

**RISK ASSESSMENT REPORT
OF THE GENETIC MODIFICATION
ADVISORY COMMITTEE (GMAC)
FOR
AN APPLICATION FOR APPROVAL FOR
RELEASE OF PRODUCTS OF
MON87429 MAIZE FOR SUPPLY OR
OFFER TO SUPPLY**

**NBB REF NO: JBK(S) 600-2/1/24
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, dicamba, glufosinate, quizalofop and 2,4-dichlorophenoxyacetic acid tolerant MON 87429 maize with tissue-specific glyphosate tolerance. 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 14 February 2022 to 15 March 2022 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Consumers Association of Penang (CAP), Agro-Biotechnology Institute Malaysia (ABI), Malaysia Palm Oil Board (MPOB), Federation of Malaysian Consumers Associations (FOMCA), The Malaysian Agroecology Society for Sustainable Resource Intensification (SRI-Mas) and the Food Security and Sovereignty Forum (FKMM). GMAC took into consideration the comments that were relevant to the risk assessment including concern that four (4) genes were stacked to create the LMO, possible unintended changes in the genome, possible genetic contamination to conventional corn, possible higher level of survivability, use of the genetic manipulation technology per se, unintentional release and spillage and lack of information about this event, as it is relatively “new”.

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, dicamba, glufosinate, quizalofop and 2,4-dichlorophenoxyacetic acid tolerant MON87429 maize with tissue-specific glyphosate tolerance. 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). The earliest approval for MON87429 maize for food was in 2020 by Australia and New Zealand followed by Argentina, Canada, Japan and Philippines in 2021 for food and feed. 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 MON87429 maize

MON87429 maize was developed to confer tolerance to the herbicides dicamba, glufosinate, aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitors (so called “FOPs” herbicides such as quizalofop) and 2,4-dichlorophenoxyacetic acid (2,4-D). In

addition, it provides tissue-specific glyphosate tolerance to facilitate the production of hybrid maize seeds.

MON 87429 contains a demethylase gene (*dmo*) from *Stenotrophomonas maltophilia* that expresses a dicamba mono-oxygenase (DMO) protein which confers tolerance to dicamba herbicide, phosphinothricin-N-acetyltransferase (*pat*) gene from *Streptomyces viridochromogenes* that expresses the PAT protein conferring tolerance to glufosinate herbicide and the *ft_t* gene, a modified version of the R-2,4-dichlorophenoxypropionate dioxygenase (*Rdpa*) gene from *Sphingobium herbicidovorans*, that expresses a FOPs and 2,4-D dioxygenase protein (FT_T) that confers tolerance to FOPs and 2,4-D herbicides. MON 87429 maize also contains a *cp4 epsps* gene from *Agrobacterium sp.* strain CP4 which produces the 5-enolpyruvylshikimate-3-phosphate synthase protein (CP4 EPSPS) for glyphosate tolerance in all tissues except pollen.

Information and data from studies demonstrate that the DMO, PAT, FT_T and CP4 EPSPS proteins are unlikely to be allergens or toxins or other biologically active proteins. This is based on the assessment of the donor organisms, *Stenotrophomonas maltophilia* strain DI-6, *Streptomyces viridochromogenes*, *Sphingobium herbicidovorans* and *Agrobacterium tumefaciens* strain CP4 which are not known for human or animal toxicity, and are not commonly allergenic (Heller et al., 2016; Lira et al., 2017; Kämpfer, 2006; Takeuchi et al., 2001; Chaudhary et al., 2017; FAO-WHO, 2001).

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".

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) Nutritional equivalence

No major significant differences between MON87429 maize and conventional maize were reported from proximate analysis, analysis of fibre, amino acids, key nutrients and anti-nutrients present in maize. The composition of MON87429 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 MON87429 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 MON87429 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 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 MON87429 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, dicamba, glufosinate, quizalofop and 2,4-dichlorophenoxyacetic acid tolerant MON87429 maize with tissue-specific glyphosate tolerance, 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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**GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN
SPECIFIC RISK ASSESSMENT AREAS FOR THE APPROVAL FOR RELEASE OF
PRODUCTS OF MON87429 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)