



Biotechnology Notification File No. 000188 CVM Note to the File

Date: December 19, 2024

From: Lei Dai, BVSc, Ph.D.

To: Administrative Record, BNF No. 000188

Subject: Event PY1203 Corn

Keywords: Corn, Maize, *Zea mays* L., Altered AppA phytase enzyme, Phy02 phytase, *Escherichia coli* (*E. coli*), Phosphomannose isomerase (PMI), *manA* gene, OECD Unique Identifier AGV-PY203-5, Agrivida, Inc., Animal Food GRAS Notice (AGRN) 32, New Protein Consultation (NPC) 000015

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 PY1203 corn (hereafter referred to as PY1203 corn), and additional information afterwards.

Agrivida had previously submitted to FDA NPC 000015 and AGRN 32 regarding its conclusions about the safety of the altered phytase enzyme when potentially, inadvertently present in human or animal food at low levels and the use of ground grain from PY1203 corn as a source of the enzyme in swine and poultry diets, respectively. FDA's Human Foods Program summarizes its evaluation of PY1203 corn in human food in a separate document.

The intended effect of the modification in PY1203 corn is seed-specific expression of the Phy02 phytase protein in the GE corn variety. To confer this trait, Agrivida introduced a codon optimized phytase gene, which is similar to the *appA* gene from *Escherichia coli* (*E. coli*) strain K12, that encodes an altered phytase protein¹. Agrivida also introduced the *E. coli manA* gene encoding the enzyme phosphomannose isomerase (PMI) which was used as a selectable marker².

In its submission, Agrivida stated that PY1203 corn is intended for use as a source of the Phy02 enzyme to improve phosphorus utilization when added to poultry and swine diets. FDA's Center for Veterinary Medicine (CVM, we) has already evaluated Agrivida's

¹ Agrivida states that Phy02 protein differs from the native *E. coli* AppA phytase protein by 16 of the 410 total amino acid residues in the mature protein.

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.

Generally Recognized as Safe conclusion for the intended use of PY1203 corn in animal food in AGRN 32³: ground grain obtained from PY1203 corn to increase the digestibility of phytin-bound phosphorus or to increase phosphorus availability from phytate in swine feeds when used to provide 500-4500 phytase activity units (FTU)/kilogram (kg) complete feed, or poultry feeds when used to provide 250-6000 FTU/kg complete feed; therefore, CVM does not intend to evaluate the information on PY1203 corn in Biotechnology Notification File (BNF) 000188. Should Agrivida change its intended uses to include other uses of PY1203 corn in animal food in the United States, we recommend Agrivida contact CVM's Division of Animal Food Ingredients.

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³ AGRN 32 submission is available at <https://www.fda.gov/media/140655/download?attachment>, and CVM's AGRN 32 response letter is available at <https://www.fda.gov/media/137127/download?attachment>.