RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCT OF MON 89788 GLYPHOSATE TOLERANT SOYBEAN (RoundupReady2Yield™) FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/9

APPLICANT: MONSANTO MALAYSIA SDN. BHD.

DATE SUBMITTED: 23 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 24 April 2012 for an application for approval for importation for release [sale/placing on the market] of a product of a Living Modified Organism (Glyphosate Tolerant Soybean MON89788). The application was filed by Monsanto Malaysia Sdn. Bhd. (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 16 July 2012 to 14 August 2012 via advertisement in local newspapers. There were comments received from Consumer's Association of Penang (CAP) and Third World Network (TWN) regarding the traces of herbicide or herbicide residues in the food products. The potential health risk of glyphosate (Roundup) was highlighted by both CAP and TWN. GMAC has taken note of the information received from CAP and TWN on the toxicity associated with glyphosate and response from other regulatory authorities on this issue. GMAC assessment is based on the comparison of non GM and GM soy, and not based on glyphosate residues.

GMAC had five (5) 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 (Glyphosate Tolerant Soybean MON89788) 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, there will be no difference in use of product of Soybean MON89788 compared to conventional soybeans already on the market.

Soybean is grown as a commercial crop in over 35 countries. 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.

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 soyfoods 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 Soybean MON89788 are compositionally and nutritionally equivalent to those of the conventional soybeans.

Information about genetically modified Soybean MON89788

The recipient or parental plant is *Glycine max* (soybean). The soybean has been genetically modified to be tolerant to glyphosate, the active ingredient in Roundup® agricultural herbicides.

Soybean MON89788 (Roundup Ready 2 Yield™ Soybean) was produced by incorporation of the *cp4 epsps* coding sequence derived from the common soil bacterium *Agrobacterium sp*. strain CP4. The *cp4 epsps* coding sequence directs the production of the 5-enolpyruvyl shikimate-3-phosphate synthase (termed CP4 EPSPS) that is less sensitive to inhibition by glyphosate compared to plant endogenous EPSPS. The CP4 EPSPS renders MON89788 soybean tolerant to glyphosate, which is the active ingredient in Roundup® agricultural herbicides.

Soybean MON89788 may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.
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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 five (5) 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 novel proteins, potential allergenicity, mutagenic/teratogenic/carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in the digestive tract, the pathogenic potential of donor microorganisms and nutritional equivalence were examined.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, anti-nutritional properties, survivability and animal product contamination were examined.

(iii) **Effects on the environment**

Issues pertaining to unintentional release and planting, weediness, gene transfer to bacteria, accumulation of toxin, cross pollination and toxic effects on non-target organisms were examined.

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 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).

The potential risk of soybean MON89788 was evaluated in equivalence to, and above any potential risk reported for unmodified soy. However as a precautionary measure GMAC recommends that the proposed terms and conditions under section IV should be adhered to.

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 describing the product by the exporter which shall be declared to the Customs of the importing country.

b) There shall be clear labeling of the product from importation down to all levels of marketing to state 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 scientifically proven information that confirms any adverse effect of MON89788 soybean, the National Biosafety Board authority shall be informed immediately.

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

e) Transportation of the consignment from the port of entry to any destination within the country must be in closed containers.

f) A post-monitoring plan should be implemented, whereby the approved person shall submit a yearly report to the National Biosafety Board in compliance with procedures for handling any spillage.

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.

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

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

2. Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the MON89788 soybean.

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 (Soybean MON89788, glyphosate tolerant 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, subject to approval by other relevant agencies (e.g. Department of Agriculture).

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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 MON 89788 GLYPHOSATE TOLERANT SOYBEAN (RoundupReady2YieldTM) 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**

   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.)