

Voluntary Premarket Consultation on MON 87411 Corn (BNF 145)

Jason Dietz

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Background

- MON 87411 is a corn variety developed by Monsanto.
- The variety has insect resistance (Corn rootworm) and herbicide tolerance (glyphosate).
- Submission Date: Nov. 15, 2013, completed Oct. 17, 2014
- Introduced Proteins:
 - Cry3Bb1 from *Bacillus thuringiensis*
 - 5-Enolpyruvylshikimate-3-phosphate synthase (EPSPS) from cp4 epsps gene of *Agrobacterium* sp. strain CP4.
- Inserted genes (gene fragments):
 - double stranded RNA with the partial sequence of the Snf7 transcript from the western corn rootworm (*Diabrotica virgifera virgifera*)
- The introduced proteins and genes (including gene fragments) are regulated by EPA as PIPs.

Background

- The focus of FDA's evaluation was:
 1. Whether there were any added substances other than PIPs
 2. Has the food (for humans and animals) changed in ways that would be unsafe (e.g., unintended effects)?
 - Inheritance and stability are considered to ensure this assessment would be relevant to future generations of the plant.
 - Composition of key components of the food are considered to assess whether they have changed (i.e., increased or decreased concentrations) in a way that is meaningful to safety or nutrition.

Inheritance and Stability

- Monsanto performed whole genome sequencing and junction sequence analyses on a total of five breeding generations to confirm the genomic stability and Mendelian inheritance pattern of the inserted DNA.
 - Monsanto detected identical junction sequences in each of the generations tested.
 - NOTE: FDA's interest is only on the inserted DNA and not the entire genome sequence. In this case, whole genome sequencing was used simply as a method to gather data about the inserted DNA. FDA did not request or receive the entire genome sequence.
- Monsanto concluded that the insert is stable over multiple generations and was integrated at a single, chromosomal locus.

Food & Feed Use

- MON 87411 corn is intended to be used as other corn varieties.
 - Corn can be consumed fresh or processed (including dry- and wet-milling).
 - A high proportion of corn is used in livestock feed. Whole corn grain is usually ground and incorporated into feed.
 - Corn milling produces by-products that are also used in animal feeds, including meal, fiber, and protein.
 - The above-ground portion of the plant is chopped and fermented to produce silage, which is used as animal feed.

Composition

- Monsanto measured 78 components in forage and grain derived from MON 87411 corn and compared the resulting data with data from a control variety (LH244 x HCL645) which has a similar genetic background to MON 87411.
 - Monsanto also compared the composition of MON 87411 corn with that of 20 commercial reference varieties grown alongside MON 87411 corn and the control. Monsanto states that components were selected based on the Organisation for Economic Co-operation and Development (OECD) consensus document on corn.

Composition



- Study Design
 - Monsanto describes its study design, noting that MON 87411 corn, the control, and reference varieties were grown at eight sites in corn-growing regions of Argentina during the 2011-12 growing season. Monsanto states that Argentina's corn-growing regions occur at similar latitudes to the U.S. Corn Belt with comparable average temperatures and precipitation.

Composition

- Compositional Analysis of Corn Forage:
 - Monsanto reports mean values for eight components in corn forage from MON 87411 corn, the control, and reference varieties: crude protein, crude fat, ash, carbohydrates by calculation, acid detergent fiber (ADF), neutral detergent fiber (NDF), calcium, and phosphorus.
 - Monsanto concludes that forage from MON 87411 corn is compositionally equivalent to forage from conventional corn.

Composition

- Compositional Analysis of Corn Grain:
 - Monsanto analyzed 69 components in grain from MON 87411 corn, the control, and reference varieties.
 - Monsanto statistically analyzed values for 52 components.
 - Monsanto reported results for proximates (crude protein, crude fat, ash, and carbohydrates by calculation); ADF; NDF; total dietary fiber (TDF); eight fatty acids; 18 amino acids; seven vitamins (vitamin A, vitamin E, selected B vitamins, niacin, and folate); eight minerals; anti-nutrients (phytic acid and raffinose); and secondary metabolites (ferulic acid, and p-coumaric acid).
 - Monsanto concluded that these differences are not biologically relevant from a food and feed safety or nutritional perspective.

Composition

- Conclusion about composition
 - Monsanto states that compositional analysis supports the conclusion that MON 87411 corn is compositionally equivalent to conventional corn varieties. Monsanto concludes that the small differences in the levels of the components described above are not biologically relevant from a food and feed safety or nutritional perspective.

Completed Consultation

- No unresolved questions about any added substances under FDA's purview and no unresolved questions about composition of the food.
- Monsanto has concluded that its corn variety, MON 87411 corn, and the foods and feeds derived from it are as safe as conventional corn varieties and are not materially different in composition or any other relevant parameter from other corn varieties now grown, marketed, and consumed in the United States. At this time, based on Monsanto's data and information, the agency considers Monsanto's consultation on MON 87411 corn to be complete.

Completed Consultation



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BNF No. 145

Corn

MON 87411

MON-87411-9

Developer:	Monsanto Company 800 North Lindbergh Blvd St. Louis, MO 63167
Trait(s):	Insect resistance (Corn rootworm) Herbicide Tolerance (glyphosate)
Submission Date :	Nov 15, 2013
Introduced Protein: (source):	Cry3Bb1 <i>Bacillus thuringiensis</i>
Introduced Protein 2: (source):	5-Enolpyruvylshikimate-3-phosphate synthase (EPSPS) from cp4 epsps gene <i>Agrobacterium</i> sp. strain CP4
Inserted genes (gene fragments):	double stranded RNA with the partial sequence of the Snf7 transcript from the western corn rootworm <i>Diabrotica virgifera virgifera</i>
Contains EPA-regulated trait:	Yes
FDA's Memo(s):	Human and Animal Food Uses Oct 17, 2014
FDA's letter	Human food and animal food Oct 17, 2014
Completion date:	



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