

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-115898-1

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 Oilseed Rape (Canola) MS11 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-112988-2](#) | BCS-BNØ12-7 - Male Sterile/ Fertility Restored Herbicide Tolerant Canola | Changes in physiology and/or production - Reproduction - Male sterility Resistance to herbicides - Glufosinate

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

Oilseed rape is also a source of a few anti-nutrients. Glucosinolates, phenolic compounds like sinapine, phytic acid, and tannins are considered anti-nutritional factors. However, these are in very low amounts in current low erucic acid and low glucosinolate rapeseed meal. Moreover, processing steps including heat treatment eliminates or inactivates anti-nutritional factors.

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Likelihood that the potential adverse effects will be realized

Both the barnase and barstar genes were derived from *Bacillus amyloliquefaciens*. Expression of the barnase gene in the anther results in the absence of viable pollen and male sterility. Barstar gene, on the other hand, encodes for the barstar protein, which is a known inhibitor of the Barnase protein and was utilized in this event to enhance the transformation frequency. Both genes are non-allergenic and have no biologically relevant identities with any toxic proteins from the Bayer's toxin database.

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The bar gene, on the other hand, was isolated from *Streptomyces hygroscopicus*, a common microbe in the soil. This gene encodes for phosphinothricin acetyltransferase (PAT/bar) protein, which confers tolerance to glufosinate ammonium. Bar and its homologues have no record of being toxic or allergenic in humans or animals.

Possible consequences

There are no in silico toxicological findings associated with the PAT/bar protein from the toxin database. There was also an acute oral gavage study for the PAT/bar protein which was done at a dose level of 2000mg/kg body weight for 15 using 20 C57BL/6J, 10 females and 10 males. No signs of systemic toxicity were noted.

Microbially-produced PAT/BAR protein and plant produced PAT/BAR protein showed functional and structural equivalence.

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An acute oral toxicity test with the Barnase protein was also done at 2000 mg/kg body weight via the oral route. It did not produce any signs of systemic toxicity in the male (10) and female (10) C57BL/6J mice. Peptide mapping of the microbially-produced protein demonstrated 100% coverage against the theoretical amino acid sequence of the Barnase protein and was 100% identical to the amino acid sequence predicted from the nucleotide sequence of the MS11 insert.

Estimation of the overall risk

For MS11 canola, weight of evidence approach indicates the substantial equivalence of the single event in terms of nutritional composition and food safety, with the conventional canola other than the tolerance to glufosinate-containing herbicides and male sterility.

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The direct use of MS11 canola, whether for food, feed or for processing will not cause any

significant adverse effect on the environment.

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

History of safe use is attributed on the host organism (*Brassica napus*) and donor organisms (*Bacillus amyloliquefaciens* and *Streptomyces hygroscopicus*) which is not known to be toxic or allergenic to humans and animals. . The transgenic crop will not be able to transfer its pollen grains to its wild relatives due to the expression of Barnase-barstar system, which was due to the insertion of the bar and barstar genes. Baxnase expression causes the lack of viable pollen grains and male sterility in the transgenic crop while barstar inhibits barnase expression causing fertility restoration
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

Safety assessment based on the nutritional data is not applicable since MS11 is male sterile. For MS11 canola, weight of evidences approach indicates the substantial equivalence of the single event in terms of nutritional composition and food safety, with the conventional canola other than the tolerance to glufosinate-containing herbicides and male sterility.

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Receiving environment(s) considered

The application of oilseed rape/canola MS11 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

Oilseed rape/canola MS11 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=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.

**Secretariat of the Convention
on Biological Diversity**

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