Australian Government
Department of Health
Office of the Gene Technology Regulator

Risk Assessment and Risk Management Plan

for

Register 002

Inclusion of dealings with cut flowers of GM carnations modified for flower colour, on the GMO Register

Applicant: International Flower Developments Pty Ltd

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Section 1 Legislation

1. The *Gene Technology Act 2000* (the Act) contains a number of requirements related to the GMO Register. There must be a Register (The Register) which must be maintained by the Gene Technology Regulator (the Regulator) (s76). For any dealing included on The Register, the Regulator must specify a description of the dealing with the genetically modified organism (GMO); and any condition to which the dealing is subject (s77).

2. The Regulator may, by a legislative instrument, determine that a dealing with a GMO is to be included on the GMO Register. To do so, the Regulator must be satisfied that the dealing is, or has been, authorised by a GMO licence; or the GMO concerned is a GM product and is a GMO only because of regulations made under the definition (s10) of ***genetically modified organism***. This decision may be made in response to an application by the licence holder or on the initiative of the Regulator. The decision to include dealings on the GMO Register comes into effect on the day specified in the decision (s78). Because the determination is made by legislative instrument, the Regulator must also undertake appropriate consultation with experts in the field and persons likely to be affected by the proposed instrument in accordance with section 17 of the *Legislation Act 2003*.

3. The Regulator must not decide to include dealings with a GMO on the GMO Register unless satisfied that any risks posed by the dealing are minimal, and that it is not necessary for persons undertaking the dealing to hold, or be covered by, a GMO licence in order to protect the health and safety of people or to protect the environment (s79(1)).

4. The Regulator must consider any available data about adverse effects posed by the dealing; other information as to risks associated with the dealing including information provided to the Regulator by a licence holder (s65) or by another person (s66); whether there is a need for the dealing to be subject to conditions; any other information in relation to whether the dealing should be authorised by a GMO licence (s79(2)). The Regulator may have regard to other matters they consider relevant (s79(3)).

5. Although the Regulator is not required to seek comment on the RARMP under the Act, consultation was undertaken as means of gaining any available information for consideration in relation to s79(2) and s79(3), and to fulfil the requirements of the *Legislation Act 2003*. Consultation included the Gene Technology Technical Advisory Committee (GTTAC), State and Territory Governments, Australian Government authorities or agencies, the Minister for the Environment, Australian local councils, contacts in the flower industry, and the public. The advice from the experts, agencies and authorities and how it was taken into account is summarised in Appendix A. One public submission was received and its consideration is summarised in Appendix B.

6. Currently there is only one entry in the GMO Register (Register 001/2004), which was included on the Register in 2007. Register 001/2004 authorises dealings for commercial scale release of four lines of colour modified GM carnations (Moonlite™, Moonshade™, Moonshadow™ and Moonvista™). The dealings permitted include: to make, develop, produce or manufacture, conduct experiments with, breed or propagate the GMO; use the GMO in the course of manufacture of a thing that is not the GMO; grow, raise or culture, import the GMO; and possess, supply, use, transport or dispose of the GMO for the purpose of, or in the course of, a dealing mentioned.

Section 2 Background

2.1 The application

7. This application from International Flower Developments Pty Ltd (IFD) is to include dealings with three GM carnations on The Register. The GMOs proposed for inclusion are carnations modified for altered flower colour, sold commercially as Moonaqua™, Moonberry™ and Moonvelvet™. Unique identifiers

assigned by the Organisation for Economic Co-operation and Development (OECD) for the carnations are FLO-40689-6 (Moonaqua™), IFD-25958-3 (Moonberry™) and IFD-26407-2 (Moonvelvet™).

8. Dealings with these GMOs are currently authorised under the licence for DIR 134 "Commercial import and distribution of GM carnation cut-flowers with altered flower colour". The dealings permitted under the licence are import, transport and disposal, and possession or supply of the GMOs in the course of any of those dealings. The licence does not permit growing the GMOs in Australia. The Risk Assessment and Risk Management Plan (RARMP) for DIR 134 was published in 2015.

