Risk Assessment for
Register 001/2004

Inclusion of dealings with GM carnation lines, modified for flower colour, on the GMO Register

Applicant: Florigene Pty Ltd

November 2006

Executive Summary

Introduction

The Gene Technology Regulator (the Regulator) has made a determination to include dealings with four genetically modified (GM) carnation lines on the Genetically Modified Organism (GMO) Register, (Register 001/2004). These dealings were previously authorised under licence DIR 030/2002.

According to section 79 of *the Gene Technology Act 2000* (the Act) the Regulator must not make a determination unless satisfied that any risks posed by the dealings are minimal and that it is not necessary for persons undertaking the dealings to hold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment. The Regulator will be satisfied that the risks are minimal if the risk estimates of identified risks are low or negligible, or if there are no identified risks.

More information about the GMO Register and on the risk analysis process followed by the Regulator is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030).

The application

Florigene Pty Ltd (Florigene) applied to include dealings with four lines of GM carnation on the GMO Register. The carnation lines were modified by the insertion of genes that affect the production of blue coloured (anthocyanin) pigments, leading to violet, mauve or purple coloured flowers. The introduced genes were derived from pansy and petunia. The GM carnation lines also contain a herbicide tolerance marker gene from tobacco, which helped identify and select GM plants during their development in the laboratory.

The proposed dealings were first authorised under the former voluntary system in 1995 and licenced in 2003 (DIR 030/2002). They include the propagation, growth, and distribution of both GM plants and cut flowers Australia-wide without containment measures to limit the spread and persistence of the GMOs or the introduced genes.

Risk assessment

The Risk Assessment and Risk Management Plan (RARMP) that formed the basis of the Regulator's decision to issue licence DIR 030/2002 concluded that the commercial release of the four carnation lines modified for flower colour posed no risks to the health and safety of people or the Australian environment. Accordingly, no risk treatment conditions were imposed in the licence.

A Risk Assessment was prepared for application Register 001/2004 based on additional data obtained from Florigene, together with information from the scientific literature published since the licence was issued, and advice in submissions received through consultation with a wide range of experts, agencies and authorities, and the public. No risks were identified that required further analysis. In addition, there have been no adverse effects reported over the 10 years in which the GM carnation lines have been grown and sold commercially in Australia or from extensive cultivation and distribution overseas.

The Risk Assessment considered one new hazard (an event that may cause harm) but no risk from this event was identified. Therefore, the risks posed by the dealings specified in application Register 001/2004 were considered, by definition of the Act, to be minimal. Hence it was not considered necessary for persons undertaking the dealings to hold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment.

In conclusion, the dealings specified in application Register 001/2004 involving the ongoing commercial release of four GM carnation lines modified for flower colour, are considered to meet the criteria for inclusion on the GMO Register, and not require the dealings to be subject to conditions.

Risk assessment

1. Background

1.1 The GMO Register

The Gene Technology Regulator (the Regulator) may make a determination to include dealings with genetically modified organisms (GMOs) on the GMO Register according to section 78 of the *Gene Technology Act 2000* (the Act). Such dealings are required to be, or have been, authorised by a GMO licence.

According to section 79 of the Act the Regulator must not make a determination unless satisfied that any risks posed by the dealings are minimal and that it is not necessary for persons undertaking the dealings to hold, or be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment. The Regulator will be satisfied that the risks are minimal if the risk estimates of identified risks are low or negligible, or if there are no identified risks (see *Risk Analysis Framework*).

Matters that the Regulator must have regard to include a safe history of use, information as to risks associated with the dealing and whether there is a need for the dealings to be subject to conditions.

1.2 Risk assessment process for inclusion on the GMO Register

Florigene Pty Ltd (Florigene) has applied to include dealings covered by licence DIR 030/2002 on the GMO Register (Register 001/2004). Further data to those assessed in the Risk Assessment and Risk Management Plan (RARMP) for DIR 030/2002 were obtained from the company to support the application, including additional comparative molecular, morphological and toxicity data. A Risk Assessment has been prepared based on these data together with new information obtained from the scientific literature, published since the licence was issued, and advice in submissions received through consultation with a wide range of experts, agencies and authorities, and the public.

Hazard identification is carried out to identify events that may lead to an adverse outcome related to the new data and information. Events are particular sets of circumstances that might occur through interaction between the GMO and the environment as a result of the proposed dealings. A risk is identified only when there is some chance that harm to people or the environment will occur. Events that do not lead to an adverse outcome or could not reasonably occur do not represent an identified risk.

