Ashley Fisher, Ph.D.
Regulatory Manager
J.R. Simplot Company
5369 West Irving Street
Boise, ID 83706

RE: Biotechnology Notification File No. BNF 000174

Dear Dr. Fisher:

This letter addresses J.R. Simplot Company's (Simplot) 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 potato, Z6 potato. According to information Simplot has provided, Z6 potato is derived from V11 potato (the subject of BNF 000152). The additional traits in Z6 potato are intended to lower the levels of reducing sugars, thus preventing excess darkening during frying and contributing to lower the likelihood of acrylamide formation under certain processing conditions, by lowering the levels of vacuolar invertase in the potato. In addition, Z6 potato expresses the resistance protein VNT1 from *Solanum venturii*, a wild potato species native to South America. Expression of VNT1 is intended to increase resistance to the late blight-causing oomycete *Phytophthora infestans*. The administrative record for this consultation has been placed in a file designated BNF 000174. 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 the Z6 potato, which FDA received on April 4, 2019. Simplot submitted additional information, received by FDA on July 22 and December 16, 2020; and March 10, 2021. 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 Z6 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 Z6 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 (PIP), which include both the active and inert ingredients. Z6 potato contains the resistance protein VNT1, a PIP, which is within the purview of EPA. It is Simplot'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 Z6 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 Z6 potato or products containing Z6 potato are advised to consult with CFSAN's Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, to discuss any required or voluntary labeling under the Federal Food, Drug, and Cosmetic Act including statements relating to attributes of this potato and its potential to lower acrylamide levels during processing 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. Producers, distributors, and marketers of Z6 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 Z6 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 000174 and copies of FDA's memoranda summarizing the information in BNF 000174 will be made available to the public at http://www.fda.gov/bioconinventory.

Sincerely,

Dennis M. Keefe -S

Digitally signed by Dennis M. Keefe -S
Date: 2021.08.23 11:33:10 -04'00'

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