9. Import of cut flowers into Australia is subject to biosecurity conditions administered by the Department of Agriculture. The GM carnation stems imported under DIR 134 from Colombia and Ecuador must be immersed in a solution of 1.8 g/L (0.5%) glyphosate for 20 minutes to a depth of at least 35 cm from the cut end or to within 5 cm of the flower head in the country of production. Conditions can be found in the Department of Agriculture Cut flower devitalisation treatment guide. This treatment is designed to ensure that all imported cut flowers are devitalised prior to import and would therefore apply to any GM carnations imported under REG-002 (if approved).

10. The application to include dealings with three GM carnations on the GMO Register is for the same dealings – import, transport and disposal, and possession or supply of the GMOs in the course of any of those dealings – as those currently authorised by the licence for DIR 134.

11. This RARMP provides background information on the GMOs and outlines the conclusions of the RARMP for DIR 134. It also surveys relevant information about the GMOs that has emerged since 2015, including new information provided by IFD and a wide range of other sources, and assesses whether this information indicates any new risks or increased levels of risk from the GMOs. The purpose of this RARMP is to provide information to enable the Regulator to decide whether the level of risk is such that it is not necessary for persons undertaking the dealing to hold, or be covered by a GMO licence, in order to protect the health and safety of people and the environment. If the Regulator decides that this is the case, then inclusion of dealings with the GM carnations on the GMO Register is appropriate.

2.2 The genetic modifications

12. The GMOs contain modifications for blue or purple flower colour and tolerance to sulfonylurea, imidazolinone and triazolopyrimidine herbicides. The herbicide tolerance phenotype is used for selection of plants in the laboratory. Figure 1 shows each of the GM carnations with its parental line.

Figure 1: GM carnations with parental lines, showing the effect of the modification on flower colour. From top to bottom: Moonaqua™, Moonberry™, Moonvelvet™. (Supplied by the licence holder).

13. Figure 2 shows a schematic for each of the constructs used to transform the GM carnation lines. The vectors used for transformation are indicated and the genetic elements (genes, promoters, terminators and other genetic elements) in each construct are shown, as are the sources for the inserted genetic elements. The vector used for transformation for Moonaqua™ was also used for Moonshadow™ and Moonvista™ GM carnations. Dealings with Moonshadow™, Moonvista™, Moonlite™ and Moonshade™ carnations were included on the Register (Reg-001/2004).

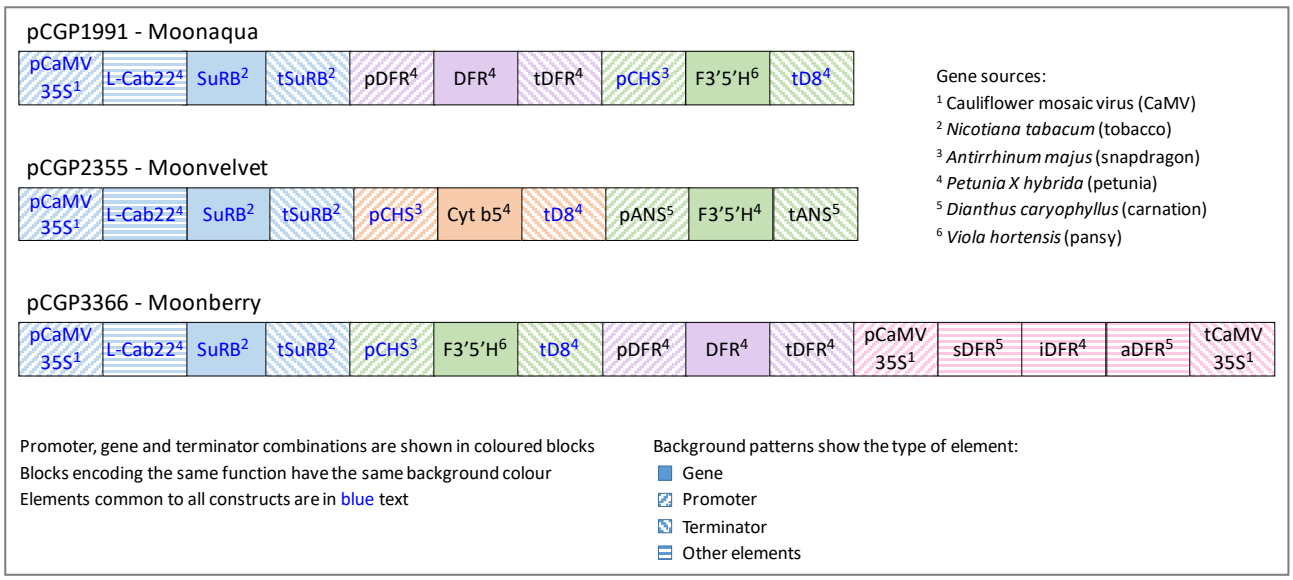

Figure 2: Schematic of the constructs used to transform the GM carnation lines. Adapted from information supplied by the licence holder and from the Biosafety Clearing House LMO Register (accessed 3 December 2019). For further information refer to the RARMP for DIR 134. Vectors used for transformation are indicated for each construct. *F3'5'H* - Flavonoid 3'5'-hydroxylase; *DFR* - Dihydroflavonol reductase; sDFR/iDFR/aDFR - RNAi construct consisting of partial sequences for the carnation DFR sense and antisense, separated by an intron from the petunia DFR-A gene; *Cyt b5* - Cytochrome b5; *SuRB* - Acetolactate synthase; pCaMV 35S - Cauliflower mosaic virus (CaMV) promoter; L-Cab22 - 5' untranslated leader of chlorophyll a/b-binding protein; pDFR - Dihydroflavonol-4-reductase promoter; pCHS - Chalcone synthase gene promoter; pANS - Anthocyanidin synthase gene promoter; tSuRB - Acetolactate Synthase (ALS) gene terminator; tDFR - Dihydroflavonol-4-reductase terminator; tD8 - D8 gene terminator; tCaMV 35S - CaMV 35S terminator; tANS - Anthocyanidin synthase gene terminator.

2.3 Experience with GM carnations

2.3.1 Approvals for GM carnations

14. GM carnations have been authorised for production and trade for a number of years, with 19 events listed on the ISAAA GMO database. These include the four varieties of carnations currently included on the OGTR GMO Register and the three for which inclusion on the Register is currently being sought. Authorisations for Moonaqua™, Moonberry™ and Moonvelvet™ globally are summarised in Table 1 below.

Table 1: Authorisations for GM carnations Moonaqua™, Moonberry™ and Moonvelvet™.

Country/Region	Year	Type of Authorisation
		Moonaqua™
Australia	2015	Import, distribution (cut flowers)[1]
Canada	1999	Cut flowers[4, 5]
Colombia	2000	Greenhouse production for export[1]
Ecuador	1997	Unspecified[5]
EU[2]	2009[3]	Placing on the market[1]
Japan	2009	Cultivation; Import, use without conditions[1]
Malaysia	2012	Ornamental purposes, not for planting[1]
Singapore	2013	Unspecified[5]
USA	1997	Cut flowers[4, 5]
		Moonberry™
Australia	2015	Import, distribution (cut flowers)[1]
Canada	1999	Cut flowers[4, 5]
Colombia	2008	Greenhouse cultivation for export[1]
EU[2]	2017	Import, not for use as food or feed or for cultivation; processing, import/use with conditions
Japan	2013	Cultivation; Import, use without conditions[1]
Malaysia	2012	Ornamental purposes, not for planting[1]
Singapore	2013	Unspecified[4]
USA	1997	Cut flowers[4, 5]

Country/Region	Year	Type of Authorisation
		Moonvelvet™
Australia	2015	Import, distribution (cut flowers)[1]
Canada	1999	Cut flowers[4, 5]
Colombia	2008	Greenhouse cultivation for export[1]
EU[2]	2017	Import, not for use as food or feed or for cultivation; processing, import/use with conditions
Japan	2013	Cultivation; Import, use without conditions[1]
Malaysia	2012	Ornamental purposes, not for planting[1]
Singapore	2013	Application under review[4]
USA	1997	Cut flowers[4, 5]

[1] Information from GMO databases: ISAAA GMO database; Biosafety Clearing House LMO database; EU GMO Register; Biotrack Product Database

[2] Documentation provided by Netherlands, decision for EU

[3] Ten year approval, renewed in 2019 (document in Dutch)

[4] Information provided by applicant

[5] Exempt from regulation

15. Of these authorisations, two have occurred since the licence for DIR 134 was issued. These were authorisations for 'placing on the market' (import of cut flowers) of Moonberry™ and Moonvelvet™ in the EU. The authorisation for 'placing on the market' of Moonaqua™ (originally granted in 2009 for ten years) in the EU was renewed in 2019. In addition to these, authorisations for other GM carnations were granted (Moonvista™ in 2019) or renewed (Moonlite™ in 2017) in the EU for 'placing on the market'. Decision and consent documents for release onto the market in the EU can be found in the EU GMO database, "Deliberate Release and Placing on the EU Market of GMOs - GMO Register".

