RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF DAS-68416-4 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/38

APPLICANT: DOW AGROSCIENCES (MALAYSIA) SDN. BHD.

DATE: 18 SEPTEMBER 2017

I - Summary of Assessment Process

On 14 July 2017, 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, herbicide tolerant DAS-68416-4 soybean. The application was filed by Dow AgroSciences (Malaysia) Sdn. Bhd. (hereafter referred to as "the applicant").

A public consultation for this application was conducted from 10 July 2017 to 10 August 2017 via advertisements in the local newspapers. There was a general concern from an individual regarding herbicide residues in imported GM soybean.

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 DAS-68416-4 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, DAS-68416-4 soybean has been registered in a number of countries for cultivation as well as for food, feed and for processing. DAS-68416-4 soybean is approved in United States of America, Canada, Brazil, Japan, Mexico, Colombia, Korea, Taiwan Australia and New Zealand 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 soybean. According to the applicant, there will be no difference in use of DAS-68416-4 soybean compared to conventional soybean already in the market.

A major food use of soybean is as purified oil, utilized in margarines, shortenings and cooking and salad oils. It is also used in various food products including tofu, simulated milk, soybean sprouts, soymilk film (yuba), soynuts, green vegetable soybean (e.g. edamame), whereas the fermented soyfoods include soybean paste (miso), soybean sauce, natto and *tempeh*. Soybean also is the most commonly grown oilseed in the world. In 2008/09, approximately 211 MMT (millions metric tons) of harvested seed were produced, representing 56% of the world's oilseed production.

Other than that, soybean meal is used as a supplement in feed rations for livestock. Soybean meal is the most valuable component obtained from processing the soybean, accounting for

roughly 50-75% of its overall value. By far, soybean meal is the world's most important protein feed, accounting for nearly 65% of world supplies. Industrial use of soybean ranges from the production of yeasts and antibodies to the manufacture of soaps and disinfectants. A sizeable amount is also used in pet food.

The applicant claims that soybean grain and forage derived from DAS-68416-4 soybean are compositionally and nutritionally equivalent to those of the conventional soybeans. The type of expected use of the products derived from DAS-68416-4 soybean in Malaysia will be the same as the expected usage for products derived from conventional soybean. Potential users of products derived from DAS-68416-4 soybean such as grains are feed millers, food processors and other industrial use.

Information about DAS-68416-4 soybean

The recipient or parental plant is *Glycine max* (L.) Merr. (soybean). Soybean is grown as a commercial crop in over 35 countries without any detrimental effect on the environment. Soybean is a largely self-pollinated species, although low levels of natural cross-pollination can occur. In studies with cultivated soybean where conditions have been optimized to ensure close proximity and flowering synchrony, natural cross-pollination generally has been found to be very low. Cultivated soybean seeds rarely display any dormancy characteristics and only under certain environmental conditions grow as volunteers in the year following cultivation. If this should occur, volunteers do not compete well with the succeeding crop.

DAS-68416-4 soybean produces aryloxyalkanoate dioxygenase 12 (AAD-12) protein, expressed by aad-12 gene derived from *Delftia acidovorans* that provides tolerance to 2,4-D herbicide. In addition, DAS-68416-4 also produces phosphinothricin acetyltransferase (PAT) protein expressed by *pat* gene derived from *Streptomyces viridochromogenes* that confers tolerance to glufosinate-ammonium.

DAS-68416-4 soybean may enter Malaysia as grain, food ingredients for processing or packaging, or as finished products ready for distribution, or as feed meal for animals.

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 took cognizance of the following as suggested 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.

A Risk Matrix was prepared based on an assessment mechanism developed by Office of the Gene Technology Regulator, Australia (OGTR, 2009). In applying this matrix, 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 Risk Assessment was conducted over a series of four (4) meetings. To start with, the possible pathways to risk/hazard arising from release of the products were identified and listed. The potential hazards were identified in three main areas:

(i) **Effects on human health**

Issues pertaining to acute toxicity of novel protein / altering / interference of metabolic pathways, potential allergenicity of the novel protein, production of proteins or metabolites with mutagenic / teratogenic / carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in digestive tract, pathogenic potential of donor microorganisms and nutritional equivalence.

(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, cross pollination leading to transfer of transgenes, toxic effect on non-target organisms were examined.

Based on the above, a final list of 21 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. Soybean 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) Compromised Nutritional Content

The potential risk of DAS-68416-4 soybean was evaluated in equivalence to, and above any potential risk reported for unmodified soybean.

Analyses of seed and forage from several studies demonstrate that DAS-68416-4 soybean is nutritionally and compositionally similar to, and as safe and nutritious as conventional soybean.

However as a precautionary measure GMAC recommends that the proposed terms and conditions under section IV should be adhered to.

IV - Proposed Terms and Conditions for Certificate of Approval

Based on the 21 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 down 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 DAS-68416-4 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 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 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 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 DAS-68416-4 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 DAS-68416-4 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 I

GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) MEMBERS INVOLVED IN RISK ASSESSMENT FOR THE APPROVAL FOR RELEASE OF PRODUCTS OF DAS-68416-4 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. The GMAC members involved in the risk assessment are as below:

- **Dr. Ahmad Parveez bin Hj Ghulam Kadir (Malaysian Palm Oil Board) (GMAC Chairman)**
- **Assoc. Prof. Dr. Mohd. Faiz Foong bin Abdullah (Universiti Teknologi MARA) (Environment sub-committee leader)**
- **Madam T.S. Saraswathy (Institute for Medical Research) (Human health sub-committee leader)**
- **Prof. Dr Jothi Malar Panandam (Universiti Putra Malaysia) (Animal health sub-committee leader)**
- Dato' Dr. Sim Soon Liang (Sarawak Biodiversity Centre)
- Dr. Rahizan binti Issa (Institute for Medical Research)
- Dr. Kodi Isparan Kandasamy (Malaysian Bioeconomy Development Corporation Sdn. Bhd.)
- Madam Atikah binti Abdul Kadir Jailani (Department of Agriculture)
- Dr. Norliza Tendot binti Abu Bakar (Malaysian Agricultural Research & Development Institute)
- Dr. Adiratna binti Mat Ripen (Institute for Medical Research)
- Dr. Norwati binti Muhammad (Forest Research Institute of Malaysia)
- Madam Laila Rabaah binti Ahmad Suhaimi (Ministry of Health)
- Assoc. Prof. Dr. Chan Kok Gan (Universiti Malaya)
- Prof. Dr. Abd Rahman Milan (Universiti Malaysia Sabah)
- Assoc. Prof. Dr. Choong Chee Yen (Universiti Kebangsaan Malaysia)
- Dr. Teo Tze Min (Entomological Society of Malaysia)
- Dr Saifullizam bin Abd Kadir (Department of Veterinary Services Malaysia)
- Madam Elliza binti Mat Noor (Department of Chemistry Malaysia)