

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-115900-1

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 Combined Trait Product Soybean MON87769 x MON89788 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-104778-3](#) | MON-87769-7 x MON-89788-1 - Soybeans with modified fatty acid profile and glyphosate tolerance | Changes in quality and/or metabolite content - Lipid and fatty acids
Resistance to herbicides - Glyphosate
[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/>

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

(English)

Methodology and points to consider

Potential adverse effects identified in the risk assessment

Soybean is considered to be a common allergenic food. Therefore, any potential change in the endogenous allergenicity of the GM plant when compared with that of its comparator(s) should be assessed. Such assessments were performed for the single-event soybeans MON 87769 and MON 89788, and no reasons for concern were identified.

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Likelihood that the potential adverse effects will be realized

MON 87764 which contains the Pj. $\Delta 6D$ and Nc.Fad3 proteins are members of a family of integral membrane fatty acid found in all eukaryotic organisms and some prokaryotes while MON 89788 which contains CP4 EPSPS belongs to the family of EPSPS synthases which are involved in the shikimic acid pathway producing aromatic amino acids in the chloroplasts of the plants.

The expression cassette of Pj $\Delta 6D$ and Nc.Fad3 does not have specific transit peptide unlike CP4 EPSPS which indicates that Pj $\Delta 6D$ and Nc.Fad3 will accumulate in the cytoplasm. CP4 EPSPS is targeted to accumulate in the chloroplast due to the presence of chloroplast transit peptide. This indicates that the gene products will accumulate in different subcellular compartments of the plant parts.

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Possible consequences

Pj. $\Delta 6D$ is a single polypeptide $\Delta 6$ desaturase which creates double bond at the 6th position from the carboxyl end of a fatty acid yielding significant levels of stearidonic Acid (SDA) in the seeds of MON 87769 while Nc.Fad3 is a single polypeptide $\omega 3$ desaturase which creates a double bond between the third and fourth carbon from the methyl end of a fatty acid yielding significant levels of SDA.

Pj $\Delta 6D$ is required to convert alpha linolenic acid (ALA) to SDA in the omega 3-fatty acid biosynthetic pathway. Expression of the introduced delta -6 desaturase gene (Pj.D6D) also results in the conversion of linoleic acid (LA) to gamma linolenic acid (GLA), in the omega-6 fatty acid pathway. While Nc $\Delta 15D$ catalyses the conversion of Linoleic acid (LA) to alpha linolenic acid (ALA), thereby increasing the pool of ALA available for conversion to SDA and gamma linolenic acid (GLA) to SDA.

CP4 EPSPS proteins are involved in the biochemical shikimic pathway producing aromatic amino acid in the chloroplasts. It catalyzes the transfer of enolpyruvyl group from phosphoenol pyruvate (PEP) to the 5-hydroxyl of shikimate-3-phosphate (S3P) producing inorganic phosphate and 5 enolpyruvylshikimate-3-phosphate. This mechanism is being inhibited with glyphosate binding which blocks the binding of EPSPS to PEP. CP4 EPSPS, on the other hand, has higher affinity for PEP thus allowing the catalysis. This enzyme catalyzes the reaction wherein the enolpyruvyl group from phosphoenol pyruvate (PEP) is transferred to the 5-hydroxyl of shikimate-3-phosphate (S3P) to form 5-enolpyruvylshikimate-3-phosphate (EPSPS) and inorganic phosphate (Pi). Based on these

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information, the gene products have different mode of action and are involved in different metabolic pathway.

Estimation of the overall risk

Upon extensive review and evaluation of the application for direct use as food and feed or for processing, including the scientific evidences from provided references, literature and other studies, soybean MON87769 x MON89788 is safe as its conventional counterpart and is not expected to pose any significant risk to the environment.

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

Soybean MON87769 x MON89788 is as safe as its conventional counterpart and shall not pose any significant risk to human health and the environment. The regulated article does not require changes in the usual practices in transport, storage and processing. 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

Based on the documents provided by the proponent, there is no possible interaction that would affect the stability and expression level of either one of the genes. The expression of the genes in the stacked trait is inherited and functioning properly indicating that there is no gene interaction.

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Receiving environment(s) considered

Soybean MON87769 x MON89788 application of 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 MON87769 x MON89788 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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