

SPS International, Inc.

Application to FSANZ for the Inclusion of BG25 Potatoes with late blight protection, *Potato virus Y* protection, lower reducing sugars, and reduced polyphenol oxidase in Standard 1.5.2 Food Produced Using Gene Technology

Executive Summary

SPS International, Inc. (SPSII) has developed the SPS-ØBG25-7 (BG25) potato event as a new transformation of the Russet Burbank potato variety, hereafter referred to as event BG25. This is a Gen3 event with a single insertion that has late blight protection, *Potato virus Y* (PVY) protection, lower reducing sugars, and reduced polyphenol oxidase (PPO).

The BG25 event follows Simplot's Gen1 and Gen2 potatoes (Richael, 2021) by improving the variety Russet Burbank, one of the most grown potato varieties across Australasia and North America. The Russet Burbank is a premier storage variety that is excellent for the fresh market and for processing. The traits in BG25 potatoes were introduced through *Agrobacterium*-mediated transformation of Russet Burbank with the plasmid pSIM4363 and include:

- Durable foliar and tuber protection against late blight infection from three potato resistance genes (R-genes) that are cis-genes
- Protection against PVY infection by inhibition of viral replication using viral coat protein (CP) sequences to trigger the plant's RNA interference (RNAi) pathway
- Lower reducing sugars (fructose and glucose) from down regulation of vacuolar invertase (VINV) using RNAi; and
- Reduced black spot from the down regulation of polyphenol oxidase (PPO) using RNAi.

A modified potato (*Solanum tuberosum*) acetolactate synthase gene (*StmAls*) was also used as a marker for selecting transformed events *in vitro*. The *StmALS* protein is expressed in BG25 but is not a commercial trait.

FSANZ has previously reviewed a single late blight R-gene (*Rpi-vnt1*) in four SPSII Gen2 events (SPS-ØØØW8-4, SPS-ØØX17-5, SPS-ØØØY9-7, and SPS-ØØØZ6-5; A1139). In comparison to these potato events previously reviewed by FSANZ, BG25 has two additional late blight R-genes, PVY protection, and a modified potato ALS marker gene. This event still has down regulated VINV and PPO but does not have a reduction in asparagine. The late blight R-genes are cis-genes from wild *Solanum* species.

Late blight is a serious potato disease managed through frequent sprays of preventive fungicides. The introduction of late blight protection into commercial potato varieties enables reduced fungicide applications (Ghislain et al., 2019), which further reduces both the costs and the release of fungicide into the environment. Combining three resistance proteins (R-proteins) that recognise different pathogen effector proteins reduces the chance that the pathogen can overcome the late blight protection, and this is expected to improve durability of the late blight protection trait.

The addition of PVY protection in BG25 addresses a long-standing issue in the potato industry: the reduction of viruses in certified virus-free potato seed tubers. *Potato virus Y* protection benefits the potato seed producer and protects the grower from potential yield loss due to PVY infection.

FSANZ has previously reviewed lower reducing sugars and reduced black spot in four SPSII Gen1 events (SPS-ØØE12-8 in A1128; SPS-ØØF10-7 and SPS-ØØØJ3-4 in A1139; SPS-ØØV11-6 in A1199) and four Gen2 events noted above (A1139). Reducing sugars increase during tuber storage and lead to dark colours in fries and lower the processing quality of tubers. Black spot develops in fresh potato tubers from handling during harvest, transport, storage, and processing. This discoloration of tubers is undesirable for both consumers and processors and results in food waste.

This submission contains the following information and data demonstrating the food safety of BG25 compared to Russet Burbank and other conventional potato varieties:

- Information on the development of event BG25

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- Molecular characterisation of the insert in BG25, evaluating the insert structure, flanking sequence, insert copy number, integration site and demonstrating absence of vector backbone sequences
- Stability of the insert over several generations
- Characterisation and safety assessments for the four expressed proteins
- Small interfering RNA (siRNA) safety assessment
- Compositional assessment evaluating levels of key nutrients (proximates, vitamins, minerals, starch, fibre), and glycoalkaloids; and
- A comparative analysis for similarity between open reading frames (ORFs) introduced into BG25 and known allergens or toxins.

Based on these analyses, SPSII concludes that the foods derived from BG25 potatoes are as safe as those from conventional varieties. Except for the intended changes, the BG25 potatoes are not different in composition, safety, or any relevant food safety parameter to comparable potato varieties that are grown, marketed, and consumed in Australia or New Zealand.

Collectively, results support this application for amendment to the *Australia New Zealand Food Standards Code* to allow inclusion of the potato event BG25 in **Standard 1.5.2-Food Produced Using Gene Technology**.

References

- Ghislain M, Byarugaba A A, Magember E, Njoroge A, Rivera C, Roman M L, Tovar J C, Gamboa S, Forbers G A and Kreuze J F. (2019). Stacking three late blight resistance genes from wild species directly into African highland potato varieties confers complete field resistance to local blight races. *Plant Biotechnology Journal* 17: 1119–29.
- Richael, C.M. (2021). Development of the Genetically Modified Innate[®] Potato. *Plant Breeding Reviews* 44, 57–78.