Ms. Jaylee DeMond
Regulatory Associate
J.R. Simplot Company
5369 West Irving Street
Boise, ID 83706

RE: Biotechnology Notification File No. BNF 000197

Dear Ms. DeMond:

This letter addresses J.R. Simplot Company (Simplot)'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 potato, BG25. According to information Simplot has provided, BG25 potato is genetically engineered to express the Resistance to *Phytophthora infestans* (Rpi) proteins AMR3, BLB2, and VNT1 to confer resistance against potato late blight disease, and the StmAls protein, which confers tolerance to acetolactate synthase (ALS)-inhibiting herbicides was used as a selectable marker. In addition, the BG25 potato is genetically engineered to suppress the expression of *Potato virus Y* Coat Protein (PVY-CP) and induce resistance to PVY using RNA interference. Lastly, the BG25 potato is engineered to suppress expression of vacuolar invertase (VINV), and polyphenol oxidase (PPO) to lower levels of reducing sugars and reduce enzymatic browning, referred to as "black spot", respectively, using RNA interference. The administrative record for this consultation has been placed in a file designated BNF 000197. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, Simplot submitted to FDA a summary of its safety and nutritional assessment of BG25 potato, which FDA received on May 25, 2023. Simplot submitted additional information, received by FDA on August 31, 2023, and on April 15, 2024. These communications informed FDA of the steps taken by Simplot 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 Simplot has conducted, it is our understanding that Simplot has concluded that human and animal food from BG25 potato are not materially different in composition, safety, and other relevant parameters from potato-derived human and animal food currently on the market, and that genetically engineered BG25 potato does not raise issues that would require premarket review or approval by FDA.

The United States Environmental Protection Agency (EPA) regulates plant-incorporated protectants (PIPs), which include both the active and inert ingredients. BG25 potato contains

PIPs which are within the purview of EPA. It is Simplot'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 BG25 potato.

As always, it is a producer's or distributor's responsibility to ensure that labeling of the foods it markets meets applicable legal requirements. Companies marketing BG25 potato or products containing BG25 potato are advised to consult with CFSAN's Office of Nutrition and Food Labeling, Division of Food Labeling and Standards, to discuss any required or voluntary labeling under the Federal Food, Drug, and Cosmetic Act including statements relating to attributes of this potato such as reduced browning or any other type of claim.

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. Food manufacturers, importers, and retailers of BG25 potato are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information Simplot has presented to FDA, we have no further questions concerning human or animal food derived from BG25 potato at this time. However, as you are aware, it is Simplot'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 this letter responding to BNF 000197 and copies of FDA's memoranda summarizing the information in BNF 000197 will be made available to the public at https://www.fda.gov/bioconinventory.

Sincerely,

Kristi L. Muldoon Jacobs -S

Digitally signed by Kristi L. Muldoon Jacobs -S
Date: 2024.09.19 16:12:07 -04'00'

Kristi L. Muldoon Jacobs, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition