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 Snowden event SPS-∅∅∅Z6-5, hereafter referred to as event Z6. This event was developed to address the needs of the potato growers, industry and consumers for potatoes with late blight protection, low free asparagine, lowered reducing sugars and reduced black spot.

The event Z6 was developed by transforming the potato variety Snowden with pSIM1278 and pSIM1678. FSANZ has previously received submissions from SPSII for potato events transformed with pSIM1278 and pSIM1678: FSANZ Application Number A1128 and A1139. FSANZ has not identified any public health and safety concerns in its assessment of the potato events.

The Z6 event was developed by transforming Snowden with pSIM1278 (Event V11) and subsequently transforming V11 with pSIM1678. Events similar to V11 and Z6, containing an insert either from pSIM1278 or both pSIM1278 and pSIM1678, have previously been assessed and authorised by the U.S. and Canadian regulatory agencies, including USDA, FDA, Health Canada, Canadian Food Inspection Agency and FSANZ.

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 the plant's 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 Z6 event with the desired modified traits was characterised and is the subject of this submission. In addition, SPSII asks that the *Australia New Zealand Food Standards Code* be amended to include event V11, which is the primary event for Z6.

The levels of free amino acids, reducing sugars, and PPO activity were measured as an assessment of trait efficacy. These results demonstrated that Z6 has the expected phenotype. 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 Z6 tubers. Additionally, the efficacy testing for PPO down regulation confirmed that PPO activity was significantly reduced in Z6 tubers, consistent with effective down regulation of PPO in each event.

Molecular characterisation of the event was performed to determine the number of copies, arrangement, and stability of the inserted DNA from both vectors. The event was 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 Z6 potatoes.

Analysis of the event Z6 has not revealed any biologically relevant differences compared to the conventional variety, 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 event Z6 as well as the primary event V11 in **Standard 1.5.2**-*Food Produced Using Gene Technology*.