RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF MON 89034 FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/18

APPLICANT: MONSANTO MALAYSIA SDN. BHD.

DATE SUBMITTED: 9 APRIL 2015

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 27 August 2014 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 (lepidopteran insect-resistant MON 89034 corn). The application was filed by Monsanto Malaysia Sdn. Bhd. (hereafter referred to as "the applicant").

A public consultation for this application was conducted from 30 Sept 2014 to 30 Oct 2014 via advertisements in the local newspapers. A few technical and scientific issues were raised through the Public Consultation for this application regarding the release. These issues have been considered by GMAC in the risk assessment.

GMAC had four 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 MON 89034 (lepidopteran insect-resistant 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, MON 89034 has been registered in a number of countries for cultivation as well as for importation for direct use an feed and for processing, e.g. United States, Canada, Argentina, Philippines, Brazil and South Africa, 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 corn. The type of expected use of the products derived from MON 89034 corn in Malaysia will be the same as the expected usage for products derived from conventional corn. Potential users of products derived from MON 89034 corn such as grains are feed millers, food processors and other industrial use.

Information about MON 89034 corn

The recipient or parental plant is *Zea mays* L.spp *mays* (field or sweet corn). Corn is extensively cultivated and has a long history of safe use as a food or feed. It is the largest cultivated crop in the world followed by wheat (*Triticum* sp.) and rice (*Oryza sativa* L.) in total global metric ton production (FAOSTAT, 2009).

MON 89034 is a corn product that is protected from damage caused by larval feeding of lepidopteran insect pests. MON 89034 produces the *Bacillus thuringiensis* (*B.t.*) Cry1A.105 and Cry2Ab2 proteins that are active against lepidopteran insects. MON 89034 is a second-generation product that will effectively address a corn grower's need to control a wide spectrum of lepidopteran pests. The combination of the Cry1A.105 and Cry2Ab2 insecticidal proteins in a single plant provides excellent control of lepidopteran insect pests and offers an effective insect resistance management tool.

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 four 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**

Relevant scientific publications on MON 89034 corn 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 and nutritional equivalence.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, compromised nutritional content, anti-nutritional content and performance.

(iii) **Effects on the environment**

Issues pertaining to unintentional release and planting, potential of transgenes being transferred to bacteria, weediness, cross pollination leading to transfer of transgenes, toxic effect on non-target organisms were examined.

Based on the above, a final list of 33 potential hazards was identified. Most of these hazards were rated as having an Overall Risk of 1 or "negligible". The safety assessment reports were based on studies conducted by independent experts on the molecular characterization, biochemical, toxicological, nutritional, and allergenicity data of the introduced proteins, in accordance with guidelines from World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the Codex Alimentarius Commission.

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.

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 sweetcorn. It is proposed that a post monitoring plan should be implemented and any spillage incident should be managed. 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

Applicant concludes that MON 89034 is substantially equivalent to conventional corn, and this conclusion extends to the foods and feeds produced from MON 89034. The levels of the various analytes in MON 89034 were compared to those of conventional control corn, which has the background genetics representative of MON 89034 but does not contain the *cry1A.105* and *cry2Ab2* genes or produce the Cry1A.105 and Cry2Ab2 proteins. Additionally, the grain and forage from 15 conventional corn hybrids produced in the same field trials alongside MON 89034 and control corn, were also subjected to compositional analyses. Values derived from these conventional hybrids were used as references to generate a 99% tolerance interval for each of the analytes for conventional corn. MON 89034 was found to be compositionally equivalent to conventional corn, and thus is considered as nutritious as conventional corn for food and feed uses.

However, applicant is required to update NBB immediately if additional tests indicates potential adverse effects or the possible presence of toxin or allergen proteins.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 33 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) Any spillage (during loading/unloading) shall be collected and cleaned up immediately.

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

d) A post monitoring plan for reporting adverse health effects in human and animals shall be implemented.

e) Should the approved person receive any scientifically proven information/evidences that confirms any adverse effect of MON 89034 corn, the National Biosafety Board authority shall be informed immediately for a review (as in Section 18 of the Biosafety Act).

f) 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 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

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

b) Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the MON 89034 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 (lepidopteran insect-resistant MON 89034 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 MON 89034 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. potential of transgenes being transferred to bacteria, weediness, cross pollination leading to transfer of transgenes, toxic effect on non-target organisms).

- **Assoc. Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (Leader)**
- Dato' Dr. Sim Soon Liang (Sarawak Biodiversity Centre)
- Dr. Kodi Isparan Kandasamy (Malaysian Biotechnology Corporation Sdn. Bhd.)
- Madam Atikah binti Abdul Kadir Jailani (Department of Agriculture)
- Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Insitute)
- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)

2. HUMAN HEALTH

Effect on human health (e.g. 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 and nutritional equivalence).

- **Madam T.S. Saraswathy (Institute of Medical Research)(Leader)**
- Dr. Rahizzan Issa (Institute of Medical Research)
- Dr. Adiratna Mat Ripen (Institute of Medical Research)
- Madam Laila Rabaah Ahmad Suhaimi (Ministry of Health)

- Dr. Chan Kok Gan (Universiti Malaya)
- Prof. Dr. Abd Rahman Milan (Universiti Malaysia Sabah)

3. ANIMAL HEALTH

Effect on animal health (e.g. allergenicity, toxicity, compromised nutritional content, anti-nutritional content and performance).

- **Prof. Dr Jothi Malar Panandam (Universiti Putra Malaysia) (Leader)**
- Dr. Ahmad Parveez bin Hj Ghulam Kadir (Malaysian Palm Oil Board)
- Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
- Assoc. Prof. Dr. Zunita Zakaria (Universiti Putra Malaysia)
- Dr. Noor Zaleha binti Awang Saleh (ex-Department of Chemistry)
- Dr. Teo Tze Min (Entomological Society of Malaysia)