



James Nyangulu, Ph.D.
U.S. Agencies Regulatory Affairs Manager
Monsanto Company
1300 I Street, NW – Suite 450E
Washington, DC 20005

RE: Biotechnology Notification File No. BNF 000160

Dear Dr. Nyangulu:

This letter addresses Monsanto Company's (Monsanto) consultation with the Food and Drug Administration (FDA, we) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on genetically engineered cotton, event MON 88702. According to information Monsanto has provided, MON 88702 cotton is genetically engineered to express the Cry51Aa2.834_16 protein derived from *Bacillus thuringiensis* to protect against feeding damage caused by targeted hemipteran and thysanopteran insect pests. The administrative record for this consultation has been placed in a file designated BNF 000160. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Monsanto submitted to FDA a summary of its safety and nutritional assessment of the MON 88702 cotton, which FDA received on March 29, 2017. Monsanto submitted additional information, received by FDA on November 10, 2017. These communications informed FDA of the steps taken by Monsanto 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 Monsanto has conducted, it is our understanding that Monsanto has concluded that human and animal food from MON 88702 cotton are not materially different in composition, safety, and other relevant parameters from cotton-derived human and animal food currently on the market, and that genetically engineered MON 88702 cotton does not raise issues that would require premarket review or approval by FDA.

The United States Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIP), which include both the active and inert ingredients. MON 88702 cotton contains a PIP, which is within the purview of EPA. It is Monsanto's responsibility to obtain all appropriate clearances, including those from EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from MON 88702 cotton.

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 MON 88702 cotton are responsible for following the requirements issued by USDA relevant to the labeling of their products.

Based on the information Monsanto has presented to FDA, we have no further questions concerning human or animal food derived from MON 88702 cotton at this time. However, as

U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
www.fda.gov

you are aware, it is Monsanto'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 000160, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000160, is available for public review and copying at <http://www.fda.gov/bioconinventory>.

Sincerely,

**Dennis M.
Keefe -S**

Digitally signed by Dennis M. Keefe -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=13000727
73, cn=Dennis M. Keefe -S
Date: 2018.09.21 17:34:07 -0400'

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

cc: Liselot Bertho
Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167