RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

MON 95275 MAIZE FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/31

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

DATE: 30 APRIL 2025

I - Summary of Assessment Process

On 6 March 2025 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 MON 95275 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 15 August 2023 to 13 September 2023 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Malaysian Palm Oil Board (MPOB), Malaysia Food Sovereignty Forum (FKMM) and Pertubuhan Pelindung Khazanah Alam Malaysia (PEKA). GMAC took into consideration comments that were relevant to the risk assessment including safety assessment of the product, source and safety of the genes involved (pathogenicity of donor organism), spillage of the GMO grains during transportation, emergency response plan for unintentional release and labelling of the product.

GMAC had two (2) 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 95275 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, MON 95275 maize has been registered in a number of countries for cultivation as well as for food, feed and for processing. MON 95275 maize was first approved in 2023 in Brazil, United States of America, Australia, New Zealand and Philippines and in 2024 in Canada, Indonesia, Thailand and Taiwan and may be imported, stored and processed for use in food, animal feed and industrial products. The expected use of the products derived from MON 95275 maize in Malaysia will be the same as the expected usage for products derived from conventional maize. This application does not cover environmental release and MON 95275 maize may be imported to Malaysia as food or feed products or for further processing.

Information about MON 95275 maize

MON 95275 maize was developed to provide growers with new options for protection of maize against the feeding damage from targeted coleopteran pests, including western corn rootworm (WCR; *Diabrotica virgifera virgifera*), and northern corn rootworm (NCR; *Diabrotica barberi*). Insect resistant MON 95275 maize was developed through Agrobacterium-mediated DNA transfer and contains three gene cassettes, the DvSnf7.1 suppression cassette and the mpp75Aa1.1 and vpb4Da2 expression cassettes that express the DvSnf7.1 transcript and Mpp75Aa1.1 and Vpb4Da2 proteins respectively.

The Mpp75Aa1.1 insecticidal protein is derived from *Brevibacillus laterosporus* and the Vpb4Da21 insecticidal protein is derived from *Bacillus thuringiensis (Bt).* The DvSnf7.1 double-stranded RNA transcript from an inverted repeat sequence was designed to match the WCR Snf7 gene. The Mpp75Aa1.1 and Vpb4Da2 proteins combined with DvSnf7.1 RNA provide protection from feeding damage caused by targeted coleopteran insect pests.

The DNA sequence of the inverted repeat in MON 95275 is similar to that in MON 87411 which was granted food, feed, and processing (FFP) approval in 2020 in Malaysia (JBK (S) 600-2/1/2). The only difference between the full length DvSnf7.1 RNA expressed in MON 95275 and the full length DvSnf7 RNA expressed in MON 87411 is 5' UTR, which was optimized to increase *in planta* expression.

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, and

(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, 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, survivability, anti-nutritional properties 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/grain and cross pollination leading to transfer of transgenes.

Based on the above, a final list of **19** potential hazards was identified. Most of these hazards were rated as having an Overall Risk of 1 or "negligible".

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 corn 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 on small scales. Thus, there is a likelihood of outcrossing of the GM corn with these cultivated corns. Repeated cycles of spill-and-growth also increase the likelihood for the development of feral GM populations.

Any spillage (during loading/unloading) shall be collected and cleaned up immediately. Transportation of the consignment from the port of entry to any destination within the country 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 corn 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) Weediness

The possibility of plants grown unintentionally may develop characteristic of weediness and become invasive was considered. Maize is highly domesticated and its weediness/invasiveness is effectively limited by multiple characteristics, including poor seed dispersal mechanisms and poor competitive ability. Fundamental changes to such limiting characteristics, including competitive ability, would be required for it to become invasive or weedy. MON 95275 maize lacks plausible hypotheses under which they would cause such fundamental changes. MON 95275 maize does not exhibit characteristics that increase its fitness compared to conventional maize, and is highly unlikely to become weedy or invasive. There are no native Malaysian species sexually compatible to maize. Coleopteran-protected traits such as MON 95275 maize would have little or no impact on non-agricultural habitats that generally do not receive pesticide applications. Any MON 95275 maize that invades agricultural habitats could be easily controlled with mechanical cultivation and herbicides.

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.

Any spillage (during loading/unloading) shall be collected and cleaned up immediately.
Transportation of the consignment from the port of entry to any destination within the country must be in secured and closed conditions.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the **19** 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 MON 95275 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 MON 95275 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 long term use release of this product

a) Continuous monitoring is required from the approved person and any unanticipated adverse effect caused by the MON 95275 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 MON 95275 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.

VIII – Bibliography

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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 MON 95275 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. **Dr. Mohd Hefni Rusli (Malaysian Palm Oil Board) (GMAC Chairman)**
2. **Dr. Kumitaa Theva Das (Universiti Sains Malaysia) (Environment sub-committee Leader)**
3. **Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia - retired) (Human Health sub-committee Leader)**
4. **Dr. Teo Tze Min (Entomological Society of Malaysia) (Animal Health sub-committee Leader)**
5. **Dr. Adiratna Mat Ripen (Institute of Medical Research) (Notification Assessment sub-committee Leader)**
6. Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA)
7. Dr. Kodi Isparan Kandasamy (Industry Representative)
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