



Dr. Dan Voytas  
Chief Science Officer  
Calyxt, Inc.  
600 Country Road D West  
Suite 8  
Minneapolis, MN 55112

RE: Biotechnology Notification File No. BNF 000164

Dear Dr. Voytas:

This letter addresses Calyxt Inc.'s consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on FAD2KO soybean. According to information Calyxt has provided, this soybean has increased levels of oleic acid and decreased levels of linoleic acid as a result of mutations in the fatty acid desaturase genes *FAD2-1A* and *FAD2-1B*. The administrative record for this consultation has been placed in a file designated BNF 000164. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Calyxt submitted to FDA a summary of its safety and nutritional assessment of FAD2KO soybean, which FDA received on November 14, 2017. Calyxt submitted additional information, which FDA received on August 30, 2018. These communications informed FDA of the steps taken by Calyxt to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment Calyxt has conducted, it is our understanding that Calyxt has concluded that human food derived from FAD2KO soybean is as safe as high oleic soybean-derived human food currently on the market. Calyxt notes that oil from FAD2KO soybean is similar to other high oleic oils, and that the name "high oleic soybean oil" is an appropriate common or usual name for oil from FAD2KO soybean.<sup>1</sup> Calyxt anticipates that meal derived from FAD2KO soybean is the only material from the new soybean variety that would be used in animal food and Calyxt has concluded that meal derived from FAD2KO soybean is not materially different in composition, safety, and other relevant parameters from soybean-derived meal currently on the market. Use of FAD2KO soybean in human food and FAD2KO soybean meal in animal food does not raise issues that would require premarket review or approval by FDA.

It is Calyxt's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency and the United States Department of Agriculture, before marketing human or animal food derived from FAD2KO soybeans.

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<sup>1</sup> The fatty acid profile of oil from FAD2KO soybeans is consistent with other high oleic soybean oils and meets the specification for high oleic soybean oil in the Food Chemicals Codex, Edition 11, 2018.

Based on the information Calyxt has presented to FDA, we have no further questions concerning human food ingredients derived from FAD2KO soybean and animal food derived from FAD2KO soybean meal at this time. However, as you are aware, it is Calyxt'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 the text of this letter responding to BNF 000164, as well as a copies of the text of FDA's memoranda summarizing the information in BNF 000164, are available for public review and copying at <http://www.fda.gov/bioconinventory>.

Sincerely,

**Dennis M.  
Keefe -S**

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Dennis M. Keefe, Ph.D.  
Director  
Office of Food Additive Safety  
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