



April 9, 2021

Dr. Ali Scott
Global Head Regulatory Affairs- Seeds
BASF Agricultural Solutions
2 TW Alexander Dr.
Research Triangle Park, NC 27709

Dear Dr. Scott:

This responds to your letter of March 26, 2021, regarding LBFLFK canola. In your letter, you state that low levels of LBFLFK canola have been detected in two canola hybrid-seed production fields and in a small number of commodity canola fields. Based on your description, our understanding is that these low levels of LBFLFK canola are inadvertently present in these seeds. 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 several fatty acid desaturases and elongases in the seed. You explain that LBFLFK canola is the subject of an ongoing voluntary premarket biotechnology consultation with FDA. Your letter states that food containing LBFLFK canola does not present a food safety concern and that the low levels of LBFLFK canola inadvertently present in the food supply will not impact the use of canola oil, the use of canola meal, or the overall composition of human or animal food. You follow with a request for FDA's views on the safety of LBFLFK canola when inadvertently present in food at low levels.

In its June 2006, "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,"¹ FDA explained that it believes that any food safety concern related to material from new plant varieties inadvertently present in the human and animal food supply at low levels would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible people or could be a toxin in people or animals. The data and other information in your voluntary premarket biotechnology consultation on food from LBFLFK canola establish that the new proteins expressed in LBFLFK canola are not likely to be allergenic to humans and are not toxins to people or animals. Additionally, you state in your letter of March 26, 2021, that the low levels of LBFLFK canola inadvertently present in the food supply will not impact the use of canola oil, the use of canola meal, or the overall composition of human or animal food. Based on information supplied during your voluntary premarket biotechnology consultation for LBFLFK canola and in your letter of March 26, 2021, FDA has no questions about the safety of LBFLFK canola when inadvertently present in the food supply at low levels, as you have described.

While this letter addresses low levels of LBFLFK canola inadvertently present in the human and animal food supply, FDA is continuing to evaluate your voluntary premarket biotechnology

¹ Guidance available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced>

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consultation on human and animal food from this variety. The biotechnology consultation process evaluates the full complement of food safety and regulatory issues based on the characteristics of the food for humans and animals, including potential unintended changes in the composition of the food.

Sincerely,

Dennis M.
Keefe -S

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Dennis M. Keefe, Ph.D.
Director
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