2.3.2 Findings of the previous Risk Assessment and Risk Management Plan

16. The RARMP for DIR 134 concluded that the commercial release of the three GM carnation varieties posed negligible risks to human health and safety and the environment and as such no specific risk treatment measures were imposed.

17. The RARMP for DIR 134 considered information on the inserted genes and the pathways in which they are involved, the proteins encoded by the genes, the anthocyanin composition, the stability of the transgenes, detailed molecular characterisation, morphology including vegetative and reproductive morphology of the GM carnations and compared these with non GM carnations. Credible pathways to potential harm considered in the RARMP for DIR 134 included: exposure of people or other organisms through contact with, or ingestion of, GM carnation flowers; spread and persistence of GM plants or hybrid offspring leading to increased toxicity or allergenicity in people or increased toxicity in other desirable organisms and; reduced establishment of desirable plants and reduced biodiversity.

18. The principal reasons for the conclusion of negligible risks were:

- The GM carnations are not authorised for food or feed. Additionally, in the unlikely event of accidental consumption, the proteins encoded by the inserted genes are widely consumed by humans in a range of foods and beverages and are not known to be toxic or allergenic. Effects on other desirable organisms are unlikely due to minimal exposure as a result of the dealings. Adverse effects from siRNA intake are unlikely and could be expected to be transient.
- The GM carnations are unlikely to spread and persist in the environment as the result of a number of factors.
  - Due to the morphology of carnation flowers, the GM carnations are highly unlikely to release any pollen. Insect pollination is highly unlikely as a result of both flower morphology that restricts insect access to pollen in the flower and because access to cut flowers by pollinators is unlikely.

- Carnations rarely set large numbers of seeds and the time taken to produce seed is greater than the vase life of cut carnation flowers, thus it is highly unlikely that cut flowers would set viable seed before being discarded.
- Propagation of carnations through cuttings is not authorised under DIR 134 and requires specific conditions for successful propagation even if it were attempted.
- In addition, the cut flowers are devitalised before import.

Section 3 Risk assessment: evaluation of new information

3.1 Information received as part of DIR 134 licence conditions

19. DIR licence conditions require reporting of any information about any adverse impacts, unintended effects, or new information relating to risks to human health and safety or the environment caused by the GMOs or material from the GMOs. Annual reports for DIR 134 do not report any adverse or unintended effects.

20. Since approving licence DIR 134, the Regulator has not received any other reports of adverse impacts, unintended effects, or new risks posed by the GM carnations.

3.2 Information supplied by IFD

3.2.1 Import volumes for GM carnations since 2015

Since the licence for DIR 134 was issued in 2015, a total of 630,000 stems of the three GM carnations authorised under that licence have been imported into Australia from Colombia and Ecuador. Over the same period, a total of approximately 2,500,000 of the GM carnations currently included on the GMO Register have also been imported into Australia.

3.2.2 Authorisations for GM carnations

21. Since the issue of DIR 134, no applications for authorisation of dealings with the three GM carnation lines have been withdrawn or expired. During this time, EU authorisations have been renewed for all three lines (Table 1). No applications for permits or licences for dealing with the GMOs have been refused.

3.2.3 Monitoring information from commercial releases of GM carnations

22. Authorisations for import and distribution of the GM carnations in the EU include requirements for a general post market evaluation and monitoring plan (PMEM). Requirements for these are available in European Commission documents produced for each carnation line (European Commission, 2015a, b, 2018). Briefly, reporting from these requirements indicated that no adverse effects were reported by people handling the GM carnations during import and marketing, nor from customers purchasing the GM carnations. No weedy populations were found in Europe or at production sites and no changes to disease or pests of the GM carnations were reported.

