

Voluntary Premarket Consultation on DP23211 Corn (BNF 175)

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Completed Consultations are available on FDA website

<https://www.fda.gov/food/programs-food-new-plant-varieties/recently-published-biotechnology-consultations>

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BNF No. 175

Corn

DP23211

DP-Ø23211-2

Developer:	Pioneer Hi-Bred International, Inc. 7100 NW 62nd Avenue P.O. Box 1000 Johnston, IA 50131
Trait(s):	Insect resistance Herbicide tolerance (glufosinate ammonium)
Submission Date :	May 31, 2019
Introduced Protein: (source):	IPD072Aa protein <i>Pseudomonas chlororaphis</i>
Introduced Protein 2: (source):	Phosphinothricin N-acetyltransferase (PAT protein) <i>Streptomyces viridochromogenes</i>
Introduced Protein 3: (source):	Phosphomannose isomerase (PMI protein) <i>Escherichia coli</i>
Inserted genes (gene fragments):	Smooth septate junction protein 1 (<i>dvssj1</i>) gene fragments <i>Diabrotica virgifera virgifera</i>
Contains EPA-regulated trait:	Yes
FDA's Memo(s):	Human Food Use - CFSAN (PDF, 292 kB) Jul 29, 2022 Animal Food Use - CVM (PDF, 277 kB) Jul 18, 2022
FDA's letter:	Human and Animal Food (PDF, 214 kB) Jun 31, 2022
Completion date:	Jun 31, 2022

The purposes of FDA's evaluation

(1) to assess whether a developer will introduce into human/animal food a substance requiring premarket approval as a food additive.

(2) to determine whether use of the new plant variety in human/animal food raises other regulatory issues with respect to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

- 1. Molecular Characterization**
- 2. Protein Safety for PAT**
- 3. Compositional analysis**

Molecular Characterization

- Transformation method – *Agrobacterium* mediated transformation.
- Four expression cassette – *dvssj1* dsRNA, *ipd072Aa*, PMI and PAT.
- Copy number of T-DNA, insertion intactness – A single insertion into genome.
- Absence of vector backbone DNA and other unintended sequences.
- Inheritance and stability.
- Open reading frame analysis.

Protein Safety for PAT

- **Phosphinothricin N-acetyltransferase (PAT) is identical to the PAT in plant varieties that have been assessed by FDA.**
- **PAT is identical to the PAT found in previously authorized crops in 20 different countries.**
- **Publication addresses the safety of PAT protein.**
- **The expression levels of PAT protein in DP23211 corn were lower or similar to the PAT protein that have been reviewed by FDA.**

Compositional analysis

- **Forage and grain, control corn and 14 non-GE corn varieties.**
- **Seven locations, four replicates at each location.**
- **The selected components were based on the OECD corn composition consensus document-- proximates, fiber components, 18 amino acids, 9 minerals, 16 fatty acids, 11 vitamins, 4 secondary metabolites, and 3 anti-nutrients.**
- **No statistically significant differences for most components.**
- **6 components--statistically significant differences the values fell within the range of values in the public literature or reference varieties.**
- **DP23211 corn is comparable in nutrient composition to conventional corn varieties.**

Conclusions

- **DP23211 corn and the animal food derived from it are as safe as and are not materially different in composition or any other relevant parameter from conventional corn varieties grown, marketed, and consumed in the United States.**
- **CVM did not identify any safety or regulatory issues under the FD&C Act that would require further evaluation at this time.**