Determination of the Safety of BASF’s

Cotton GHB614

for Direct use as Food, Feed, or Processing

The product dossier of BASF Philippines’ cotton GHB614 was reviewed for safety and nutritional differences compared to the conventional cotton. The focus of the food/feed safety assessment is based on the following issues: (a) the nature of the genetic modification; (b) novel protein expression; (c) in vitro digestibility; (d) toxicological assessment; (e) allergenic potential; and (f) compositional and nutritional assessment.

A biosafety permit for cotton GHB614 and all progenies derived from crosses of the product with any conventionally bred cotton and cotton containing approved-biotech events for direct use as food, feed or for processing, was issued to BASF Philippines Inc. on October 22, 2018. The permit is valid for five years and shall expire on October 21, 2023 subject to the terms and conditions set forth in DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1 series of 2016. The said product was included in the Lists of Approval Registry being prepared by the Department of Agriculture – Bureau of Plant Industry.

This approval is for use as Food, Feed or Processing only. This does not include cultivation of GHB614 in the Philippines. Food and Feed use of MIR604 and its by-products is therefore authorized as of October 22, 2018. The biosafety permit (No. 18-019FFP) stated that GHB614 is as safe for human food, livestock feed and for processing as its conventional counterparts.

1. Brief Identification of the Genetically Modified Organism (Living Modified Organism)

Designation: Cotton GHB614

Applicant: **BASF PHILIPPINES, INC.**

11F HHIC Building, 1128 University Parkway,

Bonifacio Global City, Taguig

Plant Species:

Name: Cotton (Gossypium hirsutum)

Parent Material: Cotton GHB614

Center of Origin: United States

Toxic Factors/Allergen(s): Gossypol

Trait Description: Glyphosate herbicide tolerance

Trait Introduction Method: Agrobacterium tumefaciens-mediated transformation

**Donor Organisms***:*Corn *(Zea mays)*

Pathogenicity: *2mepsps* decreases binding affinity for glyphosate, thereby increasing tolerance to glyphosate herbicide

Proposed Use: For direct use as food, feed or for processing

## Background Information

On November 22, 2016, Bayer CropScience Inc. submitted cotton GHB614 for direct use as food and feed, or for processing, as original application under the DOST-DA-DENR-DOH-DILG Joint Department Circular (JDC) No. 1 Series of 2016.

Bayer CropScience Inc., on their letter last August 22, 2018, stated that in light of their acquisition of Monsanto, Bayer AG and its affiliates signed an agreement to sell selected CropScience Businesses to BASF SE. According to the said agreement, ownership of this transformation event needs to be transferred from Bayer CropScience Inc. to BASF Philippines Inc. by changing the applicant name in all pending applications and accordingly direct future correspondences relevant to events with valid biosafety permits.

After reviewing the Risk Assessment Report and attachments submitted by the applicant, the assessors namely: Scientific and Technical Review Panel (STRP), BPI Plant Products Safety Services Division (BPI-PPSSD) and Bureau of Animal Industry- Biotech Team (BAI-BT), concurred that cotton GHB614 is as safe for human food and animal feed as its conventional counterpart.

The Department of Environment and Natural Resources – Biosafety Committee (DENR-BC), after a thorough scientific review and evaluation of the documents related to Environmental Risk along with the submitted sworn statement and accountability of the proponent, recommended the issuance of a biosafety permit for this regulated event provided the conditions set by DENR are complied.

Also, the Department of Health – Biosafety Committee (DOH-BC), after a thorough scientific review and evaluation of documents related to Environmental Health Impact, concluded that cotton GHB614 will not pose any significant risk to the health and environment and that any hazards could be managed by the measures set by the department. DOH-BC also recommended for the issuance of biosafety permit for cotton GHB614.

Furthermore, the Socio-economic, Ethical and Cultural (SEC) Considerations expert also recommended for the issuance of biosafety permit for this regulated article after assessing the socio-economic, social and ethical indicators for the adoption of Genetically Modified Organisms.

The DA-Biosafety Committee evaluated the assessment of all agencies including the SEC experts and recommended for the approval of the said application.

Food and Feed Safety

## Description of Novel (Introduced) Traits

GHB614 cotton expresses the 2mEPSPS protein encoded by the 2mepsps gene from corn, Zea mays. The modification of 2mEPSPS confers a decreased binding affinity of the protein for glyphosate allowing it to maintain sufficient enzymatic activity in the presence of the herbicide. Therefore, plants bearing the 2mepsps gene become tolerant to herbicide products containing glyphosate.