23. At the growing sites (for example around composting areas) in Colombia and Ecuador, surveys were conducted to determine whether any populations of GM carnations had established outside cultivation. Five surveys were conducted in Ecuador between April 2016 and April 2019, while in Colombia 11 surveys were conducted between January 2016 and October 2019. No populations were found.

3.2.4 GM Carnation morphology

24. The average number of anthers for GM carnation flowers have been monitored at 13 time points from 2013 until 2019 at the production site in Colombia. No increase in the average number of anthers over time was observed, although for Moonberry™ the average number varies between less than one and four per flower at different time points. No anthers were observed in Moonaqua™, while in Moonvelvet™ average anther number was less than one for 12 of the 13 observations.

25. Petal numbers have been assessed at 21 time points from 2013 to 2019 at the production site in Columbia. Numbers of petals per flower show some fluctuation at different time points, but there no trend for increasing or decreasing petal numbers.

3.2.5 GM carnation sequencing

26. Re-sequencing of the insert and flanking regions for the GM carnations was requested by the EU in 2017. Both Moonberry™ and Moonvelvet™ sequences were identical to those originally provided. The sequence for Moonaqua™ showed a single nucleotide deletion in the flanking region of one of three insertion loci when compared with the sequence submitted in 2006. Analysis of open reading frames, including the inserted genes, showed no biologically significant homology to known toxins or allergens (European Food Safety Authority et al., 2018).

3.3 Plant database searches

27. The following flora databases were also accessed in December 2019 to search for records of *D. caryophyllus* in Australia during the period from 2015 (the licence for DIR 134 was issued in October 2015) to 2019:

- Global Biodiversity Information Facility (GBIF) Backbone Taxonomy. (GBIF Secretariat - https://doi.org/10.15468/39omei Accessed via https://www.gbif.org/occurrence/search?continent=OCEANIA&taxon_key=3085420&year=2015,2019). No occurrences listed for *D. caryophyllus* from 2015 to 2019 in Oceania.
- Atlas of Living Australia (ALA - https://www.ala.org.au/) showed only one recent record (2017) of a sample collected in NSW.
- The Australasian Virtual Herbarium (AVH - https://avh.chah.org.au/) contained no recent records.
- The Australian Plant Name Index (APNI - https://biodiversity.org.au/nsl/services/apni) and Australian Plant Census (APC - https://biodiversity.org.au/nsl/services/apc) yielded no matches, nor did links from this site to other plant flora surveys.
- The Weeds of National Significance (WoNS - https://www.environment.gov.au/cgi-bin/biodiversity/invasive/weeds/weedspeciesindex.pl?id=701) list does not include *D. caryophyllus,* nor any other Dianthus species.
- Individual state floral databases (many of which feed into AVH and ALA) did not record *D. caryophyllus* as naturalised or weedy.

28. From the information available across these databases, it is apparent that no weedy populations have established in Australia since the previous review made under DIR 134. Thus, it appears that despite a long history of commercial cultivation, carnation is not a weedy species in Australia.

3.4 Literature review

29. Literature searches were conducted mainly in Google Scholar, but also in AGRICOLA, Proquest (Agriculture and Environment), and Science Direct using search terms including ‘carnation’, ‘Dianthus’, ‘Dianthus caryophyllus’, individually and in conjunction with terms such as ‘transgenic’, ‘genetically modified’, ‘genetically engineered’, ‘environment’, ‘allergy’, ‘toxicity’ (and wildcards for these terms as appropriate). Searches were conducted for material published since 2014 in order to target information that may not have been available when the RARMP for DIR 134 was completed.

30. References that included pertinent information are cited and a list of the references found through the literature searches that have not been directly cited in this RARMP can be found in the Appendix, grouped by general subject area.

31. A number of references detail information about floral surveys for other regions – mainly European - in which the presence of species as naturalised or weedy in natural ecosystems is examined. *D. caryophyllus* is not listed in any of these surveys as weed or as being naturalised or present as large

populations (Pyšek et al., 2012; Milović et al., 2016; Pergl et al., 2016; Crawley, 2017; Mayer et al., 2017; Gawhari et al., 2018).

