

Determination of the Safety of Monsanto' s
Soybean Mon 89788((Herbicide Tolerant soybean)
for Direct Use as Food, Feed, and for Processing

Food and Feed Safety:

The product dossier on Soybean MON 89788 were 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 corn. At the end of the safety assessment, a conclusion was made that the Soybean MON 89788 is as safe as the conventional soybean taking into account dietary impact of any changes in nutritional content or value.

A biosafety permit for MON 89788 Soybean 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 were issued to Monsanto Philippines Inc. on November 16, 2007. The permit is valid for five years and shall expire on November 15, 2012 subject to the terms and conditions set forth in DA Administrative order No. 8, Series of 2002, as amended by DA Administrative Order No. 22, Series of 2007. The said MON89788 soybean was included in the Lists of Approval Registry (Delisting) being prepared by the Department of Agriculture-Bureau of Plant Industry

This approval is for use as Food, Feed and Processing only. This does not include cultivation of Herbicide tolerant MON 89788 soybean in the Philippines. Food and Feed use of MON 89788 soybean its by-products is therefore authorized as of November 16, 2007. The biosafety permit (No. 07-027) stated that "Herbicide tolerant soybean" is as safe for human food, livestock feed and for processing as its conventional counterparts".

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

Designation: MON 89788 Soybean

Applicant: **MONSANTO PHILIPPINES, INC.**
7th Floor, Ayala Life-FGU Center
Alabang-Zapote Road cor Acacia Avenue
Madrigal Business Park
Alabang 1770, Muntinlupa City
Philippines

Plant Species:

Name: Soybean (*Glycine max* L.)

Parent Material: A3244, a non transgenic conventional variety developed by Asgrow Seed company

Center of Origin: Northeastern part of China

Toxic Factors/Allergen(s): Soybean grain is a host of a number of anti-nutritional factors, such as trypsin inhibitors, lectins, isoflavones (daidzein, genistein and glycitein), stachyose, raffinose, and phytic acid.

Trait Description:	Herbicide tolerant soybean
Trait Introduction Method:	<i>Agrobacterium</i> mediated
Donor Organisms:	<i>Agrobacterium</i> sp. strain CP4, source of <i>cp4 epsps</i> gene that provides tolerance to the action of glyphosate, the active ingredient in Roundup agricultural herbicides.
Pathogenicity:	<i>Agrobacterium</i> sp. strain CP4, the donor organism, is not a known human or animal pathogen and is not known to induce allergenic responses in human. As also the donor organism for other Roundup Ready crops, the safety of this organism has been reviewed a number of times.
Proposed Use:	For direct use as food, feed or for processing

II. Background Information

Developments in biotechnology and molecular assisted breeding have enabled Monsanto to develop a second generation glyphosate tolerant soybean product, Roundup Ready2Yield or MON 89788.

Soybean event MON 89788 (Trade name: Roundup RReady2Yield Soybean), is a second-generation glyphosate-tolerant soybean product. In addition to providing flexibility, simplicity, and cost-effective weed control options similar to Roundup Ready Soybean 40-3-2, MON 89788 and varieties containing the trait have the potential to enhance yield and thereby further benefit farmers and the soybean industry.

Monsanto Philippines, Inc submitted an application with attached technical dossiers to the Bureau of Plant Industry on November 29, 2006 requesting for biosafety permit under Administrative Order (AO) No. 8 Part 5 for soybean MON 89788 which has been genetically modified for herbicide tolerance. Monsanto Philippines, Inc. has provided data on the identity of soybean MON 89788, a detailed description of the transformation method, data and information on the gene insertion sites, copy number 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 and non-target organisms. Relevant scientific publications were supplied.

Soybean MON 89788 has been evaluated according to BPI's safety assessment by concerned agencies [Bureau of animal Industry (BAI), Bureau of Agriculture, Fisheries and Product Standards (BAFPS) 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 general safety issues, toxicological issues and nutritional issues associated with modified soybean.

The petitioner/applicant published the Public Information Sheet (PIS) of the said application on two widely circulated newspapers: Malaya on August 16, 2007 and The Daily Tribune on August 17, 2007 for public comment/review. During the 30-day comment period, BPI had not received negative comments on the said application.

Review of results of evaluation by the BPI Biotech Core Team in consultation with DA-Biotechnology Advisory Team (DA-BAT) completed the approval process.

III. Description of Novel (Introduced) Traits

Soybean MON 89788 contains CP4EPSPS protein (5-enolpyruvyl shikimate -3-phosphate synthase protein from *Agrobacterium* sp. Strain CP4) that provides tolerance to the action of glyphosate which is the active ingredient in Roundup agricultural herbicides. MON 89788 was developed through *Agrobacterium*-mediated transformation of soybean meristematic tissue using the binary vector, PV-GMGOX20. The *Agrobacterium* strain, ABI used in the transformation contains a disarmed Ti plasmid in which the tumor inducing gene was deleted and therefore not capable of inducing tumor formation. *Agrobacterium* is known pathogenic causing tumor formation to plants only but not humans and animals. The genes introduced by *Agrobacterium*-mediated transformation have been shown to be stably integrated in the plant genome (Malone-Schonenberg *et al* (1994).

