RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

DP915635 MAIZE FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/32

APPLICANT: CORTEVA AGRISCIENCE (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 and herbicide tolerant DP915635 maize. The application was filed by Corteva Agriscience (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 16 October 2023 to 15 November 2023 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Consumers Association Penang (CAP), Ministry of Science, Technology and Innovation (MOSTI), GEC-Community Sustainable Peatland Centre (GEC-CoSPeC), Sarawak Biodiversity Centre and Malaysian Palm Oil Board (MPOB). GMAC took into consideration comments that were relevant to the risk assessment including safety assessment of the novel proteins and product, exposure to glufosinate, use of genome editing technology, 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 insect resistant and herbicide tolerant DP915635 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, DP915635 maize has been registered in a number of countries for cultivation as well as for food, feed and for processing. DP915635 maize was first approved in 2021 for use as animal feed in Colombia then in Canada and Taiwan in 2022 followed by Australia, New Zealand, European Union, Indonesia, Japan, Korea, Mexico and the United States of America in 2024 and may be imported, stored and processed for use in food, animal feed and industrial products. The expected use of the products derived from DP915635 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 DP915635 maize may be imported to Malaysia as food or feed products or for further processing.

Information about DP915635 maize

DP915635 maize was developed through a two-step process to achieve a site-specific integration into the maize genome. The first step is the introduction of plasmids by microparticle bombardment, creating recombination sites at a specific location using transiently expressed CRISPR/Cas9. This is followed by the integration of the genes of interest, i.e. *pmi, mo-pat* and *ipd079ea* into the genome via Agrobacterium-mediated transformation.

DP915635 maize expresses the insecticidal iPD079Ea protein from the fern *Ophioglossum pendulum* which has a pore-forming mode of action against feeding larvae, making it resistant to Western corn rootworm (*Diabrotica virgifera*). The protein binds receptors in the insect's midgut which are different from the receptors that Bt toxins interact with, allowing the maize to overcome Bt-resistance in Coleoptera pests. It also expresses a modified phosphinothricin N-acetyltransferase (PAT) protein from the bacteria *Streptomyces viridochromogenes*, which confers tolerance to glufosinate by inactivating the herbicidal compound through acetylation. The PMI protein from *Escherichia coli* allows for the modified maize to use mannose as a carbon source and thus used as a selectable marker during transformation.

The PAT and PMI proteins are identical to the PAT and PMI proteins from several previously assessed maize events by GMAC and approved in Malaysia by the National Biosafety Board such as MIR 604 (2016), MIR 162 (2016), 5272 (2016), MON 87419 (2021), DP202216 (2022), MON87429 (2023) and MON95379 (2023).

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. DP915635 maize lacks plausible hypotheses under which they would cause such fundamental changes. DP915635 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 DP915635 maize would have little or no impact on non-agricultural habitats that generally do not receive pesticide applications. Any DP915635 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 DP915635 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 DP915635 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.

f) Administrative regulatory procedures shall be arranged between Department of Biosafety and Ministry of Health to ensure that herbicide residues in maize consignments are below the maximum residual level established.

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 DP915635 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 and herbicide tolerant DP915635 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.

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 DP915635 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)
8. Madam T.S. Saraswathy (Institute of Medical Research - retired)
9. Assoc. Prof. Dr. Sharifah binti Syed Hassan (Monash University Malaysia)
10. Dr Jothi Malar Panandam (Universiti Putra Malaysia - retired)
11. Dr. Rahizan Issa (Institute of Medical Research - retired)
12. Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Institute)
13. Madam Shafini Abu Bakar (Ministry of Health)
14. Madam Sabariah Kamis (Department of Agriculture)
15. Mr. Harun bin Ahmad (Department of Chemistry Sabah)
16. Dr. Sara Jane Chiu (Industry Representative)
17. Dr. Yuwana Podin (Universiti Malaysia Sarawak)
18. Prof. Dr. Chan Kok Gan (Universiti Malaya)