RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

MON 87701 SOYBEAN

FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/46

APPLICANT: MONSANTO (MALAYSIA) SDN. BHD.

DATE: 1 AUGUST 2019

I - Summary of Assessment Process

On 23 July 2019, 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 MON 87701 soybean. The application was filed by Monsanto (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 3 May 2019 to 1 June 2019 via advertisements in the local newspapers. Comments were received from Mr. Ung Eng Huan. GMAC took into considerations comments regarding his concern if used as a feed in aquaculture industry.

GMAC had one (1) meeting 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 Lepidoptera-protected soybean MON 87701. 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, MON 87701 soybean has been registered in a number of countries for cultivation as well as for food, feed and for processing. MON 87701 soybean is approved in Australia, Argentina, Canada, China, European Union, Indonesia, Japan, Korea, Mexico, New Zealand, Philippines, Russian Federation, Singapore, Taiwan, Vietnam and United States of America 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. According to the applicant, there will be no difference in use of MON 87701 soybean compared to conventional soybean already in the market.

A major food use of soybean is as purified oil, utilized in margarines, shortenings and cooking and salad oils. It is also used in various food products including tofu, simulated milk, soybean sprouts, soymilk film (yuba), soynuts, green vegetable soybean (e.g. edamame), whereas the fermented soyfood include soybean paste (miso), soybean sauce, natto and *tempeh*. Soybean also is the most commonly grown oilseed in the world. In 2008/09, approximately 211 MMT (millions metric tons) of harvested seed were produced, representing 56% of the world's oilseed production.

Other than that, soybean meal is used as a supplement in feed rations for livestock. Soybean meal is the most valuable component obtained from processing the soybean, accounting for roughly 50-75% of its overall value. By far, soybean meal is the world's most important protein feed, accounting for nearly 65% of world supplies. Industrial use of soybean ranges from the production of yeasts and antibodies to the manufacture of soaps and disinfectants. A sizeable amount is also used in pet food.

The applicant claims that soybean grain and forage derived from MON 87701 soybean are compositionally and nutritionally equivalent to those of the conventional soybeans. The type of expected use of the products derived from MON 87701 soybean in Malaysia will be the same as the expected usage for products derived from conventional soybean. Potential users of products derived from MON 87701 soybean such as grains are feed millers, food processors and other industrial use.

Information about MON 87701 soybean

The recipient or parental plant is *Glycine max* (L.) Merr. (soybean). Soybean is grown as a commercial crop in over 35 countries without any detrimental effect on the environment. Soybean is a largely self-pollinated species, although low levels of natural cross-pollination can occur. In studies with cultivated soybean where conditions have been optimized to ensure close proximity and flowering synchrony, natural cross-pollination generally has been found to be very low. Cultivated soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions grow as volunteers in the year following cultivation. If this should occur, volunteers do not compete well with the succeeding crop.

MON 87701 soybean produces the Cry1Ac insecticidal crystal (Cry) protein (&-endotoxin) derived from *Bacillus thuringiensis* (Bt) subsp. *kurstaki*. The Cry1Ac protein provides protection from feeding damage caused by targeted lepidopteran pests. The MON 87701 product concept is to reduce or replace current insecticide applications to control lepidopteran pests in tropical and subtropical soybean production regions where these insects cause significant plant damage and yield loss.

MON 87701 soybean may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

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, 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**

Relevant scientific publications on the genetic modifications were reviewed for potential animal health risks and issues pertaining to allergenicity, toxicity, survivability and animal product contamination.

(iii) **Effects on the environment**

Relevant scientific publications on the genetic modifications were reviewed for 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 was 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. 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) Compromised Nutritional Content

Compositional analyses of the seed and forage showed no significant difference in nutritional composition between MON 87701 soybean and conventional soybean.

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 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 MON 87701 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 conditions.

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 soybean consignments are below the 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 MON 87701 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, insect resistant MON 87701 soybean, 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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4. Farias D. F. et al. 2014. Evaluation of Cytotoxic and Antimicrobial Effects of Two *Bt* Cry Proteins on a GMO Safety Perspective. Research Article: BioMed Research International.

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6. OECD. 2000. Consensus Document on the Biology of Glycine max (L.) Merr. (Soybean). Series on Harmonisation of Regulatory Oversight in Biotechnology (Number 15).

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8. OECD. 2001b. Consensus Document on Compositional considerations for new varieties of soybean: Key food and feed nutrients and anti-nutrients. www.oecd.org/dataoecd/15/60/46815135.pdf.

9. OECD. 2001c. Consensus Document on Compositional considerations for new varieties of soybean: Key food and feed nutrients and anti-nutrients. www.oecd.org/dataoecd/15/60/46815135.pdf.

10. Paul, J.H., 1999. Microbial gene transfer: An ecological perspective. Journal of Molecular Microbiology and Biotechnology 1, 45-50.

Appendix I

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN SPECIFIC RISK ASSESSMENT AREAS FOR THE APPROVAL FOR RELEASE OF PRODUCTS OF MON87701 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) (Notification Assessment sub-committee Leader)**
- Dato' Dr. Sim Soon Liang (Sarawak Biodiversity Centre)
- Prof. Dr. Abd Rahman Milan (Universiti Malaysia Sabah)
- Assoc. Prof. Dr. Chan Kok Gan (Universiti Malaya)
- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)
- Assoc. Prof. Sharifah Syed Hassan (Monash University 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)
- Madam Atikah binti Abdul Kadir Jailani (Department of Agriculture - retired)
- Madam Norizan Jaafar (Department of Chemistry Malaysia)
- Madam Shafini Abu Bakar (Ministry of Health)