

NATIONAL BIOSAFETY BOARD DECISION

AN APPLICATION FOR APPROVAL FOR CONFINED FIELD EVALUATION OF DELAYED RIPENING TRANSGENIC EKSOTIKA PAPAYA

NBB REF. NO: JBK(S) 602-1/1/12

**APPLICANT: MALAYSIAN AGRICULTURAL RESEARCH
AND DEVELOPMENT INSTITUTE (MARDI)**

DATE OF DECISION: 29 MAY 2013

The National Biosafety Board (NBB) on the 29 May 2013 granted approval with terms and conditions to an application from Malaysian Agricultural Research and Development Institute (MARDI) to conduct confined field evaluation of delayed ripening transgenic Eksotika Papaya.

The purpose of the confined field trial is to evaluate the delayed fruit ripening characteristic of the transgenic papaya transformed with antisense *ACC Oxidase 2* gene in a 24 m x 18 m x 5.2 m confined environment under a nethouse structure (netting with size 50 mesh). The trial is of utmost importance since field evaluation is needed to confirm that the transgenic papaya lines are incorporated with the anticipated delayed fruit ripening characteristic and to collect biosafety data for subsequent open field trial.

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 8 March 2013 to 6 April 2013. Comments were received from Consumer Association of Penang (CAP) and Third World Network (TWN) regarding the integrity of the nethouse structure, risk of gene flow, mechanism for conferring the delayed ripening trait and risk of using marker gene *nptII* and *ACC oxidase* gene. 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

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Transgenic Eksotika Papaya**

- 1) The Institutional Biosafety Committee (IBC) of MARDI shall ensure that the nethouse is inspected regularly to maintain the integrity of the nethouse and Standard Operating Procedures are complied with.
- 2) The National Biosafety Board shall be informed immediately if there is any containment breach or security breach in the confined field trial.
- 3) No parts of the GM papaya plants from this confined field trial shall be consumed or utilised for any other purpose other than this trial.
- 4) There shall be no planting of papaya plants within 1 km buffer zone from the nethouse, and all existing papaya plants in this zone shall be removed.
- 5) Should the approved person receive any scientifically proven information that confirms any adverse effect of transgenic Eksotika Papaya, the National Biosafety Board shall be informed.