RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

MON88302 CANOLA FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 600-2/1/22

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

DATE: 22 JUNE 2022

I - Summary of Assessment Process

On 18 February 2022, the Genetic Modification Advisory Committee (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 herbicide tolerant MON88302 canola. 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 October 2021 to 2 November 2021 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Consumers Association of Penang (CAP) and Malaysian Palm Oil Board (MPOB). GMAC took into consideration the comments that were relevant to the risk assessment including glyphosate toxicity and allergenicity to human and toxicity to farm animals, unintended release of the product and emergency response plan as well as requirement for labelling of the MON88302 canola.

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 herbicide tolerant MON88302 canola. 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, MON88302 canola has been approved in a number of countries for cultivation as well as for food, feed and for processing. MON88302 canola is approved in the European Union, United States of America, Australia, New Zealand, Canada, China, Colombia, Japan, Korea, Mexico, Philippines, Singapore, Taiwan and Vietnam 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 canola. The type of expected use of the products derived from MON88302 canola in Malaysia will be the same as the expected usage for products derived from conventional canola. Potential users of products derived from MON88302 canola such as seeds are feed millers, food processors and other industrial use.

Canola is primarily grown for its seed oil, which is used as a cooking oil and for other food and industrial applications. The seed meal which remains after oil extraction is used as animal feed. The term canola refers to varieties of *B. napus* that contain less than 2% erucic acid in the oil and less than 30 µmoles/g of glucosinolates in the seed meal, so are considered suitable for human and animal consumption.

Information about MON88302 canola

The recipient or parental plant is *Brassica napus* L. (canola). MON88302, a second-generation herbicide tolerant canola product, was developed to improve weed control through greater flexibility for glyphosate herbicide application. MON88302 produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready crop products, via the incorporation of a *cp4 epsps* gene derived from *Agrobacterium sp*. strain CP4. The CP4 EPSPS protein confers tolerance to the herbicide glyphosate, the active ingredient in the family of Roundup agricultural herbicides.

The enhanced CP4 EPSPS expression in male reproductive tissues provides MON88302 tolerance to glyphosate during the sensitive reproductive stages of growth and enables the application of glyphosate at later stages of development.

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, 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, 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 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. Transportation of the consignment must be in secured and closed conditions. Any spillage shall

be collected and cleaned up immediately. Canola is not grown as an economic crop in Malaysia, thus, there is no issue of outcrossing.

b) Planting of seeds

Plants may be grown by uninformed farmers and perpetuated through small scale cultivations. 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

The compositional analysis of MON88302 and controlled canola showed eight statistically significant differences in total dietary fiber (TDF) and seven fatty acids (palmitoleic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, arachidic acid, and behenic acid). However, in all cases, the differences were small, and the analyte levels were within the references ranges observed for commercial canola varieties. Therefore, the nutritional quality of MON88302 canola seeds is comparable to conventional canola varieties.

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 MON88302 canola, 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.

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; and GM food labelling guidelines.

f) Administrative regulatory procedures shall be arranged between Department of Biosafety and Ministry of Health to ensure that herbicide residues in canola consignments are below the acceptable maximum residual level established. It is recommended that importers are required to provide certificate of analysis for herbicide residues prior to shipment.

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 MON88302 canola 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 herbicide tolerant MON88302 canola 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 MON88302 CANOLA 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)
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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)