

SPS International Inc.

Application to FSANZ for the Inclusion of Potatoes with Low Acrylamide Potential and Reduced Black Spot in Standard 1.5.2 Food Produced Using Gene Technology

Part 1 General Requirements

Executive Summary

SPS International Inc. (SPSII) has pioneered a new approach that marks a significant and vital advance in plant breeding. Innate® technologies transform potato plants with potato genomic DNA, without the incorporation of selectable markers or vector backbone sequences.

Innate® technologies were used to address two critical potato quality issues: (1) an acrylamide by-product that is produced when potatoes are heated, causing reducing sugars to react with asparagine through the Maillard reaction, that also results in a variety of desired compounds contributing to flavour, aroma, and browning; and (2) susceptibility to enzymatic darkening and discoloration, which happens when polyphenol oxidase leaks out of damaged plastids of bruised and cut potatoes. In the cytoplasm, the enzyme oxidises phenols, which then rapidly polymerise to produce dark pigments.

The potato variety Russet Burbank was transformed with a DNA insert containing two RNA interference cassettes in an *Agrobacterium* vector (pSIM1278). The resulting event (E12) has reduced expression of four potato enzymes (asparagine synthetase, polyphenol oxidase, water dikinase and phosphorylase). No new polypeptides are produced from this construct as the RNA catalyses the degradation of specific mRNA that down-regulates the target genes within the plant. The E12 event with the desired modified traits was characterised and is the subject of this submission (OECD Unique Identifier: SPS-ØØE12-8).

In addition to the analysis of the desired traits, molecular characterisation of the event was performed to determine the number of copies, arrangement and stability of the inserted DNA. The event was confirmed to be free of *Agrobacterium*-derived backbone DNA. In the United States confined field trials were undertaken over three years, with the conventional variety and other cultivated varieties as controls. Observations at these trials looked for changes which 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 to determine if any biologically relevant differences existed that could result in increased risk to humans or other non-target organisms. There are no new polypeptides produced from the inserted DNA and thus there are no new potential toxins or allergens produced in Innate® potatoes.

Analysis of the E12 potato event has not revealed any biologically relevant differences compared to the conventional variety, except for the intended low free asparagine, low reducing sugars, and low polyphenol oxidase activity. Collectively, results of the molecular characterisation, agronomic assessment, and composition analysis support our application for amendment to the *Australia New Zealand Food Standards Code* to allow inclusion of the Innate® potato event E12 in **Standard 1.5.2-Food Produced Using Gene Technology**.