

## Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-116096-1

LAST UPDATED: 11 JUN 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 COTTON GHB811 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

Elliptical Road, Diliman

Quezon City

1100, Philippines

Phone: +632 920-3986, +632 924-1278 local 2802

Fax: +632 920-3986

Email: [osec.da@gmail.com](mailto:osec.da@gmail.com)Website: <http://www.da.gov.ph>

## Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-113966-2](#) | BCS-GH811-4 - Herbicide tolerant cotton | Bayer CropScience |  
Resistance to herbicides (Glyphosate)

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](http://biotech.da.gov.ph/Decision_docs_jdc_direct.php) ( English )

## Methodology and points to consider

### Potential adverse effects identified in the risk assessment

Certain fatty acid forms like sterculic, malvalic and dihydrosterculic acids are found in cotton. These are classified as anti-nutrients.

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Gossypol is a toxic substance in cottonseed and its by-product meal.

### Likelihood that the potential adverse effects will be realized

SDS-PAGE and western blot analysis showed that digestibility of HPPD W336 in simulated gastric fluid (SGF) with pepsin at pH 1.2 is within 30 seconds after incubation. It was also assessed in simulated intestinal fluid (SIF) with pancreatin at pH 7.5. Results showed that the 90% of the protein was completely broken down in less than 30 seconds of incubation. These results indicate that it is unlikely to cause toxicological risk to human health.

Bioinformatics analyses using FASTA algorithm associated with the BLOSUM50 scoring matrix sequence alignment tool showed that no relevant structural similarities were observed between the HPPD W336 and human and animal toxins. This indicates that HPPD W336 will not cause toxicity or health risk to human health.

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No Observed Effect Level (NOEL) for 2mEPSPS protein was observed at 2000 mg/kg body weight, with no signs of treatment-related clinical signs and no changes in food consumption. The mean food consumption of the treated samples was significantly lower in both sexes compared to control, but the values were within normal range.

### Possible consequences

Two in silico approaches using the FASTA algorithm with BLOSUM50 scoring matrix were used. Based on the bioinformatics analysis, there are no toxicological in silico findings associated with the 2mEPSPS protein. Acute oral toxicity was also performed in male and female C57BL/6J mice. There were no mortalities, no treatment-related clinical signs, no effects on the body weight and food consumption parameters as well as no macroscopic changes in necropsy in C57BL/6J mice after acute oral administration of the 2mEPSPS protein at 2000 mg/kg body weight.

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Again, two in silico approaches using the FASTA algorithm with BLOSUM50 scoring matrix were used to check HPPD W336 for homology with known allergens. Based on the bioinformatics analysis, there are no allergenic in silico findings associated with the HPPD W336 protein.

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

Bioinformatics analyses using FASTA algorithm associated with the BLOSUM50 scoring matrix sequence alignment tool showed that no relevant structural similarities were observed between the HPPD W336 and human and animal toxins. This indicates that HPPD W336 will not cause toxicity or health risk to human.

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Further, acute oral toxicity assessment was then conducted using E. coli-produced HPPD W336 protein in 6 male and 6 female C57BL/6J mice at a total dose level of 2000 mg/kg body weight [5]. Based on the toxicity study, there were no treatment-related effects on survival,

clinical observations, body weight gain, food consumption or gross pathology, thus the NOAEL for HPPD W336 was 2000 mg/kg bw, the highest dose tested.

Find no evidence that COTTON GHB811 applied for human food and animal feed use is as safe as its conventional counterpart and shall not pose any significant risk to human and animal health.

A biosafety permit for direct use can be issued for the said event.

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

With the use of two in silico approaches using FASTA algorithm with BLOSUM50 scoring matrix, an overall identity search with all protein sequences in NCBI non-redundant and internal toxin databases with E-value threshold of 0.1 and 10, respectively was performed to assess if the double mutated 5-enol pyruvylshikimate-3-phosphate synthase (2mEPSPS) protein has a similarity with known toxins. Results in general protein database showed various proteins from different origins but has no potential hazard recorded.

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Receiving environment(s) considered

The application of COTTON GHB811 is not for propagation. This LMO will be directly used for food, feed and for processing.

The direct use of the regulated article whether for food, feed or for processing will not cause any significant adverse effect on the environment and biodiversity. The transgenic crop will not increase its weediness potential in case the seeds spill out into the environment because cotton has limited potential to survive outside agricultural settings, and the introduced genes are not expected to increase its ability to spread and persist.

The genetically modified crop is substantially similar to its conventional counterpart except for the herbicide tolerance trait.

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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

COTTON GHB811 is intended for direct use as food, feed and for processing.

All relevant references were 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 were provided.

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Other relevant website addresses and/or attached documents

[http://biotech.da.gov.ph/Decision\\_docs\\_jdc\\_direct.php](http://biotech.da.gov.ph/Decision_docs_jdc_direct.php) ( *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**

413 rue Saint-Jacques, suite 800

Montreal, Québec, H2Y 1N9

Canada

Fax: +1 514 288-6588

Email: [secretariat@cbd.int](mailto:secretariat@cbd.int)