NATIONAL BIOSAFETY BOARD DECISION

AN APPLICATION FOR APPROVAL FOR RELEASE OF TRANSGENIC RUBBER (*Hevea brasiliensis*) TREES FOR CONFINED FIELD TRIAL FOR RESEARCH AND DEVELOPMENT PURPOSE

NBB REF. NO : JBK(S) 602-1/1/17
APPLICANT : MALAYSIAN RUBBER BOARD
DATE OF DECISION : 28 JULY 2015

The National Biosafety Board (NBB) on the 28 July 2015 granted approval with terms and conditions to an application from Malaysian Rubber Board to for release of genetically modified rubber (*Hevea brasiliensis*) trees for confined field trial for research and development purpose.

The aim of the field trial is to evaluate the expression of the transgenes in the leaf and latex of the GM rubber (*Hevea brasiliensis*) trees at different stages of growth, under field conditions. According to Malaysian Rubber Board, the transgene products are not intended to enter the food chain and no part of the GM rubber tree is intended for human use, other than verification of leaf and latex samples for expression of transgene and transgene product.

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. This recommendation was based on GMAC thorough evaluation which determined that the confined field trial 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 Department of Agriculture when making their decision on the application. A public consultation for this application was conducted from 30 October 2014 to 28 November 2014. There were comments received from Third World Network (TWN) expressing concern on the use of human and animal (mouse) genes and CaMV 35S promoter in the GM rubber trees as well as the impact of the GM rubber trees on the soil, food webs and forest ecosystems over long periods. GMAC reviewed the input received and it was found that all the issues raised have been considered and taken into account in the risk assessment by GMAC.

TERMS AND CONDITIONS FOR CERTIFICATE OF APPROVAL

Approval for Release of Transgenic Rubber (*Hevea Brasiliensis*) Trees for Confined Field Trial for Research and Development Purpose

Part A

Actions to be taken and reported to the National Biosafety Board prior to the start of the field trial

(i) A consent letter to conduct the confined field trial from the Local Council for the district where the site is located shall be provided.

(ii) Proper signage shall be present at the trial site informing of the presence of GM rubber trees as according to the Confined Field Trial Guidelines. Access to the confined field trial site shall be limited to authorised personnel only.

(iii) Appropriate training shall be given to workers who will be handling the GM rubber trees and latex.

(iv) Medical surveillance plan for all the staff, including contract workers, handling latex and working in the confined field trial site shall be developed.

(v) Pest and animal control measures shall be in place at the confined field trial site.

(vi) The owner of the plot of land on which the confined field trial site is situated (LGM) must consent, in writing, to a post-trial land use restriction period of 2 years.

(vii) An Emergency Response Plan shall be prepared and approved by GMAC to handle possibility of cross pollination of GM and non-GM rubber trees.

Part B

Actions to be taken and reported to the National Biosafety Board during the field trial

(i) The approved Standard Operating Procedures (SOPs) for transportation of all GM rubber trees and materials from the greenhouse to the confined field trial site shall be adhered to. Records shall be kept for all GM rubber trees transported to the confined field trial site.

(ii) An isolation zone shall be established, whereby the confined field trial site must be separated by a distance of at least 1100 meters from other rubber trees or sexually compatible species on all sides. This isolation zone shall be monitored regularly and maintained free of

volunteers of the rubber trees or sexually compatible species. All such volunteers shall be removed and destroyed.

(iii) A buffer zone of 15 meters immediately surrounding the confined trial site shall be established. Regular bi-monthly inspection shall be carried out to ensure that there are no volunteers in the vicinity of the buffer zone. Any volunteers found shall be collected and destroyed. A record of this inspection exercise and of the numbers of volunteers destroyed shall be maintained. The buffer zone is subjected to post-trial land use restrictions (see Part C below), and these inspections shall be extended for a period of two (2) years after the trial has ended.

(iv) If a breach of the isolation zone and buffer zone should occur, the National Biosafety Board shall be informed immediately.

(v) Routine sampling and random testing of volunteers in neighboring or nearby rubber plantations shall be conducted. If outcrossing events are detected, the National Biosafety Board shall be informed immediately. Such sampling and testing shall be extended for a period of 2 years after the confined field trial has ended.

(vi) The Emergency Response Plan approved by GMAC must be implemented if there is a cross pollination of GM and non-GM rubber trees.

(vii) Records of all plant materials, seeds, etc. that are removed from the trial site for storage or analysis off-site shall be kept. The SOPs for transporting such materials shall be strictly adhered to.

(viii) Since there is potential toxicity and allergenicity, bioinformatics studies to identify any allergenic motifs in the sequence of the expressed recombinant proteins shall be carried out.

(ix) Allergenicity test with the latex from each of the three types of GM rubber trees shall be conducted.

(x) Appropriate and continuous training shall be provided to workers who will be handling the GM rubber trees and latex.

(xi) Medical surveillance for all the staff, including contract workers, handling latex and working in the confined field trial site shall be conducted.

(xii) Pest and animal control measures shall be implemented. Regular inspection of the fence shall be carried out to ensure its integrity at all times.

(xiii) The Biosafety related approved SOPs that have been approved under this application shall be strictly adhered to and personal protection equipment shall be used to avoid exposure to latex.

(xiv) No changes shall be made to the Biosafety related SOPs that have been approved under this application. Any changes proposed shall be submitted to and approved by GMAC.

(xv) Additional conditions may be imposed based on a monitoring visit by GMAC and these conditions shall be complied with.

(xvi) An annual report shall be submitted through LGM Institutional Biosafety Committee on the types and numbers of GM trees planted,

removed, or destroyed. An updated map of the planting shall be included with the annual report.

Part C

Actions to be taken and reported to the National Biosafety Board at termination of the field trial

(i) At the termination of the field trial, all residual plant materials in the confined field trial site shall be rendered non-viable using methods approved by GMAC. The confined field trial site and the buffer zone are subjected to post-trial land use restrictions for a period of two (2) years. Part or all of the isolation zone, may also be subjected to similar restrictions, if a breach has occurred during the confined field trial.

(ii) During this 2-year period, the confined field trial site, buffer zone and other affected areas shall not be planted with plants of the same species (GM or non-GM) without prior approval from the National Biosafety Board. The confined field trial site and buffer zone shall be continuously monitored for growth of volunteers, which shall be collected and destroyed. Proper records of these post-trial activities shall be maintained and submit a report shall be submitted to the National Biosafety Board upon the expiry of the post-trial period.