

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-MY-105097-2

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 Imidazolinone-Tolerant CV127 Soybean for Supply or Offer to Supply

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Date of the risk assessment

02 Oct 2013

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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Contact details of the main responsible risk assessor

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

PERSON

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Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-100994-7](#) | BPS-CV127-9 - Herbicide-tolerant soybean | BASF S.A. Resistance to herbicides - Imidazolinone, Sulfonylurea

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 BASF CV127 soybean](#) (*English*)

Methodology and points to consider

Potential adverse effects identified in the risk assessment

Please refer to the Risk Assessment Report

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Likelihood that the potential adverse effects will be realized

Please refer to the Risk Assessment Report

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Possible consequences

Please refer to the Risk Assessment Report

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Estimation of the overall risk

Please refer to the Risk Assessment Report

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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 (Imidazolinone-Tolerant CV127 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.

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LMO detection and identification methods proposed

The event-specific method for the quantification of CV127 soybean is based on a real-time

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quantitative TaqMan PCR procedure to determine the relative content of CV127 to total soybean DNA in a sample. The protocol was shown to be capable of detecting 0.04 % CV127 soybean DNA in a mixture of non-transgenic soybean DNA. The protocol consists of a method module for DNA extraction from soybeans and a method module for event-specific quantification of CV127 soybean DNA. For quantitative event-specific detection of CV127 soybean two real-time PCR systems are used: a soybean-specific reference PCR system and a PCR system for event- specific detection of CV127 soybean. The soybean-specific reference PCR system is based on the sequences of the soybean Le1 (lectin) gene. The event-specific real- time PCR system for CV127 soybean is located at the 3' insert-to-genomic soybean DNA junction. The forward primer-binding site is located in the CV127 insert, the binding site of the reverse primer is within genomic soybean DNA and the binding site of the probe spans the junction between the CV127 insert and genomic DNA.

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 \(English \)](#)

? [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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