32. No references were found that recorded weediness of carnations in Australia and the most recent update of the Global Compendium of Weeds did not include any records of weediness in Australia (Randall, 2017). This is consistent with the results of flora database searches.

3.4.1 Risk assessments published

33. A number of risk assessments for GM carnations have been published by European regulatory bodies since the licence for DIR 134 was issued. For the renewal of authorisation for 'placing on the market' of Moonaqua™, risk assessment documents from a number of agencies, including Commissie Genetische Modificatie (COGEM – Netherlands), European Food Safety Authority (EFSA), Vitenskapskomiteen for mattyrgghet (VKM, Norwegian Scientific Committee for Food Safety) were published. Each of these assessments concluded that there were negligible risks to human safety or to the environment from the import of Moonaqua™ carnations for cut flowers (VKM, 2015a; COGEM, 2018; European Food Safety Authority et al., 2018). Likewise for Moonberry™ and Moonvelvet™, the risk assessments concluded that there were negligible risks to human safety or to the environment from the import of Moonberry™ and Moonvelvet™ carnations for cut flowers (EFSA Panel on Genetically Modified Organisms, 2014a, b; VKM, 2015b, c).

34. Decision and consent documents relating to authorisation for import of the GM carnations into the EU can be found on the European Commission (EC) website (Deliberate Release and Placing on the EU Market of GMOs - GMO Register).

35. No information was found from literature searches that indicated any changed or unexpected risk from the commercial release of the GM carnations in a number of countries, either through escape into the environment of through risks to human health.

36. No new risks were identified in the submissions received during consultation on the RARMP, nor was any information received to indicate risk ratings greater than negligible for previously identified risks.

3.5 Conclusion of the risk assessment

37. Based on available information, there is no indication that any adverse or unexpected events have occurred either in Australia or in other countries where cultivation and/or import and distribution of the GM carnations Moonaqua™, Moonberry™ and Moonvelvet™ has been authorised. No information was found in the literature review or from plant databases to indicate altered or increased risks to human health and safety or to the environment from GM carnations. The conclusion of the risk assessment for DIR 134 remains valid.

38. Thus, the dealings with GM carnations represent minimal risk to human health and the environment.

Section 4 Risk management plan

39. Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan addresses risks evaluated as requiring treatment.

40. Under Section 79(1) of the Act, the Regulator must not decide to include dealings with a GMO on the GMO Register unless satisfied that any risks posed by the dealing are minimal and it is not necessary for persons undertaking the dealing to hold, or be covered by, a GMO licence in order to protect the health and safety of people or to protect the environment.

41. A licence is not considered necessary for the proposed dealings, because:

- the risk was assessed as negligible and previous experience in dealing with the GM carnations demonstrated safe use which indicates minimal risk as a result of gene technology; and
- neither statutory (s65 and s66 of the Act) nor application-specific licence conditions (DIR 134) resulted in a finding that would justify continued licensing to manage this minimal risk.

42. If the Regulator makes a determination to include dealings with a GMO on the Register, under Section 77(b) specific conditions might be included on the GM Register to manage risks. However, based on the risk assessment presented here and on previous experience with dealings with similar GM carnations under Reg-001/2004, such specific conditions are not considered necessary.

Section 5 Conclusions of the consultation Risk Assessment and Risk Management Plan

43. The dealings transport, storage and disposal of cut flowers of Moonaqua™, Moonberry™ and Moonvelvet™ carnations pose minimal risk to the health and safety of people or the environment as a result of gene technology. As the risks associated with the dealings are minimal and no justification was found for continued licencing to manage the minimal risk, it is proposed that the dealings could be safely undertaken by anyone without the need for a licence. No conditions are proposed if the Regulator makes a determination to include those dealings on The Register.

Section 6 Literature Cited

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VKM (2015c). Final health and environmental risk assessment of genetically modified carnation Moonvelvet IFD-26407-2. Scientific opinion on genetically modified carnation Moonvelvet IFD-26407-2 from Florigene with modified petal colour for import as cut flowers for ornamental use under Part C of Directive 2001/18/EC (Application C/NL/09/02). Report No. 2015:18. (Oslo, Norway.: Panel on Genetically Modified Organisms of the Norwegian Scientific Committee for Food Safety).

Section 7 Literature reviewed in preparation of the consultation RARMP

References found through the literature searches described in the body of this document, but not subsequently cited directly are provided in this list. References are grouped generally, but some may have relevance to more than one area.

1. Medicinal properties, traditional knowledge and uses

Carnations

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Appendix A: Summary of submissions from experts, agencies and authorities

Advice received by the Regulator from experts, agencies and authorities[1] on the consultation RARMP is summarised below. All issues raised in submissions that related to risks to the health and safety of people and the environment were considered in the context of the currently available scientific evidence and were used in finalising the RARMP that formed the basis of the Regulator's decision to include dealings with GM carnations on the GMO Register.

Submission	Issues raised	Comment
1	Not a specialist expert, so will not provide comment.	Noted.
2	Broadly supportive of application DIR 134 (sic). Notes that it is for flowers cut overseas which have been dipped in glyphosate prior to arrival so that they are not viable for propagation. This presents a negligible risk to Australia.	Noted.
3	Agrees with the conclusions of the RARMP that the risks to the health and safety of people and the environment posed by the dealings with the GM carnations are negligible.	Noted.
	Include clearer text describing why the Regulator is consulting on the RARMP.	The RARMP now includes information regarding consultation in Section 1.
	Section 2.3.2 should include additional text to explain the factors contributing to the conclusions of negligible risk of toxicity to humans or other desirable organisms and negligible risk of spread to the environment.	Section 2.3.2, paragraph 18, outlines the principal reasons for conclusions of negligible risk for risk scenarios assessed in the RARMP for DIR 134. As the GM carnations are only available as cut flowers, contact by desirable organisms including beneficial insects is considered to be unlikely. In addition, links to the RARMP for DIR 134 are included in the current RARMP for those seeking further information.
	Should include supporting information from the RARMP from Reg 001/2004 regarding consultation and import of the carnations included on the GMO Register.	Although similar, neither the GM carnation lines, nor a number of the dealings included on the GMO Register under Reg-001/2004, are the same as those in the current application. Therefore, whilst these are mentioned briefly in Section 1 and Section 2.2, they are not the focus of this RARMP so further discussion is not included. We have however provided a link to the documents for Register 001/2004 in Section 1 for those seeking further information.

[1] Agencies include GTTAC, State and Territory Governments, relevant local governments, Australian Government agencies and the Minister for the Environment.

Submission	Issues raised	Comment
4	Not clear whether these GM carnations are subject to biosecurity conditions and required to follow the Commonwealth Department of Agriculture, Water and Environment instructions on the devitalisation process to render them non-viable prior import into Australia. This is a biosecurity requirement and is the responsibility of the importer.	Section 2 (paragraph 9) discusses the biosecurity requirements for cut flowers imported into Australia, including the GM carnations that are the subject of this RARMP. These requirements would not be affected by inclusion of the dealings on the GMO Register.
	Supported the conclusion that inclusion of dealings with GM carnations on the GMO Register pose negligible risk of harm to human health and safety and the environment.	Noted.
5	Agrees that the conclusions of RARMP for DIR 134 remain valid. Agrees that the information gathered for this application is sufficient and no new information was identified. Agrees with the overall conclusions of this RARMP.	Noted.

Appendix B: Summary of submissions from the public on the consultation RARMP

The Regulator received one submission from the public on the consultation RARMP. The issues raised in the submission are summarised in the table below. All issues that related to risks to the health and safety of people and the environment were considered in the context of currently available scientific evidence in finalising the RARMP that formed the basis of the Regulator's decision to include dealings with GM carnations on the GMO Register.

Submission	Issues raised	Comment
1	Should remain necessary for people undertaking dealings with the GM blue carnations to hold or be covered by a GMO licence. Would not support this application.	Under the Gene Technology Act 2000 (the Act), which is legislation passed by the Parliament of Australia, a GM licence holder may apply to have dealings with a licensed GMO included on the GMO Register. The Gene Technology Regulator (the Regulator) must not include dealings on the GMO Register unless satisfied that any risks posed by the dealings are minimal and that it is not necessary for persons undertaking the dealings to have, or be covered by a GMO licence. This application has been assessed as posing negligible risk to human health and safety and to the environment and the Regulator is satisfied that a licence is not required for dealings with the GM carnations.