RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

H7-1 SUGAR BEET FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 600-2/1/13

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 H7-1 sugar beet. The application was filed by Monsanto (Malaysia) Sdn. Bhd. (hereafter referred to as "the applicant").

A public consultation for this application was conducted from 26 August 2020 to 24 September 2020 via advertisements in the local newspapers, e-mail announcements and social media. Comments were received from the public. However, the comments provided were not taken into consideration in GMAC's risk assessment, as it was not technical/scientific information.

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 H7-1 sugar beet. 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, H7-1 sugar beet has been registered in a number of countries for cultivation as well as for food, feed and for processing. H7-1 sugar beet is approved in the United States of America, Australia, New Zealand, Canada, China, European Union, Colombia, Japan, Korea, Mexico, Philippines, Russian Federation, Singapore and Taiwan 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 sugar beet. The type of expected use of the products derived from H7-1 sugar beet in Malaysia will be the same as the expected usage for products derived from conventional sugar beet. This application does not cover environmental release and H7-1 sugar beet may be imported to Malaysia as food or feed products or for further processing.

Information about H7-1 sugar beet

Beta vulgaris L. ssp. *maritima*, wild sea beet, is regarded as the mother species of the Beta beets (fodder beet, sugar beet, beetroot, yellow beet, Swiss chard) (Mc Farlane J.S., 1971). It is indigenous to European coastal regions, particularly the Mediterranean. Beet spinach, *convar. cicla*, has been cultivated in the Mediterranean region since 2000 B.C. Sugar beet originates from the cultivated form of beet around the Mediterranean area (Pernès J., 1984). Sugar beet is cultivated world-wide, but primarily in warm and temperate climates with little precipitation. It was introduced in North America around 1830 (OECD, 2001) and South America circa 1850 (Mansfeld, 1986).The area of distribution extends eastward to Iran, India, China and other Asian countries (Højland and Pedersen, 1994).

Beet is a protandrous and self-incompatible plant (the stigma is not fully mature when the flower opens). Plants set few or no seeds at all when isolated (OECD, 1993; Smith, 1980; Valdeyron, 1984). Sugar beet is an allogamous species, mostly pollinated by wind and occasionally by insects. Some cross-pollinations are also achieved by thrips and syrphids (Free J.B. *et. al*., 1975; Valdeyron, 1984).

Sugar beet possesses long-lived dormant seeds that can become a volunteer weeds in sugar beet fields (Højland and Pedersen, 1994). Sugar beet seeds may remain in the soil for ten years or more and still retain some germination capacity (OECD, 1993b; Brouwer *et al.*, 1976; Lysgaard, 1991). Since commercial sugar producing sugar beet is biennial and is harvested during the first year whilst still in the vegetative phase, sexual reproductive organs (floral parts) never develop.

Sugar beet root is seldom used directly for food or feed, but is processed into refined sugar. Byproducts of sugar production such as pulp, molasses, fibre, etc. are used as feed. When sugar beet is grown in areas of livestock production, leaves of the plant may also be used for fodder. More recently, sugar beet has been used for molasses production. Molasses are used for alcohol production and in other forms of fermentation.

H7-1 sugar beet was developed through *Agrobacterium*-mediated transformation of the conventional sugar beet. H7-1 sugar beet produces 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein expressed by the *cp4 epsps* gene derived from *Agrobacterium* sp. strain CP4 which confers glyphosate tolerance.

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 components.

(ii) **Effects on animal health**

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

(iii) **Effects on the environment**

Issues pertaining to accidental release of seeds, unintentional release and planting, weediness and invasiveness, increased fitness due to genetic modification, potential of transgenes being transferred to bacteria (soil bacteria, bacterial flora of animal gut), 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 20 potential hazards were identified. All 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 plant materials

Viable plant materials may be accidentally released during transportation. These can germinate and grow along transportation routes and in areas surrounding storage and processing facilities. Sugar beet is not grown as an economic crop in Malaysia, thus, there is no issue of outcrossing.

b) Planting of sugar beet

Sugar beet 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

No significant differences were observed in levels of key nutrients between H7-1 and conventional sugar beet. The composition of H7-1 is comparable to that of the conventional sugar beet 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 H7-1 sugar beet, 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 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 sugar beet 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 H7-1 sugar beet 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 H7-1 sugar beet 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 H7-1 SUGAR BEET 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)