FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

Biotechnology Notification File No. 000178
CVM Note to the File

Date: June 16, 2023

From: Jing Ning, Ph.D.

To: Administrative Record, BNF No. 000178

Subject: Event *Del/Ros1*-N Tomato

Keywords: Tomato, *Solanum lycopersicum* L., Transcription factor, Delila, Rosea1, Snapdragon, *Antirrhinum majus* L., Neomycin phosphotransferase II (NPT II), *Escherichia coli* Tn5, Anthocyanins, Norfolk Plant Sciences

Norfolk Plant Sciences (NPS) is participating in the biotechnology consultation program with the Food and Drug Administration (FDA) and submitted a safety and nutritional assessment for a genetically engineered tomato, transformation event *Del/Ros1*-N (hereafter referred to as *Del/Ros1*-N tomato). The *Del/Ros1*-N tomato is genetically engineered to increase the levels of anthocyanins in tomato fruit, ranging from 0.17 to 0.4 milligram/gram fresh weight at ripe stage in the MoneyMaker background, when compared to non-detectable levels in conventional red tomatoes. The intended modification in *Del/Ros1*-N tomato was achieved by introducing two transcription factors from the snapdragon (*Antirrhinum majus* L). The two transcription factors, when co-expressed, induce anthocyanin biosynthesis in tomato fruit.[1] FDA's Center for Food Safety and Applied Nutrition summarizes its evaluation of uses of *Del/Ros1*-N tomato in human food in a separate document.

NPS states that *Del/Ros1*-N tomato is intended for use in human food and is not intended for use in animal food in the United States. NPS also states that if there are future uses for *Del/Ros1*-N tomato or its by-products in animal food in the United States that NPS will contact Center for Veterinary Medicine's Division of Animal Food Ingredients. Since NPS does not intend to use *Del/Ros1*-N tomato and its by-products in animal food in the United States, CVM does not need to conduct an in-depth review of the scientific data provided in the notification at this time.

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[1] Butelli, E., L. Titta, M. Giorgio, H.P. Mock, A. Matros, S. Peterek, E.G.W.M. Schijlen, R.D. Hall, A.G. Bovy, J. Luo, and C. Martin. 2008. Enrichment of tomato fruit with health-promoting anthocyanins by expression of select transcription factors. Nat Biotechnol 26:1301–1308.