Response to technical comments and questions C/NL/06/01_001 (Event FLO-40689-6)

Contact; Dr Stephen Chandler
Phone; +61 409 387 386
schandler@florigene.com.au

October 23 2018

1. Introduction

This document provides information in response to a request for further information from a CA following an application for renewal of transgenic carnation event FLO-40689-6 (C/NL/06/01_001; Florigene©Moonaqua™). The requests for additional information relate to labelling and socio-economic benefits (sustainability, benefit to society, and ethical considerations).

2. Labeling

2.1 Information on labelling

The CA asked for information on how labelling would be carried out. The current labeling used for event FLO-40689-6 will be continued if marketing approval for the event is renewed. Information is provided on a label printed on each plastic sleeve in which flowers are exported to the EU. Figure 1 shows the sleeves in which flowers for the EU are packed and the wording which is printed on each sleeve.

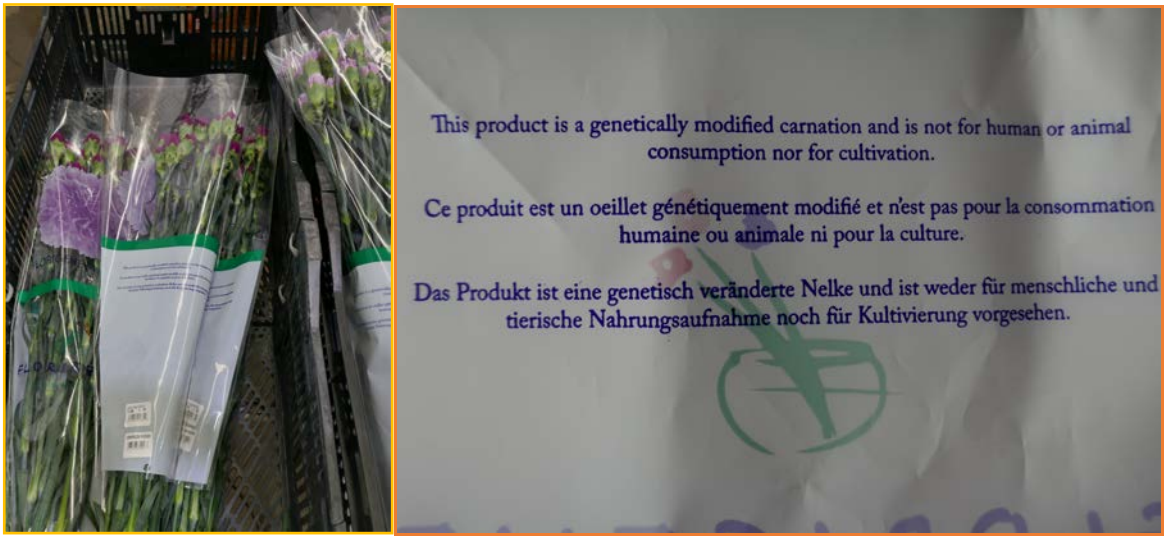

Figure 1. Label used for export of transgenic carnation flowers to the EU. Flowers are packed in sleeves ready for transportation from Colombia (shown in left-hand side photograph). The right-hand side photograph shows the wording used on each sleeve. Flowers were photographed in Colombia in October 2018.

2.2 Absence of labeling at retail level

The CA made an observation that flowers were found in stores (we assume retail stores) without labels (the term "proper labeling" was used by the CA). We have stated in response to CAs in recent marketing applications for transgenic carnation and in the renewal application for event C/NL/04/02 that labeling cannot be guaranteed to the retail and final consumer level. We assume the flowers found in the stores were removed from the plastic sleeves for sale. We have in the past provided stickers, tags and gift cards for florists, but these are not always used and have been used for other products.

It remains the case that it is impractical to tag or label the stems of individual flowers, which is the only realistic way to attempt to ensure labeling throughout the whole chain. Distributors are very likely to remove labels. Florists are even more likely to do so, whether GM flowers or not, because they are selling their creativity or retail brand. There are no precedents in the flower industry for the individual labeling of carnation flowers.

The complexity of flower distribution makes it very difficult for a notifier to ensure labeling of the event once cut-flowers has been imported into the EU;

1. Flowers are imported in bulk and then distributed through two, three or more parties to the final customer, usually across more than EU country. Customers may also exchange flowers between themselves. There are therefore numerous avenues by which the imported flowers could reach the final customer as the distribution chain in Europe comprises importers, national based wholesalers, local wholesalers and florists, any of whom could unpack flowers and re-pack, often in combination with other flowers. The same could occur at the numerous points of sales, which not only includes florists but Flying Dutchman, supermarkets, market stalls, grocery and mixed purpose shops, garages etc.
2. As indicated in point (1) there is no means to know where a flower from the importer in the Netherlands will ultimately be sold, and which retail outlet will be the final point of sale.
3. Flowers may be purchased for display, such as in restaurants, hotels, public events etc..

