

## Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-258570-1

LAST UPDATED: 06 JAN 2022

### 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 LLCotton25 for Direct Use as Food, Feed and for Processing

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Date of the risk assessment

Date not available

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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Website: <http://www.da.gov.ph>

### Risk assessment details

Living modified organism(s)

[BCH-LMO-SCBD-14851-7](#) | ACS-GHØØ1-3 - Liberty Link™ cotton | Resistance to herbicides - Glufosinate  
[Show detection method\(s\)](#)

Scope of the risk assessment

LMOs for direct use as food  
LMOs for direct use as feed  
LMOs for processing

? <http://biotech.da.gov.ph/> ( English )

## Methodology and points to consider

### Potential adverse effects identified in the risk assessment

Cotton contains gossypol and it is toxic to non-ruminants and has male sterility properties. The free gossypol is the toxic form with toxicity of 24 mg per head per day.

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

Raw cottonseed is not used for food. It needs to be processed first before it becomes available for consumption of both human and livestock.

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### Possible consequences

For raw agricultural products, more than 99% of the PAT protein was found in the kernel fractions of cottonseeds. Seed cotton and delinted cottonseed contain an average of 32.1 ug/g and 114 ug/g of PAT protein, respectively. The maximum amount of gossypol that should be fed to dairy cows should be 18 mg.

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### Estimation of the overall risk

The only new protein encoded by the bar gene from *S. hygroscopicus* PAT. Several in silico findings showed that the protein associated with the pat/bar protein is neither toxic nor allergenic.

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

LLCotton25 has been approved for feed use in the USA, Taiwan, Canada, Japan, South Korea, Mexico, Australia/New Zealand, European Union, Colombia, China, South Africa and Brazil. Consumption patterns are not expected to change as a result of the introduction of the novel trait as cottonseed derived from GHB119 Cotton is nutritionally and substantially equivalent to cotton derived from conventional breeding practices.

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

There were no significant differences between the modified product and the conventional product and were more pronounced for protein and crude fiber. The developer provided information on the comparison between the parent line Coker 312 and the GM LLCotton25. Treatments were grown in the same environmental conditions. Comparisons with ranges of commercial varieties were within the range.

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### Receiving environment(s) considered

The application of **LL25COTTON** 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

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detection of transgenes. For higher sensitivity, real-time PCR methods may be used.

### Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

No

### Additional Information

**LL25COTTON** is intended for direct use as food, feed and for processing.

During the long history of use, no adverse effects to human and animal have been attributed to the residual toxicant (gossypol) in properly processed, refined, bleached and deodorized cottonseed oil, hence no health risk.

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Other relevant website addresses and/or attached documents

? <http://biotech.da.gov.ph/> ( *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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