Andrew Olson, Ph.D.
US Regulatory Manager
BASF Corporation
2 TW Alexander Drive
Research Triangle Park, NC 27709

RE: Biotechnology Notification File No. BNF 000165

Dear Dr. Olson:

This letter addresses BASF Plant Science, L.P.'s (BASF) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)), on genetically engineered canola, LBFLFK canola. According to information BASF has provided, LBFLFK canola is genetically engineered to enable biosynthesis of long chain polyunsaturated fatty acids (LCPUFAs), including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), through expression of fatty acid desaturases and elongases in the seed. LBFLFK canola is also engineered to express a modified acetohydroxy acid synthase that confers imidazolinone herbicide tolerance. The administrative record for this consultation has been placed in a file designated BNF 000165. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, BASF submitted to FDA a summary of its safety and nutritional assessment of LBFLFK canola, which FDA received on January 30, 2018. BASF submitted additional information, received by FDA on June 4, 2019; August 12, 2019; December 15 and 18, 2019; April 14, 2020; June 10, 2020; and October 28, 2020. These communications informed FDA of the steps taken by BASF to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction.

CFSAN evaluated BASF's submissions to determine whether oil derived from LBFLFK canola raises any safety or regulatory issues with respect to its use in human food because the oil produced from LBFLFK canola contains LCPUFAs (including approximately 4.5% EPA and DHA) that would not otherwise be present in canola oil. Based on the safety and nutritional assessment BASF has conducted, it is CFSAN's understanding that BASF has concluded that the oil derived from LBFLFK canola is as safe for human food use as other oils that contain LCPUFAs and are currently on the market, including menhaden oil. Accordingly, BASF explained that oil derived from LBFLFK canola is intended for use in human food subject to the limitations in the Generally Recognized As Safe (GRAS) affirmation regulation for menhaden oil

(21 CFR 184.1472), which are related to the intake of EPA and DHA from menhaden oil.[1] It is CFSAN's understanding that BASF has concluded that such use is GRAS and does not raise issues that would require premarket review or approval by FDA.

BASF acknowledged that protein fractions from canola have minor uses in human food. Based on the safety and nutritional assessment BASF has conducted, it is CFSAN's understanding that BASF has concluded that solvent-extracted meal from LBFLFK canola would not be materially different in composition, safety, or other relevant parameters from conventional solvent-extracted canola meal and that use of protein fractions from solvent-extracted LBFLFK canola meal in human food does not raise issues that would require premarket review or approval by FDA.

CVM evaluated BASF's submissions to determine whether solvent-extracted meal derived from LBFLFK canola raises any safety or regulatory issues with respect to its uses in animal food. CVM focused on the meal derived from LBFLFK canola, and not the whole seed or oil derived from LBFLFK canola, because according to BASF, the meal will be used in animal food in the United States. Based on the safety and nutritional assessment BASF has conducted, it is CVM's understanding that BASF has concluded that solvent-extracted meal derived from LBFLFK canola is not materially different in composition, safety, and other relevant parameters from solvent-extracted canola meal currently on the market, and that solvent-extracted meal from LBFLFK canola in animal food does not raise issues that would require premarket review or approval by FDA. Should BASF change its intended uses to include other products derived from LBFLFK canola in animal food in the United States, we recommend BASF contact CVM's Division of Animal Food Ingredients.

It is BASF's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency (EPA) and the United States Department of Agriculture (USDA), before marketing human or animal food derived from LBFLFK canola.

It is a producer's or distributor's responsibility to ensure that labeling of the foods it markets derived from LBFLFK canola meets applicable legal requirements, including disclosure of any material differences (for example, differences in composition and nutritional or safety profiles) in the food as compared to its conventional counterpart. It is our understanding that LBFLFK canola may be used in various food applications. Depending on the particular human food application, the altered fatty acid composition of the oil may be considered a material fact requiring disclosure under Sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Companies marketing LBFLFK canola oil or products containing LBFLFK canola oil for use in human food applications are advised to consult with CFSAN's Office of Nutrition and Food Labeling, Division of Food Labeling and Standards, to discuss any required or voluntary labeling including statements relating to attributes of this canola variety and human food products produced from it. Failure to do so may result in the misbranding of human food products produced from LBFLFK canola oil within the meaning of Sections 201(n) and 403(a)(1) of the FD&C Act.

---

[1] Paragraphs (a)(3) and (a)(4) of the GRAS affirmation regulation for menhaden oil (21 CFR 184.1472) establish limits on the use of menhaden oil to avoid total dietary intake of EPA or DHA above 3.0 grams/person/day. Paragraph (a)(3) limits maximum use levels of menhaden oil in specific food categories; paragraph (a)(4) restricts use of menhaden oil in combination with any other added oil that is a significant source of EPA or DHA.

In evaluating the common or usual name appropriate for animal food ingredients derived from LBFLFK canola meal, CVM considered that this new canola variety was genetically engineered to synthesize omega-3 LCPUFAs, and that the intended use in animal food is as solvent-extracted meal. CVM recognizes that when used in animal food, the appropriate name for solvent-extracted LBFLFK canola meal is "canola meal."

On July 29, 2016, the National Bioengineered Food Disclosure Law (Public Law 114-216) charged the USDA's Agricultural Marketing Service with developing a national mandatory system for disclosing the presence of bioengineered material in human food. Producers, distributors, and marketers of LBFLFK canola are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information BASF has presented to FDA, we have no further questions about BASF's current intended uses of LBFLFK canola in human or animal food at this time. However, as you are aware, it is BASF's continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000165 and copies of FDA's memoranda summarizing the information in BNF 000165 will be available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

Dennis M. Keefe -S

Digitally signed by Dennis M. Keefe -S
Date: 2022.03.25 14:11:58 -04'00'

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition