Application to FSANZ to Vary Food Standard 1.5.2 to Include the Double-Herbicide-Tolerant Soybean Event SYHT0H2

(Bayer CropScience Pty Ltd/Syngenta Seeds Pty Ltd)

Executive Summary

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Bayer CropScience Pty Ltd seeks to vary FSANZ Standard 1.5.2 to allow the use of genetically modified soybean (*Glycine max* L. Merr.) derived from transformation event SYHT0H2 in the Australian and New Zealand food industries. Five food products are derived from soybean: whole soybeans, oil, meal, hulls and protein. Soybean oil is the primary food product consumed by humans in Australia, with the other products used either as food products or as components of animal feed.

SYHT0H2 soybean contains the transgene *avhppd-03* encoding an HPPD enzyme, designated AvHPPD-03, that is more than 99.7% identical in amino acid sequence to the native HPPD in common oat (*Avena sativa*). HPPD is a ubiquitous enzyme in the tyrosine catabolic pathway that is essential to plants, animals, and many microbes. In comparison with the native soybean HPPD, the HPPD isozyme from oat has lower binding affinity for HPPD-inhibiting herbicides, such as mesotrione, and confers tolerance to herbicide application rates that would otherwise injure soybean. SYHT0H2 soybean also contains the transgene *pat* derived from *Streptomyces viridochromogenes*, a ubiquitous soil microbe. The gene *pat* encodes phosphinothricin acetyltransferase (PAT), an enzyme that inactivates glufosinate-ammonium herbicide, an inhibitor of glutamine synthetase. Expression of *pat* confers a glufosinate-tolerance phenotype.

SYHT0H2 soybean was produced by transformation of immature soybean seed of variety 'Jack' using disarmed *Agrobacterium tumefaciens*. The region of the plasmid vector, pSYN15954, intended for insertion into the soybean genome consisted of three gene-expression cassettes: (1) the gene *avhppd-03* regulated by the figwort mosaic virus (FMV), cauliflower mosaic virus (CaMV) 35S, and tobacco mosaic virus (TMV) enhancer sequences, the synthetic minimal plant promoter sequence, and the nopaline synthase (NOS) terminator sequence, (2) the gene *pat-03-01* regulated by the CaMV 35S promoter sequence and NOS terminator sequence, and (3) the gene *pat-03-02* regulated by the Cestrum yellow leaf curling virus promoter (CMP) sequence, TMV enhancer sequence, and NOS terminator sequence. Both versions of *pat* (*pat-03-01* and *pat-03-02*) encode the identical PAT protein sequence.

Genetic characterization studies demonstrated that SYHT0H2 soybean contains, at a single locus within the soybean genome that is stably inherited, a single copy of *avhppd-03*, four copies of *pat*, a single copy of the *avhppd-03* enhancer complex sequence, two copies of the CaMV 35S promoter, two copies of the CMP promoter, two copies of the TMV enhancer, and five copies of the NOS terminator. It does not contain any extraneous DNA fragments of these functional elements elsewhere in the SYHT0H2 soybean genome, and it does not contain the FMV enhancer or plasmid backbone sequence from pSYN15954. Analyses comparing the soybean genomic sequence flanking the SYHT0H2 insert with sequences in public databases indicated that the inserted DNA does not disrupt any known endogenous soybean gene.

Analyses of seed and forage from several U.S. field testing sites demonstrate that SYHT0H2 soybean is nutritionally and compositionally similar to, and as safe and nutritious as, conventional soybean. The levels of endogenous allergens are not higher in SYHT0H2 soybean than in conventional soybean varieties. No deleterious effects of SYHT0H2 soybean on animal performance were observed in a study wherein rapidly growing broiler chickens were fed diets prepared with SYHT0H2 soybean meal or conventional soybean meal for 42 days.

Well-characterized modes of action, physicochemical properties, and results of safety studies demonstrate that the AvHPPD-03 and PAT proteins present in SYHT0H2 soybean

present no risk of harm to humans or livestock that consume soybean products or to wildlife potentially exposed to SYHT0H2 soybean.