RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCT OF IMIDAZOLINONE-TOLERANT CV127 SOYBEAN (*Glycine max*) FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 602-1/1/13

APPLICANT: BASF MALAYSIA SDN. BHD.

DATE: 2 OCTOBER 2013

I - Summary of Assessment Process

The Genetic Modification Advisory Committee, under the purview of the National Biosafety Board was given the dossier by the Department of Biosafety on 2 January 2012 for an application for approval for importation for release [sale/placing on the market] of a product of a Living Modified Organism (Imidazolinone-Tolerant CV127 Soybean). The application was filed by BASF Malaysia Sdn. Bhd. (hereafter referred to as "the applicant"). GMAC members also took the opportunity to obtain further clarification on certain details of the activity. Additional information was also provided by the applicant as requested. Please refer to **Lampiran IB** for Additional Information provided by the applicant.

A public consultation for this application was conducted from 27 May 2013 to 25 June 2013 via advertisement in local newspapers. There were comments received from individuals, Consumer's Association of Penang (CAP), Pesticide Action Network Asia and The Pacific (PANAP) and Third World Network (TWN) regarding the potential allergenicity of *Arabidopsis thaliana,* toxicity study and *AtSEC61γ* subunit. GMAC has taken note of the information received and deliberated on it. Please refer to **Lampiran III** for comments received from public consultation.

GMAC had three 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 commercially import and release a product of a Living Modified Organism (Imidazolinone-Tolerant CV127 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, there will be no difference in use of product of CV127 Soybean compared to conventional soybeans already on the market.

Soybean is grown as a commercial crop in over 35 countries. 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.

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 soy foods 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 reported minor differences in composition between CV127 soybean and conventional varieties. The applicant reports that the mean levels of some components of CV127 soybean were statistically significantly different from the levels in the control soybean and conventional varieties and stated that they are likely due to the natural heterogeneity of soybean varieties grown in Brazil.

Information about genetically modified Imidazolinone-Tolerant CV127 Soybean

The recipient or parental plant is *Glycine max* (soybean). The CV127 soybean has been genetically modified to be tolerant to imidazolinone herbicides. The CV127 soybean is derived from a single transformation event and was produced by introduction of the imidazolinone-tolerant acetohydroxyacid synthase large subunit (*ahasl)* gene *csr1-2* with its native promoter from *Arabidopsis thaliana* into the soybean plant genome via biolistics transformation technology. *A. thaliana* is a member of the mustard (Brassicaceae) family that have a history of safe human consumption.

The *csr1-2* gene from *A. thaliana* encodes an acetohydroxyacid synthase large subunit enzyme that is tolerant to imidazolinone herbicides due to a point mutation that result in a single amino acid substitution in which the serine residue at position 653 is replaced by asparagine (S653N). The Arabidopsis AHASL (AtAHASL) catalytic subunit encoded by the *csr1-2* gene has altered herbicide binding properties such that imidazolinone herbicides do not bind to the enzyme while retaining its normal biosynthetic function in the plant.

The herbicide tolerance CV127 soybean will allow farmers to treat the soybean crop with imidazolinone herbicides for weed control causing injury to the soybean plant at normal field application rates.

CV127 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.

Although the applicant has applied for an approval to import for the purpose of feed and processing only, GMAC had conducted a thorough assessment and widened the scope of the risk assessment to include the purpose of food as well.

The Risk Assessment was conducted over a series of three meetings and email consultations among GMAC members. 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 the novel proteins, alteration or interference of metabolic pathways, potential allergenicity, modifications result in production of proteins or metabolites with mutagenic / teratogenic / carcinogenic effects, reproductive toxicity, potential transfer of antibiotic resistance genes in the digestive tract, the pathogenic potential of donor microorganisms and nutritional equivalence were examined.

(ii) **Effects on animal health**

Issues pertaining to allergenicity, toxicity, anti-nutritional properties, survivability and animal product contamination were examined.

(iii) **Effects on the environment**

Issues pertaining to unintentional release and planting, weediness, gene transfer to bacteria, accumulation of toxin, cross pollination and toxic effects on non-target organisms were examined.

Based on the above, a final list of 31 potential hazards was identified. All of these hazards were rated as having an Overall Risk of 1 or "negligible" (please refer to the **Lampiran IIA/*Risk Matrix*** for details).

The potential risk of CV127 soybean was evaluated in equivalence to, and above any potential risk reported for unmodified soy. 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 31 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 describing the product by the exporter which shall be declared to the Customs of the importing country.

b) There shall be clear labeling of the product from importation down to all levels of marketing to state 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 scientifically proven information that confirms any adverse effect of CV127 soybean, the National Biosafety Board authority shall be informed immediately.

d) Any spillage (during loading/unloading) shall be collected and cleaned up immediately.

e) Transportation of the consignment from the port of entry to any destination within the country must be in closed containers.

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) Department of Biosafety shall inform the Ministry of Health of the possibility that Imidazolinone-tolerant CV127 Soybean may have herbicide residue which may need monitoring.

VI - Identification of issues to be addressed for long term use release of this product

1. No additional issues have been identified that would be important during the assessment of an application for long term usage of this product.

2. Continuous monitoring is required from the approved person to report any unanticipated adverse effect caused by the CV127 soybean.

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 (Imidazolinone-Tolerant CV127 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, subject to approval by other relevant agencies.

VIII – Bibliography

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