

NATIONAL BIOSAFETY BOARD DECISION

APPLICATION FOR APPROVAL FOR IMPORT FOR RELEASE OF PRODUCTS OF MON89788 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF. NO: JBK(S) 602-1/1/9

APPLICANT: MONSANTO MALAYSIA SDN BHD

DATE OF DECISION: 27 NOVEMBER 2012

The National Biosafety Board (NBB) on the 27 November 2012 granted approval with terms and conditions to an application from Monsanto Malaysia Sdn. Bhd. for release activities of MON89788 Glyphosate Tolerant Soybean (RoundupReady2Yield™).

This approval permits the import for release of products of MON89788 soybean for supply or offer to supply for sale or placing in the market. The product is aimed only for the purpose of food, feed and processing (FFP) and is not to be used as planting material.

The recommendation of the Genetic Modification Advisory Committee (GMAC) to the NBB was for an approval with terms and conditions in accordance with the provisions of subsections 16(3) and 16(4) of the Biosafety Act for the release of MON89788 soybean. This recommendation was based on GMAC thorough evaluation which determined that the release of this product does not endanger biological diversity or human, animal and plant health. Proper risk management strategies are to be followed as stipulated through the terms and conditions imposed (Appendix 1).

NBB also considered inputs from Ministry of Health, Department of Chemistry, Department of Veterinary Services, Department of Agriculture and Malaysian Quarantine and Inspection Services when making their decision on the application. Public consultation for this application was done from 16 July 2012 until 14 August 2012. There were comments received from Consumer's Association of Penang (CAP) and Third World Network (TWN) regarding the traces of herbicide or herbicide residues in the food products. The potential health risk of glyphosate (Roundup) was highlighted by both CAP and TWN. GMAC has taken note of the information received from CAP and TWN on the toxicity associated with glyphosate and response from other regulatory authorities on this issue. GMAC assessment is based on the comparison of non GM and GM soy, and not based on glyphosate residues.

TERMS AND CONDITIONS FOR CERTIFICATE OF APPROVAL

Approval for Import for Release of Products of MON89788 Soybean for Supply or Offer to Supply for Sale or Placing in the Market

- 1) There shall be clear documentation describing MON89788 soybean by the exporter which shall be declared to the Customs at the entry points of Malaysia.
- 2) 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.
- 3) Should the approved person receive any scientifically proven information that confirms any adverse effect of MON89788 soybean, the National Biosafety Board authority shall be informed immediately.
- 4) Any spillage (during loading/unloading) shall be collected and cleaned up immediately.
- 5) Transportation of the consignment from the port of entry to any destination within the country must be in closed containers.
- 6) A post-monitoring plan should be implemented, whereby the approved person shall submit a yearly report to the National Biosafety Board in compliance with procedures for handling any spillage.