

Regulatory Decision on the Application of Soybean GMB151
for Direct Use as Food and Feed, or for Processing

I. Brief Identification of the Genetically Modified Organism

Designation: Soybean GMB151

Applicant: BASF Philippines Inc.

Host Plant: *Glycine max* (L.) Merr.

Trait Description: Event soybean GMB151 expresses a Cry14Ab1 protein that confers nematode resistance. The plants also express an modified p-hydroxyphenyl pyruvate dioxygenase (HPPD) enzyme that confers tolerance to HPPD inhibiting herbicides.

Trait Introduction Method: *Agrobacterium tumefaciens*-mediated transformation

Donor Organism(s): The donor organism for *cry14Ab-1.b* gene is *Bacillus thuringiensis*, which is a spore-forming bacterium known for producing insecticidal proteins known as δ -endotoxins, while *hppdPf4Pa* gene encoding modified p-hydroxyphenyl pyruvate dioxygenase (HPPD) enzyme was derived from *Pseudomonas fluorescence*, a non-pathogenic saprophyte and aerobic bacterium which inhabits soil, water and plant surface environments and rhizosphere.

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

II. History of Safe Use of the Host Plant

Soybean has a long history of safe use as food and is known to be a rich source of plant protein. The major soybean commodity products are seeds, oil, and meal. Whole soybeans are utilized to produce soy sprouts, baked soybeans, roasted soybeans, full fat soy flour and the traditional soy foods (miso, soy milk, soy sauce, and tofu). In addition to whole oil used for human consumption, refined soybean oil has many other technical and industrial applications. Soy protein isolate is used as a source of amino acids in the production of infant food formula and other food products.

III. Characteristics of Host Plant

Soybean, *Glycine max* (L.) Merrill, is an annual self-pollinated diploid legume (subfamily Fabaceae). The main product derived from soya beans for human consumption is oil. The by-product from oil extraction, soybean meal, contains significant amounts of protein making it suitable for feeding livestock. The soybean is grown world-wide as an important staple and commercial crop.

To date, GMB151 soybean had been granted food/feed approvals in Australia, New Zealand, Brazil, Canada, South Africa, Colombia, US, EU, and Paraguay countries.

IV. Characteristic and safety assessment of the GM product

Apart from the intended genetic modification resulting in herbicide and nematode resistance in event soybean GMB151, there is no change in the agronomic and phenotypic characteristics of these plants compared with conventional soybean. The integrity and order of the genetic elements are demonstrated through a series of Western blot and SDS-PAGE analyses, other molecular, and sequence analyses of soybean GMB151. Multi-generational stability test using bioinformatics junction sequence analysis of whole-genome next-generation sequence data shows that stability of the inserted gene was observed in multiple generations - following a stable, Mendelian pattern of inheritance. The transgene was intact within the soybean genome. Furthermore, the expression levels of the proteins in leaf, root, flower, forage, grain and whole plant were determined by Enzyme-Linked ImmunoSorbent Assay (ELISA).

The potential amino acid sequence homology of the Cry14Ab-1 protein with known allergens and known toxins was evaluated using several *in silico* approaches. The overall identity search showed no biologically relevant identity between the query protein and any known allergenic and toxic proteins. In conclusion, there are neither allergenic nor toxicological *in silico* findings associated with the Cry14Ab-1 protein. Composition analyses were conducted to determine the levels of nutrients and anti-nutrients in soybean grain and select nutrients in soybean forage samples from multiple field trials and conduct a comparative assessment between GMB151 soybean (not treated and treated with trait-specific herbicide), the non-genetically modified (non-GM) counterpart, and non-GM reference varieties. The expression of these proteins are within the reported range of values.

Based on the data and other information provided, food/feed derived from soybean line GMB151 is considered to be as safe for consumption by both human and animals as the conventional counterpart.

V. Regulatory Decision

After reviewing the scientific data and information relevant to the application of the BASF Philippines Inc., the Bureau of Plant Industry (BPI) has approved the direct use as food and feed, or for processing for soybean GMB151. The BPI issued Biosafety Permit for Direct Use as Food and Feed, or for Processing of soybean GMB151 with conditions that need to be complied with by the permit holder. Copy of the Biosafety Permit issued may be accessed through the BPI Biotechnology website.