

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY AN INDEPENDENT OR NON-REGULATORY
PROCESS (IRA)

BCH-IRA-PH-114760-1

LAST UPDATED: 30 MAY 2019

General information

Title of the risk assessment

ASSESSORS' CONSOLIDATED REPORT ON MONSANTO'S APPLICATION FOR DIRECT USE AS
FOOD AND FEED, OR FOR PROCESSING OF COMBINED TRAIT PRODUCT SOYBEAN MON87705
x MON87708 x MON89788

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Date of the risk assessment

10 Jul 2018

Institution responsible for the risk assessment

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

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Phone: +632 920-3986, +632 924-1278 local 2802
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- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-PH-46436-4 | [BCH-CNA-PH-46436-4](#)**COMPETENT NATIONAL AUTHORITY**

Department of Environment and Natural Resources
Visayas Avenue
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- **COMPETENT NATIONAL AUTHORITY:** BCH-CNA-PH-46523-2 | [BCH-CNA-PH-46523-2](#)

COMPETENT NATIONAL AUTHORITY

Department of Health
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Contact details of the main responsible risk assessor

- **PERSON:** MS. MA. LORELEI U. AGBAGALA | [BCH-CON-PH-111734-2](#)

PERSON

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RELATED ORGANIZATION

Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-111515-1](#) | MON-87705-6 x MON-87708-9 x MON-89788-1 - Soybeans with modified fatty acid profile and herbicide 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/upload/CONSOLIDATED-MON87705-x-MON87708-x-MON89788.pdf> (English)
? [ASSESSORS' CONSOLIDATED REPORT ON MONSANTO'S APPLICATION FOR DIRECT USE AS FOOD](#)

Methodology and points to consider

Potential adverse effects identified in the risk assessment

The STRP, BAI, and BPI-PPSSD concurred that the likelihood of interaction of the two proteins involved in the combined trait product DMO and CP4EPSPS is highly unlikely to produce any known allergen or toxins to human and animals because of the difference on their mode of action. There is no known mechanism of interaction among the RNA-based suppression and the proteins that could lead to adverse effects in humans, animals or environment which is not likely to interact. Furthermore, the assessors affirmed that there are no possible unintended effects of stacked genes on the metabolism of the plant based on the previous assessments of individual transformation events. In addition, stability and expression of the gene will never be affected since molecular analyses also indicated the absence of any marker gene in MON87705 x MON87708 x MON89788 genome.

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Likelihood that the potential adverse effects will be realized

Based on the documents provided by the developer, the two (2) proteins being expressed in the combined trait product, DMO and CP4 EPSPS, will not interact to produce any known allergen or toxins to human and animals. There is no known mechanism of interaction among the RNA-based suppression and the proteins that could lead to adverse effects in humans, animals or environment which is not likely to interact.

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Possible consequences

There is no known mechanism of interaction among the RNA-based suppression and the proteins that could lead to adverse effects in humans, animals or environment which is not likely to interact

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Estimation of the overall risk

The regulated article applied for direct use as food and feed or processing is safe as its conventional counterpart and shall not pose any significant risk to human and animal health and environment.

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

DENR recommendation:

After thorough and scientific review and evaluation of the documents provided by the Bureau of Plant Industry (BPI) to the DENR Biosafety Committee within the prescribed period pursuant to Joint Department Circular (JDC) No.1 s.2016 on the application of Monsanto Philippines, Inc. for direct use for feed, food or processing of Genetically Modified Soybean tolerant to glyphosate herbicide stacked trait product MON87705 x MON87708 x MON89788, the following are the observations and recommendations:

1. The effect of the regulated article on the environment depends largely on the viability of the product to be utilized for direct use. If the article is transported in a nonviable form, there is no danger to the environment;
2. Due to the absence of a specified Environmental Management Plan (EMP) by the traders/importers, the Committee would like to recommend that it be added to the requirements for

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the issuance of an import permit by the Bureau of Plant Industry (BPI) (Article VIII, Section 26 of JDC No.1 s.2016);

3. It is suggested that BPI ensure the following:

- a) development of guidelines on the EMP in coordination with DENR;
- b) implementation of the EMP by the traders/importers involved in the import, handling, processing and transport of viable soybean MON87705 x MON87708 x MON89788 commodity products; and
- c) Strict monitoring of the regulated article from port of entry to the trader's/importer's storage/warehouse (Section 32 of the JDC No. 1 s.2016);

Based on the above considerations and with the submitted sworn statement and accountability of the proponent, a biosafety permit may be issued to the proponent if the abovementioned recommendations are followed.

DOH recommendation:

1. Find that regulated article applied for direct use for food and feed or for processing (FFP) does not require changes in the usual practices in unloading, loading, transport, storage and processing. As such, the regulated article is as safe as its conventional counterpart and is not expected to pose any significant risk to human and animal health and environment while in transit, storage and processing.

2. Scientific pieces of evidences from provided references i.e. literatures show that regulated article applied for direct use as food and feed or for processing (FFP) is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health and on the environment.

3. It is suggested that Bureau of Plant Industry (BPI) ensure the following:

- a. Strict monitoring of the regulated article from port of entry to the trader's / importer's storage/warehouse as stated in Section 32 of the JDC No. 1 series, 2016.
- b. The BPI to include in the insurance of permit for the release of this product the following conditions:
 - b.1. Any spillage (during unloading and loading/hauling and transport unloading and storage) shall be collected and cleaned up immediately.
 - b.2. Transportation of the consignment from the port of entry to any destination within the country shall be in closed containers.
 - b.3. There shall be a clear labeling of the product from importation down to all levels of marketing stating that it is only for the purpose of direct use for food and feed or for processing and is not to be used as planting materials.

4. Based on the above considerations and with the submitted sworn statement and accountability of the proponent, this recommendation is being submitted to BPI related to the processing and issuance of a biosafety permit for direct use as food and feed or for processing of soybean MON87705 x MON87708 x MON89788.

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

Stacked trait Soybean MON87705 x MON87708 x MON89788 is found substantially equivalent to conventional counterpart and does not pose any significant risk to animal and human health.

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Receiving environment(s) considered

This application is not for propagation of the Stacked trait Soybean MON87705 x MON87708 x MON89788. This LMO will be directly used for food, feed and for processing.

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LMO detection and identification methods proposed

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

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Additional Information

Stacked Trait Soybean MON87705 x MON87708 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, BAI, PPSSD, DENR, DOH and SEC Expert during the evaluation of this event.

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Other relevant website addresses and/or attached documents

? [ISAAA](#) (English)

[BCH-IRA-PH-114760-1](#)

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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