A. Executive Summary

SPS International Inc. (SPSII) has pioneered a new approach that uses Innate® technologies to transform potato plants with potato genomic DNA, without the incorporation of selectable markers or vector backbone sequences. SPSII has developed the Russet Burbank event SPS-∅∅∅W8-4, Ranger Russet event SPS-∅∅X17-5, and Atlantic event SPS-∅∅∅Y9-7, hereafter referred to as events W8, X17, and Y9, respectively. These events were developed to address the needs of the potato growers, industry and consumers for potatoes with late blight protection, lower acrylamide potential, reduced black spot, and lower reducing sugars.

The events W8, X17, and Y9 were developed by transforming the potato varieties Russet Burbank, Ranger Russet, and Atlantic, respectively, with pSIM1278 and pSIM1678. FSANZ has previously received a submission from SPSII for a potato event transformed with pSIM1278: Russet Burbank E12 (FSANZ Application Number A1128). FSANZ has not identified any public health and safety concerns in its assessment of the potato event E12.

The W8 event was developed by transforming Russet Burbank with pSIM1278 (Event E56) and subsequently transforming it with pSIM1678. W8 was developed independently from Russet Burbank E12, which is currently under review by FSANZ. Events similar to E12 (Ranger Russet F10, and Atlantic J3 and J55), containing an insert from pSIM1278, have previously been assessed and authorised by the U.S. and Canadian regulatory agencies, including USDA, FDA, Health Canada and Canadian Food Inspection Agency. The F10 and J3 events were transformed a second time with pSIM1678 to produce events X17 and Y9, respectively.

The T-DNA of pSIM1278 contains DNA sequences intended to down regulate endogenous enzymes through the mechanism of RNA interference (RNAi). The sequences were chosen from genes of enzymes present in potato tubers:

- *Asn1* (asparagine synthetase) for reduced free asparagine, contributing to low acrylamide potential;
- *R1* (water dikinase) for lower reducing sugars, contributing to low acrylamide potential;
- *PhL* (phosphorylase-L) for lower reducing sugars, contributing to low acrylamide potential; and
- *Ppo5* (polyphenol oxidase-5) for reduced black spot.

The pSIM1678 T-DNA contains the late blight resistance gene *Rpi-vnt1.* Late blight, caused by the oomycete *Phytophthora infestans* (*P. infestans*), is a serious disease of potatoes. The *Rpi-vnt1* gene produces the VNT1 resistance protein (R-protein), found in the wild *Solanum* species *Solanum venturii* and *Solanum phureja*, which protects against foliar late blight. The VNT1 protein does not have a pesticidal mode of action, but rather enables the potato plant to detect a *P. infestans*-specific effector, Avr-Vnt1, and initiate its native immune response. In addition, the T-DNA of pSIM1678 contains potato vacuolar invertase (*VInv*) DNA sequence designed to down regulate the potato vacuolar invertase enzyme though RNAi, resulting in lower reducing sugars.

The W8, X17, and Y9 events with the desired modified traits were characterised and are the subject of this submission. In addition, SPSII asks that the *Australia New Zealand Food Standards Code* be amended to include events E56, F10 and J3, which are the primary events for W8, X17 and Y9, respectively.

The levels of free amino acids, reducing sugars, PPO activity, and field late blight protection were measured as an assessment of trait efficacy. These results demonstrated that W8, X17, and Y9 have reduced levels of free asparagine and lower levels of reducing sugars compared to their controls.

The changes to levels of free amino acids and reducing sugars are not nutritionally consequential as they do not affect the levels of essential amino acids or other key nutrients important to potato (OECD, 2002). The significantly lower levels of free asparagine and reducing sugars resulted in lower acrylamide in fries and chips made from W8, X17, and Y9 tubers. Additionally, the efficacy testing for PPO down regulation confirmed that PPO activity was significantly reduced in W8, X17, and Y9 tubers, consistent with effective down regulation of PPO in each event. Lastly, the late blight field efficacy studies confirmed that events W8, X17, and Y9 are each significantly more resistant to four strains of late blight than the Russet Burbank, Ranger Russet, and Atlantic control varieties.

Molecular characterisation of the events was performed to determine the number of copies, arrangement, and stability of the inserted DNA from both vectors. The events were confirmed to be free of *Agrobacterium*-derived backbone DNA. In the United States, confined field trials were undertaken, with the conventional variety and other cultivated varieties used as controls. Results from these trials confirmed no changes were observed that could have an impact on the environment or affect genetic stability. Compositional analysis was performed on field-grown tubers to compare nutritional and anti-nutritional compounds and showed no biologically relevant differences existed that could result in increased risk to humans or other non-target organisms. Analysis of the VNT1 protein and putative polypeptides produced from the inserted DNA indicated there are no sequences with significant homology to known allergens or toxins in these Innate® potatoes.

Analysis of the events W8, X17, and Y9 have not revealed any biologically relevant differences compared to the conventional varieties, except for the intended late blight protection, low free asparagine, low reducing sugars, and low polyphenol oxidase activity. Collectively, results of the molecular characterisation, agronomic assessment, and composition analysis support this application for amendment to the *Australia New Zealand Food Standards Code* to allow inclusion of the Innate® potato events W8, X17, and Y9 as well as their primary events E56, F10 and J3 respectively in **Standard 1.5.2**-*Food Produced Using Gene Technology*.

References

OECD (2002). Organization for Economic Co-Operation and Development. Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants.