

Aan de minister van
Infrastructuur en Waterstaat
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DATUM 05 oktober 2021
KENMERK CGM/211005-01
ONDERWERP Advies wijziging van het monitoringsplan voor gg-anjers

Geachte mevrouw Visser,

Naar aanleiding van een adviesvraag over de aanpassing van het monitoringsplan voor genetisch gemodificeerde anjers deelt de COGEM u het volgende mee.

Samenvatting:

In Europa zijn er zes verschillende genetisch gemodificeerde (gg-) anjer 'events' toegelaten. De snijbloemen van deze gg-anjers mogen hier worden geïmporteerd en verkocht. De vergunninghouder is verplicht om te monitoren of zich daarbij onverwacht schadelijke effecten voordoen. De vergunninghouder doet dit door jaarlijks de wetenschappelijke literatuur en Europese floristische databases te bekijken, door anjerveredelaars en botanici te vragen om bijzondere planten te melden en door instituten en wetenschappers onder andere via e-mail te vragen om eventuele bijzonderheden in anjercollecties en populaties door te geven.

De vergunninghouder wil stoppen met het mailen van instituten en wetenschappers, omdat er in de afgelopen twaalf jaar geen wilde populaties van anjervariëteiten zijn gemeld en het efficiënter is om met behulp van literatuur- en databaseonderzoek na te gaan of er aanwijzingen zijn dat gg-anjervariëteiten zich in Europa vestigen of hybridiseren met wilde anjersoorten. De vergunninghouder heeft daarom een verzoek ingediend om de monitoringsstrategie te mogen wijzigen.

De COGEM is gevraagd om over deze wijziging te adviseren. De COGEM is van mening dat de andere methoden die door de vergunninghouder worden gebruikt voldoende zijn om schadelijke effecten van de gg-anjers op tijd te kunnen detecteren wanneer deze zich onverwacht zouden voordoen. Zij adviseert daarom positief over de voorgestelde wijziging van het monitoringsplan.



De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

Prof. dr. ing. Sybe Schaap
Voorzitter COGEM

- c.c.
- Drs. Y. de Keulenaar, Hoofd Bureau ggo
 - Ministerie van IenW, Directie Omgevingsveiligheid en Milieurisico's
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Proposal to adapt the monitoring strategy for genetically modified carnations

COGEM advice CGM/211005-01

1. Introduction

In the European Union, import, distribution and retail of cut flowers of six genetically modified (GM) carnation events for ornamental use is authorised.¹ The first authorisation for a GM carnation event was granted in 2007.

One of the conditions of these authorisations is that the consent holder monitors whether any adverse effects on human health and the environment arise from handling or use of the GM carnations. A so-called 'general surveillance' plan which describes the monitoring strategy, is part of each application. The consent holder recently submitted a request to adapt the monitoring strategy which was described in the 'general surveillance' plans for these GM carnations.* COGEM has been asked to advice on the proposed adaptation.

1.1 Characteristics of the GM carnations

Cultivated carnations are semi-winter hardy, have no weedy characteristics and even after decades of cultivation have never shown to be able to establish themselves in the wild.² They belong to the species *Dianthus caryophyllus* of the widely cultivated genus *Dianthus*. The non-horticultural form of *D. caryophyllus* is native to the Mediterranean coastal region and other *Dianthus* species occur in Europe as well.^{2,3,4,5} In the Netherlands, several native *Dianthus* species occur.⁶ There has never been any evidence of spontaneous hybridisation between carnation and wild *Dianthus* species, despite the fact that carnation has been cultivated worldwide for centuries.

In all six GM carnation events sequences are introduced which enable carnation to produce the blue pigment delphinidin. Carnations are normally unable to produce this pigment which gives flowers like lobelias and hyacinths their blue colour, and which is also required for the purple colour of verbena and freesias. Because the GM carnations are able to produce delphinidin they have purple flowers, a colour which is normally not observed in carnation flowers.

The GM carnations also produce a mutant acetolactate synthase (ALS) protein, which confers tolerance to ALS inhibiting herbicides (i.e. sulfonylurea). Due to this trait, transformants can easily be selected.

The modified flower colour and herbicide tolerance do not introduce a potential for weediness in the GM carnations.

* Notification numbers of the six authorised GM events: C/NL/04/02_001, C/NL/06/01_001, C/NL/09/01, C/NL/09/02, C/NL/13/01, C/NL/13/02.

1.2 Previous COGEM advices

COGEM has issued advices on all six GM carnation events.^{7,8,9,10,11,12,13,14} For two of these GM carnations COGEM did not only assess the first application for an authorisation, but the application for renewal of the authorisation as well.^{7,8} For all six GM carnation events COGEM concluded that import, distribution and retail of the cut flowers of these events pose a negligible risk to human health and the European environment.

