification, these bioinformatics analyses demonstrate that this GMO is unlikely to have a greater allergenic or toxic potential as compared to its non-GM counterparts.

Risks to human health

The notification does not include food use within its scope. However, the notifier has considered the consequences of individuals using petals or leaves from SHD-27531-4 carnation to garnish salads.

DFR, F3'5'H and ALS proteins are common in plants. DFR and F3'5'H are present in foods that contain delphinidin and these include a number of fruits and vegetables *e.g.* blackcurrants, aubergines and blueberries. ALS protein is common to plants, bacteria and fungi and there are a number of commercial crop varieties that contain ALS mutations conferring herbicide resistance *e.g.* imidazolinone resistant maize, wheat, oilseed rape, lentil and rice. The notifier has not identified a commercial crop variety that contains the *SuRB* gene mutation (i.e. *S4-Hra*) that is present in SHD-27531-4 carnation. However, the notifier has searched databases of known allergens and toxins for short stretches of homology with the deduced amino acid sequence of the *S4-Hra* gene inserted into SHD-27531-4 carnation. None were detected.

This lack of significant homology between the deduced amino acid sequences of the inserted genes (i.e. *DFR, F3'5'H and ALS*) and known allergens along with the results of bioinformatic analysis of DNA flanking these inserts, supports our conclusion that any pollen produced by this GMO is unlikely to have a greater allergenic potential as compared to its not GM counterparts. We note that SHD-27531-4 carnation is double flowered and has a reduced number of reproductive structures (including stamens and anthers) compared to its parental line, which will affect pollen production and dispersal.

SHD-27531-4 carnation has been grown commercially outside of the EU since 2001 and flowers have been shipped to the US, Canada and Japan. There have been no reports of adverse effects by wholesalers, retailers or consumers exposed to this product.

Environmental exposure and environmental impact

ACRE agrees with the notifier that it is very unlikely that cut carnation flowers will:

1. produce vegetative structures (without human assistance) and survive in the environment after disposal;

2. set viable seed or

3. release pollen that will generate hybrids with wild carnations, other *Dianthus* species or other members of the *Carophyllaceae* family.

Consequently, environmental exposure and therefore, the risk that SHD-27531-4 carnations pose to the environment is negligible. However, it is possible that individuals will propagate leaf and/or stem cuttings in glasshouses or in gardens. This is not legal as carnation SHD-27531-4 is not approved for cultivation in the EU. If this does happen, ACRE considers that there is sufficient information in this notification to conclude that the impact on the environment will be minimal. There is no evidence that gene flow from

garden-cultivated carnations into related species would occur or that these plants will become invasive or weedy.

Post-market monitoring

ACRE considers that the post-market monitoring plan for SHD-27531-4 carnation is compatible with the environmental risk assessment provided in the notification. We are content that no risks have been identified in this assessment and as such, case-specific monitoring is not required. Consequently, it is appropriate that the monitoring plan for this GMO is based on general surveillance for unanticipated adverse effects. Florigene will submit annual monitoring reports if the GMO is approved for import, distribution and retail in the EU.

17 October 2013