RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR COMMERCIAL IMPORT OF CUT FLOWERS OF NOVEL FLOWER COLOUR VARIETIES OF GENETICALLY MODIFIED CARNATION (*Dianthus caryophyllus* L.)

NBB REF NO: JBK(S) 602-1/1/8

APPLICANT: SUNTORY HOLDINGS LTD.

DATE SUBMITTED: 11 APRIL 2012

I - Summary of Assessment Process

The Genetic Modification Advisory Committee (GMAC, please refer to ***Appendix 1*** for details of GMAC), under the purview of the National Biosafety Board was given the dossier by the Department of Biosafety on 17 April 2012 for an application for approval for importation for release [sale/placing on the market] of a product of a Living Modified Organism (cut flowers of genetically modified carnation, *Dianthus caryophyllus* L.). The application was filed by Suntory Holdings Ltd. (hereafter referred to as "the applicant"). GMAC members also took the opportunity to obtain further clarification on certain details of the activity. Additional information was also provided by the applicant as requested.

A public consultation for this application was conducted from 3 September 2012 to 2 October 2012 via advertisement in local newspapers. No technical and scientific issues have been raised through the Public Consultation for this application regarding the release.

GMAC had four (4) meetings pertaining to this application and prepared the Risk Assessment Report and Risk Assessment Matrix along with its recommended decision, for consideration by the National Biosafety Board.

II - Background of Application

This application is for approval to commercially import and release a product of a Living Modified Organism (i.e. cut flowers of genetically modified carnation, *Dianthus caryophyllus* L.) The aim of the import and release is to supply or offer to supply for sale/placing on the market of the cut flowers which are novel colour varieties of the genetically modified carnation (*Dianthus caryophyllus* L.). The applicant is applying for approval for the following eight (8) varieties of the product:

	Commercial name (variety)	Unique Identification Code
1	FLORIGENE® Moonaqua™	FLO-40689-6
2	FLORIGENE® Moonlite™	FLO-40644-6
3	FLORIGENE® Moonshade™	FLO-40619-8
4	FLORIGENE® Moonvista™	FLO-40685-2
5	FLORIGENE® Moonberry™	IFD-25958-3
6	FLORIGENE® Moonvelvet™	IFD-26407-2
7	FLORIGENE® Moonique™	IFD-19907-9
8	FLORIGENE® Moonpearl™	IFD-25947-1

Some or all of the varieties above are marketed in countries outside of Malaysia, such as Canada, the United States of America, the European Union, Japan, Australia, Ecuador and Colombia. Applications for approval for some of the above varieties are also currently underway in Japan, Singapore and the European Union.

According to the applicant, the product is harvested in Colombia and will be imported in dry cardboard boxes and unpacked by the importer/retailer for rehydration, followed by

distribution for sale. The cut flowers will be used mainly for ornamental purposes in the form of amateur and professional flower arrangements, as gifts, home and business decoration and event decoration (weddings, functions, etc.).

Information about genetically modified carnation, *Dianthus caryophyllus* L.

The recipient or parental plant is *Dianthus caryophyllus* (carnation). Carnation is probably native to the Mediterranean region belonging to taxonomic family of Caryophyllaceae and has been extensively cultivated for the last 2,000 years. Today, major centres of carnation production are Colombia, China, Spain and Italy. However, carnation is grown in virtually every non-equatorial country where there are suitable climates and other important production centres include Brazil, Ecuador, California, Netherlands, Russia as well as Malaysia. Carnation is not known to be a toxic or allergenic plant. It is vegetatively propagated and does not produce wind-dispersed pollen.

The carnation has been genetically modified to produce novel flower colours as well as resistance to sulfonylurea herbicide chlorsulfuron. Flower colour is primarily due to anthocyanins and carotenoid biosynthesis in the petal tissue. There are three (3) groups of anthocyanins, the delphinidins (produces purple-blue flower colour), cyanidins (red or pink flower colour) and pelargonidind (orange or brick red colour).

The anthocyanin biosynthesis pathway is an intermediate of the phenylporpanoid pathway. The enzyme chalcone synthase catalyses the biosynthesis of 4,2',4',6'-tetrahydroxychalcone which is eventually converted to dihydroflavanol dihydrokaempferol (DHK). In order to produce novel flower colours, additional enzymes and genes from various flowering plants [e.g. snapdragon (*Antirrhinum majus*), Petunia (*Petunia hybrida*) and black pansy (*Viola* sp.)] were inserted, resulting in the creation and conversion of colourless dihydroflavanols to coloured anthocyanins.