2. Monitoring strategy and proposed adaptation

The monitoring strategy that has been followed since 2008 uses several approaches. Scientific literature and on-line European floral databases (i.e. online floras, herbaria and vegetation mapping databases) are reviewed annually for new reports on *Dianthus*, the genus to which carnation (*Dianthus caryophyllus*) belongs. The consent holder has also engaged the services of carnation breeders and botanists with an interest in *Dianthus*. They are asked to report any unusual hybrids they may find during their normal survey activities.

In addition to the above described activities, the consent holder sends letters and e-mails to institutions (botanical gardens, herbaria, universities, government agencies and research institutions) and individual scientists across Europe to alert them of the import of GM carnations in Europe and to ask them to take this into account when reviewing *Dianthus* collections. The consent holder recently submitted a request to discontinue this so-called ‘mail out’ for all six GM carnation events that are currently authorised in the European Union.

The consent holder is of the opinion that that the ‘mail out’ was comprehensive enough and has been carried out over a long enough period to reach the conclusion that carnation has not escaped from cultivation in Europe. Over the 12 years that the ‘mail out’ was carried out 817 responses were received, from 37 countries across Europe and from all types of institutions contacted. Dozens of responses concerned *D. caryophyllus* observations or records. All of these were of wild-type *D. caryophyllus*. Only six of the responses concerned observations or descriptions of carnation. Five were reports on carnation plants in cultivation or in or near a garden. One response concerned a herbarium specimen of a cut flower from a cultivated carnation. Populations of carnation outside of cultivation were not reported.

The consent holder considers it more effective to carry out database and literature reviews as they are more comprehensive and are known to be effective. If necessary, the consent holder will contact literature authors, vegetation databases and collectors to follow-up and investigate whether an observation or record concerns a carnation population.

Before discontinuing the ‘mail out’ in 2023, the consent holder will email all entities that never responded to letters. This approach has been tested and shown to trigger responses in about half of the non-responders. The consent holder therefore expects that this will add more comprehensiveness to the overall outcome of the institutional mail out. The consent holder will also let the entities that regularly responded know that the ‘mail out’ will be discontinued, but that the general monitoring

will continue. They will be given contact details so that they can report observations of escape carnation populations if these would occur in future years.

3. Conclusion and advice

The consent holder recently submitted a request to discontinue the so-called ‘mail out’ that has been part of the GM carnation monitoring strategy in the last 12 years. During this time no populations of carnations were reported outside of cultivation and GM carnation plants were not reported. All *D. caryophyllus* observations and records were of wild-type *D. caryophyllus*. The applicant provides a clear justification for the discontinuation of the ‘mail out’ and states that the other parts of the monitoring strategy will remain in place. Scientific literature and floral databases will continue to be reviewed and carnation breeders and botanists with an interest in *Dianthus* will still be asked to report any unusual hybrids.

COGEM is of the opinion that the monitoring methods that will remain in place are sufficient to allow a timely observation of any adverse effects on human health and the environment of the GM carnation cut flowers if these would occur. COGEM therefore advises positively on the proposed adaptation of the monitoring strategy.

References

1. European Commission. Deliberate release and placing on the EU market of GMOs. GMO register. Notifications authorised under Directive 2001/18/EC- GMO Part C https://webgate.ec.europa.eu/fip/GMO_Registers/GMO_Part_C.php (visited September 29th, 2021)
2. CABI (2007). Crop Protection Compendium, 2007 Edition. Wallingford, United Kingdom
3. Office of the Gene Technology Regulator (2015). The biology of *Dianthus caryophyllus* L. (Carnation). Australian Government. Department of Health
4. Tela Botanica - *Dianthus caryophyllus* L. <http://www.tela-botanica.org/bdtfx-nn-22083-synthese> (visited September 29th, 2021)
5. Flora Italiana - *Dianthus caryophyllus* L. <http://luirig.altervista.org/flora/taxa/index1.php?scientific-name=dianthus+caryophyllus> (visited September 29th, 2021)
6. Duistermaat L (2020). Heukels' Flora van Nederland. 24ste druk. Noordhoff Naturalis Biodiversity Center
7. COGEM (2018). Renewal of the authorisation for import, distribution and retail of genetically modified carnation FLO-40689-6. COGEM advice CGM/180613-02
8. COGEM (2016). Renewal of the consent for import, distribution and retail of genetically modified carnation FLO-40644-6. COGEM advice CGM/160706-03
9. COGEM (2013). Import, distribution and retail of GM carnation FLO-40685-1. COGEM advice CGM/131217-01
10. COGEM (2013). Import, distribution and retail of cut flowers with modified flower colour (GM carnation SHD-27531-4). COGEM advice CGM/130711-01
11. COGEM (2009). Import, distribution and retail of GM carnation IFD-26407-2. COGEM advice CGM/090504-06

12. COGEM (2009). Import, distribution and retail of GM-carnation IFD-25958-3. COGEM advice CGM/090429-01
13. COGEM (2007). Import of genetically modified carnation 'Moonaqua'. COGEM advice CGM/070206-02
14. COGEM (2005). Import of cut flowers of the genetically modified carnation variety 'Florigene Moonlite' (C/NL/04/02). COGEM advice CGM/050207-01