RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF DP73496 CANOLA FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/41

APPLICANT: DU PONT (MALAYSIA) SDN. BHD.

DATE: 4 APRIL 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, herbicide tolerant DP73496 canola. 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 consideration comments regarding possible presence of glyphosate residue in imported DP73496 canola products.

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 herbicide tolerant DP73496 canola. 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, DP73496 canola has been registered in a number of countries for cultivation as well as for food, feed and for processing. DP73496 canola is approved in United States of America, Canada, Japan, Mexico, Korea, South Africa, Taiwan, Australia and New Zealand 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 canola. The type of expected use of the products derived from DP73496 canola in Malaysia will be the same as the expected usage for products derived from conventional canola. Potential users of products derived from DP73496 canola such as seeds are feed millers, food processors and other industrial use.

Canola is primarily grown for its seed oil, which is used as a cooking oil and for other food and industrial applications. The seed meal which remains after oil extraction is used as animal feed. The term canola refers to varieties of *B. napus* that contain less than 2% erucic acid in the oil and less than 30 µmoles/g of glucosinolates in the seed meal, so are considered suitable for human and animal consumption.

Information about DP73496 canola

Genetically modified (GM) DP73496 canola is a new event that has been transformed with a single genetic construct containing the GAT4621 protein and which confers tolerance to the herbicidal active ingredient, glyphosate. The gene (*gat4621)* is derived from *B. licheniformis*, a common gram positive soil bacterium. The gene encodes a glyphosate N-acetyltransferase enzyme (GAT), which belongs to a family of N-acetyl transferases known as the GNAT superfamily. The GAT4621 protein, besides conferring tolerance to the herbicidal active ingredient glyphosate through acetylation of glyphosate into non-phytotoxic *N*-acetylglyphosate, is also known to acetylate certain free amino acids (L-aspartate, L-glutamate, glycine, L-serine, and L-threonine), resulting in the respective production of acetylated amino acids *N*-acetylaspartate, *N*-acetylglutamate, *N*-acetylglycine, *N*-acetylserine, and *N*-acetylethreonine (NAA, NAG, NAGly, NAS, and NAT, respectively). GAT proteins provide an alternative mechanism of glyphosate tolerance by acetylating the secondary amine of glyphosate to produce N-acetyl glyphosate. This is a larger molecule than glyphosate and is unable to bind effectively to the active site of EPSPS. The normal activity of EPSPS is not inhibited and consequently the herbicide is no longer phytotoxic

The *gat4621* was optimised for expression in plants by codon substitutions and one codon addition. The GAT4621 protein sequence is 75-78% identical and 90-91% similar to the sequences of each of the three native *B. licheniformis* GAT proteins.

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 also referred to the following recommendation 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 and toxic effect on non-target organisms were examined.

Based on the above, a final list of 21 potential hazards were identified. Most 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. Canola is not grown as an economic crop in Malaysia, thus, there is no issue of outcrossing.

b) Planting of seeds

Plants may be grown by uninformed farmers and perpetuated through small scale cultivations. There should also be clear labeling 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 seed samples showed no significant difference in nutritional composition between DP73496 canola and conventional canola.

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

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 21 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 DP73496 canola, the National Biosafety Board shall be informed immediately (for a review as in Section 18 of the Biosafety Act).

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 canola 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 DP73496 canola 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 herbicide tolerant DP73496 canola 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 RISK ASSESSMENT FOR THE APPROVAL FOR RELEASE OF PRODUCTS OF DP73496 CANOLA 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 which were environment, human health and animal health. The GMAC members involved in the risk assessment are as below:

- **Dr. Ahmad Parveez bin Hj Ghulam Kadir (Malaysian Palm Oil Board) (GMAC Chairman)**
- **Assoc. Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (Environment sub-committee leader)**
- **Madam T.S. Saraswathy (Previously from Institute for Medical Research) (Human health sub-committee leader)**
- **Prof. Dr Jothi Malar Panandam (Previously from Universiti Putra Malaysia) (Animal health sub-committee leader)**
- Dato' Dr. Sim Soon Liang (Academy of Sciences Malaysia)
- Dr. Rahizan binti Issa (Institute for Medical Research)
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- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)
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