In addition to the genes responsible for the production of flower colour, a selectable marker gene was also inserted to allow for *invitro* selection. The marker gene used is a mutation of the tobacco *SuR*B gene which codes for a mutant acetolactate synthase protein (ALS) that confers resistance to sulfonylurea herbicides.

III - Risk Assessment and Risk Management Plan

GMAC evaluated the application with reference to the following documents:

(i) CODEX Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants**.**

(ii) Roadmap for Risk Assessment of Living Modified Organisms, (according to Annex III of the Cartagena Protocol on Biosafety produced by the *Ad Hoc* Technical Expert Group (AHTEG) on Risk Assessment and Risk Management of the Convention on Biological Diversity).

(iii) The risk assessment and risk management plan submitted by the applicant.

GMAC took cognizance of the following as suggested within the AHTEG guidelines:

(i) That the risk assessment exercise be specific to the details of this particular application

(ii) That the risk assessment exercise be specific to the receiving environment in question, and

(iii) That any risk identified be compared against that posed by the unmodified organism.

A Risk Matrix was prepared based on an assessment mechanism developed by Office of the Gene Technology Regulator, Australia (OGTR, 2005). In applying this matrix, GMAC identified potential hazards, and then added a value/rank for the likelihood of each hazard as well as its consequences. The likelihood of each hazard occurring was evaluated qualitatively on a scale of 1 to 4, with 1 for 'highly unlikely', and 4 for 'highly likely'. The consequences of each hazard, if it were to occur, were then evaluated on a scale of 1 to 4, with 1 for 'marginal' and 4 to denote a 'major consequence'. A value was finally assigned for the overall risk from the identified potential hazard. The general formula: Overall Risk = Likelihood x Consequence was employed. GMAC also proposed risk management strategies for potential hazards, where appropriate. This methodology of assessment follows the procedure of Risk Assessment in Annex III of the Cartagena Protocol on Biosafety.

Although the applicant has applied for an approval to import for the purpose of feed and processing only, GMAC had conducted a thorough assessment and widened the scope of the risk assessment to include the purpose of food as well.

The Risk Assessment was conducted over a series of four (4) meetings. To start with, the possible pathways to risk/hazard arising from release of the products were identified and listed. The potential hazards were identified in three main areas:

(i) **Effects on human health**

Issues pertaining to acute toxicity of the proteins [flavonoid 3', 5' hydroxylase (F3'5'H), dihydroflavonol 4-reductase (DFR), and acetolactate synthase (ACL)] to human were examined.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, anti-nutritional properties, carcinogenicity, effect on organs (e.g. reproductive), compromised nutritional content, metabolites, increased mortality, horizontal gene transfer and animal product contamination were examined.

(iii) **Effects on the environment**

Issues pertaining to unintentional release and planting without permission, potential of gene to transfer to bacteria and harm on non-target organisms were examined.

Based on the above, a final list of 14 potential hazards was identified. Most of these hazards were rated as having an Overall Risk of 1 or “negligible”.

GMAC also took extra caution and further discussed pre-emptive mitigation procedures for hazards where the Overall Risk was estimated to be above the minimal, and also for a few hazards that required further evaluation and data acquisition. Some of these risks are expected to be managed effectively with the risk management strategies proposed (please refer to section IV of this document).

A potential hazard where the Overall Risk was found to be 2 or “low” is highlighted below along with the appropriate management strategy.

Planting of GM Carnation

Plants may be grown without permission by uninformed farmers /gardening enthusiasts from cuttings taken from the cut flowers and perpetuated through small scale cultivation. A small portion of the GM carnations sold as cut flowers may contain vegetative buds or shoots, which make it possible to propagate plants from cuttings. The stalk of cut flower has leaves with axillary bud in each. When the leaf is peeled off from the stalk it can strike root easily when placed in suitable rooting medium. The axillary bud will develop shoots and the rooted cutting can be grown into a plant. However, the viability of the axillary buds may be lost due to treatment to satisfy phytosanitary requirement and also due to cold shipment condition. There should be clear labeling that the flower is only for the ornamental purposes and not to be used as planting material.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 14 potential hazards identified and assessed, GMAC has drawn up the following terms and conditions to be included in the certificate of approval for the release of this product:

a) There shall be clear labeling of the product from importation down to all levels of marketing to state that it is only for the ornamental purposes in the form of amateur and professional flower arrangements, as gifts, home and business decoration and event decoration (weddings, functions, etc.) and is not to be used as planting material.

b) Should the approved person have any new or additional scientific information on adverse effect of GM Carnation, the National Biosafety Board authority shall be informed immediately.

