RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF J101 ALFALFA FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 600-2/1/16

APPLICANT: MONSANTO MALAYSIA SDN. BHD.

DATE: 4 MAY 2021

I - Summary of Assessment Process

On 12 March 2021, 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 Glyphosate tolerant J101 alfalfa. The application was filed by Monsanto 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 26 November 2020 to 25 December 2020 via advertisements in the local newspapers. Comments were received from Consumers Association of Penang (CAP), Malaysia Demeter Association and 24 individuals. GMAC took into consideration the comments from CAP regarding genetic contamination of the environment, safety assessment, and glyphosate residues, as well as animal toxicity studies. GMAC also took into consideration the comment from Malaysia Demeter on the need for proper assessment on J101 alfalfa.

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 glyphosate tolerant J101 alfalfa. 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, J101 alfalfa has been registered in a number of countries for cultivation as well as for food, feed and for processing. J101 alfalfa is approved in a few countries including the United States of America, Australia, New Zealand, Canada, Japan, Korea, Philippines and Singapore 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 alfalfa. The type of expected use of the products derived from J101 alfalfa in Malaysia will be the same as the expected usage for products derived from conventional alfalfa.

Information about J101 alfalfa

The recipient or parental plant is alfalfa (*Medicago sativa* L.). Alfalfa is among the most important forage crops in the United States and ranks as the fourth most widely grown crop by acreage, after corn, soybean, and wheat. In certain regions, alfalfa is cultivated as a mixture with perennial grasses where it may be harvested as forage or used for grazing livestock. As a legume, it is also desired for rotational use to improve soil characteristics such as nitrogen content (Undersander *et al.,* 2011).

Many alfalfa plants exhibit various forms of genetic self-incompatibility or self-sterility and will not successfully self-pollinate (Viands *et al.,* 1988). Alfalfa is adversely affected by inbreeding, i.e., self-fertilized plants commonly demonstrate a dramatic reduction in forage and seed yield potential (Rumbaugh *et al.,* 1988). Inbreeding depression may be due to the loss of heterosis and/or accumulation and unmasking of deleterious recessive alleles that occur as a result of self-pollination and/or pollination among close relatives. Flowers do not shed pollen to the wind. After pollination, alfalfa seed requires four to six weeks of adequate growing conditions to ripen. Rainfall during the ripening period will cause poor seed quality and decrease seed yield (Canada Biology Document, 2005).

Alfalfa has a history of minor use as human food, dietary supplements and herbal remedies (OECD 2005). Vast majority of alfalfa is grown and harvested for animal feed (Higginbotham *et al.,* 2008). In Malaysia, alfalfa is used as feed in the form of pellet, dry blocks or bales of hay. For example, pellets are used as feed for rabbits and guinea pigs.

J101 alfalfa contains the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 that encodes for the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein, which confers tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides.

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 content.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, anti-nutritional content, survivability and animal product contamination.

(iii) **Effects on the environment**

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 were examined.

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. 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. However rainfall causes poor seed quality and decrease, seed yield (Canada Biology Document, 2005). Therefore, the likelihood of a feral population is quite low.

b) Planting of seeds

Plants may be grown by uninformed farmers and perpetuated through small scale cultivations. This GM alfalfa may pollinate the non-GM alfalfa. 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) Compromised nutritional content

Compositional analyses of the forage and grain samples showed no significant difference in nutritional composition between J101 alfalfa and conventional alfalfa.

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 receives any credible and/or scientifically proven information that indicates any adverse effect of J101 alfalfa, 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 condition.

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 Regulations 1985 for labelling of GM food.

f) Administrative regulatory procedures shall be arranged between Department of Biosafety and Ministry of Health to ensure that herbicide residues in alfalfa 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

Continuous monitoring is required from the approved person and any unanticipated adverse effect caused by the J101 alfalfa 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 glyphosate tolerant J101 alfalfa 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 J101 ALFALFA 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:

- **Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (GMAC Chairman)**
- **Dr. Kodi Isparan Kandasamy (Industry Representative) (Environment sub-committee Leader)**
- **Madam T.S. Saraswathy (Institute of Medical Research - retired) (Human Health sub-committee Leader)**
- **Prof. Dr Jothi Malar Panandam (Universiti Putra Malaysia - retired) (Animal Health sub-committee Leader)**
- **Dr. Rahizan Issa (Institute of Medical Research - retired) (Notification Assessment sub-committee Leader)**
- Dato' Dr. Sim Soon Liang (Academy of Sciences Malaysia)
- Prof. Dr. Abd Rahman Milan (Universiti Malaysia Sabah - retired)
- Assoc. Prof. Dr. Chan Kok Gan (Universiti Malaya)
- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)
- Dr. Adiratna Mat Ripen (Institute of Medical Research)
- Dr. Norliza Tendot Abu Bakar (Malaysian Agricultural Research & Development Institute)
- Dr. Norwati Muhammad (Forest Research Institute of Malaysia)
- Dr. Saifullizam bin Abdul Kadir (Department of Veterinary Services)
- Dr. Teo Tze Min (Entomological Society of Malaysia)
- Dr. Mohd Hefni Rusli (Malaysian Palm Oil Board)
- Madam Shafini Abu Bakar (Ministry of Health)
- Madam Sabariah Kamis (Department of Agriculture)
- Mr. Harun bin Ahmad (Department of Chemistry Malaysia)