

A. Executive Summary

Bioceres Crop Solutions has developed a genetically modified (GM) soybean 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 soybean event described in this application has the unique OECD code: IND-ØØ41Ø-5 and is referred to as 'HB4 soybean' in this submission.

HB4 soybean was developed using *Agrobacterium*-mediated transformation of the soybean (*Glycine max*) variety Williams 82 (Bernard and Cremeens, 1988) with the binary plasmid *pIND2-HB4*. The selected event (IND-ØØ41Ø-5) has been field evaluated over many growing seasons in Argentina and the United States with data supporting the conclusion that the *HaHB4* gene confers increased tolerance to environmental stresses that reduce crop yields, and that soybean event IND-ØØ41Ø-5 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 single T-DNA locus comprised of a single copy of the selectable bar marker-gene, a single copy of the *HaHB4* gene, and their respective regulatory sequences. No unintended components from the binary vector DNA are present in IND-ØØ41Ø-5.

Field trials were undertaken with soybean event IND-ØØ41Ø-5 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 soybean event IND-ØØ41Ø-5 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 soybean (OECD, 2012). 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 soybean.

Analysis of the HB4 soybean 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 soybean in **Standard 1.5.2-Food Produced Using Gene Technology**.

References

1. Bernard R and Cremeens C (1988). Registration of 'Williams 82' soybean. *Crop Science* 28, 1027-1028.
2. OECD (2012). Revised Consensus Document on Compositional Considerations for New Varieties of Soybean [*Glycine Max* (L.) Merr.]: Key Food and Feed Nutrients, Antinutrients, Toxicants and Allergens. ENV/JM/MONO(2012)24. Series on the Safety of Novel Foods and Feeds No. 25 (Paris, France: Organisation for Economic Cooperation and Development).