



Donald J. MacKenzie, Ph.D.  
Regulatory Affairs & Stewardship Leader  
International Rice Research Institute  
DAPO Box 7777  
Metro Manila 1301  
Philippines

RE: Biotechnology Notification File No. BNF 000158

Dear Dr. MacKenzie:

This letter addresses the International Rice Research Institute's (IRRI) consultation with the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) on genetically engineered rice, GR2E rice. According to information IRRI has provided, GR2E rice is genetically engineered to produce provitamin A carotenoids (mainly beta ( $\beta$ )-carotene) in the rice endosperm. To develop rice producing provitamin A carotenoids, IRRI introduced genes encoding phytoene synthase and carotene desaturase, which are components of the carotenoid biosynthetic pathway. The administrative record for this consultation has been placed in a file designated BNF 000158. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of bringing this consultation to closure, IRRI submitted to FDA a summary of its safety and nutritional assessment of GR2E rice, which FDA received on November 14, 2016. These communications informed FDA of the steps taken by IRRI to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. In its submission, IRRI informed FDA that although GR2E rice is not currently intended for cultivation or marketing in the United States,<sup>1</sup> it anticipates that GR2E rice, or human and animal food products derived from GR2E rice, may enter the U.S. food supply via imports from countries of production. Based on the safety and nutritional assessment IRRI has conducted, it is our understanding the IRRI concludes that human and animal food from GR2E rice is not materially different in composition, safety, or other relevant parameters from rice-derived food currently on the market except for the intended  $\beta$ -carotene change in GR2E rice. IRRI also concludes that genetically engineered GR2E rice does not raise issues requiring premarket review or approval by FDA.

Although GR2E rice is not intended for human or animal food uses in the United States, when present, it would be a producer's or distributor's responsibility to ensure that labeling of human and animal foods marketed in the United States, meets applicable legal requirements. Although the concentration of  $\beta$ -carotene in GR2E rice is too low to warrant a nutrient content claim, the  $\beta$ -carotene in GR2E rice results in grain that is yellow-golden in color. We note that the name "Golden Rice" has been used by IRRI and

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<sup>1</sup> According to IRRI, GR2E rice is intended for cultivation and use in human food in certain south and southeast Asian countries as a source of dietary provitamin A carotenoids (mainly  $\beta$ -carotene) for populations in which vitamin A deficiency is common.

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

others for many years to identify  $\beta$ -carotene-expressing rice varieties under development. CFSAN's Office of Nutrition and Food Labeling, Food Labeling and Standards Staff (ONFL/FLSS) considers that this name would accurately describe GR2E rice if present in human food. If companies market GR2E rice in human food in the United States, we advise them to consult with ONFL/FLSS to discuss any required or voluntary labeling including statements relating to attributes of this rice or any other type of claim.


FDA's Center for Veterinary Medicine, Office of Surveillance and Compliance, Division of Animal Feeds (OSC/DAF) has determined that "rice" is the appropriate name for GR2E rice if present in animal food. OSC/DAF notes that although GR2E rice is altered in color, color is not an important attribute of animal food unless it would be expected to impact food coloration despite the other ingredients that could be present in the food.

On July 29, 2016, the National Bioengineered Food Disclosure Law (Public Law 114-216) charged the U.S. Department of Agriculture'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 GR2E rice are responsible for following the requirements issued by USDA relevant to the labeling of their products.

Based on the information IRRI has presented to FDA, we have no further questions concerning human or animal food derived from GR2E rice at this time. However, as you are aware, it is IRRI'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 000158, as well as a copy of the text of FDA's memorandum summarizing the information in BNF 000158, 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,  
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cn=Dennis M. Keefe -S  
Date: 2018.05.24 10:17:48 -04'00'

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