



Scott Thenell  
Thenell & Associates LLC  
1181 Keaveny Ct  
Walnut Creek, CA 94597

RE: Biotechnology Notification File No. BNF 000163

Dear Mr. Thenell:

This letter addresses Texas A&M AgriLife Research's (Texas A&M's) 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 cotton, TAM66274. According to information Texas A&M has provided, TAM66274 cotton is genetically engineered to have reduced levels of gossypol in seed through seed-specific RNA interference-mediated suppression of transcription of the *delta-cadinene synthase* gene, which encodes a key enzyme in the synthesis of gossypol and related terpenoids. The dehulled seed from this new cotton variety contains no more than 0.04% free gossypol. TAM66274 cotton was also engineered to express a neomycin phosphotransferase (NPTII) protein that was used as a selectable marker during transformation. Texas A&M's intended uses for TAM66274 in human food include general uses customary for conventional cotton and uses authorized for glandless cottonseed in 21 CFR §172.894. Texas A&M's intended uses for TAM66274 in animal food include general uses customary for conventional cotton (including hulls, meal, and other cotton plant byproducts in ruminant diets and low gossypol cottonseed meal in animal diets). The administrative record for this consultation has been placed in a file designated BNF 000163. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Texas A&M submitted to FDA a summary of its safety and nutritional assessment of TAM66274 cotton, which FDA received on September 25, 2017. Texas A&M submitted additional information, received by FDA on February 16, 2018 and June 2, 2019. These communications informed FDA of the steps taken by Texas A&M 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 Texas A&M has conducted, it is our understanding that Texas A&M has concluded that human and animal food from TAM66274 cotton is as safe as and, with the exception of reduced levels of gossypol in seed, does not differ in composition from cotton-derived human and animal food currently on the market. Texas A&M has also concluded that genetically engineered TAM66274 cotton does not raise issues that would require premarket review or approval by FDA.

As always, it is a producer's or distributor's responsibility to ensure that labeling of the foods it markets meets applicable legal requirements. Texas A&M has concluded that the following common or usual names are appropriate for human food ingredients from TAM66274 cottonseed: roasted cottonseed kernels, raw cottonseed kernels, cottonseed kernels, partially defatted cottonseed flour, defatted cottonseed flour, and cottonseed oil. CFSAN's Office of

**U.S. Food and Drug Administration**  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

Nutrition and Food Labeling, Food Labeling and Standards Staff agrees that these are sufficiently descriptive terms.

In evaluating the common or usual name appropriate for animal food ingredients from TAM66274 cotton, CVM considered that this new cotton variety was genetically engineered to reduce gossypol in seed alone, and its dehulled seed contains no more than 0.04% free gossypol. CVM recognizes that when used in animal food, the appropriate name for dehulled cottonseed derived from TAM66274 cotton is "low gossypol dehulled cottonseed," and the appropriate name for dehulled cottonseed meal derived from TAM66274 cotton is "low gossypol dehulled cottonseed meal." CVM recognizes that for all other uses of TAM66274 cotton and derived products in animal food, "cotton" is the appropriate name (for example, "cottonseed hulls," "cottonseed screenings," and "cotton plant byproduct").

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 TAM66274 cotton are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Texas A&M has presented to FDA, we have no further questions concerning human or animal food derived from TAM66274 cotton at this time. However, as you are aware, it is Texas A&M's continuing responsibility to ensure that foods marketed by Texas A&M are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of this letter responding to BNF 000163 and copies of FDA's memoranda summarizing the information in BNF 000163 are available to the public at <http://www.fda.gov/bioconinventory>.

Sincerely,

Dennis M. Keefe -S

Digitally signed by  
Dennis M. Keefe -S  
Date: 2019.10.01  
16:16:19 -04'00'

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