

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-115899-1

LAST UPDATED: 19 FEB 2021

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 Potato E12 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

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Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-106428-3](#) | SPS-ØØE12-8 - Innate™ Russet Burbank Potato | J.R. Simplot Company | Changes in quality and/or metabolite content (Pigmentation / Coloration, Protein and amino acids)

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/>

Methodology and points to consider

Potential adverse effects identified in the risk assessment

Glycoalkaloids are the reported toxicants contained by potato tubers and are found in its periphery (peeling) and internal part. Other potential toxicants include calystegines; multiple heat-labile proteins that can induce hypersensitivity reactions; patatin which induces allergic reactions; and IgE binding component that neutralize the effects of several proteins (OECD, 2002). Processing of the tubers such as washing, peeling, cutting, rinsing and heat treatment usually result in its removal.

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Likelihood that the potential adverse effects will be realized

Based on the Southern Blot Analysis, deletion of 24 bp was observed in the LB and 119 bp in the RB. It was verified, based on scientific evidences that the deletions observed in the E12 insert do not have the potential for creating novel chimeric ORFs. Elements of the pSIM1278 DNA inserts are specific to potato and have not been used in approved crops other than potato.

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Possible consequences

Vegetative propagation may alter processes responsible for genetic variation, meiosis, recombination and segregation. The Southern blot analysis on G0 and G3 plants showed consistent banding pattern demonstrating that the integrity of the insert was maintained across vegetative propagation.

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Estimation of the overall risk

Potato E12 does not produce a novel protein. The T-DNA is designed to down-regulate the Asn, Ppo, PhL, and R1 genes in tubers leading to reduced expression of the ASN, PPO, PhL, and R1 proteins. Northern blot analysis showed reduced expression of Asn and Ppo in the tuber and Asn in the flower. Expression of Asn, Ppo, PhL, and R1 genes in the leaves, stems and roots were unchanged.

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

Potato E12 will not pose any significant risk to the health and environment and that any hazards could be managed by the measures set by the department. History of safe use is attributed on the host organism (*Solanum tuberosum*) and donor organisms (*Solanum tuberosum* and *S. verrucosum*) which are not known to be toxic or allergenic to humans and animals. A biosafety permit for direct use can be issued for the said event.

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Need(s) for further information on specific issues of concern

Weight of evidence approach indicate that Potato E12 is as safe as its conventional counterpart with regards to substantial equivalence and food safety.

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Receiving environment(s) considered

The application of potato E12 is not for propagation. This LMO will be directly used for food, feed and for processing.

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LMO detection and identification methods proposed

Diagnostic lateral flow strips, ELISA and PCR for routine qualitative and semi-quantitative detection of transgenes. For higher sensitivity, real-time PCR methods may be used.

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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

Potato E12 is intended for direct use as food, feed and for processing.

All relevant references submitted by the technology developer in their application; other references requested by the Scientific and Technical Review Panel (STRP) members during the evaluation of this combined trait product.

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Other relevant website addresses and/or attached documents

http://biotech.da.gov.ph/Decision_docs_jdc_direct.php?fbclid=IwAR1DfDu4QHnejzgo7mOdByQboQaHxxmQzFUMcRI6EoKw492
(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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