If certain events in the original RARMP are re-assessed as having an increased level of risk from that previously estimated, then there may be a need for risk treatment measures. In addition, new events (not previously assessed) arising from information obtained subsequent to preparation of the original RARMP may give rise to new identified risks. If the risks are not considered minimal then the Regulator will not make a determination to include the dealings on the GMO Register.

Information on the process of risk analysis (the *Risk Analysis Framework*) is available from the Office of the Gene Technology Regulator (OGTR) (Free call 1800 181 030).

2. Risk assessment context

For this application, establishing the risk assessment context includes consideration of:

- proposed dealings and details of the GMOs
- conclusions of the RARMP for DIR 030/2002
- new data obtained from the applicant
- submissions received through consultation
- other information as to risks associated with the dealings
- adverse effects posed by the dealings
- international approvals.

2.1 Proposed dealings and details of the GMOs

The proposed dealings of four genetically modified (GM) carnation lines include the propagation, growth, and distribution of both GM plants and cut flowers Australia-wide, and were first approved in 1995 under the former voluntary system overseen by the Genetic Manipulation Advisory Committee (general release, GR-2).

The four GM carnation lines were produced after transformation with one of two binary vectors, pCGP1470 or pCGP1991 (see Table 1).

Table 1. Characteristics of the four GM carnation lines

Trade Name	Binary Vector	Transformation Event	Flower colour[1]
Florigene Moonlite™	PCGP1470	123.2.38	violet
Florigene Moonshade™	PCGP1470	123.2.2	blueish purple
Florigene Moonshadow™	PCGP 1991	11363	intense mauve violet
Florigene Moonvista™	PCGP1991	123.8.8	black, blue-purple

[1] flower colours taken from the Florigene website (http://www.florigene.com.au/)

As shown in Tables 2a & 2b, the lines contain two introduced genes from the anthocyanin biosynthetic pathway, DFR (dihydroflavonol 4-reductase) from petunia (*Petunia hybrida*) and F3'5'H (flavonoid 3', 5' hydroxylase) from petunia or pansy (*Viola* spp.). as well as the selectable marker, SuRB (sulfonylurea resistance gene B) from tobacco (*Nicotiana tabacum*), that confers tolerance to sulfonylurea herbicides and a range of other acetolactate synthase (ALS) inhibiting herbicides. The GM carnation lines also contain short, commonly used regulatory sequences from a range of plant, viral and bacterial sources. These regulatory sequences are not infectious or capable of causing disease.

Table 2a. Gene construct of binary vector pCGP1470

Promoter	origin	Gene	origin	Terminator	origin
35S	CaMV (cauliflower mosaic virus)	*SuRB*	*N. tabacum* (tobacco)	*SuRB* 3'	*N. tabacum* (tobacco)
CHS	*A. majus* (snap dragon)	*F3'5'H*	*Petunia*	*D8* 3'	*Petunia*
mac	CaMV and *A. tumefaciens* (crown gall)	*DFR*	*Petunia*	*mas* 3'	*A. tumefaciens* (crown gall)

Abbreviations: *35S* = 35S region of CaMV; *CHS* = chalcone synthase; *D8* = phospholipid transfer protein; *mas* = mannopine synthase; *mac* = chimera of CaMV + *mas*

Table 2b. Gene construct of binary vector pCGP1991

Promoter	origin	Gene	origin	Terminator	origin
35S	CaMV	*SuRB*	*N. tabacum*	*SuRB* 3'	*N. tabacum*

			(tobacco)		(tobacco)
CHS	*A. majus*	*F3'5'H*	*Viola*	*D8 3'*	*Petunia*
	(snap dragon)		(pansy)		
DFR 5'	*Petunia*	*DFR*	*Petunia*	*DFR 3'*	*Petunia*

Abbreviations: as for Table 2a

2.2 Conclusions of the RARMP for DIR 030/2002

The RARMP prepared for application DIR 030/2002 concluded that "the hazards posed by this commercial release….are unlikely to present any risks to the health and safety of people or the Australian environment that are different to conventional carnation".

In making a decision to issue a licence in respect of application DIR 030/2002, the Regulator concluded that no risk treatment conditions were required and that the licence need only contain general conditions, as set out in Sections 63, 64 and 65 of the Act, to oversight the release on an ongoing basis. Included in these conditions was a requirement for the licence holder to provide the Regulator with a written report within 90 days of each anniversary of the licence, including information on any adverse impacts on human health and safety or the environment, caused as a result of the GMO or viable material from the GMO.

