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

Biotechnology Notification File No. 000166
CVM Note to the File

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From: Kathleen M. Jones, Ph.D.

To: Administrative Record, BNF No. 000166

Subject: DBN9936 Corn

Keywords: Corn, Maize, *Zea mays*, Cry1Ab, *Bacillus thuringiensis*, insect resistance, lepidopteran insects, 5-enolpyruvylshikimate-3-phosphate synthase, EPSPS, *Agrobacterium* CP4, herbicide tolerance, glyphosate, DBN9936, OECD Unique Identifier: DBN-Ø9936-2, Beijing DaBeiNong Biotechnology Co., Ltd.

Purpose

This document summarizes the Food and Drug Administration (FDA) Center for Veterinary Medicine's (CVM, we) evaluation of biotechnology notification file (BNF) number 000166. Beijing DaBeiNong Biotechnology Co., Ltd. (DBNBC) submitted a safety and nutritional assessment of grain from a genetically engineered (GE) corn variety, transformation event DBN9936 (DBN9936 corn), and additional information afterwards.

DBNBC states the majority of DBN9936 corn grain will be used domestically in China, and some will end up in Chinese-produced human food products that may be exported to the United States. DBNBC also anticipates that a small amount of DBN9936 corn grain may be used in animal food products that might be exported to the United States. DBNBC expects that the majority of its GE corn will be used in human food products intended for domestic and export use.

CVM evaluated the information in DBNBC's submission to ensure that regulatory and safety issues regarding the intermittent low levels of DBN9936 corn grain in animal food in the United States have been resolved prior to commercial distribution. FDA's Center for Food Safety and Applied Nutrition summarizes its evaluation of DBN9936 corn grain in human food in a separate document.

In CVM's evaluation, we considered all of the information provided by DBNBC as well as publicly available information and information in the agency's files.

Intended Effects

The intended effects of the modifications in DBN9936 corn are protection against feeding damage caused by lepidopteran insects and tolerance to the herbicide

glyphosate. To confer insect resistance, DBNBC introduced a *cry1Ab* gene from *Bacillus thuringiensis* that encodes for a Cry1Ab protein. To confer tolerance to glyphosate, DBNBC introduced an *epsps* gene from *Agrobacterium* CP4 that encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein. EPSPS also served as a selectable marker.

Regulatory Considerations

The purpose of this evaluation is to determine whether intermittent low levels of the new plant variety in animal food raises safety or regulatory issues under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The Environmental Protection Agency (EPA) defines a plant-incorporated protectant (PIP) as "a pesticidal substance that is 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" (40 CFR 174.3). EPA regulates PIPs under the Federal Insecticide, Fungicide, and Rodenticide Act and the FD&C Act. Under EPA regulations, the Cry1Ab protein and the genetic material used to express it in DBN9936 corn are considered pesticidal substances, and the EPSPS protein and the genetic material used to express it are considered inert ingredients. Therefore, the safety assessment of these products falls under the regulatory purview of EPA.

DBNBC states that it conferred with EPA to confirm that the Cry1Ab protein in DBN9936 corn meets the existing tolerance exemption for residues of Cry1Ab protein in food (40 CFR 174.511). In addition, DBNBC states that the EPSPS protein in DBN9936 corn meets the existing tolerance exemption for residues of CP4 EPSPS in food when used as a PIP inert ingredient (40 CFR 174.523).

Animal Food Use

In its submissions, DBNBC states that it does not intend to grow DBN9936 corn in the United States or to import viable seed. As a consequence, DBNBC states it is not requesting regulatory action related to DBN9936 corn from EPA or from the United States Department of Agriculture.

Currently, corn intended for use in animal food is not typically imported into the United States from China. Under these conditions, DBN9936 corn from China may only be present in animal food in intermittent low levels. The primary food safety considerations under these conditions are the safety of any new substances introduced into the food.[1] For DBN9936 corn, the new substances introduced into the corn variety, including all residues that are expressed as the result of the genetic engineering are pesticidal residues, and therefore fall under the EPA's jurisdiction to determine whether these residues are safe and legal in food.

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[1] Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced.

Corn (*Zea mays* L.) is a commodity crop grown worldwide for various uses, including human and animal food. In the United States, the world's leading producer of corn, several different types of corn are cultivated, including field corn (e.g., yellow dent, white dent), sweet corn, and popping corn. Corn is an important crop for animal food. Corn grain and byproducts of corn processing may be included in diets for most animal species. Corn silage is a readily digestible, high energy, fermented forage product. It is fed primarily to ruminants (e.g., cattle, sheep and goats). For animal nutrition, corn is considered to be an important source of energy, essential fatty acids and some of the essential amino acids.

Conclusion

CVM has evaluated potential safety and regulatory issues associated with intermittent low levels of DBN9936 corn grain in animal food; CVM has not evaluated DBN9936 corn grain for general use in animal food. It is DBNBC's responsibility to ensure that any pesticidal residues present in DBN9936 corn are safe and legal when present in animal food in the United States. Based on the information DBNBC has provided to FDA, CVM has no questions concerning the safety of intermittent low levels of DBN9936 corn grain in animal food. CVM recommends that should DBNBC or distributors of DBN9936 corn intend to market the corn or its byproducts as animal food in the United States, they should contact CVM's Director for the Division of Animal Feeds, David Edwards at David.Edwards@fda.hhs.gov.

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