V - Other Regulatory Considerations

a) Administrative regulatory procedures shall be arranged between the Department of Biosafety and the Malaysian Quarantine and Inspection Services (MAQIS) to impose post entry requirements involving the GM product.

b) Administrative regulatory procedures shall be arranged between the Department of Biosafety and relevant agencies to ensure clear labeling of the product is implemented.

VI - Identification of issues to be addressed for long term use release of this product

a) No additional issues have been identified that would be important during the assessment of an application for long term usage of this product.

b) Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the genetically modified carnation *Dianthus caryophyllus* L.

VII – Conclusion and Recommendation

GMAC has conducted a thorough evaluation of the application for approval for importation for release [sale/placing on the market for commercial use of a product of a Living Modified Organism (cut flowers- *Dianthus caryophyllus* L.) and has determined that the release of this product does not endanger biological diversity or human, animal and plant health. GMAC recommends that the proposed application for release be **APPROVED WITH TERMS AND CONDITIONS** as listed in section IV - Proposed Terms and Conditions for Certificate of Approval, subject to approval by other relevant agencies (e.g. Department of Agriculture).

VIII - Bibliography

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Appendix I

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN SPECIFIC RISK ASSESSMENT AREAS FOR THE APPROVAL FOR COMMERCIAL IMPORT OF CUT FLOWERS OF NOVEL FLOWER COLOUR VARIETIES OF GENETICALLY MODIFIED CARNATION (Dianthus caryophyllus L.)

Genetic Modification Advisory Committee (GMAC) members divided the task of looking up more information for the Risk Assessment matrix based on three broad categories. The scope of research aspects for each group is as listed below. Each sub-committee had a nominated leader to coordinate the work and report back to the main GMAC. The respective leader contacted the sub-committee members and discussed the work process with their members. The groupings of GMAC sub-committee members and their assigned tasks are as below:

1. **ENVIRONMENT**

   Effect on ecology of receiving environment due to unintentional release and planting (e.g. weediness, gene transfer to bacteria, accumulation of the PAT protein in the environment, cross pollination and toxic effects on non-target organisms)

   - **Assoc. Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) - Leader**
   - Dr. Sim Soon Liang (Sarawak Biodiversity Centre)
   - Dr. Martin Abraham (Malaysian Society of Marine Sciences)
   - Madam Atikah binti Abdul Kadir Jailani (Department of Agriculture)
   - Puan Jasbeer Kaur (Department of Chemistry)
   - Dr. Mohamed Mohd Salleh (Entomologist)

2. **HUMAN HEALTH**

   Effect on human health (e.g. acute toxicity of the novel protein, potential allergenicity, mutagenic/tetragenic/carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in the digestive tract, the pathogenic potential of donor microorganisms and nutritional equivalence)

   - **Madam T.S. Saraswathy (Institute of Medical Research) - Leader**
   - Dr. Tan Swee Lian (Academy of Science Malaysia)
   - Madam Hasimah Hafiz Ahmad (Malaysian Agricultural Research & Development Insitute)
   - Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
   - Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Insitute)
   - Dr. Rahizzan Issa (Institute of Medical Research)
   - Dr. Adiratna Mat Ripen (Institute of Medical Research)

3. ANIMAL HEALTH

Effect on animal health (e.g. allergenicity, toxicity, anti-nutritional properties, compromised nutritional content, metabolic breakdown of products, survivability, horizontal gene transfer and animal product contamination)

- **Prof. Dr Jothi Malar Panandam (Universiti Putra Malaysia) - Leader**
- Dr. Ahmad Parveez bin Hj Ghulam Kadir (Malaysian Palm Oil Board)
- Prof. Dr. Helen Nair (Academy of Science Malaysia)
- Dr. Kodi Isparan Kandasamy (Malaysian Biotechnology Corporation Sdn. Bhd.)