2.3 New data obtained from the applicant

2.3.1 Morphological characterisation of the four GM carnation lines

The applicant measured (Florigene, unpublished a, b, c) a number of morphological characteristics (whole plant measurements: stem length at 7 nodes, length of 5th node, thickness of 5th node, leaf length; flower measurements: flower diameter, petal number, outer petal width, calyx height, calyx diameter, number of lobes per calyx, corolla height, number of styles, style length) of the four GM carnation lines released under DIR 030/2002, and compared these characteristics to the non-GM parent. The data showed that, for whole plant measurements, there were many statistically significant differences between various characters of the transgenic lines and the non-GM parent. These differences, however, fall within normal varietal variation. There were also statistical differences for flower measurements of which only two characters for the line Moonshadow™ (see Table 3) fall outside normal varietal variation.

Table 3. Flower morphology measurements in the GM carnation line Moonshadow™ showing significant differences from the non-GM parent

Measurement	Non-GM parent	Florigene Moonshadow™
Petal number	Range: 43 – 65 Mean: 56	Range: 33 – 55 Mean: 43
Style length (cm)	Range: 1.2 – 2.4 Mean: 1.64	Range: 1.7 – 3 Mean: 2.21

2.3.2 Toxicity tests

Florigene provided data (Florigene a, c) from three studies that examined the potential toxicity of the four GM carnation lines.

a) **An Ames assay system** (Ames *et al*., 1973) using four different strains of *Salmonella typhimurium* to evaluate the mutagenic potential of leaf extracts from

the four GM carnation lines. No significant mutagenic effect was detected in any of the lines compared to extracts from the non-GM parent carnation.

b) **An *in vitro* cytotoxicity study** (Florigene in-house procedure) examining the effects of leaf extracts, from either the GM carnation lines or the non-GM parent, on the growth of cultured human intestinal cells. When compared to those of the non-GM parent, extracts from all four transgenic carnation lines showed no significant differences in effect on cell growth.

c) **A 14-day animal feeding trial** (based on OECD 2001) considering post-feeding clinical observations and body weight gain in mice (over the 14 days after administration of either GM or non-GM carnation petal extracts) and post-mortem observation of internal tissues and organs of the animals. No apparent abnormalities were observed throughout the experimental period or following autopsy. Additionally, the extracts from the four transgenic carnation lines had no significant effect on the weight gain of mice over a 14 day period compared to extracts from the non-GM parent carnation.

2.3.3 Molecular characterisation of two of the GM carnation lines

Florigene provided data (unpublished, b), from two of the GM carnation lines (Moonlite™ and Moonvista™), on Northern blot analysis, updated estimates of copy number of the inserted genes (from Southern blot analysis) and information on the *tetA* marker gene (that was inserted to select bacteria carrying the vectors in the laboratory).

Florigene used Northern blot analysis to confirm expression of the inserted genes in the two GM carnation lines, Total RNA was extracted from petals from tight flower buds. The *SuRB*, *F3'5'H* and *DFR* genes were expressed in both transgenic lines, but not in the non-GM parent. The level of gene expression was not quantified.

Florigene used Southern blot analyses to estimate the approximate copy number of the inserted genes in the two GM lines and to determine if any of the transformation vector sequences are present in the carnation genome. The gene copy number results are shown in Table 4. A single copy of the *SuRB* and *F3'5'H* genes and between one and two copies of the *DFR* gene have been inserted into the Moonlite™ genome. The Moonvista™ genome contains four copies of the *SuRB* and *DFR* genes, and seven copies of the *F3'5'H* gene.

Table 4. Approximate copy number of introduced genes, and the right and left borders of the T-DNA

GM carnation line	LB	*SuRB*	*F3'5'H*	*DFR*	RB
Florigene Moonlite™	1	1	1	1-2	3
Florigene Moonvista™	4	4	7	4	9

Key: LB = left border, RB = right border

The new estimate of copy number of the introduced genes in Moonvista™ is considerably higher than that given in the RARMP prepared for DIR 030/2002. The difference can be explained by the improved quality of the autoradiographs used in calculating copy number from the most recent set of Southern hybridisations.

