RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF DP 4114 MAIZE FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/40

APPLICANT: DU PONT (MALAYSIA) SDN. BHD.

DATE: 18 JULY 2018

I - Summary of Assessment Process

On 16 January 2018, the Genetic Modification Advisory Committee (GMAC, please refer to Appendix 1 for details of GMAC) received from the Department of Biosafety an application for the approval for importation for release [sale/placing on the market for direct use as food, feed and for processing (FFP)] of a product of a Living Modified Organism, insect-resistant and herbicide-tolerant DP 4114 maize. The application was filed by DuPont (Malaysia) Sdn. Bhd. (hereafter referred to as "the applicant"). After an initial review, GMAC requested for additional information from the applicant.

A public consultation for this application was conducted from 8 November 2017 to 8 December 2017 via advertisements in the local newspapers. Comments were received from Third World Network (TWN). GMAC took into considerations comments regarding potential non-target effects of the proteins as well as interactive effects between proteins, molecular characterization, safety assessment and glufosinate herbicide residue concerns in imported DP 4114 maize.

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 import and release products of a Living Modified Organism insect-resistant and herbicide-tolerant DP 4114 maize. The aim of the import and release is to supply or offer to supply for sale/placing on the market for direct use as food, feed and for processing (FFP). According to the applicant, DP 4114 maize has been registered in a number of countries for cultivation as well as for food, feed and for processing. DP 4114 maize is approved in Australia, New Zealand, Canada, Colombia, Japan, Korea, Mexico, South Africa, Taiwan and the United States and may be imported, stored and processed for use in food, animal feed and industrial products in the same way as other conventional, non-transgenic corn. The type of expected use of the products derived from DP 4114 maize in Malaysia will be the same as the expected usage for products derived from conventional corn. Potential users of products derived from DP 4114 such as grains are feed millers, food processors and other industrial use.

Information about DP4114 maize

The recipient or parental plant is *Zea mays* L. spp *mays* (field or sweet corn). Corn is extensively cultivated and has a long history of safe use as a food or feed. It is one of the largest cultivated crop in the world followed by wheat (*Triticum* sp.) and rice (*Oryza sativa* L.) in total global metric ton production (FAOSTAT, 2016).

DP4114 maize produces Cry1F, Cry34Ab1 and Cry35Ab1 proteins expressed by the *cry1F, cry34Ab1* and *cry35Ab1* genes derived from *B. thuringiensis* conferring the insect resistant trait and phosphinothricin acetyltransferase (PAT) protein expressed by the *pat* gene derived from *Streptomyces viridochromogenes* which confers glufosinate-ammonium herbicide tolerance.

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.

In conducting the risk assessment, 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.

The potential hazards were identified in three main areas:

(i) **Effects on human health**

Relevant scientific publications on the genetic modifications were reviewed for potential human health risks and issues pertaining to acute toxicity of novel protein / altering / interference of metabolic pathways, potential allergenicity of the novel protein, production of proteins or metabolites with mutagenic / teratogenic / carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in digestive tract, pathogenic potential of donor microorganisms, nutritional equivalence and anti-nutritional content.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, survivability and animal product contamination.

(iii) **Effects on the environment**

Issues pertaining to accidental release of seeds, unintentional release and planting, potential of transgenes being transferred to bacteria (soil bacteria, bacterial flora of animal gut), increased fitness, weediness and invasiveness, accumulation of the protein in the environment via feces from animals fed with the GM plant/grain, cross pollination leading to transfer of transgenes, toxic effect on non-target organisms and potential interaction of the multiple gene inserts resulting in undesirable effects on non-target organisms were examined.

Based on the above, a final list of 22 potential hazards was identified. All of these hazards were rated as having an Overall Risk of 1 or "negligible".

GMAC also took caution and discussed a few of the 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).

Some of the potential hazards are highlighted below along with the appropriate management strategies:

a) Accidental release of viable seeds

Seeds may be accidentally released during transportation. These seeds can germinate and grow along transportation routes and in areas surrounding storage and processing facilities (JBK Report Number No. 04, 2015). In the conducive warm and humid climate of Malaysia, there is a high likelihood of these volunteers maturing to the flowering and seed-setting stages. Although corn is not grown as an economic crop in Malaysia and there ~~is~~ are no wild relatives, some varieties of baby corn and sweet corn are cultivated on small scales. Thus, there is a likelihood of outcrossing of the GM corn with these cultivated corns.

