NATIONAL BIOSAFETY BOARD DECISION

APPLICATION FOR APPROVAL FOR IMPORT FOR RELEASE OF PRODUCTS OF HB4 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF. NO: JBK(S) 600-2/1/20
APPLICANT: INSTITUTO DE AGROBIOTECNOLOGIA ROSARIO
(INDEAR)
DATE OF DECISION: 2 NOVEMBER 2023

The National Biosafety Board (NBB) on the 2 November 2023 granted <u>approval with terms and conditions</u> (stipulated in Appendix 1) to an application from Instituto de Agrobiotecnologia Rosario (INDEAR) for release activities of abiotic stress and herbicide tolerant HB4 soybean.

This approval permits the import for release of products of HB4 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 <u>approval with terms and conditions</u> in accordance with the provisions of subsections 16(3) and 16(4) of the Biosafety Act for the release of HB4 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 <u>risk management strategies</u> are to be followed through the terms and conditions imposed.

NBB also considered inputs from Department of Chemistry, Ministry of Health, Malaysian Quarantine and Inspection Services, Department of Agriculture, Department of Veterinary Services and Department of Fisheries when making their decision on the application. Public consultation for this application was done from 20 October 2021 to 18 November 2021. A few technical and scientific issues were raised through the Public Consultation for this application regarding the release. These issues have been considered by GMAC in the risk assessment. Other non-technical issues were reviewed by the Socio-economic Advisory Committee (SEAC) and recommendations on addressing these issues were made to the NBB.

TERMS AND CONDITIONS FOR CERTIFICATE OF APPROVAL

Approval for Import for Release of Products of HB4 soybean for Supply or Offer to Supply for Sale or Placing in the Market

- 1) There shall be clear documentation by the exporter describing the product which shall be declared to the Royal Malaysian Customs.
- 2) 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.
- 3) Should Institute de Agrobiotecnologia Rosario (INDEAR) receive any credible and/or scientifically proven information that indicates any adverse effect of HB4 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 shall be in secured and closed containers.
- 6) Instituto de Agrobiotecnologia Rosario (INDEAR) shall comply with all risk management strategies.
- 7) Instituto de Agrobiotecnologia Rosario (INDEAR) shall co-operate with government agencies in regulating the import and release of HB4 soybean.