FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

# Biotechnology Notification File No. 000181
# CVM Note to the File

**Date:** December 19, 2024

**From:** Jing Ning, Ph.D.

**To:** Administrative Record, BNF No. 000181

**Subject:** Event FG259 Corn

**Keywords:** Corn, Maize, *Zea mays* L., Altered AC1 beta-glucanase, environmental DNA library, Phosphomannose isomerase (PMI), *manA* gene, *Escherichia coli* (*E. coli*), OECD Unique Identifier AGV-FG259-5, Agrivida, Inc., Animal Food GRAS Notices (AGRN) 31 and 50, New Protein Consultation (NPC) 000018

Agrivida, Inc. (Agrivida) is participating in the biotechnology consultation program with the Food and Drug Administration (FDA) and submitted a safety and nutritional assessment for a genetically engineered (GE) corn, transformation event FG259 corn (hereafter referred to as FG259 corn), and additional information afterwards.

Agrivida had previously submitted to FDA NPC 000018, AGRN 31, and AGRN 50 regarding its conclusions about: the safety of the altered beta-glucanase[1] enzyme when potentially, inadvertently present in human or animal food at low levels; the use of ground grain from FG259 corn as a source of the altered AC1 beta-glucanase enzyme in poultry diets; and the use of the ground grain from FG259 corn as a source of the AC1 altered beta-glucanase enzyme in swine diets, respectively. FDA's Human Foods Program summarizes its evaluation of FG259 corn in human food in a separate document.

The intended effect of the modification in FG259 corn is seed-specific expression of the altered AC1 beta-glucanase in the GE corn variety. To confer this trait, Agrivida introduced an altered *AC1 beta glucanase* gene from an environmental DNA library, that encodes an altered AC1 glucanase protein. Agrivida also introduced the *Escherichia coli manA* gene encoding the enzyme phosphomannose isomerase (PMI) which was used as a selectable marker.[2]

In its submission, Agrivida stated that FG259 corn is intended for use as a source of the AC1 beta-glucanase enzyme when added to poultry and swine diets. FDA's Center for

[1] Agrivida described this enzyme as carbohydrase AC1 protein in NPC 000018.
[2] Negrotto, D., M. Jolley, S. Beer, A.R. Wenck, and G. Hansen. 2000. The use of phosphomannose-isomerase as a selectable marker to recover transgenic maize plants (*Zea mays* L.) via *Agrobacterium* transformation. Plant Cell Rep 19(8): 798-803.

Veterinary Medicine (CVM, we) has already evaluated Agrivida's Generally Recognized as Safe conclusion for the intended use of FG259 corn in animal food: in AGRN 31[3], ground grain obtained from FG259 corn to decrease the viscosity of digesta in poultry consuming feed containing high amounts of soluble non-starch polysaccharides when used to provide 200-500 beta-glucanase activity units per kilogram (kg) of complete feed; and in AGRN 50[4], ground grain obtained from FG259 corn in swine feed at a use rate of 50-500 glucanase activity units per kg of complete feed; therefore, CVM does not intend to evaluate the information on FG259 corn in Biotechnology Notification File (BNF) 000181. Should Agrivida change its intended uses to include other uses of FG259 corn in animal food in the United States, we recommend Agrivida contact CVM's Division of Animal Food Ingredients.

Jing Ning -S

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Date: 2024.12.19 15:30:38 -05'00'

Jing Ning, Ph.D.
Molecular Biology Staff Fellow

[3] AGRN 31 submission is available at https://www.fda.gov/media/140657/download?attachment, and CVM's AGRN 31 response letter is available at https://www.fda.gov/media/136827/download?attachment.

[4] AGRN 50 submission is available at https://www.fda.gov/media/165244/download?attachment, and CVM's AGRN 50 response letter is available at https://www.fda.gov/media/159457/download?attachment.