RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

MON94313 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/33

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

DATE: 8 SEPTEMBER 2025

I - Summary of Assessment Process

On 6 June 2025 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 MON 94313 soybean. 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 23 January 2024 to 21 February 2024 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from Malaysian Palm Oil Board (MPOB) and Consumers Association of Penang (CAP). GMAC took into consideration comments that were relevant to the risk assessment including spillage of the GMO grains during transportation, emergency response plan for unintentional release and labelling of the product.

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 MON 94313 soybean. 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, MON94313 soybean has been registered in a number of countries for cultivation as well as for food, feed and for processing. MON94313 soybean was first approved in 2023 in Canada and the United States of America followed by Australia, New Zealand, Brazil, Indonesia and Taiwan in 2024 and recently in Korea, Paraguay and Mexico in 2025 and may be imported, stored and processed for use in food, animal feed and industrial products. The expected use of the products derived from MON94313 soybean in Malaysia will be the same as the expected usage for products derived from conventional soybean. Soybean is used in various food products, including tofu, soy sauce, soymilk, energy bars, and meat products. A major food use for soybean is purified oil, for use in margarines, shortenings, cooking, and salad oils. Soybean meal is a high-value component obtained from processing of soybean, and is used as a supplement in feed rations for livestock. Industrial edible and industrial uses of soybean range from a carbon/nitrogen source in the production of yeasts via fermentation to the manufacture of soaps, inks, paints, disinfectants, and biodiesel. This application does not cover environmental release and MON94313 soybean may be imported to Malaysia as food or feed products or for further processing.

Information about MON94313 soybean

Herbicide tolerant MON94313 soybean was developed to be tolerant towards the herbicides glufosinate (2-amino-4-(hydroxymethylphosphinyl) butanoic acid), dicamba (3,6 dichloro-2-methoxybenzoic acid), 2,4-D (2,4-dichlorophenoxyacetate), and mesotrione (2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione) in order to offer growers flexibility to use combinations of any of these four herbicides representing multiple modes-of-action for effective and durable weed management system for soybean production.

MON94313 soybean was developed through Agrobacterium-mediated DNA transfer and contains the *dmo, pat,* ft_t.1 and TDO genes that express the DMO, PAT, FT_T.1 and TDO proteins respectively.

Wild type DMO was initially purified from *Stenotrophomonas maltophilia (S. maltophilia)* strain DI-6 (Herman et al., 2005; Palleroni and Bradbury, 1993). In the construction of the plasmid vector used in the development of MON 94313, a CTP coding sequence from Arabidopsis thaliana (APG6) was joined to the *dmo* coding sequence; Data from N-terminal sequencing analysis of the MON 94313 produced DMO indicate that processing of the DMO precursor protein expressed in MON 94313 produced a single isoform of the mature MON 94313 DMO protein with no additional N-terminal residues remaining from partial processing of the of the APG6 transit peptide. Except for an additional leucine at position two, the MON 94313 DMO protein has an identical sequence to the wild-type DMO protein from the DI-6 strain of *S. maltophilia* (Herman et al., 2005) and provides tolerance to dicamba herbicide. The MON 94313 DMO protein is identical to the DMO protein expressed in MON 87708 soybean (JBK (S) 602-1/1/47) which was granted food, feed, and processing (FFP) approval in 2019 by the NBB and almost identical in amino acid sequence to the DMO protein expressed in MON 88701 cotton (JBK (S) 6002/1/12), MON 87419 maize (JBK (S) 602-2/1/11) and MON 87429 maize (JBK (S) 600-2/1/24), which were granted FFP approval by the NBB in 2021 and 2023.

The PAT protein produced in MON 94313 is from the *pat* gene, and is identical to the wild type PAT protein encoded by S. viridochromogenes, except for the first methionine that is removed due to co-translational processing in MON 94313. N-terminal methionine cleavage is common and naturally occurs in the vast majority of proteins (Meinnel and Giglione, 2008). The PAT protein in MON 94313 is identical to the PAT protein expressed in several commercially available glufosinate tolerant products, including those approved previously by the NBB (MON87429 maize, MON87419 maize, BT11 maize, A2704-12 soybean and T25 maize).

The FT_T.1 protein produced in MON 94313 is encoded by the *ft_t.1* gene that provides tolerance to 2,4-D herbicide. FT_T.1 in MON 94313 soybean is a modified version of the FT_T protein present in MON 87429 maize which was approved for food, feed, and processing (FFP) in 2023 in Malaysia (JBK (S) 600-2/1/24). The FT_T protein itself is a modified version of RdpA, an Fe(II)/alpha-ketoglutarate-dependent dioxygenase from the common soil bacterium *Sphingobium* *herbicidovorans*. FT_T was created through modifications to the RdpA amino acid sequence to improve the enzyme activity towards herbicide substrates, including 2,4-D, and to maintain high activity at temperatures experienced during the hotter summer growing months (Larue et al., 2019). As soybeans, are highly sensitive to 2,4-D, FT_T was further modified to enhance its enzymatic activity towards 2,4-D herbicide. The result was FT_T.1, which provides the 2,4-D tolerance in MON 94313 soybean necessary for in-crop herbicide applications (Larue et al., 2019). The FT_T.1 protein in MON 94313 soybean differs from the FT_T protein in MON 87429 maize (JBK (S) 600-2/1/24 which was approved by the NBB for FFP in 2023) by 3 amino acids, and is >98% identitical at the amino acid level.

Triketone dioxygenase (TDO) protein encoded by the TDO gene provides tolerance to mesotrione. TDO is a codon-optimized version of the HPPD INHIBITOR SENSITIVE 1 (HIS1) gene from rice that has the same amino acid sequence as the HIS1 protein.

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 **18** 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

Soybean grain may be accidentally released during transportation. Most of the spilled grains are unlikely to survive for long outside intended cultivation. Furthermore, the storage temperature and humidity from harvest to arrival at a port would likely negatively impact the germination and vigor of soybean seeds. In addition, physical damage to soybean seeds like splits and cracks, increase during transportation.

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

Soybean is not a major crop in Malaysia, however, plants may be grown by uninformed farmers and perpetuated through small scale cultivations. There should 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. Soybean 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. MON94313 has similar characteristics with conventional soybean and lacks plausible hypotheses under which the herbicides tolerant trait would cause such fundamental changes. MON 94313 soybean does not exhibit characteristics that increase its fitness compared to conventional soyabean, and is highly unlikely to become weedy or invasive.

Any MON94313 soybean that invades agricultural habitats could be easily controlled with mechanical cultivation and herbicides.

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 **18** 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 MON94313 soybean, 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 MON94313 soybean 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 MON94313 soybean consignments are below the 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 the MON94313 soybean 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 MON94313 soybean 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 MON94313 SOYBEAN 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-retired)
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. Dr. Sara Jane Chiu (Industry Representative)
16. Dr. Yuwana Podin (Universiti Malaysia Sarawak)
17. Dr. Sarenasulastri binti Awang Besar (Department of Veterinary Services)
18. Ts. Dr. Saiful Effendi Bin Syafruddin (UKM Medical Molecular Biology Institute)