

Biosafety Clearing-House (BCH)

RISK ASSESSMENT GENERATED BY A REGULATORY PROCESS (RA)

BCH-RA-PH-115895-1

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 Cotton GHB614 x T304-40 x GHB119 x COT102 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-108242-1](#) | BCS-GH002-5 x BCS-GH004-7 x BCS-GH005-8 x SYN-IR102-7 - Glytol™ x Twinlink™ x VPCOT™ Cotton | Resistance to antibiotics - Hygromycin Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths) - Cotton bollworm (*Helicoverpa* spp.), armyworm (*Spodoptera frugiperda*) Resistance to herbicides - Glufosinate, Glyphosate Selectable marker genes and reporter genes

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

Cotton is widely cultivated and has a history of safe use. Cotton is not considered harmful or pathogenic to humans; however, the plant does produce gossypol and cyclopropenoid fatty acids (CPFA), which are anti-nutrients. All of the anti-nutritional factors are subject to neutralization during processing. Free gossypol binds to lysine and other products, and then becomes unavailable to animals. Cyclopropenoid fatty acids are deactivated or removed from the oil by hydrogenation or during deodorization at 230-235°C.

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Likelihood that the potential adverse effects will be realized

There is no plausible interaction of the resulting novel protein products, in which a new allergen or a new toxin could be produced. Cry1Ab, Cry2Ae, Vip3Aa19, PAT/bar, 2mEPSPS, and APH4 proteins indeed do not act on the same metabolic pathways and do not share any intermediate metabolites in the biochemical pathways that the proteins act on or interfere with. Without the lack of interaction, there is no expected adverse effect on the target trait that the transgenes confer, more so, no new allergen nor toxin will be produced.

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The resulting novel protein products will accumulate in the cytoplasm of the transgenic plant cells. Despite this co-localization, Cry1Ab, Cry2Ae, Vip3Aa19, PAT/bar, 2mEPSPS, and APH4 proteins indeed would not act on the same metabolic pathways and do not share any intermediate metabolites in the biochemical pathways that the proteins act on or interfere with.

Possible consequences

The expression levels of the novel proteins were not biologically different between the stacked transgenic plant under evaluation and its parental genotypes. The measurements done by the proponents using ELISA and subsequent statistical analysis clearly demonstrated that there is indeed no significant difference among the expression levels of the novel proteins. Even though there are five statistically significant difference found, it is indeed acceptable because it does not imply biological significance when viewed in the box-plot perspective.

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Estimation of the overall risk

The individual events of the gene stacked Cotton GHB614 x T304-40 x GHB 119 x COT 102 has undergone rigorous safety assessment, and is considered safe to humans, animals and is less likely to pose any significant adverse effect on the environment.

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

The individual events of the gene stacked Cotton GHB614 x T304-40 x GHB 119 x COT 102 have biosafety permits for direct use, which were previously issued. Therefore, each event has undergone rigorous safety assessment, and is considered safe to the environment, biodiversity, and non-target organisms. A biosafety permit for direct use can be issued for the

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said event.

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

The incorporation of gene stacked event is through conventional breeding, which is regarded as innocuous for its long history of safe use. Furthermore, the method of crossing individual transgenic parents is similar with that of non-transgenic parents. This method does not introduce any greater variation in the genome beyond what is obtained.

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Receiving environment(s) considered

The application of cotton GHB614 x T304-40 x GHB 119 x COT 102 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

Cotton GHB614 x T304-40 x GHB 119 x COT 102 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](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.

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on Biological Diversity**

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