RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF BT11 CORN FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/6

APPLICANT:SYNGENTA CROP PROTECTION SDN. BHD.

DATE SUBMITTED:10 AUGUST 2011

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 22 August 2011 for an 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 and herbicide-tolerant Bt11 corn). The application was filed by Syngenta Crop Protection 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 provided by the applicant as requested.

A public consultation for this application was conducted from 13 December 2011 to 12 January 2012 via advertisements in the local newspapers. No technical and scientific issues were raised through the Public Consultation for this application regarding the release.

GMAC had five 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 (insect-resistant and herbicide-tolerant Bt11 corn). 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, Bt11 corn is grown in a number of countries, e.g. United States, Canada, Argentina, Philippines, Brazil and South Africa, and may enter Malaysia as a food ingredient for processing and packaging or as finished products ready for distribution, or as feed meal or pellets for animals. Furthermore, foodstuffs derived from Bt11 corn kernel-based ingredients such as oil, high fructose corn syrup and starch products and may include canned or frozen corn, flour, breakfast cereals, snack foods, bakery products, confectionery and food coatings, and have been in international commerce since the cultivar was first approved in 1996.

Information about Bt11 corn

The recipient or parental plant is *Zea mays* L.spp *mays* (field or sweet corn). Corn is one of the world's leading cereal crops, ranked after wheat and rice, and is grown in over 25 countries. Corn covers about 140 million ha in the world and this plant has no detrimental effect on the environment. Moreover, corn has no wild relatives in Asia; therefore, it cannot hybridize with any other species in Asia.

Bt11 corn has been genetically modified to be protected against feeding damage caused by the larvae of certain insect pest species, mainly the European corn borer (*Ostrinia nubilalis*), through the expression of an insecticidal protein in the plant.

Bt11 corn contains two novel genes. The first, *cry1Ab*, derived from the common soil bacterium *Bacillus thuringiensis* var *kurstaki,* encodes the insecticidal Cry1Ab (Btk) protein. This crystal protein protects the plant from insect damage. When eaten by the insect pests, the *Btk* protein is broken down by digestive enzymes in the larva's alkaline intestine, generating a shorter protein that binds to the wall of the intestine. This damages the cell membrane, making it leaky, and stops the feeding of the larva in its tracks.

The second gene, *pat*, derived from the soil bacterium *Streptomyces viridochromogenes,* is present as a selectable marker and encodes the phosphinotrichin acetyl transferase (PAT) protein that gives the plant tolerance to glufosinate ammonium, an active ingredient in herbicides. Glufosinate ammonium inhibits glutamine synthetase in plants, resulting in an accumulation of ammonia in the plant tissues leading to their death.

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.

The Risk Assessment was conducted over a series of five 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 the donor microorganisms and nutritional equivalence were examined.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, anti-nutritional properties, compromised nutritional content, metabolic breakdown of products, survivability, horizontal gene transfer 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 the Bt toxin, cross-pollination and toxic effects on non-target organisms were examined.

Based on the above, a final list of 23 potential hazards was identified. Most 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).

A few potential hazards where the Overall Risk was found to be 2 or “low” are highlighted below along with the appropriate management strategies.

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. Spillage of seed is likely, however, it is unlikely that these spilled seeds will germinate and become established in the ecosystem as the post-harvest drying process of forcing hot air through the grains (seeds) would affect the viability of the seeds. Furthermore, corn generally does not survive well without human cultivation. It is an annual plant. Outcrossing with any locally cultivated corn or wild relative of corn is unlikely as corn is not grown as an economic crop in Malaysia and there is no wild relative. However, as some baby corn and sweet corn are grown in this country, there is a likelihood of outcrossing of the GM corn with these. 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 following GMAC-approved SOP.

b) Planting of seeds

Plants may be grown through the ignorance of uninformed farmers and perpetuated through small scale cultivations. It is noted that the post-harvest drying process of forcing hot air through the grains, affects the viability of the corn grains. Corn is not a major crop in Malaysia. Nevertheless, there could be persistence of GM crop plants in the environment, albeit at low level. These GM corn may pollinate the non-GM baby corn and/or sweet corn. It is proposed that a post monitoring plan should be implemented and any spillage incident should be managed following GMAC-approved SOP. 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) Effect on Animal Mortality

Studies show no significant differences in the percentage survival at any age between broiler birds fed GM and conventional corn. However, applicant is required to update NBB immediately regarding any reported adverse effects.

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) Any spillage (during loading/unloading) shall be collected and cleaned up immediately with strict adherence to the GMAC-approved SOP.

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

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

d) Should the approved person receive any scientifically proven information that confirms any adverse effect of Bt11 corn, the National Biosafety Board authority shall be informed immediately.

e) There shall be clear labeling of the product from importation down 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.

V - Other Regulatory Considerations

a) Administrative regulatory arrangement shall be carried out 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.

b) Administrative regulatory arrangement shall be carried out between the Department of Biosafety and the Department of Veterinary Services so that any unanticipated adverse effects in animals caused by any consumption of the GM products shall be reported immediately.

c) Administrative regulatory arrangements shall be carried out between the Department of Biosafety and relevant agencies to ensure clear labeling of the product is implemented

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

No additional issues have been identified that would be important during the assessment of an application for the long-term usage of this product. Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the Bt11 corn.

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 feed and for processing (FFP)) of a product of a Living Modified Organism (insect-resistant and herbicide-tolerant Bt11 corn) 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.

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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 BT11 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)

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. S. Ravigadevi (Malaysian Palm Oil Board)
   - Madam Shamsinar binti Abdul Talib (Ministry of Health)
   - Dr. Chow Keng See (Malaysian Rubber Board)
   - Prof. Dr Son Radu (Universiti Putra Malaysia)

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)
- Dr. Tan Swee Lian (Academy of Science Malaysia)
- Prof. Dr. Helen Nair (Academy of Science Malaysia)