In deriving the data on copy number, Florigene assumed, from its interpretation of Southern data generated during the study, that the two GM lines are periclinal chimeras in which the transgenes occur only in the L1 layer of tissue. The inference from this is that, because cells

in this lineage do not contribute to the production of germ cells, it is unlikely that any pollen produced by the lines would contain transgenic material; this would reduce the likelihood of gene flow. This was also noted by the Advisory Committee on Releases to the Environment (ACRE 2005) in advice provided to agencies within the United Kingdom following an application by Florigene to have Moonlite™ cut flowers placed on the European market (SNIF 2004).

Data submitted as part of the consideration of the DIR 030/2002 application, indicated that there had been some extra-border integration from the binary vector into Moonlite™ and Moonshade™; this may have included tetracycline A resistance (*tetA)* sequences. The *tetA* gene is present on the backbone of the binary vectors used for transformation and is used to select for bacteria carrying the vectors. The new data supplied by Florigene from PCR-based studies showed that an intact *tetA* gene is not present in either Moonlite™ or Moonvista™. The inference (see e.g. Yamaguchi *et al*, 1983) is that lack of an intact gene prevents any expression of *tetA.*

It should be noted that the original RARMP prepared for DIR 030/2002 included an assessment of the risks that may be involved should an entire plasmid vector backbone (i.e. including an intact *tetA* sequence) be present in the GM carnation lines and that this risk was considered not to be any greater than that associated with *tetA* genes already present in the environment. Assessment of Florigene data on the *tetA* sequence by European agencies (Netherlands Competent Authority 2005; European Food Safety Authority (EFSA) 2006), in response to an application to have Moonlite™ cut flowers placed on the European market (SNIF 2004), is in agreement with the conclusions reached in the RARMP for DIR 030/2002.

2.4 Submissions received through consultation

The *Gene Technology Act 2000* does not require any consultation to be conducted on applications to include dealings with GMOs on the GMO Register. However, a determination to include dealings on the GMO Register is considered to be a legislative instrument that is registered on the Federal Register of Legislative Instruments (FRLI) and tabled in both Houses of Parliament; under the *Legislative Instruments Act (2003),* there is a requirement for agencies to consult before making a legislative instrument, if it is appropriate and reasonably practical.

Consultation was undertaken for an 8-week period commencing in August 2005 with relevant Australian Government agencies, State and Territory governments and the Gene Technology Technical Advisory Committee. The public was also invited to provide comment via a notice published on the OGTR website and in leading national, state and territory newspapers (see OGTR 2006b). The consultation process particularly sought advice on any evidence of adverse effects associated with the licensed commercial release of the GM carnation lines.

All submissions were considered in the context of currently available scientific evidence that was used in the preparation of the Risk Assessment (see Appendices A & B). No risks to human health and safety or the environment were identified as requiring further assessment.

All of the experts, agencies and authorities and three of the six submissions from the public supported the inclusion of the dealings on the GMO Register. Two of the public submissions raised issues outside the scope of assessments under the Act.

2.5 Other information as to risks associated with the dealings

An updated search of the scientific literature was undertaken[1] to ascertain whether any information had become available, relating to the potential risks of dealings with the GM carnations to human health and safety and the environment, particularly with regard to toxicity, allergenicity and weediness. No new information that was relevant to the dealings was found.

2.6 Examination of adverse effects posed by the dealings

In 2006, Florigene estimated that close to 4.5 million GM carnation flowers had been sold within Australia since 1995 and about 5.5 million GM carnations had been produced in the USA, Japan, Eucador and Colombia. Annual reports provided by the licence holder stated that no unintended or adverse effects had been reported in any of the countries in which the GM lines were grown and/or sold. In addition, other data available to the Regulator provides no evidence of adverse effects.

2.7 International approvals

Since the issuing of licence DIR 030/2002, Florigene has lodged a successful application (SNIF 2004) for the placing on the (European) market of the genetically modified carnation Moonlite™ for import, distribution and retailing in the cut flower sector. The application was assessed by the Dutch Commission on Genetic Modification (COGEM 2005) and the Netherlands Competent Authority (2005) in accordance with Directive 2001/18/EC and consent to place the product on the market was given in March 2005. In 2005, the Advisory Committee on Releases to the Environment (ACRE 2005) agreed with the Netherlands Competent Authority assessment and concluded that the import and distribution of cut flowers from Moonlite™ does not pose an increased risk to human health or the environment compared with non-GM carnation varieties. In 2006, the Scientific Panel on Genetically Modified Organisms (the GMO Panel) of the European Food Safety Authority (EFSA 2006) carried out a further assessment following questions raised by several Member States after they had conducted evaluations at the national level. The GMO Panel concluded that, in the context of its intended use, Moonlite™ is unlikely to have adverse effects on human and animal health or the environment.

Successful applications by Suntory Flowers Ltd. to have the four GM lines with modified flower colour approved for Type 1 use (in which no preventive measures against their dispersal into the environment are required) were registered on the Japan Biosafety Clearing House database in 2004 (J-BCH 2004).

The Biosafety Clearing-House (BCH) is an information exchange mechanism established by the United Nations Cartagena Protocol on Biosafety and assists Governments to make informed decisions regarding the importation or release of living modified organisms. The latest update (BCH 2006) of an entry on the BCH website regarding carnations genetically modified for flower colour includes the four GM lines and indicates that there are no characteristics related to biosafety that are of concern.

3. Risk evaluation

3.1 Morphological characterisation of the four GM carnation lines

[1] Several databases and search engines (Google Advanced, PubMed, Agricola, Biosis) were accessed using 'carnation' or 'Dianthus caryophyllus' as the main search term. The search was then refined using a number of descriptors (e.g.'transgenic', 'environmental impact', 'allergy', 'pollinators').

With regard to the data on morphological characterisation, some differences were noted between the GM and non-GM plants. While alterations to floral structure have the potential to impact on pollination and fertilization the fact that, in both non-GM carnation and the GM lines, little pollen is produced and pollen viability is low (percentage pollen germination for some lines is less than 10%), would suggest that the altered characteristics would not have reproductive significance (see the RARMP prepared for DIR 030/2002 (OGTR 2003) for a discussion of these factors). This conclusion is further supported by the fact that in deliberate cross-pollination experiments involving one of the lines (Moonlite™) seed set did not occur. Pollination factors associated with non-GM carnations, such as virtual self-sterility due to asynchrony in timing of stigma receptivity and anthesis, lack of wind involvement in pollen dispersal, and lack of evidence about insect pollinators in Australia (see Biology and Ecology document in OGTR 2006a) further add to a low likelihood of morphological differences in the GM lines affecting reproductive ability. A similar conclusion was made by EFSA (2006) in their assessment of data supplied by Florigene to the EU (SNIF 2004) on Moonlite™.

In conclusion, these new data on morphological characteristics are not considered to alter the findings of the risk assessment provided in the RARMP prepared for DIR 030/2002.

3.2 Toxicity tests

The results from the additional toxicity tests indicate that the GM lines are unlikely to prove more toxic to other organisms than non-GM carnation. The EFSA (2006) also assessed these toxicological data supplied by Florigene and concluded that there would be no increased toxicity of Moonlite™ petals compared to the non-GM parent in the event of consumption of GM petals.

In conclusion, the new data on toxicity tests are not considered to alter the findings of the risk assessment provided in the RARMP prepared for DIR 030/2002.

3.3 Molecular characterisation of two of the GM carnation lines

The new data on Northern analysis did not alter the conclusions drawn in the RARMP prepared for DIR 030/2002. However, the Southern analysis data showing an increased estimate of copy number in Moonvista™, resulted in one new event being identified that may lead to an adverse outcome. This event is summarised in Table 5.

Table 5. Summary of the risk assessment of new data

Hazard category	Event that may give rise to an adverse outcome	Potential adverse outcome	New event?	New identified risk or increased level of risk?	Reasons
Unintended changes in toxicity	**Event 1.** Exposure of people and other organisms to progeny of GM Moonlite™ carnations with different copy numbers of the introduced genes.	Toxicity or allergenicity in people; toxicity in vertebrates, invertebrates or microorganisms.	Yes	No	♦ The main product of the introduced genes is delphinidin. This anthocyanidin occurs naturally in many plants and is not known to be a toxic compound. • There is a low likelihood of successful crosses being made between Moonlite™ and other carnation cultivars

As a result of the increased copy number in Moonvista™ it is possible that if the line were used as a parent for crossing with another carnation cultivar the offspring may have altered biochemical properties (eg increased delphinidin levels) as a result of segregation of the copies of the introduced gene(s).

Humans and other organisms are already exposed to delphinidin at much higher levels than those occurring in Moonvista™ because of its occurrence naturally in the environment (eg in flowers such as hibiscus, and pansy and fruits such as blueberry and cherries) without evidence of toxicity or allergenicity to humans or to other organisms.

Given the reproductive characteristics of carnation (discussed above with regard to the impact of morphological differences in the GM lines) the likelihood of crosses between Moonvista™ and other cultivars being successful is very low.

In conclusion, the new data on molecular characterisation indicate that the increased copy number in Moonlite™ may result in exposure of people and other organisms to progeny of Moonlite with different copy numbers of the introduced genes. Although this was not considered in the RARMP prepared for DIR 030/2002, this event does not give rise to a new identified risk.

3.4 Consideration of whether there is a need for the dealings to be subject to conditions

One new event that may lead to an adverse outcome has been considered after assessing the data supplied by the applicant. However, no risk from this event has been identified and there have been no reports of adverse effects on people or the environment from this commercial release to date. No specific risk management conditions were imposed in licence DIR 030/2002 and it is not considered necessary to require conditions for dealings in Register 001/2004.

Under the Act, a determination to include dealings with a GMO on the GMO Register is a disallowable instrument. This determination will come into effect if and when the disallowance period for Parliamentary scrutiny has elapsed.

4. Conclusion

The RARMP prepared for licence DIR 030/2002 concluded that the commercial release of carnation lines modified for flower colour posed no risks to the health and safety of people or the Australian environment. No risk treatment conditions were imposed in the licence.

A Risk Assessment has been prepared based on additional data obtained from Florigene, together with information from the scientific literature published since the licence was issued, and advice in submissions received through consultation with a wide range of experts, agencies and authorities, and the public. No risks have been identified that required further analysis. In addition, there have been no adverse effects reported over the 10 years in which the GM carnation lines have been grown and sold commercially in Australia or from extensive cultivation and distribution overseas.

The Risk Assessment for Register 001/2004 considers one new hazard (an event that may cause harm) but no risk from this event is identified. Therefore, the risks posed by the dealings specified in Register 001/2004 are considered, by definition of the Act, to be minimal. Hence it is not considered necessary for persons undertaking the dealings to hold, or

be covered by a GMO licence, in order to protect the health and safety of people or to protect the environment.

In summary, the dealings specified in application Register 001/2004 involving the ongoing commercial release of four GM carnation lines modified for flower colour, are considered to meet the criteria for inclusion on the GMO Register, and not require the dealings to be subject to conditions.

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Appendix A: Summary of submissions received from experts, agencies and authorities for Register 001/2004

GMO: 4 lines of GM carnations modified for flower colour
Applicant: Florigene Pty Ltd

None of the experts, agencies and authorities consulted on application Register 001/2004 identified any risks to human health and safety or the environment that required further analysis or consideration, and all were supportive of the dealings being placed on the GMO Register.

Appendix B: Summary of submissions received from the public for Register 001/2004

GMO: 4 lines of GM carnations modified for flower colour

Applicant: Florigene Pty Ltd

Abbreviations:

Issues raised: **EN**: environmental risks, **H**: human health and safety, **OSA**: outside the scope of assessment.

Submission number	Summary of issues raised	Type of Issue	Consideration of issue
1	♦ Pollen flow	EN	Both GM and non-GM carnations produce little viable pollen. No risks to human health and safety or the environment were previously identified in the RARMP prepared for the commercial release of GM carnation lines (application DIR 030/2002).
	♦ Health concerns	H	The introduced genes are prevalent in many other plants, including edible fruits and vegetables, and the proteins they produce are not known to be toxic. No risks to human health and safety or the environment were previously identified in the RARMP prepared for the commercial release of GM carnation lines (application DIR 030/2002).
	♦ Pesticide resistance	OSA	The GM carnation lines do not contain inserted genes for pesticide resistance.
	♦ Crop contamination	OSA	Issues concerned with marketing of crops contaminated with GM products are outside the scope of risk assessments conducted under the *Gene Technology Act 2000*.
	♦ Ethical issues associated with biotechnology yet to be addressed	OSA	The Regulator can seek advice on ethical issues relating to gene technology from the Gene Technology Ethics Committee. However, none are identified in relation to this proposed dealing.
2	♦ Blue carnations are not natural	OSA	noted
3	♦ Not prepared to accept unidentified risks to human health and environment	H, EN	noted
	♦ Future risks to human health and environment cannot be identified	H, EN	The introduced genes are prevalent in many other plants, including edible fruits and vegetables, and the proteins they produce are not known to be toxic. There have been no reports of adverse impacts after ten years of commercial cultivation of the GM carnation lines in Australia or from overseas.
4 - 6	♦ Extensive period of commercial release demonstrates no risk to human health and environment and, therefore, dealings with GM carnations are suitable for inclusion on the GMO Register.		noted