

Determination of the Safety of Bayer CropScience's  
Corn T25 (Herbicide -Tolerant Corn)  
for Direct Use as Food, Feed and For Processing

---

**Food and Feed Safety:**

The product dossiers on Corn Event T25 were reviewed for safety and nutritional differences compared with the conventional corn. 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 Corn Event T25 is as safe as the conventional corn taking into account dietary impact of any changes in nutritional content or value.

A biosafety permit for Corn Event T25 and all progenies derived from crosses of the product with any conventionally-bred corn and corn containing approved-biotech events for direct use as food, feed and for processing was issued to Bayer CropScience, Inc. on December 5, 2003. The permit is valid for five years and shall expire on December 6, 2008 subject to the terms and conditions set forth in DA Administrative Order No. 8, Series of 2002. The said Corn Event (T25) was included in the Lists of Approval Registry (Delisting) being prepared by the Department of Agriculture-Bureau of Plant Industry.

*This approval is for direct use as food, feed and for processing only. This does not include cultivation of Glufosinate Ammonium tolerant corn T25 in the Philippines. Food, Feed and use of its by-products is therefore authorized as of December 5, 2003. The biosafety permit (No.03-014) stated that "Glufosinate Ammonium-Tolerant Corn Event T25 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)**

<b>Designation:</b>	Corn Event T25 (LibertyLink™ Maize)
<b>Applicant:</b>	BAYER CROPSCIENCE, INC. 3/F Bayer House, Canlubang Industrial Estate Calamba, Laguna, 4028 Philippines
<b>Plant Species:</b>	
Name:	Corn ( <i>Zea mays</i> )
Parent Material:	Inbred corn lines produced by Bayer CropScience
Center of Origin:	Mexico, Central America and South America
Toxic Factors/Allergen(s):	Trypsin inhibitor, phytic acid, and secondary metabolites such as raffinose, ferulic acid and p-coumaric acid are present in low amount, 2,4-dihydroxy-7-methoxy-2H-1,4-benzoxazin-3(4H)-1 (DIMBOA) is a potential toxicant but declines rapidly as the plant grows
<b>Trait Description:</b>	Herbicide (Glufosinate-ammonium) tolerance
<b>Trait Introduction Method:</b>	Polyethylene glycol mediated protoplast transformation
<b>Donor Organism:</b>	<i>Streptomyces viridochromogenes</i> , source of <i>pat</i> gene which encodes for phosphinothricin acetyltransferase
<b>Pathogenicity:</b>	<i>Streptomyces viridochromogenes</i> is a non-pathogenic microorganism. No overall homology was found with known toxins and pathogens.
<b>Proposed Use:</b>	For direct use as food, feed and for processing

**II. Background Information**

Bayer CropScience Inc. developed corn Event T25. The genetically modified corn plants are tolerant to glufosinate and were produced by the introduction of a modified phosphinothricin acetyltransferase (*pat*) gene from *Streptomyces viridochromogenes*.

On June 27, 2003, Bayer CropScience, Inc. submitted an application to the Bureau of Plant Industry requesting for biosafety permit under AO#8 for Corn Event T25 that has been genetically modified for herbicide resistance.

Bayer has provided data on the identity of Corn Event T25, 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.

Corn Event T25 has been evaluated according to BPI's safety assessment by concerned agencies: [Bureau of Animal Industries (BAI), Bureau of Agriculture Fisheries and Product Standards (BAFPS)] and a Scientific Technical Review Panel (STRP). The process involves an intensive analysis of the nature of the genetic modification together with a consideration of general safety issues, toxicological issues and nutritional issues associated with the modified corn.

The petitioner/applicant published the Public Information Sheet of the said application on two widely circulated newspapers (Malaya and Daily Tribune) on October 31, 2003 for public comment/review. BPI received no comment on the petition during the 30-day comment period.

