RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCT OF A5547-127 Soybean

NBB REF NO: JBK(S) 602-1/1/14

APPLICANT: Bayer Co. (Malaysia) SDN. BHD.

DATE: 8 January 2014

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 21st October 2013 for an application for approval for release importation for release [sale/placing on the market] of a product of a Living Modified Organism (A5547-127 Soybean). The application was filed by Bayer Co. (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 1 to 30 November 2013 via advertisement in local newspapers. There were comments received from Third World Network (TWN) and Consumer's Association of Penang regarding the use of CaMV 35S promoter, toxicological assessment and herbicide residues. GMAC has taken note of the information received and deliberated on it.

GMAC had a 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 commercially import and release a product of a Living Modified Organism (A5547-127 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, there will be no difference in use of product of Soybean A5547-127 compared to conventional soybeans already on the market.

Soybean is grown primarily for the production of seed, has a multitude of uses in the food and industrial sectors, and represents one of the major sources of edible vegetable oil and of proteins for livestock feed use.

A major food use is as purified oil, utilized in margarines, shortenings and cooking and salad oils. It is also used in various food products including tofu, soya sauce, simulated milk and meat products. Soybean meal is used as a supplement in feed rations for livestock.

Industrial use of soybeans ranges from the production of yeasts and antibodies to the manufacture of soaps and disinfectants. Most soybean meal, 97%, is used in animal feed with 46% going to poultry, 32% to swine and 9% each going to dairy and beef cattle feed. A sizable amount is also used in pet food. Today, there are three major soybean commodity products: seeds, oil and meal.

The applicant reports that the Soybean A5547-127 products are substantially equivalent to conventional soybean and provide the same nutritional value as soybean currently being consumed by all age groups.

Information about genetically modified Glufosinate tolerant A5547-127 soybean

The recipient or parental plant is *Glycine max* (L) Merr (soybean). The A5547-127 soybean has been genetically modified to be tolerant to herbicide glufosinate ammonium. The A5547-127 soybean produced through transformation by the the particle acceleration method using vector PB2/35SAcK that contains a synthetic version of the phosphinothricin-N-acetyltransferase (*pat*) gene which was isolated from *Streptomyces viridochromogenes* strain Tu494.

Expression of the PAT enzyme is detected by spraying plantlets in axenic culture with glufosinate herbicide. Surviving plantlets are transferred to soil, grown in the greenhouse and then screened for glufosinate tolerance.

The herbicides bialaphos, phosphinothricin and its chemically synthesized form glufosinate ammonium are potent inhibitors of glutamine synthetase (GS), the enzyme that plays a central role in the assimilation of ammonia and in the regulation of the nitrogen metabolism in the plant. The *pat* gene from *Streptomyces viridochromogenes* codes for a PAT protein that metabolizes glufosinate to an inactive, acetylated derivative conferring the plant tolerant to glufosinate ammonium. The plants not carrying the transgene can be recognized and destroyed by using the herbicide at an early stage of plant development.

If A5547-127 soybean is approved to be imported into Malaysia, it will be used as feed, food ingredients for processing or packaging or as finished products ready for distribution, but not for planting.

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, 2009). 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 three meetings and email consultations among GMAC members. 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, modifications resulting in production of proteins or metabolites with 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, compromised nutritional content, effect on production performance, histopathological parameters, survivability, animal product contamination were examined and horizontal gene transfer.

(iii) **Effects on the environment**

Issues pertaining to accidental spillage of seeds and release during handling and transportation, unintentional release and planting, weediness, horizontal transfer of transgenes, accumulation of toxin, cross pollination and toxic effects on non-target organisms were examined.

Based on the above, a final list of 26 potential hazards was identified. All of these hazards were rated as having an Overall Risk of 1 or “negligible”.

Accidental release of viable seeds

Seeds may be accidentally released during transportation and these spilled seeds may germinate and become established in the ecosystem. However, soybean generally does not survive well without human intervention and it is an annual plant. Outcrossing with any locally cultivated soybean or wild relative of soybean is unlikely as soybean is not grown as an economic crop in Malaysia and there is no wild relative. As spillage of seed during transportation is likely, it is proposed that a post monitoring plan should be implemented and any spillage incident should be managed.

a) Planting of seeds

Plants may be grown through the ignorance of 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.

b) Compromised Nutritional Content

Soybean A5547-127 is nutritionally equivalent to non-GM counterparts (Oberdoerfer, R. 2013 M-360323-02-1).

The potential risk of A5547-127 soybean 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 26 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 or quarantine and inspection authority 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 A5547-127 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.

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, Department of Agriculture 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, the Department of Veterinary Services (DVS) and Department of Fisheries (DOF) so that any unanticipated adverse effects in animals caused by any consumption of the GM products shall be reported immediately.

e) Administrative regulatory procedures shall be arranged between Department of Biosafety and Ministry of Health to ensure that glufosinate residues in A5547-127 soybean consignments are below minimum residual level (2 mg/kg) established by CODEX Alimentarius.

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

Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the A5547-127 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 (Glufosinate tolerant A5547-127 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.

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 TC1507 CORN 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)
   - Dr. Tan Swee Lian (Academy of Science Malaysia)
   - Dr. Mohamed Mohd Salleh (previously Malaysian Agricultural Research & Development Institute)

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. Norwati Muhammad (Forest Research Insitute Malaysia)
   - Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Institute)
   - Dr. Rahizzan Issa (Institute of Medical Research)
   - Mr. Jamal Khair b Hashim (Ministry of Health)
   - 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)
- Dr. Fuzina Nor Hussein (Universiti Putra Malaysia)