





Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-MY-105269-2

LAST UPDATED: 13 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 Product of Glufosinate tolerant A5547-127 Soybean for Supply or Offer to Supply

ΕN

Date of the risk assessment

08 Jan 2014

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 Lebuh Perdana Timur,

Precinct 1 Putrajaya

62000, Malaysia

Phone: +603 80917 317 Fax: +603-8091 7371

Email: 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, Lebuh Perdana Timur, Precinct 1

Putrajaya, Putrajaya 62000, Malaysia

Phone: +603 - 80917 319

Email: norwati@biosafety.gov.my Website: http://www.biosafety.gov.my

Risk assessment details

Living modified organism(s)

BCH-LMO-SCBD-14857-8 | ACS-GMØØ6-4 - Liberty Link™ soybean | Resistance to herbicides -Glufosinate

Show detection method(s)

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 RA Report Bayer A5547-127 soybean (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

ΕN Please refer to the Risk Assessment Report

Possible consequences

ΕN Please refer to the Risk Assessment Report

Estimation of the overall risk

ΕN Please refer to the Risk Assessment Report

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 (Glufosinate tolerant A5547-127 soybean) 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 subject to approval by other relevant agencies.

ΕN

LMO detection and identification methods proposed

Haelterman (2008, Annex 9 M-299045-01-1) describes an event-specific real-time quantitative PCR method for detection and determination of the relative content of A5547-127 event DNA to total soybean DNA in a sample.

ΕN

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

? Department of Biosafety Malaysia (<code>English</code>)

? FAO GM Foods Platform - Malaysia (English)

BCH-RA-MY-105269-2

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