

## Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-MY-115774-1

LAST UPDATED: 20 NOV 2020

### General information

Country

[Malaysia](#)

**PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY**

**ENTRY INTO FORCE: 02 DEC 2003**

Title of the risk assessment

RISK ASSESSMENT REPORT OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)  
FOR AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF X17 POTATO FOR  
SUPPLY OR OFFER TO SUPPLY

EN

Date of the risk assessment

07 Jul 2020

Competent National Authority(ies) responsible for the risk assessment

- [COMPETENT NATIONAL AUTHORITY: BCH-CNA-MY-48230-11](#) | [BCH-CNA-MY-48230-11](#)

#### COMPETENT NATIONAL AUTHORITY

Department of Biosafety Malaysia

Ministry of Environment and Water Level 4, Block F11, Complex F Lebuh Perdana Timur,  
Precinct 1

Putrajaya

62000, Malaysia

Phone: +603 8886 1579, +603 8886 1746

Fax: +603-8890 4935

Email: [dob@biosafety.gov.my](mailto:dob@biosafety.gov.my)

Website: <http://www.biosafety.nre.gov.my>

Contact details of the main responsible risk assessor

- [PERSON: DR. NORWATI ADNAN](#) | [BCH-CON-MY-111514-6](#)

#### PERSON

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#### RELATED ORGANIZATION

## Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-112929-1](#) | SPS-ØØX17-5 - Innate® Acclimate Ranger Russet Potato | SPS International Changes in quality and/or metabolite content - Carbohydrates, Pigmentation / Coloration, Protein and amino acids Resistance to diseases and pests - Fungi

Scope of the risk assessment

LMOs for direct use as food  
LMOs for direct use as feed  
LMOs for processing

Risk assessment report / summary

? [Department of Biosafety Malaysia \( English \)](#)  
? [GMAC Malaysia RA Report X17 potato \( English \)](#)

## 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 importation for release [sale/placing on the market for direct use as food, feed and for processing (FFP)] of a product of a Living Modified Organism X17 potato with late blight protection as well as reduced acrylamide formation and browning and has determined that the release of this product does not endanger biological diversity or human, animal and plant health. GMAC

EN

recommends that the proposed application for release be APPROVED WITH TERMS AND CONDITIONS as listed in section IV - Proposed Terms and Conditions for Certificate of Approval.

### Information sharing with other databases

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

No

Should this risk assessment be forwarded to the OECD Secretariat for possible inclusion in the [BioTrack Product Database](#)?

No

Is this risk assessment related to food safety?

No

Was it conducted in accordance with the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*?

No

Should this information be forwarded to the Secretariat of the [FAO GM Foods Platform](#)?

No

### Additional Information

Other relevant website addresses and/or attached documents

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

? [FAO GM Foods Platform - Malaysia \( English \)](#)

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## 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

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