### Safety of the Expressed Proteins

Safety assessments conducted on GHB614 cotton demonstrate no potential effects on human and animal health and the environment. Findings from a comprehensive safety assessment of GHB614 demonstrate that the host cottonseed products are safely consumed by humans and animals, the 2mepsps gene is expected to present negligible safety concerns, the 2mEPSPS protein is deemed to be as safe as the wild type EPSPS proteins, and a reasonable certainty of no harm can be derived on GHB614 when compared to its parental line Coker 312. The 2mEPSPS protein does not possess properties that contribute to its toxic and allergenic potentials (e.g. no sequence homology to known toxins and allergens; rapid degradation in simulated gastric and intestinal fluids; no alteration in the N-glycosylation status; and no harm to animals when administered orally at a high dose). The wild type epsps gene is derived from Zea mays, a crop widely consumed as food and feed with no known pathogenic, toxic, or allergenic effects. The endogenous EPSPS proteins are ubiquitous in nature, and have been consumed safely for a long period of human history.

## Nutritional Composition (Compositional Analysis)

The compositional equivalence of GHB614 to conventional cotton was assessed through comparison with non-transgenic cotton variety, Coker 312, and comparison with range of literature values of commercial cotton varieties.

Most of the proximate, key nutrients (minerals, vitamins, amino acids and fatty acids) and anti-nutrients levels in GHB614 seeds were comparable to non-transgenic cotton. Values obtained from GHB614 seeds were mostly within the range of reported values from cotton literatures. Deviance from the literature ranges cannot be directly attributed to the genetic transformation since the same levels of composition were observed in non-transgenic Coker 312. These indicate that there are no statistical differences in the composition of GHB614 seeds that can be considered as biologically relevant.

## Anti-Nutritional Factors

Statistical significant differences were detected for a number of fatty acids, amongst them the anti-nutritional cyclopropenoid fatty acids. The statistical findings have no nutritional relevance since the absolute differences in the fatty acid contents are minimal, the amounts of cyclopropenoid fatty acid are lower in the transgenic samples, and all mean values are inside the reference ranges reported from literature.

Environmental Risk Assessment

After a thorough 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 the Joint Department Circular (JDC) No. 1 S 2016 on the application of BASF Philippines Inc. for direct use for feed, food or processing of Genetically Modified cotton with single-trait product GHB614, along with the submitted sworn statement and accountability of the proponent, a biosafety permit may be issued to the proponent if the conditions set by DENR are followed.

Environmental Health Risk Assessment

After a thorough scientific review and evaluation of the documents, DOH find sufficient evidence that the regulated article applied for direct use will not pose any significant risk to health and environment and that any hazards could be managed by the measures set by DOH.

Socio-economic. Ethical and Cultural Impact Assessment

The SEC Expert stated that the issue is if the imported cotton that may contain GM cotton will be used as feed, fuel or food . There is the possibility that cotton seeds, which can be milled to extract the oil, can also produce cotton oil meal. The meal can be used as feed ingredient. In other countries, this is used for cattle and sheep. The livestock in the Philippines is primarily of pigs and poultry. The oil seed meal can be processed into a feed ingredient but this is very unlikely. The technology is there but the economics of its use is not compelling. Cotton oil is not competitive with other forms of vegetable oil or even economical for industrial use. The country is not in the business of importing cotton to produce cotton oil, and therefore livestock producers would likewise be pushed to use cotton oil meal as feed ingredient on a regular basis. But there is always the possibility.

Therefore, the SEC Expert recommended for the approval and issuance of biosafety permit of the said GM product.

Regulatory Decision

Based on the results of the risk evaluation of the submitted scientific data and other information relevant to the application of BASF Philippines Inc., it is concluded that cotton GHB614, and all progenies derived from crosses of the product with any conventionally-bred cotton, and cotton containing approved-biotech events for direct use as food, feed or for processing, is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for direct use as food, feed or for processing. BASF Philippines Inc. shall duly inform the public of this approval by way of publishing in any one (1) of the top three (3) leading newspapers in the country that import of this product is covered by conditions for approval as provided in the Biosafety Permit.