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Cc: Nathan Pumplin, Ph.D.  
President/CEO  
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2800 5th St, Suite 110  
Davis, CA 95618

RE: Biotechnology Notification File No. BNF 000178

Dear Dr. Martin and Dr. Pumplin:

This letter addresses Norfolk Plant Sciences' (NPS) 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 tomato, event *Del/Ros1-N*. According to information NPS has provided, *Del/Ros1-N* tomato is genetically engineered to express Delila and Rosea1 transcription factors to induce anthocyanin biosynthesis in the fruit, and the NPTII protein as a selectable marker. The administrative record for this consultation has been placed in a file designated BNF 000178. This file will be maintained in the Office of Food Additive Safety in CFSAN.

As part of this consultation, NPS submitted to FDA a summary of its safety and nutritional assessment of *Del/Ros1-N* tomato, which FDA received on March 3, 2020. NPS submitted additional information, received by FDA on May 27, 2021, June 24, 2022, November 10, 2022, April 7, 2023, and May 25, 2023. These communications informed FDA of the steps taken by NPS 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 NPS has conducted, it is our understanding that NPS has concluded that human food from *Del/Ros1-N* tomato is not materially different in composition, safety, and other relevant parameters from tomato-derived human food currently on the market except for the intended anthocyanin change in *Del/Ros1-N* tomato. NPS also concludes that use of genetically engineered *Del/Ros1-N* tomato in human food does not raise issues that would require premarket review or approval by FDA.

**U.S. Food and Drug Administration**  
**Center for Food Safety & Applied Nutrition**  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

In its submission, NPS stated that the *Del/Ros1-N* tomato is not intended for use in animal food in the United States. However, should NPS, distributors, or processors of the *Del/Ros1-N* tomato intend to market the tomato or its byproducts as animal food in the United States, we recommend that they contact CVM's Division of Animal Food Ingredients.

It is NPS'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 *Del/Ros1-N* tomato.

It is a producer's or distributor's responsibility to ensure that labeling of the foods it markets derived from *Del/Ros1-N* tomato meets applicable legal requirements, including disclosure of any material differences (for example, differences in function, composition, and nutritional or safety profiles) in the food as compared to its conventional counterpart. It is our understanding that *Del/Ros1-N* tomato may be used in various human food applications. Depending on the particular human food application, the increased levels of anthocyanins and therefore, purple colored-fruit may be considered material facts requiring disclosure under Sections 201(n) and 403(a)(1) of the FD&C Act [21 U.S.C. § 321(n) and 343(a)(1)]. Companies marketing food from *Del/Ros1-N* tomato 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 including statements relating to attributes of *Del/Ros1-N* tomato and products produced from it.

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 *Del/Ros1-N* tomato are responsible for complying with the regulations issued by USDA relevant to the labeling of their products.

Based on the information NPS has presented to FDA, we have no further questions concerning human food derived from *Del/Ros1-N* tomato at this time. However, as you are aware, it is NPS'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 000178 and copies of FDA's memoranda summarizing the information in BNF 000178 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: 2023.06.20 16:28:17 -04'00'

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