NATIONAL BIOSAFETY BOARD DECISION

APPLICATION FOR APPROVAL FOR RELEASE OF TRANSGENIC EKSOTIKA PAPAYA FOR CONFINED FIELD TRIAL FOR RESEARCH AND DEVELOPMENT PURPOSE

NBB REF. NO: JBK(S) 600-2/1/6
APPLICANT: MALAYSIAN AGRICULTURAL RESEARCH AND DEVELOPMENT INSTITUTE (MARDI)
DATE OF DECISION: 10 DECEMBER 2019

The National Biosafety Board (NBB) on the 10 December 2019 granted approval with terms and conditions to an application from Malaysian Agricultural Research and Development Institute (MARDI) for release of transgenic Eksotika papaya to have anti-pathogenic characteristic against Papaya Dieback Disease.

The purpose of the confined field trial is to evaluate the resistance of the genetically modified Eksotika papaya variety against *Erwinia mallotivora*, the causal agent of papaya dieback disease. Field evaluation is needed to confirm that the transgenic papaya lines have been incorporated with the anticipated disease resistant characteristic and to collect biosafety data for subsequent open field trial. The genetically modified Eksotika papaya is not intended to enter the food chain and no part of the genetically modified Eksotika papaya tree is intended for human use, other than evaluation of resistance to papaya dieback disease. The confined field trial will be conducted in a restricted access, insect proof nethouse, equipped with containment features with the parameter size of 21 m x 18 m x 5.2 m (netting with size 50 mesh). The approved field trial site is located at a transgenic facility within the vicinity of the MARDI Headquarters in Serdang, Selangor.

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 Ministry of Health, Department of Agriculture, Department of Fisheries and Department of Veterinary Services when making their decision on the application. Public consultation for this application was done from 25 June 2019 to 24 July 2019. A few technical and scientific issues were raised through the Public Consultation for this application from Third World Network regarding the release. Technical issues raised include the

integrity of the nethouse structure, risk of gene flow, mechanism for conferring bacterial dieback resistance and risk of using marker gene *nptII* and *AHL lactonase* gene. GMAC reviewed each of the input received and it was found that all the technical issues raised have been considered and taken into account in the risk assessment by GMAC.

Appendix 1

TERMS AND CONDITIONS FOR CERTIFICATE OF APPROVAL

Approval for Import for Release of Transgenic Eksotika Papaya 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 genetically modified papaya 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 all personnel who will be handling the genetically modified papaya.

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

(v) The owner of the plot of land on which the confined field trial site is situated (MARDI or other parties) must consent, in writing, to a post-trial land use restriction period of 6 months.

(vi) An Emergency Response Plan shall be prepared and approved by Genetic Modification Advisory Committee to handle possible incident of breach in containment.

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 genetically modified papaya and materials from the greenhouse to the confined field trial site shall be adhered to. Records shall be kept for all genetically modified papaya 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 400 metres from other papaya plants on all sides.

(iii) Regular inspections shall be carried out to ensure that there are no volunteers (papaya and wild relatives) in the vicinity of the isolation 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.

(iv) If a breach of the isolation zone should occur, the National Biosafety Board shall be informed immediately and random sampling and testing shall be conducted to ensure no outcrossing of genetically modified papaya.

(v) The Emergency Response Plan approved by Genetic Modification Advisory Committee must be implemented to handle any incident of breach in containment.

(vi) Records of all seeds and other plant materials 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.

(vii) Bioinformatics data analysis on potential toxicity and allergenicity of the expressed proteins shall be submitted to the National Biosafety Board.

(viii) Appropriate and continuous training shall be provided to personnel who will be handling the genetically modified papaya plants.

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

(x) 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.

(xi) 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 Genetic Modification Advisory Committee.

(xii) Additional conditions may be imposed based on monitoring visit by Department of Biosafety and these conditions shall be complied with.

(xiii) Should the approved person receive any scientifically proven information that confirms any adverse effect of transgenic papaya, the National Biosafety Board shall be informed.

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

(i) No parts of the genetically modified papaya plants from this confined field trial shall be consumed or utilised for any other purpose other than this trial.

(ii) 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 Genetic Modification Advisory Committee. The confined field trial site and the isolation zone are subjected to post-trial land use restrictions for a period of 6 months.

(iii) During this 2-year period, the confined field trial site and the isolation zone shall not be planted with any plants without prior approval from the National Biosafety Board. The confined field trial site and isolation zone shall be continuously monitored for growth of papaya volunteers, which shall be collected and destroyed. Proper records of these post-trial activities shall be maintained and the report submitted to the National Biosafety Board upon the expiry of the post-trial period.