

## Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-MY-108757-2

LAST UPDATED: 17 MAY 2022

### General information

Country

Malaysia

Title of the risk assessment

RISK ASSESSMENT REPORT OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC) FOR AN APPLICATION FOR APPROVAL FOR RELEASE OF TRANSGENIC RUBBER (*Hevea brasiliensis*) TREES FOR CONFINED FIELD TRIAL FOR RESEARCH AND DEVELOPMENT PURPOSE

EN

Date of the risk assessment

16 Jun 2015

Competent National Authority(ies) responsible for the risk assessment

- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-MY-48230-13 | [BCH-CNA-MY-48230-13](#)

#### COMPETENT NATIONAL AUTHORITY

Department of Biosafety Malaysia  
Ministry of Environment and Water Level 4, Block F11, Complex F Lebuhr Perdana Timur,  
Precinct 1  
Putrajaya  
62000, Malaysia  
Phone: +603 80917 317  
Fax: +603-8091 7371  
Email: [dob@biosafety.gov.my](mailto:dob@biosafety.gov.my)  
Website: <http://www.biosafety.gov.my>

Contact details of the main responsible risk assessor

- **PERSON:** DR. NORWATI ADNAN | [BCH-CON-MY-254013-4](#)

#### PERSON

Dr. Norwati Adnan  
Director, Department of Biosafety  
Department of Biosafety, Ministry of Environment and Water Ministry of Environment and

Water, Level 4, Block F11, Complex F, Lebuhr Perdana Timur, Precinct 1  
Putrajaya, Putrajaya  
62000, Malaysia  
Phone: +603 - 80917 319  
Email: [norwati@biosafety.gov.my](mailto:norwati@biosafety.gov.my)  
Website: <http://www.biosafety.gov.my>

## Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-108912-1](#) | Rubber tree modified to express the scFv4715 antibody fragment | Dr. Sunderasan Elumalai Production of medical or pharmaceutical compounds (human or animal) - Antibodies and antigens Resistance to antibiotics - Kanamycin  
[BCH-LMO-SCBD-108906-1](#) | Rubber tree modified to express a reporter gene | Dr. Sunderasan Elumalai Resistance to antibiotics - Kanamycin Selectable marker genes and reporter genes  
[BCH-LMO-SCBD-108909-1](#) | Rubber tree modified to express Human atrial natriuretic factor | Dr. Sunderasan Elumalai Production of medical or pharmaceutical compounds (human or animal) Resistance to antibiotics - Kanamycin  
[BCH-LMO-SCBD-108908-2](#) | Rubber tree modified to express Human Protamine 1 | Dr. Sunderasan Elumalai Production of medical or pharmaceutical compounds (human or animal) Resistance to antibiotics - Kanamycin

Scope of the risk assessment

LMOs for introduction into the environment

Risk assessment report / summary

? [GMAC RA Report GM Rubber Trees \( English \)](#)

## Methodology and points to consider

Potential adverse effects identified in the risk assessment

Please refer to the Risk Assessment Report.

EN

Likelihood that the potential adverse effects will be realized

Please refer to the Risk Assessment Report.

EN

Possible consequences

Please refer to the Risk Assessment Report.

EN

Estimation of the overall risk

Please refer to the Risk Assessment Report.

EN

Recommendation(s) on whether the risks are acceptable/manageable and any management strategies

GMAC has conducted a thorough evaluation of the application for approval for release of GM

EN

rubber (*Hevea brasiliensis*) trees for confined field trial for research and development purpose and has determined that the confined field trial does not endanger biological diversity or human, animal and plant health. GMAC recommends that the proposed application for confined field trial be APPROVED WITH TERMS AND CONDITIONS as listed in section IV (Proposed Terms and Conditions for Certificate of Approval). GMAC also recommends that Section VI (Identification of Issues to be Addressed for Future Releases) be forwarded to the applicant for further reference.

### Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

No

### Additional Information

Other relevant website addresses and/or attached documents

? [Department of Biosafety Malaysia \( English \)](#)

[BCH-RA-MY-108757-2](#)

## Further Information

Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

### Secretariat of the Convention on Biological Diversity

413 rue Saint-Jacques, suite 800  
Montreal, Québec, H2Y 1N9  
Canada

Fax: +1 514 288-6588

Email: [secretariat@cbd.int](mailto:secretariat@cbd.int)