



Michael Weeks  
BASF Agricultural Solutions Seed US LLC  
2 TW Alexander Drive  
Research Triangle Park, NC 27709

RE: Biotechnology Notification File No. BNF 000161

Dear Mr. Weeks:

This letter addresses BASF Agricultural Solutions Seed US LLC (BASF)'s<sup>1</sup> 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, GHB811. According to information BASF has provided, GHB811 cotton is genetically engineered to express the double mutant 5-enol pyruvylshikimate-3-phosphate synthase (2mEPSPS) from *Zea mays*, and the modified p-hydroxyphenylpyruvate dioxygenase (HPPD) W336 from *Pseudomonas fluorescens*. Expression of the 2mEPSPS and HPPD W336 proteins are intended to confer resistance to the herbicides glyphosate and HPPD inhibitors such as isoxaflutole, respectively. The administrative record for this consultation has been placed in a file designated BNF 000161. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, BASF submitted to FDA a summary of its safety and nutritional assessment of the GHB811 cotton, which FDA received on April 26, 2017. BASF submitted additional information, received by FDA on August 30, 2017. 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. Based on the safety and nutritional assessment BASF has conducted, it is our understanding that BASF has concluded that human and animal food from GHB811 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 GHB811 cotton does not raise issues that would require premarket review or approval by FDA.

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 GHB811 cotton are responsible for following the requirements issued by USDA relevant to the labeling of their products.

Based on the information BASF has presented to FDA, we have no further questions concerning human or animal food derived from GHB811 cotton at this time. However, as you are aware, it is

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<sup>1</sup> In a letter dated August 1, 2018, Bayer CropScience reported that GHB811 cotton was divested by Bayer CropScience LP to BASF Agricultural Solutions Seed US LLC. Consequently, this letter is addressed to BASF rather than Bayer, although the submissions were received from Bayer.

**U.S. Food and Drug Administration**  
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[www.fda.gov](http://www.fda.gov)

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 the text of this letter responding to BNF 000161, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000161, is available for public review and copying at <http://www.fda.gov/bioconinventory>.

Sincerely,

**Dennis M.  
Keefe -S**  Digitally signed by  
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Dennis M. Keefe, Ph.D.  
Director  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition