

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-MY-114262-2

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 PRODUCTS OF DP 4114 MAIZE FOR
SUPPLY OR OFFER TO SUPPLY

EN

Date of the risk assessment

18 Jul 2018

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

Contact details of the main responsible risk assessor

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

PERSON

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Department of Biosafety, Ministry of Environment and Water Ministry of Environment and
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Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-104976-2](#) | DP-ØØ4114-3 - Insect-Resistant and Herbicide-Tolerant Maize | Pioneer Hi-Bred International Inc. | Resistance to diseases and pests (Insects, Coleoptera (beetles), Lepidoptera (butterflies and moths)), Resistance to herbicides (Glufosinate)

Scope of the risk assessment

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

Risk assessment report / summary

? [GMAC Malaysia RA Report DP4114 Corn \(English \)](#)

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 insect-resistant and herbicide-tolerant DP 4114 maize and has determined that the release of this product does not endanger biological diversity or human, animal and plant health. GMAC 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.

EN

Information sharing with other databases

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

Yes

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

Yes

Is this risk assessment related to food safety?

Yes

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

Yes

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

Yes

Additional Information

Other relevant website addresses and/or attached documents

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

? [Department of Biosafety 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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