It is uneconomical to label individual flowers. Individual labeling is not used in the flower industry because any potential marketing benefits are very significantly off-set by the high cost of hand- labeling.

2.3 Adherence to EU regulations

The CA requested information on how the applicant ensures that EU regulations on labelling are followed, especially concerning proper accompanying documentation. The relevant legislation is regulation 1830/2203 on traceability and labelling of GMOs[1]. The following actions have been taken in relation to these regulations;

- In the EU, a single importer based in the Netherlands imports flowers of event FLO-40689-6. The importer receives an electronic invoice with every shipment with a statement that the imported flowers are genetically modified, in compliance with article 4.1 of the legislation.
- A PCR based identification method for event 40689-6 has been validated and published[2].
- The unique identifier for the event (article 8) has been registered on the Biosafety clearing House by the EU and the Netherlands[3].
- Procedures are in place to record the quantities of import and the information is held electronically for at least five years.
- Flowers are pre-packaged in sleeves (figure 1) and wording is provided on the sleeve in accordance guidance in article 6(a).
- Each shipment is accompanied by a phytosanitary certificate and a commercial invoice which lists the variety name. We assume these commercial documents are what is meant by “proper documentation”.

3. Socio-economic benefits

A CA invited the applicant to update the impact of event FLO-40689-6 on sustainability, benefit to society, and ethical considerations.
Our response is generic to the production and sale of transgenic carnation flowers in the EU. Event FLO-40689-6 is grown and marketed in the same way as other transgenic carnation varieties and is typically distributed with those varieties.

3.1 Sustainability

The production of transgenic carnation in South America is according to general practice long established for carnation in Colombia and Ecuador. Generally speaking, the production of FLO-40689-6 is therefore as sustainable as other carnation varieties, though both farms have made efforts to increase sustainability;

- Composting and recycling of waste material into new plantings.
- Capture of rain water for irrigation purposes.
- Provision of recycling facilities for collection of non-plant waste.
- Use of trees and windbreaks to reduce pest infestation.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2003:268:TOC
[2] http://gmo-crl.jrc.ec.europa.eu/docs-valid-2001-18/CRL_Report_Flor_Moonaqua.pdf
[3] https://bch.cbd.int/database/lmo/decisions.shtml?documentid=48219

The production locations in South America have been established in either a preexisting flower production facility or in an area previously unoccupied and non-agricultural. Neither facility require expansion to maintain production as used flower beds are recycled and re-plantings.

Like all transgenic carnation varieties commercialized so far, event FLO-40689-6 carries a selectable marker gene conferring resistance to sulphonylurea herbicides. The presence of this gene has never been exploited for weed control.
There has been a recent trend in the flower industry to use dyes and paints to create new flower colours, including colours comparable to event FLO-40689-6. Distribution of FLO-40689-6 promotes sustainability as these chemicals are not used for FLO-40689-6.

3.2 Benefit to society

EU
FLO-40689-6 has flowers which are a unique flower colour. The benefits this brings to the EU consumer are that it provides a greater choice in flower colour. This is perceived as a benefit within the industry. Other benefits are;

- The pleasure the product has given to consumers.
- The contribution to the scientific knowledge base in areas such as biosafety, plant transformation, *Dianthus* ecology and biology and the long-term evaluation of transgenic plants.

Colombia and Ecuador
FLO-40689-6 is a variety contributing to the production of transgenic carnation in South America. This production has proven to be beneficial to society in the areas it is grown through creation of long-term, stable employment opportunities;

- Carnation production is labour intensive. Work created by the introduction of the transgenic carnation varieties has created approximately three hundred new, full-time jobs.
- Over the course of time and with training, staff have been able to move into higher paid supervisory roles.
- Production of the transgenic carnation is by contract and is more profitable for producers as they have no risk of waste due to unfavorable market demand. They also do not have marketing and sales costs for the contract varieties and do not pay royalties for plants. This has benefitted the farms and their employees through higher wages (to retain labour) than the industry standard and provision of better medical and dental facilities and improved retirement and benefit schemes.

In addition, investments have been made to expand the tissue culture facility and trial greenhouse area in Colombia.

4. Ethical considerations

No ethical considerations have so far emerged that can be associated with the production of flowers of FLO-40689-6. Some individuals and groups may be concerned about the ethics of producing a discretionary product such as cut-flowers but such concerns are equally applicable to non-GM flowers (of all types) and are not applicable specifically to transgenic cut flower crops.
At both locations the production of the transgenic carnation has had no effect on the production of non-GM ornamental plants in the same areas and has not resulted in the loss of land used for food production.