



Dr. Hao Chen
National Key Laboratory of Crop Genetic Improvement
Huazhong Agricultural University
No.1 Shizishan Street
Wuhan 430070
CHINA

RE: Biotechnology Notice File No. BNF 000156

Dear Dr. Chen:

This letter addresses Huazhong Agricultural University's (Huazhong) consultation with the Food and Drug Administration (FDA) (Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine) on genetically engineered rice, Huahui No.1. According to information Huazhong has provided, Huahui No.1 rice is genetically engineered to express the insecticidal protein Cry1Ab/Cry1Ac. Cry1Ab/Cry1Ac is intended to confer resistance to lepidopteran insect pests. The administrative record for this consultation has been placed in a file designated BNF 000156. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, Huazhong submitted to FDA a summary of its safety and nutritional assessment of Huahui No.1 rice grain, which FDA received on June 13, 2016. Huazhong submitted additional information, received by FDA on January 8, 2017. These communications informed FDA of the steps taken by Huazhong 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 Huazhong has conducted, it is our understanding that Huazhong has concluded that human and animal foods from Huahui No.1 rice grain are not materially different in composition, safety, and other relevant parameters from rice-derived human and animal food currently on the market, and that genetically engineered Huahui No.1 rice grain 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. Huahui No.1 rice contains a PIP, which is within the purview of EPA. Huazhong consulted with EPA and provided a copy of a letter from EPA stating the Cry1Ab/Cry1Ac protein in Huahui No. 1 rice falls under the tolerance exemption for Cry1Ac in 40 CFR 174.510. It is Huazhong's responsibility to obtain all appropriate clearances, including those from the EPA and the United States Department of Agriculture (USDA), before marketing human or animal food derived from Huahui No.1 rice.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

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 Huahui No.1 rice are responsible for following the requirements issued by USDA relevant to the labeling of their products.

Based on the information Huazhong has presented to FDA, we have no further questions concerning human and animal food derived from Huahui No.1 rice grain at this time. However, as you are aware, it is Huazhong's continuing responsibility to ensure that foods marketed by Huazhong are safe, wholesome, and in compliance with all applicable legal and regulatory requirements. A copy of the text of this letter responding to BNF 000156, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000156, is 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
Center for Food Safety