Executive Summary

Bayer Crop Science Pty Ltd seeks to vary FSANZ Standard 1.5.2 to allow the use of genetically modified canola (*Brassica napus*) derived from transformation event MS11 *B. napus* in the Australian and New Zealand food industries. We seek specifically to allow the use of genetically modified *Brassica napus* (canola) oil derived from transformation event MS11 *B. napus* in the Australian and New Zealand food industries. Canola seed contains 44% oil which is extracted and used as a cooking oil. The remainder of the seed (meal) is used as livestock feed.

Bayer's Crop Science Division (Bayer CS) has developed a highly successful breeding tool that is used to produce *Brassica napus (B. napus)* glufosinate-ammonium tolerant hybrids that are sold in Canada and the USA. Currently, BCS hybrids are based on events MS8 *B. napus* and RF3 *B. napus* MS8 *B. napus* will be phased out of use by the mid-2020's and MS11 *B. napus* will be the replacement event.

The hybrid technology comprises three components: a dominant gene for male sterility – the *barnase* gene (event MS11), a dominant gene for fertility restoration – the *barstar* gene (event RF3) and a selectable marker gene to make the system more convenient for breeding and seed production – the *bar* gene (found in both MS11 and RF3) conferring tolerance to glufosinate-ammonium. MS11 *B. napus* is a male sterile line that segregates 1:1 for sterility and fertility and is only used for the production of the MS11xRF3 *B. napus* hybrid seed. It will never be commercialized as a standalone product.

MS11 *B. napus* (male sterile line) was produced by means of *Agrobacterium* mediated transformation using the vector pTCO113. MS11 *B. napus* contains the *barnase* gene (origin *Bacillus amyloliquefaciens*) coding for a ribonuclease, Barnase. The *barnase* gene is driven by the Pta29 promoter that restricts gene expression to the tapetum cells during anther development. Expression of Barnase in the tapetum cells of MS11 *B. napus* results in lack of viable pollen and male sterility. MS11 *B. napus* contains the *barstar* gene (origin *Bacillus amyloliquefaciens*) coding for the Barstar protein, which is an inhibitor of the Barnase protein. This prophylactic *barstar* gene, driven by the Pnos promoter, is included to enhance transformation frequency. MS11 *B. napus* also contains the *bar* gene (origin *Streptomyces hygroscopicus*) coding for phosphinothricin acetyl transferase (PAT/*bar*) confering tolerance to glufosinate-ammonium. The *bar* gene is driven by the PssuAt plant promoter that is active in all green tissues of the plant. The OECD identifier of MS11 *B. napus* is BCS-BNØ12-7.

The incorporation and expression of the MS11 transgenic locus in the *B. napus* genome has been characterized according to international standards for the safety assessment of biotechnology products. This information is included with this application to support the food safety of the PAT, Barnase and Barstar proteins. Hybrid *B. napus* varieties containing MS11 *B. napus* will be grown commercially in the *B. napus* producing areas of Canada, USA and Australia.

The *bar, barnase and barstar* genes were introduced into the *B. napus* genome in a single gene construct via direct-gene transfer. The regulatory sequences used in this construct are derived from common plants or plant pathogens that are routinely used in plant biotechnology and have a history of safe use.

In the molecular characterisation of the MS11 *B. napus* transgenic locus, bioinformatics analysis of the full DNA sequence revealed no evidence supporting cryptic gene expression or unintended effects resulting from the genetic modification. The transgenic locus also shows structural stability over different generations and growing environments, and in different genetic backgrounds.

Food safety evaluation of the PAT/*bar*, Barnase and Barstar proteins was undertaken utilising guidance provided by Codex (2003). No health-related adverse effects have been associated with the proteins.

The source organism for the Barnase and Barstar proteins, *Bacillus amyloliquefaciens,* is ubiquitous in nature and found throughout the world as common soil bacteria. The Barnase and Barstar proteins

have no amino acid sequence homology to know allergens and both are rapidly degraded in simulated gastric fluid and simulated intestinal fluid assays. The Barnase and Barstar proteins have no amino acid sequence similarity to know toxins and exhibited no effects in acute oral mouse toxicity tests. Both proteins have a good history of safe use.

The source organism for the phosphinothricin acetyltransferase (PAT/*bar*) protein, *Streptomyces hygroscopicus*, is a common saprophytic bacterial species that is found worldwide, predominately in soil. The PAT/*bar* protein does not possess structural or functional similarity with known toxic proteins or allergens; it shares no sequence homology with known allergens and toxins, no N-glycosylation sites, and rapidly degrades in simulated digestive environments. The Pat/*bar* protein exhibited no effects in an acute oral mouse toxicity test. The PAT/*bar* protein has a good history of safe use. Therefore, it is concluded that MS11 *B. napus* has negligible impact on canola nutritional value.