RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCT FG72 (GLYPHOSATE AND ISOXAFLUTOLE TOLERANT) SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY

NBB REF. NO.: JBK(S) 602-1/1/16

APPLICANT: BAYER CO. (MALAYSIA) SDN. BHD.

DATE: 7 OCTOBER 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 24 January 2014 for an application for approval for importation for release [sale/placing on the market] of a product of a Living Modified Organism (Glyphosate and Isoxaflutole Tolerant Soybean FG72). 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 18 February 2014 to 19 March 2014 via advertisements in local newspapers. There were comments received from Third World Network (TWN) regarding the herbicide residues in the food products, altered metabolites of such residues, toxic metabolites, contaminants or other substances that may be relevant to human health as the CODEX Guideline recommended. The characterization and analysis of the transformation event producing FG72 was highlighted by TWN.

GMAC assessment is based on the comparison of non GM and GM soy. GMAC has also taken note of the information received from TWN on the toxicity associated with glyphosate and isoxaflutole and response from other regulatory authorities on this issue and has highlighted these concerns with recommendations..

GMAC had six 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 and Isoxaflutole Tolerant Soybean FG72). 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 FG72 compared to conventional soybeans already on the market. Soybean FG72 may enter Malaysia as grain, food ingredients for processing or packaging or as finished products ready for distribution, or as feed meal for animals.

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 FG72 are compositionally and nutritionally equivalent to those of the conventional soybeans.

Information about genetically modified Soybean FG72

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

FG72 soybean was developed through a specific genetic modification to allow for the use of isoxaflutole and glyphosate herbicides as weed control options in soybean crops. The *hppdPf W336* gene which encodes the modified 4-hydroxyphenylpyruvate dioxygenase (HPPD W336) conferring tolerance to isoxaflutole and *2mepsps* gene which encodes a double mutant 5-enolpyruvylshikimate 3-phosphate synthase (2mEPSPS) conferring tolerance to glyphosate were cloned from *Pseudomonas fluorescens* and *Zea mays* (corn), respectively.

Details of the parent organism

The recipient or parental plant is *Glycine max* (L) Merr. (soybean). Soybean is widely cultivated and has a long history of safe use for consumption as food and feed. The crop is grown primarily for the production of beans, 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. Historical and geographical evidence suggest that soybeans were first domesticated in eastern China between the 17th and 11th century B.C.

Today soybean is grown as a commercial crop in over 35 countries without any detrimental effect on the environment. The soybean plant is not weedy in character. Soybean is a largely self-pollinated species and studies have found natural cross-pollination 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.

The major soybean commodity products are seeds, oil, and meal. Whole soybeans are utilized to produce soy sprouts, baked soybeans, roasted soybeans, full fat soy flour and the traditional soy foods (miso, soy milk, soy sauce, and tofu). In addition to whole oil used for human consumption, refined soybean oil has many other technical and industrial applications.

Glycerol, fatty acids, sterols and lecithin are all derived from soybean oil. Soy protein isolate is used as a source of amino acids in the production of infant food formula and other food products. Soybean meal is rich in essential amino acids, particularly lysine and tryptophan, which are required supplements in animal diets for optimum growth and health. Soybean meal is used in diets for poultry, swine, dairy cattle, beef cattle and pets.

Legumes, and therefore also soybeans, possess several anti-nutritional factors such as phytic acid, protease inhibitors, lectins (hemagglutinins) and the oligosaccharides stachyose and raffinose. However, processing steps, including heating, inactivate anti-nutrient factors present in raw soya beans.

Details of the donor organisms

Characteristics of *Pseudomonas fluorescens*

Pseudomonas fluorescens has a long history of safe use in a wide variety of beneficial applications in agriculture, human health and bio-remediation. *P. fluorescens* is used as biopesticide on certain crops and fruits to prevent the growth of frost-forming bacterial on leaves and blossoms. It is also used as seed treatment agent for damping off diseases caused by fungi and nematodes. Due to metabolic diversity, it may be used in bioremediation applications because of it being able to degrade a variety of compounds. *P. fluorescens* strains are generally classified as non-pathogenic bacteria or non-opportunistic pathogen in immune-compromised patients in several national classifications for microorganisms. The virulence of *P. fluorescens* is low due to its inability to multiply rapidly at body temperatures and to compete with defense mechanisms of the host.

Modification method

The soybean line FG72 was produced by means of direct gene transfer with purified *Sal*I fragment from plasmid pSF10 into soybean line Jack. The plasmid pSF10 contains the *hppdPf W336* gene cassette encoding the 4-hydroxyphenylpyruvate dioxygenase of *Pseudomonas fluorescens* and *2mepsps* gene cassette coding for the double-mutant 5-enolpyruvylshikimate-3-phosphate synthase of *Zea mays*. No intermediary host was used during the genetic modification. No antibiotic resistance marker gene was used in the transformation process. Instead, the *hppdPf W336* and *2mepsps* genes that confer tolerance to the herbicides isoxaflutole and glyphosate, respectively, were used as selectable marker genes.

Characterization of the modification

Southern blot and sequence analyses of genomic DNA from FG72 soybean demonstrated that the transgenic event contains two copies of the transferred DNA of plasmid pSF10 integrated in recipient chromosomal DNA. The complete insert DNA of FG72 soybean was sequenced. Using bioinformatics analysis, no relevant known functional genes interrupted upon transformation could be identified.

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.

The Risk Assessment was conducted over a series of six 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, nutritional equivalence and effect of herbicide residues were examined.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, acute and chronic 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 and bacterial flora in the gut of animals, accumulation of protein in the environment, cross pollination and toxic effects on non-target organisms were examined.

Based on the above, a final list of 23 potential hazards was identified with 18 of these hazards rated as having an Overall Risk of 1 or "negligible", 1 hazard with an Overall Risk of 2 (with one risk estimate being "moderate" and "negligible") and 4 hazards with an Overall Risk of 3 but with a "low" risk estimate.

a) 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.

b) 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.

c) Compromised Nutritional Content

The potential risk of soybean FG72 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.

d) Effect of Soybean FG72 as livestock feed

Data on feeding studies provided by applicant sufficiently demonstrated no potential safety concern for approval of soybean FG72. Since soybean is the major protein source in animal feed, feeding studies on livestock are recommended.

e) Effects of herbicide residues on human and animal health

Residual effects of the isoxaflutole in the human has not been established. Safe use of isoxaflutole and maximum residual limits (MRL) are still under evaluation by *Codex Alimentarius*. Whole soybean and processed fractions (meal) are used as major protein source in animal feed (poultry, swine, dairy/beef cattle, fish, shrimp) as well as in pet food. As a precautionary measure GMAC recommends that all soybean import should be tested for isoxaflutole residues.

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 FG72 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 23 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 Royal Malaysian Customs.

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 credible and/or scientifically proven information that indicates any adverse effect of soybean FG72, the National Biosafety Board authority shall be informed immediately. Feeding studies on livestock are recommended and data from these studies should be provided to the National Biosafety Board.

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 a 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 procedures shall be arranged between Department of Biosafety and Ministry of Health to ensure that isoxaflutole and glyphosate residues in FG72 soybean consignments are below the maximum residual level established. It is recommended that importers are required to provide certificate of analysis for isoxaflutole and glyphosate residues prior to shipment

e) 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.

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 FG72, glyphosate and isoxaflutole 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 OF FG72 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. 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)
   - Assoc. Prof. Dr. Choong Chee Yen (University of Kebangsaan Malaysia)

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. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Insitute)
   - Dr. Rahizzan Issa (Institute of Medical Research)
   - Mr. Jamal Khair b Hashim (Ministry of Health)
   - Dr. Adiratna Mat Ripen (Institute of Medical Research)
   - Madam Laila Rabaah Ahmad Suhaimi (Ministry of Health)
   - Dr. Chan Kok Gan (University of Malaya)

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 (University of Putra Malaysia) (Leader)**
- Dr. Ahmad Parveez bin Hj Ghulam Kadir (Malaysian Palm Oil Board)
- Dr. Kodi Isparan Kandasamy (Malaysian Biotechnology Corporation Sdn Bhd)
- Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
- Assoc. Prof. Dr. Zunita Zakaria (University of Putra Malaysia)
- Dr. Noor Zaleha binti Awang Saleh (ex-Department of Chemistry)