RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

MON95379 MAIZE FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 600-2/1/25

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

DATE: 29 SEPTEMBER 2022

I - Summary of Assessment Process

On 14 July 2022, the Genetic Modification Advisory Committee (GMAC, please refer to Appendix 1 for details of GMAC) received from the Department of Biosafety an application for the 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 MON95379 maize. The application was filed by Bayer Co. (Malaysia) Sdn. Bhd. (hereafter referred to as "the applicant"). After an initial review, GMAC requested for additional information from the applicant.

A public consultation for this application was conducted from 4 April 2022 to 5 May 2022 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Consumers Association of Penang (CAP). GMAC took into consideration the comments that were relevant to the risk assessment including safety of the new Bt toxin used in the genetic modification and the technology used, risk of unintended effects and possible contamination of farmer seed varieties (including organic farming) through spillage.

GMAC had four (4) 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 MON95379 maize. 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, MON95379 maize has been fully approved in Brazil (2020) for food, feed and environment and in Canada for food, feed and environment (2020). MON 95379 maize may be imported into Malaysia as food and feed products or as grain for further processing. The application does not cover deliberate environmental release in Malaysia.

Information about MON95379 maize

MON95379 was developed to provide growers an additional tool for controlling targeted pests. Insect resistant maize MON95379 was developed through *Agrobacterium tumefaciens* mediated transformation method to produce two insecticidal proteins, Cry1B.868 and Cry1Da_7, which protect against feeding damage caused by targeted lepidopteran insect pests. The larval feeding behavior of these species typically limits the efficacy of synthetic insecticides by creating additional difficulties for the sprayed active ingredients to reach the insects (Burtet et al., 2017; Grimi et al., 2018; Reay-Jones, 2019). MON95379 produces two insecticidal proteins, Cry1B.868 and Cry1Da_7, which protect against feeding damage caused by these lepidopteran pests.

Cry1B.868 is a chimeric protein comprised of domains I and II from Cry1Be (*Bacillus thuringiensis, Bt*), domain III from Cry1Ca (*Bt* subsp. *aizawai*) and C-terminal protoxin domain from Cry1Ab (*Bt* subsp*. kurstaki*). Cry1Da_7 is a modified Cry1Da protein derived from *Bt* subsp. *aizawai*. The Cre/*lox* recombination system was used for removal of *cp4 epsps* selectable marker during the development of "marker-free" final event MON95379.

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 also referred to the following recommendations 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

(iii) That any risk identified be compared against that posed by the unmodified organism

In conducting the risk assessment, 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 potential hazards were identified in three main areas:

(i) **Effects on human health**

Relevant scientific publications on the genetic modifications 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,

reproductive toxicity, potential transfer of antibiotic resistance genes in digestive tract, pathogenic potential of donor microorganisms, nutritional equivalence and anti-nutritional properties.

(ii) **Effects on animal health**

Relevant scientific publications on the genetic modifications were reviewed for potential animal health risks and issues pertaining to allergenicity, toxicity, anti-nutritional, survivability and animal product contamination.

(iii) **Effects on the environment**

Relevant scientific publications on the genetic modifications were reviewed for potential environmental risks and issues pertaining to accidental release of seeds, unintentional release and planting, potential of transgenes being transferred to bacteria (soil bacteria, bacterial flora of animal gut), increased fitness, weediness and invasiveness, accumulation of the protein in the environment via feces from animals fed with the GM plant/seed and cross pollination leading to transfer of transgenes.

Based on the above, a final list of 20 potential hazards were identified. Most of these hazards were rated as having an Overall Risk of 1 or "negligible" (please refer to the **Lampiran IIB*/Risk Matrix*** for details).

GMAC also took caution and discussed a few of the 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).

Some of the potential hazards are highlighted below along with the appropriate management strategies:

a) Accidental release of viable seeds

Seeds may be accidentally released during transportation. These seeds can germinate and grow along transportation routes and in areas surrounding storage and processing facilities (JBK Report Number No. 04, 2015). In the conducive warm and humid climate of Malaysia, there is a high likelihood of these volunteers maturing to the flowering and seed-setting stages. Although maize is not grown as an economic crop in Malaysia and there are no wild relatives, some varieties of baby corn and sweet corn are cultivated in small scales. Thus, there is a likelihood of outcrossing of the GM maize with these cultivated maize. Repeated cycles of spill-and-growth also increase the likelihood for the development of feral GM populations.

Any spillage shall be collected and cleaned up immediately. Transportation of the consignment must be in secured and closed conditions.

b) Planting of seeds

Plants may be grown by uninformed farmers and perpetuated through small scale cultivations. These GM maize may pollinate the non-GM baby corn and/or sweetcorn. 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) Increased fitness of plant leading to weediness and invasiveness

Plants may have increased fitness due to the genetic modification and develop characteristics of weediness and become invasive. However, maize is highly domesticated and its weediness/invasiveness is effectively limited by multiple characteristics, including poor seed dispersal mechanisms and poor competitive ability. Gene flow to native species is unlikely because there are no native Malaysian species sexually compatible to maize.

d) Nutritional equivalence

No major significant differences between MON95379 maize and conventional maize were observed from proximate analysis, analysis of fibre, amino acids, key nutrients and anti-nutrients present in maize. The composition of MON95379 maize is comparable to that of the conventional maize control.

However, applicant is required to update the National Biosafety Board immediately if additional tests indicate potential adverse effects or the possible presence of toxin or allergenic proteins.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 20 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 by the exporter describing the product which shall be declared to the Royal Malaysian Customs.

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

c) Should the approved person receive any credible and/or scientifically proven information that indicates any adverse effect of MON95379 maize, the National Biosafety Board shall be informed immediately.

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

e) Transportation of the consignment from the port of entry to any destination within the country shall be in secured and closed conditions.

f) Any import or release of products derived from any new genetically modified lines bred using MON95379 maize will require a separate approval from the National Biosafety Board.

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.

e) Administrative regulatory arrangements shall be carried out by Food Safety and Quality of Ministry of Health to monitor compliance to the Food Act 1983 and Food Regulations 1985.

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

a) Continuous monitoring is required from the approved person and any unanticipated adverse effect caused by the MON95379 maize shall be reported to the National Biosafety Board.

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, insect resistant MON95379 maize, 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 1

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN SPECIFIC RISK ASSESSMENT AREAS FOR THE APPROVAL FOR RELEASE OF PRODUCTS OF MON95379 MAIZE 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 which were environment, human health and animal health. Each sub-committee had a nominated leader to coordinate the work and report back to the main GMAC. The GMAC members involved in the risk assessment are as below:

1. **Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (GMAC Chairman)**
2. **Dr. Kodi Isparan Kandasamy (Industry Representative) (Environment sub-committee Leader)**
3. **Madam T.S. Saraswathy (Institute of Medical Research - retired) (Human Health sub-committee Leader)**
4. **Prof. Dr Jothi Malar Panandam (Universiti Putra Malaysia - retired) (Animal Health sub-committee Leader)**
5. **Dr. Rahizan Issa (Institute of Medical Research - retired) (Notification Assessment sub-committee Leader)**
6. Dato' Dr. Sim Soon Liang (Academy of Sciences Malaysia)
7. Prof. Dr. Chan Kok Gan (Universiti Malaya)
8. Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)
9. Dr. Adiratna Mat Ripen (Institute of Medical Research)
10. Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Institute)
11. Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
12. Dr. Saifullizam bin Abdul Kadir (Department of Veterinary Services)
13. Dr. Teo Tze Min (Entomological Society of Malaysia)
14. Dr. Mohd Hefni Rusli (Malaysian Palm Oil Board)
15. Madam Shafini Abu Bakar (Ministry of Health)
16. Madam Sabariah Kamis (Department of Agriculture)
17. Mr. Harun bin Ahmad (Department of Chemistry Malaysia)
18. Assoc. Prof. Dr. Sharifah binti Syed Hassan (Monash University Malaysia)
19. Dr. Kumitaa Theva Das (Universiti Sains Malaysia)