Determination of the Safety of
Soybean FG72
For Direct use as Food, Feed, or for Processing

Food and Feed Safety

The product dossier on Soybean FG72 was reviewed for safety and nutritional differences compared with the conventional soybean. The focus of the review was on any new or altered expression trait and changes in composition and nutritional content or value relative to the conventional soybean. At the end of the safety assessment, a conclusion was made that the Soybean FG72 is as safe as the conventional soybean taking into account dietary impact of any changes in nutritional content or value.

A biosafety permit for Soybean FG72 and all progenies derived from crosses of the product with any conventionally-bred soybean and soybean containing approved-biotech events for direct use as food, feed or for processing was issued to Bayer CropScience, Inc. on September 9, 2015. The said soybean event will be included in the Lists of Approval Registry prepared by the Department of Agriculture- Bureau of Plant Industry.

This approval is for use as food, feed or for processing only. This does not include cultivation of Soybean FG72 in the Philippines. Food and feed use of Soybean FG72 and its by-products is therefore authorized as of September 9, 2015. The biosafety permit (No. 15-085) stated that "Soybean FG72 is as safe for human food, livestock feed and for processing as its conventional counterparts".

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

Designation:	Herbicide Tolerant Soybean (**FG72**)
Applicant:	**BAYER CROPSCIENCE PHILIPPINES** 3rd Floor, Bayer House, Canlubang Industrial Estate, Calamba, Laguna
Plant Species	
Name:	Soybean (*Glycine max*)
Parent Material:	Zygotic immature embryos from soybean plants of variety Jack
Center of Origin:	North and Central China
Toxic Factors/Allergen(s):	Soybeans naturally contain multiple endogenous anti-nutrients: Trypsin inhibitors, raffinose and stachyose, Soy saponins and lectins, condensed tannins and phytates
Trait Description:	Herbicide Tolerant
Trait Introduction Method:	Biolistic-mediated transformation
Donor Organisms:	*Zea mays* – source of *2mepsps* gene conferring tolerance to the herbicide glyphosate *Pseudomonas fluorescens*- source of *hppdPfW336* gene conferring tolerance to HPPD-inhibiting herbicides (such as isoxaflutole)
Pathogenicity:	*Zea mays* has a long history of safe use as food and feed.

	Pseudomonas fluorescens is a Gram (-) rod-shaped microorganism which produces fluorescent pigments. It is a non-pathogenic microbe that inhabits the soil, freshwater and marine environments, plants and animals.
Proposed Use:	For direct use as food, feed or for processing

Background Information

On December 21, 2012, Bayer CropScience, Inc. submitted an application to the Bureau of Plant Industry requesting for biosafety permit under Administrative Order (AO) No. 8 Part 5 for Soybean FG72 which has been genetically modified for herbicide tolerance.

Bayer CropScience, Inc. has provided data on the identity of Soybean FG72, a detailed description of the modification method, data and information on the gene insertion sites, copy numbers and levels of expression in the plant, the role of the inserted genes and regulatory sequences in donor organisms, and full nucleotide sequences. The novel proteins were identified, characterized, and compared to the original bacterial proteins, including an evaluation of their potential toxicity to livestock. Relevant scientific publications were also supplied.

The petitioner/applicant published the said application on two widely circulated newspapers: Manila Standard Today and People's Tonight on March 27, 2013 for public comment/review. During the 30-day comment period, BPI had not received comment on the said application.

Description of Novel (Introduced) Traits

Soybean FG72 has been evaluated according to BPI's safety assessment by concerned agencies [Bureau of Animal Industry (BAI), Bureau of Agriculture and Fisheries Standards (BAFS) and a Scientific and Technical Review Panel (STRP)]. The process involves an intensive analysis of the nature of the genetic modification together with the consideration of safety assessment paradigm, which includes molecular characterization, protein characterization, and food/feed composition.

Bayer CropScience has co-developed with M.S. Technologies, LLC Soybean FG72 (OECD Unique Identifier MST-FGØ72-2) which was genetically modified using *biolistic*-mediated transformation. It contains two novel genes: double mutant 5-enol-pyruvylshikimate-3-phosphate synthase (*2mepsps*) and 4-hydroxyphenylpyruvate-dioxygenase protein W336 (*hppdPfW336*), conferring tolerance to the glyphosate and isoxaflutole, respectively.

Safety of the Expressed Proteins

The *2mepsps* and *hppdPfW336* genes are well-characterized and are composed of the same basic nucleic acids as found in any DNA from known food constituents consumed as part of human or animal diets. In addition, the likelihood that DNA from ingested food/feed could transfer and be functionally integrated by gut microflora and/or human cells is negligible.

Furthermore, the 2mEPSPS and HPPD W336 proteins have a safe hazard profile. In particular, these proteins do not possess any characteristics associated with food toxins or allergens, are not similar to known allergens and known toxins, and are rapidly degraded in human simulated gastric and intestinal fluids. The putative open reading frame polypeptides are not similar to known toxins or known allergens. Therefore, no adverse effects on animal and human health are to be expected from consumption of these proteins.

A reasonable certainty of no harm is confirmed by other studies with FG72 soybean compared to its non-GM counterpart, Jack. The estimated exposures to the 2mEPSPS and HPPD W336 proteins resulting from consumption of the FG72 soybean and its food by-products are negligible. Moreover, the transgene insertion does not lead to significant modifications of composition of the soybean seeds and derived products, including levels of

endogenous anti-nutrients and allergens. Finally, no adverse effects are observed in the wholesomeness broiler chicken study at 20% incorporation.

Nutritional Composition (Compositional Analysis)

Compositional and nutritional evaluation of the soybean transformation event FG72 are performed and compared with those of a non-transgenic soybean counterpart (Jack) and other soybean lines.

Ranges on the levels of fatty acid and fat soluble vitamins of food grade oil from Transformation Event FG72 cited in literature are comparable as the levels of fatty acid and fat soluble vitamins of the food grade oil from non-transgenic soybean Jack and other commercial soybean lines. Crude lecithin from transgenic soybean event FG72 has a phospholipid content that is within the reference range and is comparable with the phospholipid profile of crude lecithin from the non-transgenic counterpart Jack and other commercial soybean lines. These data show that the nutritional value of the food is not altered as a result of genetic manipulation.

Substantial equivalence is noted in the compositional analysis of isoflavones, anti-nutrients (raffinose, stachyose, phytic acid, trypsin inhibitor and lectins) of soybean hulls, untoasted meal and toasted meal from Transformation event FG72 in comparison with a non-transgenic Jack variety and other commercial soybean lines where mean values in all parameters are within normal ranges described in literature and statistically comparable values across soybean lines. Substantial equivalence is also demonstrated in protein, total amino acid and anti-nutrient levels of a protein isolate as well as fatty acid composition, fat soluble vitamin contents of the crude oil from the transgenic event FG72, with non-transgenic soybean Jack and other commercial soybean lines as comparators.

Anti-Nutritional Factors

Raw beans and its products contain several anti-nutrients: trypsin inhibitor, lectin, stachyose, raffinose, and phytic acid.

There is substantial equivalence of the transgenic soybean FG72 with the non-transgenic Soybean Jack based on the comparable levels of anti-nutrients.

Regulatory Decision

After reviewing the scientific data and information relevant to the application of Bayer CropScience, Inc., it is concluded that Soybean FG72 and all progenies derived from crosses of this product with any conventionally-bred soybean except when such cross involves another transformation event is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for direct use as food, or feed or for processing.

Bayer CropScience, 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 imports of this product are covered by conditions for approval as provided in Department of Agriculture Memorandum Circular No. 8, Series of 2003.