



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

RE: Biotechnology Notification File No. BNF 000189

Dear Ms. DeMond:

This letter revises our response letter to BNF 189 signed on December 20, 2023. The purpose of this revised letter is to correct the first and second sentences of the original letter where the name of the new potato variety “JA36” was misspelled.

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 (CVM)) on genome edited potato, JA36 potato. According to information Simplot has provided, JA36 potato was developed by knocking out the *Gn2* gene to produce more tubers.¹ The administrative record for this consultation has been placed in a file designated BNF 000189. 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 JA36 potato, which FDA received on January 18, 2022. Simplot submitted additional information, received by FDA on January 21, 2022; March 4 and 22, 2022; June 27, 2023; and September 8, 2023. 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 JA36 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 JA36 potato does not raise issues that would require premarket review or approval by FDA.

¹ The term “*Gn2*” is used by Simplot to refer to the gene, designated by Simplot as confidential, that has been edited in JA36 potato to create the high tuber set phenotype (more tubers per plant).

It is Simplot's responsibility to obtain all appropriate clearances, including those from the United States Environmental Protection Agency and the United States Department of Agriculture (USDA), before marketing human or animal food derived from JA36 potato.

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 JA36 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 JA36 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 000189 and copies of FDA's memoranda summarizing the information in BNF 000189 will be made available to the public at <https://www.fda.gov/bioconinventory>.

Sincerely,

**Kristi L. Muldoon
Jacobs -S**

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Kristi L. Muldoon Jacobs, Ph.D.
Acting Director
Office of Food Additive Safety
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cc: Gary Rudgers, Ph.D.
Senior Director of Regulatory Affairs
J.R. Simplot Company
Simplot Plant Sciences