

Part 1 General Requirements (3.1.1)

A. Executive Summary

Trigall Genetics is a Uruguay-based joint venture between Bioceres Crop Solutions and Florimond Desprez. Trigall Genetics has developed a genetically modified wheat line using the sunflower *HaHB4* gene to confer increased tolerance to environmental stresses avoiding reduction of crop yield. The HAHB4 protein belongs to the HD-Zip family of transcription factors, characterised by the presence of two functional domains: the homeodomain (HD), responsible for DNA binding, and a leucine zipper motif (LZ) involved in protein-protein interaction and dimerisation. The wheat event described in this application has the unique OECD code: IND-ØØ412-7 and is referred to as 'HB4 wheat' in this submission.

HB4 wheat was developed using particle bombardment by co-transforming the wheat variety Cadenza with the plasmids *pIND4-HB4* and *pIND4-Bar*. The selected event (IND-ØØ412-7) has been field evaluated over several growing seasons in Argentina with data supporting the conclusion that the *HaHB4* gene confers increased tolerance to environmental stresses that reduce crop yields, and that wheat event IND-ØØ412-7 also exhibits tolerance to glufosinate-based herbicides.

Molecular characterisation of the event was performed to determine the number of copies, arrangement, and stability of the inserted DNA. Molecular analysis shows a complex integration structure. Two inserts (within a single locus) are present in wheat event IND-ØØ412-7, and the complete nucleotide sequence shows there is one complete copy of *HaHB4* gene and three copies of the *bar* gene, with the respective regulatory elements in the correct positions. Other genetic elements contained in the insertions are incomplete and/or non-functional copies of genes and genetic elements from the vectors used in the transformation.

Field trials were undertaken with wheat event IND-ØØ412-7 to compare agronomic performance and biosafety with the conventional variety and other cultivated varieties used as controls. Results from these trials confirmed no changes were observed in wheat event IND-ØØ412-7 that could have an impact on the environment. Stability of the genetic modification was assessed and confirm that the HB4 trait is stably inherited and conforms to Mendelian segregation principles.

Compositional analysis was performed following the OECD Consensus Document recommendations for wheat (OECD, 1999a, 2003) including treatments with the herbicide glufosinate (OEDC, 1999b). Comparison of nutritional and anti-nutritional compounds showed no biologically relevant differences exist that could result in increased harm to humans or other non-target organisms. Analysis of the HAHB4 and PAT proteins as well as putative polypeptides produced from the inserted DNA indicated there are no sequences with significant homology to known allergens or toxins in HB4 wheat.

Analysis of the HB4 wheat has not revealed any biologically relevant differences compared to the conventional variety, except for the intended tolerance to abiotic stress and herbicide tolerance. 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 HB4 wheat in **Standard 1.5.2-Food Produced Using Gene Technology**.