

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-104885-1

LAST UPDATED: 30 MAY 2013

General information

Country

[Philippines](#)

PARTY TO THE CARTAGENA PROTOCOL ON BIOSAFETY

ENTRY INTO FORCE: 03 JAN 2007

Title of the risk assessment

Determination for the Safety Assessment of Soybean A2704-12 for Direct Use as Food, Feed and for Processing

EN

Competent National Authority(ies) responsible for the risk assessment

- [COMPETENT NATIONAL AUTHORITY: BCH-CNA-PH-46524-5](#) | [BCH-CNA-PH-46524-5](#)

COMPETENT NATIONAL AUTHORITY

Department of Agriculture
Elliptical Road, Diliman
Quezon City
1100, Philippines
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Email: osec.da@gmail.com
Website: <http://www.da.gov.ph>

Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-14764-9](#) | ACS-GM005-3 - Herbicide-tolerant 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

? http://biotech.da.gov.ph/upload/BPI_decision_SoybeanA2704-12_final.pdf (English)

Methodology and points to consider

Likelihood that the potential adverse effects will be realized

The concentration levels of total isoflavones (phytoestrogens, including total daidzein, total genistein, and total glycitein) were all inside the Literature range and not statistically different between samples from non-transgenic and transgenic nonsprayed soybeans. The low potential for allergenicity of the PAT protein has previously been established through amino acid sequence comparisons with known protein allergens and digestibility studies using simulated gastric and intestinal fluids.

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Possible consequences

Soybean seed extracts from line A2704-12 and from non-transgenic control plants were screened against a panel of sera from 16 soy-allergic individuals using the radioallergosorbent test (RAST). The results of this study did not reveal any qualitative or quantitative difference in endogenous soybean allergen content between transgenic and non-transgenic soybean.

EN

Estimation of the overall risk

Soybean A2704-12 is as safe as its conventional counterpart and does not pose any significant risk to animal and human health.

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

A biosafety permit for Soybean A2704-12 and all progenies derived from crosses of the product with any conventionally-bred soybean and soybean containing approved-biotech events for direct use as food and feed or for processing was issued to Bayer CropScience. Soybean A2704-12 is found to be as safe as its conventional counterpart and does not pose any significant risk to human and animal health.

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Receiving environment(s) considered

This LMO will be directly used for food, feed and for processing. This application is not for propagation of this event.

EN

LMO detection and identification methods proposed

Qualitative diagnostic lateral flow strips, ELISA and PCR for routine quantitative and semi-quantitative detection of transgenes. For higher sensitivity, real-time PCR.

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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

All relevant references submitted by the technology developer in their application; other references requested by the Scientific and Technical Review Panel (STRP) members and DA regulatory agencies during the evaluation of Soybean A2704-12.

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Other relevant website addresses and/or attached documents

? http://biotech.da.gov.ph/upload/BPI_decision_SoybeanA2704-12_final.pdf (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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