

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-115901-1

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 Soybean SYHTOH2 for Direct Use as Food, Feed and for Processing

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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-105619-1](#) | SYN-ØØØH2-5 - Soy modified for tolerance to Mesotrione and Glufosinate | Bayer CropScience LP | Resistance to herbicides (Glufosinate), Resistance to Mesotrione

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

The antinutrients present in soybean such as trypsin inhibitors and lectins, stachyrose, raffinose oligosaccharides and phytic acids are degraded during processing. Soybean contains recognized allergenic proteins, but the relevant estimate of its allergenic potential is not complete. No significant level of amino acid homology exists between the PAT gene and any protein allergens.

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Likelihood that the potential adverse effects will be realized

Southern blot analysis and nucleotide sequencing were done for the extensive characterization of the DNA inserted in SYHT0H2 soybean. In addition, the soybean genome sequence flanking the SYHT0H2 inserted were identified and characterized. Results showed that the SYHT0H2 inserted did not disrupt the function of any known soybean gene. These data collectively demonstrate that no deleterious changes occurred in the SYHT0H2 soybean genome as a result of the DNA insertion.

The PAT regulatory enzymes are reportedly not associated with food toxins and allergens backed up by the absence of a sequence homology with known allergens or toxins.

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Possible consequences

The enzyme AvHPPD expressed by avhppd-03 gene confers tolerance to commercial application rates of HPPD-inhibiting herbicides such as mesotrione. It is not known to be homologous to known toxin or allergen as supported by analyses provided by developer. PAT expressed by pat-09 genes is an enzyme involved in the inactivation of glufosinate ammonium through acetylation. History of safe use was attributed to PAT proteins which are not associated with any known toxins or allergens. The developer provided sufficient information that there is no possibility of any interaction of AvHPPD and PAT in a metabolic pathway.

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Estimation of the overall risk

No safety concerns for the environment from the import and processing of soybean SYHT0H2 were identified. The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly expressed proteins and found no evidence that the genetic modification might significantly change the overall allergenicity of soybean SYHT0H2.

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

No unintended, adverse consequences of the transformation process or expression of the transgenes in SYHT0H2 were evident that will affect human health and no possible risk in animal health. 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

The protein used in the assessment of toxicity was microbially produced AvHPPD-03 from

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Eschericia coli and is reportedly non-toxic to mice as evidenced by the absence of mortality during two and 14-day observation. Sufficient data and analyses were provided by the developer indicating that the microbially produced AvHPPD-03 is biochemically and functionally equivalent to AvHPPD-03 produced in SYHT0H2 soybean and therefore is a suitable surrogate to evaluate the safety of AvHPPD-03 produced in SYHT0H2 soybean. Safety evaluation supports the innocuousness of the PAT gene which does not possess characteristics of a toxin or allergen, no N-glycosylation sites, easily degraded by gastric and intestinal fluids and devoid of adverse effects in mice after IV injection of a high dose. Utilizing the NCBI Entrez Protein Database in search of the similarity of the PAT amino acid sequences shows that it has no homologies with known toxins.

Acute Oral Gavage tests were performed, and reasonable certainty of safety is expected from the inclusion of PAT proteins in human food and animal feed.

Receiving environment(s) considered

The application of soybean SYHT0H2 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

SOYBEAN SYHT0H2 is intended for direct use as food, feed and for processing.

All relevant references submitted by the technology developer in their application; other

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references requested by the Scientific and Technical Review Panel (STRP) members during the evaluation of this combined trait product.

Other relevant website addresses and/or attached documents

http://biotech.da.gov.ph/Decision_docs_jdc_direct.php?fbclid=IwAR1DfDu4QHnejzgzo7mOdByQboQaHxxmQzFUMcRI6EoKw492
(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.

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on Biological Diversity**

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