Executive Summary: Application to Amend the Food Standards Code - New Food Produced Using Gene Technology

The Purple Tomato™ (OECD Unique Identifier NPS-01201-8)

Submitted by Norfolk Healthy Produce, Inc. (subsidiary of Norfolk Plant Sciences, Ltd.) 14 May 2025

This application seeks to amend the Australia New Zealand Food Standards Code to allow for the inclusion of The Purple Tomato™ (event Del/Ros1-N) in Standard 1.5.2-Food Produced Using Gene Technology. The application is submitted in parallel with applications to Health Canada under the Shared Assessment Process and to the Office of the Gene Technology Regulator in Australia.

Product Description

The Purple Tomato™ is a genetically modified tomato variety enriched throughout the fruit with purple anthocyanin pigments. Unlike conventional tomatoes where anthocyanins are limited to leaves and stems (or to fruit skin in some specialty varieties), The Purple Tomato™ expresses anthocyanins throughout the entire fruit flesh. The distinctive purple color results from the introduction of two genes from snapdragon (*Antirrhinum majus*): *Delila* (*Del*) and *Rosea1* (*Ros1*), which encode transcription factors that activate the tomato's existing anthocyanin biosynthesis pathway during fruit ripening.

Safety Assessment

Extensive molecular characterization confirms that The Purple Tomato™ contains a single, stable transgenic insert at a known location in the tomato genome. The inserted DNA includes the *Del* and *Ros1* genes (driven by the tomato E8 promoter) and an NPTII selectable marker gene. Whole genome sequencing verifies there are no unintended insertions or vector backbone sequences.

Key safety findings include:

- The DEL and ROS1 proteins are expressed at extremely low levels (below detection limits of mass spectrometry).
- Neither protein shows similarity to known toxins or allergens.
- Both proteins are rapidly degraded in simulated gastric conditions.
- The anthocyanins produced are identical to those naturally found in eggplant, purple potatoes, and conventional tomato leaves.
- Compositional analysis shows nutrient values within normal ranges for commercial tomatoes.

Nutritional Impact

The Purple Tomato™ contains approximately 0.4-2.8 mg of anthocyanin per gram fresh weight (varying by variety size), comparable to levels found in other anthocyanin-rich fruits and

vegetables. Conservative dietary exposure estimates indicate that even complete replacement of all tomatoes in the diet with purple tomatoes would increase anthocyanin intake to levels still within the normal range for people who regularly consume anthocyanin-rich foods. Anthocyanins are widely recognized as beneficial dietary components, with no known adverse effects at normal consumption levels.

Regulatory Status and Commercialization

The Purple Tomato™ has received regulatory approvals in the United States, where USDA determined it is not a regulated article and FDA completed a food safety consultation with no further questions. Commercial sales in the US began in 2023 (second growing season currently underway).

Norfolk Healthy Produce intends to commercialize The Purple Tomato™ in Australia in partnership with All Aussie Farmers as the initial growing/distribution partner. The product offers Australian consumers additional choice of a visually distinctive and nutritious tomato variety, while providing growers with a novel, high-value specialty crop opportunity.

Conclusion

The data presented in this application demonstrate that The Purple Tomato™ is as safe as conventional tomatoes for human consumption. Its distinguishing characteristic—high anthocyanin content throughout the fruit—represents an expansion of a trait already common in many fruits and vegetables in the human diet. The product's distinctive appearance provides inherent identity preservation, making it impossible for consumers to inadvertently consume the product.

Norfolk Healthy Produce requests that FSANZ adopt the general procedure in assessing this application, as appropriate for a thoroughly characterized food with substantial equivalence to conventional counterparts regarding safety.