NATIONAL BIOSAFETY BOARD DECISION

APPROVAL TO IMPORT TRYPSIN MODULATING OOSTATIC FACTOR (TMOF)_Yeast (TECHNICAL GRADE ACTIVE INGREDIENT, TGAI) TO PRODUCE MOUSTICIDE RH AND MOUSTICIDE WP AND IMPORT OF MOUSTICIDE WP FOR RELEASE

NBB REF. NO: JBK(S) 602-1/1/20
APPLICANT: ENTOGENEX INDUSTRIES SDN BHD
DATE OF DECISION: 17 FEBRUARY 2015

The National Biosafety Board (NBB) on the 17 February 2015 has granted an approval with terms and conditions to an application from EntoGenex Industries Sdn. Bhd. for release activities of products of LMO.

This approval permits the import of TMOF_yeast (Technical Grade Active Ingredient, TGAI) from India to use in the formulation of Mousticide Rice Husk (RH) and Mousticide Wettable Powder (WP) as well as the importation of Mousticide WP from the Philippines (formulated with TMOF_yeast produced in India) to supply, offer to supply for sale or placing on the market.

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 these products. 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).

Public consultation for this application was done from 13 January 2015 until 11 February 2015. A few technical and scientific issues were raised through the Public Consultation for this application regarding the implementation of safety studies commissioned by the NBB through the previous decision for the locally produced Mousticide RH and Mousticide WP, exposure of the product through inhalation or dermal contact, potential risk of amyloid formation, expression of inserted gene, disposal of the product, use of the product in waterways and the proposed control and emergency response plane. These issues have been considered by GMAC in the risk assessment.

Appendix 1

TERMS AND CONDITIONS FOR CERTIFICATE OF APPROVAL

Approval to Import TMOF_Yeast to Produce Mousticide RH and Mousticide WP and Import of Mousticide WP for Release

1) Release is limited to the TMOF_yeast imported from India to be formulated as Mousticide WP and Mousticide RH as end products and Mousticide WP product imported from Philippines. Any other formulation will required a new application for approval to be submitted to the NBB.
2) Product handling and safety instructions should be provided with the product. These instructions should include:
    a) the use of PPE and follow up medical supervision of staff handling the product.
    b) caution be exercised when used in combination with other larvicidal products since the safety of the combined effects have not been established.
3) Labelling should include application dosage and frequency, instructions for disposal as well as hazard warning.
4) Imported TMOF_yeast should be accompanied with data sheet that should include information on safety and standardized potency range of the product.
5) Post monitoring survey of end user to determine the effect on human health and environment. The survey should clearly outline the safety objectives to the end user and a brief product description.
6) Continuous environmental safety studies on effects of Mousticide WP and Mousticide RH to the Malaysian fauna are recommended. These studies should be carried out on the oil palm weevil and honey bee using the TMOF_yeast produced by IBD as well as TMOF_yeast imported from India.
7) Mousticide WP and Mousticide RH should not be applied to waterways such as treated drinking water sources.
8) Should the approved person receive any credible and/or scientifically proven information that indicates any adverse effect of Mousticide WP or Mousticide RH either locally or in other countries, the NBB authority shall be informed immediately.
9) If the production is to be done in a facility other than IBD, UTM, a notification of that chosen facility for contained use activity must be submitted to the NBB.