RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

MON87769 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 600-2/1/9

APPLICANT: MONSANTO (MALAYSIA) SDN. BHD.

DATE: 13 JANUARY 2021

I - Summary of Assessment Process

On 18 August 2020, 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, MON87769 soybean that contains stearidonic acid (SDA), an alternative source of omega-3 fatty acid. The application was filed by Monsanto (Malaysia) Sdn. Bhd. (hereafter referred to as "the applicant"). After an initial review, GMAC decided to request for additional information from the applicant.

A public consultation for this application was conducted from 11 March 2020 to 24 April 2020 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Consumers Association of Penang (CAP). GMAC took into consideration the comments from CAP regarding the safety of MON87769 soybean, potential unintended molecular effects of MON87769 to human health, composition of the MON87769 soybean compared to the conventional soybean, as well as lack of long term toxicology studies.

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 MON87769 soybean. 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, MON87769 soybean has been registered in a number of countries for cultivation as well as for food, feed and for processing. MON87769 soybean is approved in the United States of America, Australia, New Zealand, Canada, China, European Union, Colombia, Indonesia, Japan, Korea, Mexico, Nigeria, Philippines, Singapore, Taiwan and Vietnam 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 soybean. The type of expected use of the products derived from MON87769 soybean in Malaysia will be the same as the expected usage for products derived from conventional soybean. This application does not cover environmental release and MON87769 may be imported to Malaysia as food or feed products or for further processing.

Information about MON 87769 soybean

The recipient or parental plant is *Glycine max* (soybean). Soybean has a long history of domestication and consumption by humans, and foods containing soybean-derived products are consumed by a large proportion of the global population (Liu, 2004).

MON87751 was developed using *Agrobacterium tumefaciens*-mediated transformation of the conventional soybean variety A3525 by inserting *Pj.D6D* and *Nc.Fad3* that encode the PjΔ6D and NcΔ15D proteins, respectively. These proteins catalyzes the synthesis of stearidonic acid (SDA), an eighteen carbon fatty acid found in fish and fish/algal oil products. SDA is an alternative source of omega 3 fatty acid. *Pj.D6D* is derived from *Primula juliae*, a member of a large genus of plants commonly known as Primrose. *Nc.Fad3* is derived from *Neurospora crassa*, commonly known as bread mold, a fungus that is ubiquitous in the environment.

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 recommendations 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, mutagenic / teratogenic / carcinogenic effect, reproductive toxicity, potential transfer of antibiotic resistance genes in digestive tract, pathogenic potential of donor microorganisms, nutritional equivalence and anti-nutritional components.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, anti-nutritional components, survivability, and animal product contamination.

(iii) **Effects on the environment**

Issues pertaining to accidental release of seeds, unintentional release and planting, weediness and invasiveness, increased fitness due to genetic modification, potential of transgenes being transferred to bacteria (soil bacteria, bacterial flora of animal gut), accumulation of the protein in the environment via feces from animals fed with the GM plant/grain and cross pollination leading to transfer of transgenes.

Based on the above, a final list of 21 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. Soybean 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) Nutritional equivalence

No major significant differences between MON87769 and conventional soybean were observed from proximate analysis, analysis of fibre, amino acids, key nutrients and anti-nutrients present in soybean. The composition of MON87769 is comparable to that of the conventional soybean control.

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.

d) Anti-nutritional content

MON87769 contains stearidonic acid (SDA), an alternate source of omega 3 fatty acid. The safety of SDA is based on its long-standing history of consumption from several marine and plant sources. Since there are concerns raised about the safety of increasing dietary intake of omega-3 polyunsaturated fats, the applicant should immediately notify the National Biosafety Board of any adverse effect of MON87769 soybean.

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 MON87769 soybean, 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 Act 1983 and Food Regulations 1985; and GM food labelling guidelines.

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

a) Continuous monitoring is required from the approved person and any unanticipated adverse effect caused by the MON87769 soybean 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, MON87751 soybean that contains stearidonic acid (SDA), 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 1

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN SPECIFIC RISK ASSESSMENT AREAS FOR THE APPROVAL FOR RELEASE OF PRODUCTS OF MON87769 SOYBEAN 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. Each sub-committee had a nominated leader to coordinate the work and report back to the main GMAC. The GMAC members involved in the risk assessment are as below:

- **Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (GMAC Chairman)**
- **Dr. Kodi Isparan Kandasamy (Industry Representative) (Environment sub-committee Leader)**
- **Madam T.S. Saraswathy (Institute of Medical Research - retired) (Human Health sub-committee Leader)**
- **Prof. Dr Jothi Malar Panandam (Universiti Putra Malaysia - retired) (Animal Health sub-committee Leader)**
- **Dr. Rahizan Issa (Institute of Medical Research - retired) (Notification Assessment sub-committee Leader)**
- Dato' Dr. Sim Soon Liang (Academy of Sciences Malaysia)
- Prof. Dr. Abd Rahman Milan (Universiti Malaysia Sabah - retired)
- Assoc. Prof. Dr. Chan Kok Gan (Universiti Malaya)
- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)
- Dr. Adiratna Mat Ripen (Institute of Medical Research)
- Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Institute)
- Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
- Dr. Saifullizam bin Abdul Kadir (Department of Veterinary Services)
- Dr. Teo Tze Min (Entomological Society of Malaysia)
- Dr. Mohd Hefni Rusli (Malaysian Palm Oil Board)
- Madam Shafini Abu Bakar (Ministry of Health)
- Madam Sabariah Kamis (Department of Agriculture)
- Mr. Harun bin Ahmad (Department of Chemistry Malaysia)