



## Biotechnology Notification File No. 000179 CFSAN Note to the File

**Date:** November 7, 2022

**From:** Jianmei Zhu, Ph.D.

**To:** Administrative Record, BNF No. 000179

**Subject:** Corn<sup>1</sup> with transformation event MON 95379

**Keywords:** corn, maize, *Zea mays*, insect resistance, lepidopteran pests, Cry1B.868, Cry1Da\_7, *Agrobacterium*-mediated transformation, *Bacillus thuringiensis*, Bayer CropScience LP, OECD Unique Identifier MON-95379-3

### Summary

Bayer CropScience LP (Bayer) has completed a consultation with the Food and Drug Administration (FDA) on food derived from MON 95379 corn genetically engineered to express the Cry1B.868 and Cry1Da\_7 proteins for protection against targeted lepidopteran pests. This document summarizes Bayer's conclusions and supporting data and information that FDA's Center for Food Safety and Applied Nutrition (CFSAN, we) evaluated pertaining to human food uses of this corn. FDA's Center for Veterinary Medicine summarizes its evaluation pertaining to animal food uses in a separate document.

Based on the safety and nutritional assessment Bayer has conducted, it is our understanding that Bayer concludes that:

- it has not introduced into human food a new protein or other substances that would require premarket approval as a food additive
- human food from MON 95379 corn is comparable to and as safe as human food from other corn varieties

CFSAN evaluated data and information supporting these conclusions and considered whether MON 95379 corn raises other regulatory issues involving human food within FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act). We have no further questions at this time regarding the safety, nutrition, and regulatory compliance of human food from MON 95379 corn.

The U.S. Environmental Protection Agency (EPA) evaluates and authorizes the use of plant incorporated protectants (PIPs) under the FD&C Act and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A PIP is defined in 40 CFR 174.3 as "a pesticidal substance that is

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<sup>1</sup>This document uses the word "corn" instead of "maize" in accordance with common practice in the United States.

intended to be produced and used in a living plant, or the produce thereof, and the genetic material necessary for the production of such a pesticidal substance,” including “any inert ingredient contained in the plant, or produce thereof.” In MON 95379 corn, Cry1B.868 and Cry1Da\_7 proteins are PIPs. Bayer states that they have submitted a petition for a permanent exemption from the requirement of a tolerance for these PIP proteins. The safety of Cry1B.868 and Cry1Da\_7 proteins in MON 95379 corn is under EPA’s purview and is therefore not addressed in this document.

Bayer states that they have submitted a petition to the United States Department of Agriculture for nonregulated status of MON 95379 corn.

## Subject of the Consultation

<b>Crop</b>	Corn
<b>Designation</b>	MON 95379
<b>Intended trait</b>	Insect resistance
<b>Developer</b>	Bayer CropScience LP
<b>Submission received</b>	August 19, 2020
<b>Amendment received</b>	April 26, 2022
<b>Intended use</b>	General use in human food
<b>Transformation plasmid</b>	Plasmid PV-ZMIR522223
<b>Expression cassette 1</b>	<i>cry1b.868</i> encoding Cry1B.868, a chimeric protein comprised of domains I and II from Cry1Be, domain III from Cry1Ca, and C-terminal protoxin domain from Cry1Ab from <i>Bacillus thuringiensis</i> ( <i>Bt</i> ) for protection against lepidopteran pests
<b>Expression cassette 2</b>	<i>cry1Da_7</i> encoding Cry1Da7, a modified version of Cry1Da from <i>Bt</i> for protection against lepidopteran pests
<b>Method for conferring genetic change</b>	<i>Agrobacterium</i> -mediated transformation

## Inheritance and stability

Bayer used next generation sequencing (NGS) and segregation analysis to examine the stability and inheritance of the genetic insert in MON 95379 corn. Bayer performed NGS to DNA samples obtained from five generations of MON 95379 corn and confirmed a single copy of insert with two identical junction sequences in each generation. Chi-square analysis was conducted on the segregation data from three generations of MON 95379 corn and the results showed that a single copy of insert is inherited according to Mendelian principles. Bayer concludes that a single, intact insert is stably inherited in MON 95379 corn.

## Human Food Nutritional Assessment

The intended traits in MON 95379 corn are not expected to alter the levels of key nutrients, anti-nutrients, or secondary metabolites (key components). To ensure the absence of unintended changes to components relevant to safety or nutrition, Bayer conducted a compositional analysis comparing MON 95379 corn and a genetically comparable conventional hybrid variety (control), which were concurrently grown at five locations in the United States during the 2018 season. The compositional analyses were performed based on the principles outlined in the Organisation for Economic Co-operation and Development (OECD) consensus document for corn composition.<sup>2</sup> Bayer analyzed MON 95379 corn grain for proximates (protein, fat, ash, and carbohydrates by calculation), amino acids, fatty acids, fiber, minerals, vitamins, anti-nutrients (phytic acid and raffinose), and secondary metabolites (ferulic acid, furfural and *p*-coumaric acid). Of the components analyzed, Bayer notes that the components that had more than 50% of the observations below the assay limit of quantitation were not statistically analyzed. Bayer reports that 18 of the statistically analyzed components showed a statistically significant difference ( $p < 0.05$ ) between MON 95379 corn and the control. For these components, Bayer states that the mean values for MON 95379 corn were within the ranges of values in the literature and in the International Life Sciences Institute Crop Composition Database (ISLI 2019).<sup>3</sup> Bayer concludes that grain from MON 95379 corn is compositionally equivalent to conventional corn.

## Conclusion

Based on the information provided by Bayer and other information available to CFSAN, we have no further questions at this time about the safety, nutrition, and regulatory compliance of human food from MON 95379 corn. We consider the consultation with Bayer on MON 95379 corn to be complete.

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<sup>2</sup> OECD, 2002. Consensus document on compositional considerations for new varieties of maize (*Zea mays*): Key food and feed nutrients, antinutrients and secondary plant metabolites.

ENV/JM/MONO(2002)25. Organisation for Economic Co-operation and Development, Paris, France.

<sup>3</sup> On May 1, 2020, the International Life Sciences Institute Crop Composition Database became known as the Agriculture and Food Systems Institute Crop Composition Database.