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**

Corn Event T25 and all corn lines/hybrids derived from this Event contain the *pat* gene from an aerobic bacterium, *Streptomyces viridochromogenes*. The *pat* gene encodes for the production of the phosphinothricin acetyltransferase PAT (protein) which acetylates phosphinothricin and demethylphosphinothricin (DMPT). By acetylating the free amino group of the active herbicidal component phosphinothricin, the PAT enzyme prevents autotoxicity in the producing organisms and shows complete resistance towards high doses of phosphinothricin (PPT), bialaphos or glufosinate. Glufosinate inhibits the enzyme, glutamine synthetase, thereby causing phytotoxic levels of ammonium to accumulate in the plants.

Glufosinate (phosphinothricin; DL-homoalanin-4-yl(methyl)phosphinic acid) is a racemic phosphinico amino acid. Its ammonium salt (glufosinate-ammonium) is widely used as a non-selective herbicide and is the active ingredient of the commercial herbicide formulations Basta<sup>®</sup>, Buster<sup>®</sup>, Challenge<sup>®</sup>, Conquest<sup>®</sup>, Dash<sup>®</sup>, Final<sup>®</sup>, Finale<sup>®</sup>, Liberty<sup>®</sup>, and Ignite<sup>®</sup>. The L-isomer of glufosinate is a structural analogue of glutamate and, therefore, is a competitive inhibitor of the enzyme glutamine synthase (GS) of bacteria and plants. The D-isomer is not a GS inhibitor and is not herbicidally active.

Due to the inhibition of GS, non-tolerant plant cells accumulate large amounts of toxic ammonia produced by nitrate assimilation and photorespiration and the level of available glutamine drops. Damage of cell membranes and inhibition of photosynthesis are followed by plant cell death. The action of glufosinate is dependent on environmental conditions. Temperatures below 10°, as well as drought stress, reduce its efficacy because of the limited metabolic activity of the plant. Also, light is an important factor for the action of glufosinate.

#### **Safety of the Expressed Proteins**

The PAT protein has no known similarity with known protein toxins and allergens at even lower than 8 amino acid sequence required for allergenic epitope. It also showed no potential glycosylation sites normally found in allergenic proteins. PAT protein is rapidly degraded (within seconds) in the presence of pancreatin. PAT protein was completely digested rapidly within 30 seconds both in simulated gastric fluid and simulated intestinal fluid (digestibility *in vitro*).

Toxicity study of Corn Event T25 in rats showed no mortality, no difference in body weight, organ weight and food consumption. No dose related negative clinical signs were detected from test animals using extensive clinical tests.

#### **IV. Nutritional Composition (Compositional Analysis)**

Corn Event T25 is substantially equivalent in composition and safety to conventional corn. Under the same agronomic condition as conventional counterpart corn, pat gene does not alter the quantity and quality of the key components: proximate analysis, fatty acids, amino acids, micro-nutrients such as Vitamins and minerals.

The nutritional equivalence of Corn Event T25 is found substantially equivalent to conventional counterpart corn. Corn Event T25 is comparable in feeding value for broiler chickens relative to the commercially available corn hybrid. Therefore, the nutritive value of the glufosinate ammonium tolerant corn hybrid is equivalent to a commercially available corn hybrid.

#### **V. Anti-Nutritional Factors**

Few anti-nutrients have been established to occur in corn, which has no relevance to its food use. Though trypsin inhibitor, phytic acid, and secondary metabolites such as raffinose, ferulic acid and p-coumaric acid have been established as anti-nutrients in corn, they are present in very low amount and are below the thresholds considered to raise a food safety concern. The amount of anti-nutrients present in Corn Event T25 fell within the range found in non-transgenic corn.

#### **VI. Regulatory Decision**

After reviewing the scientific data and information relevant to the application of Bayer CropScience, Inc., it is concluded that Corn Event T25 and all progenies derived from crosses of the product with any conventionally-bred corn, and corn containing approved-biotech events for direct use as food, feed and for processing is as safe and substantially equivalent to its unmodified counterpart, and is therefore approved for direct use as food, feed and for processing. Bayer CropScience shall duly inform the public of this approval by way of publishing in any one (1) of the top three leading newspapers in the country that import of this product is covered by conditions for approval as provided in Department of Agriculture Memorandum Circular No. 8, Series of 2003.