Repeated cycles of spill-and-growth also increase the likelihood for the development of feral GM populations.

b) **Planting of seeds**

Plants may be grown by uninformed farmers and perpetuated through small scale cultivations. These GM corn may pollinate the non-GM baby corn and/or sweetcorn. There should also be clear labelling of the product to state that it is only for the purpose of food, feed and processing, and is not to be used as planting material.

c) **Compromised Nutritional Content**

Compositional analyses of the forage and grain samples showed no significant difference in nutritional composition between DP4114 maize and conventional corn.

However, applicant is required to update the National Biosafety Board immediately if additional tests indicates potential adverse effects or the possible presence of toxin or allergenic proteins.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 22 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 documentation by the exporter describing the product which shall be declared to the Royal Malaysian Customs.

b) There shall be clear labeling of the product from importation to all levels of marketing stating that it is only for the purpose of food, feed and processing and is not to be used as planting material.

c) Should the approved person receive any credible and/or scientifically proven information that indicates any adverse effect of DP 4114 maize, the National Biosafety Board shall be informed immediately.

d) Any spillage (during loading/unloading/transportation) shall be collected and cleaned up immediately.

e) Transportation of the consignment from the port of entry to any destination within the country shall be in secured and closed condition.

V - Other Regulatory Considerations

a) Administrative regulatory procedures shall be arranged between the Department of Biosafety, Royal Malaysian Customs Department and relevant agencies to ensure accurate declaration of product information and clear labeling of the product is implemented.

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

c) Administrative regulatory procedures shall be arranged between the Department of Biosafety and the Malaysian Quarantine and Inspection Services (MAQIS) and other competent agencies to impose post entry requirements for food safety compliance.

d) Administrative regulatory arrangements shall be carried out between the Department of Biosafety and the Department of Veterinary Services (DVS) so that any unanticipated adverse effects in animals caused by any consumption of the GM products shall be reported immediately.

e) Administrative regulatory arrangements shall be carried out by Food Safety and Quality of Ministry of Health to monitor compliance to the Food Regulations 1985 for labelling of GM food.

f) Administrative regulatory procedures shall be arranged between Department of Biosafety and Ministry of Health to ensure that herbicide residues in corn consignments are below the acceptable maximum residual level established. It is recommended that importers are required to provide certificate of analysis for herbicide residues prior to shipment.

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

a) Continuous monitoring is required from the approved person and any unanticipated adverse effect caused by the DP 4114 maize shall be reported to the National Biosafety Board.

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 direct use as food, feed and for processing (FFP)] of a product of a Living Modified Organism insect-resistant and herbicide-tolerant DP 4114 maize 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.

VIII – Bibliography

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Appendix I

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN SPECIFIC RISK ASSESSMENT AREAS FOR THE APPROVAL FOR RELEASE OF PRODUCTS OF DP 4114 MAIZE FOR SUPPLY OR OFFER TO SUPPLY

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

- **Assoc. Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (Leader)**
- Dato' Dr. Sim Soon Liang (Sarawak Biodiversity Centre)
- Dr. Kodi Isparan Kandasamy (Malaysian Bioeconomy Development Corporation Sdn. Bhd. - retired)
- Madam Atikah binti Abdul Kadir Jailani (Department of Agriculture - retired)
- Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Institute)
- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)

2. HUMAN HEALTH

- **Madam T.S. Saraswathy (Institute of Medical Research- retired) (Leader)**
- Dr. Rahizan Issa (Institute of Medical Research)
- Dr. Adiratna Mat Ripen (Institute of Medical Research)
- Madam Laila Rabaah Ahmad Suhaimi (Ministry of Health)
- Assoc. Prof. Dr. Chan Kok Gan (Universiti Malaya)
- Prof. Dr. Abd Rahman Milan (Universiti Malaysia Sabah)

3. ANIMAL HEALTH

- **Prof. Dr Jothi Malar Panandam (retired Universiti Putra Malaysia) (Leader)**
- Dr. Ahmad Parveez bin Hj Ghulam Kadir (Malaysian Palm Oil Board)
- Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
- Madam Elliza binti Mat Noor (Department of Chemistry Malaysia)
- Dr. Teo Tze Min (Entomological Society of Malaysia)