MON 89788 and all soybean lines/hybrids derived from this event contain the *cp4 epsps* coding sequence identical to that in Roundup Ready Soybean 40-3-2. This *cp4 epsps* coding sequence from *Agrobacterium* sp. cp4 strain, under the regulatory control of the P-FMV/Tsf1 transcriptional promoter, encodes for a glyphosate-tolerant cp4 epsps protein (5-enolpyruvylshikimate-3-phosphate synthase). This renders MON 89788 tolerant to glyphosate, the active ingredient in Roundup agricultural herbicides, which is known to be environmentally compatible. In addition, the event was based on a new technique of *Agrobacterium*-mediated gene delivery to elite soybean meristem. This allowed direct transformation of the *cp4 epsps* gene cassette into elite soybean germplasm (such as Asgrow soybean variety A3244), resulting to a product with superior agronomic characteristics and high yielding property.

Soybean event MON 89788 and progenies are approved for food/feed/processing by regulatory agencies in USA. These agencies, relying on their existing internationally-accepted guidelines, processes and principles developed by their and other international safety experts (e.g., those convened by the FAO-WHO Joint Experts consultations, the OECD, ILSI and others), arrived at the decision that MON 89788 and its products have been found to be as safe as its conventional counterpart.

Safety of the Expressed Proteins

The donor organism, *Agrobacterium* sp. Strain CP4, is not a known human or animal pathogenicity and is not known to induce allergenic responses in human. The EPA has previously reviewed and established a tolerance exemption for CP4EPSPS and the genetic material necessary for the production of this protein in or in all raw agricultural commodities. This was based on a safety assessment that included rapid digestion in simulated gastric fluids, the lack of homology to toxins and allergens and lack of toxicity in an acute oral mouse gavage study

IV. Nutritional Composition (Compositional Analysis)

Soybean MON89788 will be utilized in the same manner and for the same uses as conventional soybeans.

High levels of crude protein (43-56.3 % in soybean meal) and amino acids particularly the essential amino acids such as lysine, leucine and isoleucine which are required supplements in animal diets. Soybean was found to have the highest protein among cereals and other legumes providing the best

protein source for human and animal consumption. Soybean meal is considered the best source for complementing the limiting amino acid from other feed sources.

High content of polysaturated fats in soybean oil such as linoleic acids, (48-60% of the oil) linolenic acids (2-10%) and the unsaturated oleic (19-34 %) fatty acids. Soybean has the second highest oil content among all food legumes. Soybean oil provides the largest source of vegetable oil worldwide. In the US soybean oil constitutes 80 % of total annual consumption of edible fats and oils.

Large amount of soybean products are consumed by humans and animals as source of protein, e.g. approximately, two thirds of the total protein meal use in the world is derived from soybean.

Safety assessment proved that MON 89788 had equivalent levels of protein and fatty acids with that of the SE comparator conventional variety A 3244 as supported by the ff:

The level of these nutrients are present in forage and grains at equivalent levels in the transgenic MON 89788 with that in conventional soybean variety SE comparator, A 3244 as (values based on combined site data): a) protein in forage fiber; MON 89788 = 20.08% DW; A 3244 = 19.79; b) protein in grain; MON 89788 = 40.32; A 3244 = 40.38; c) grain essential amino acid, lysine; MON 89788 = 2.62% DW, A 3244=2.62; isoleucine, MON 89788 = 1.83; A 3244 = 1.83; d) leucine, MON 89788 = 3.18, A3244 = 3.18; e) grain fatty acid, linoleic acid, MON 89788 = 9.17, A3244 = 9.25; f) linolenic acid, MON 89788 = 1.29, A 3244 = 1.30; and oleic acid, MON 89788 = 3.53, A3244 = 3.54. There were no significant differences obtained for protein content, for 18 amino acids and 8 fatty acids analyzed between MON 89788 and A 3244.

The abovementioned information showed that soybeans contain high amount of key nutrients such as protein and fatty providing a major source of these nutrients needed by humans and animals.

V. **Anti-Nutritional Factors**

The amount of antinutrients of MON 89788 appears to be less than the conventional soybeans. Overall, the antinutrient composition of MON 89788 is comparable to the conventional soybeans. While it is mentioned that the isoflavones composition in the combined site analysis were different, it appears that that is true only for daidzein.

MON 89788 grains and forage indicators are comparable and equivalent in compositional and nutritional analyses and contents.

VI. **Regulatory Decision**

After reviewing the scientific data and information relevant to the application of Monsanto Philippines Inc., it is concluded that Soybean MON 89788 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 or feed or for processing is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for direct use as food, or feed or for processing. Monsanto 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 is covered by conditions for approval as provided in Department of Agriculture memorandum Circular No. 8, Series of 2003.