

# Safety Assessment RP1232 Genetically Modified GHB811 Cotton

Area of research interest: [Research projects](#)

Project status: Completed

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Conducted by: Regulated Products Risk Assessment Unit FSA and Risk Assessment Team FSS

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## Summary

Following the submission of application RP1232 to the Food Standards Agency (FSA) under assimilated Regulation (EC) No. 1829/2003 from BASF Agricultural Solutions Seed US LLC, FSA/FSS (Food Standards Scotland) have undertaken a safety assessment on genetically modified GHB811 cotton. To support the safety assessment by FSA/FSS, the Advisory Committee on Novel Foods and Processes (ACNFP) provided advice to FSA/FSS on the data submitted for the authorisation of genetically modified GHB811 cotton, as outlined in this document. The advice of the ACNFP has been taken into account in this safety assessment which represents the opinion of FSA/FSS on the safety of genetically modified GHB811 cotton.

GHB811 cotton is modified by the addition of the 2mepsps and hppdPfW336-1Pa gene cassettes. The 2mEPSPS protein is modified from the wild-type maize (*Zea mays*) 3-enolpyruvylshikimate-3-phosphate synthase (epsps) by two mutations, T102I and P106S. EPSPS (and 2mEPSPS) are essential for the synthesis of some amino acids and aromatic compounds in plants and are targets for glyphosate herbicides. The mutations inserted into 2mEPSPS decrease glyphosate binding affinity, thereby conferring tolerance to glyphosate herbicides. The HPPD W336 protein is modified from the soil bacterium *Pseudomonas fluorescens* A32 4-hydroxyl-phenyl-pyruvate dioxygenase by the mutation G336W and confers improved tolerance to HPPD (4-hydroxyphenylpyruvate dioxygenase) inhibitors. HPPD is involved in tyrosine catabolism in aerobic organisms, and the formation of isoprenoids in anaerobic organisms.

Cotton is primarily used worldwide for its lint; however, raw, unprocessed cottonseed may be fed to ruminants as meal, or the seed can be processed into oil. Cottonseed oil has been in use since the 19th century and is considered to be a premium quality oil. The scope of the application is for the authorisation for import, processing, and food and feed use of herbicide tolerant GHB811 cotton. The application does not cover cultivation and therefore no GHB811 cotton will be grown in the UK.

In providing its scientific advice, the ACNFP considered data provided as part of application RP1232. The molecular characterisation determined that GHB811 cotton contained a complete T-DNA at a single locus, with no disruption of endogenous genes. Bioinformatics analyses of the insert and flanking regions (including the junctions between them) found no homology with known toxic or allergenic proteins, and found no sequences that could lead to horizontal gene transfer. Genetic stability of the transgenic locus, and phenotypic stability of transgenic protein expression were both confirmed. The field trials (including locations and management practices) for the production of test materials for the comparative analysis were considered appropriate, and no differences between the GHB811 cotton and the conventional counterpart or the non-GM reference varieties that would raise safety concerns were observed. Studies on both newly expressed proteins found no evidence of potential toxicology. Both proteins have well

documented histories of safe use, and their source organisms are either commonly consumed by humans and animals, or are ubiquitous in the environment. The studies were performed using bacterially-produced proteins, and the ACNFP were satisfied that these proteins were equivalent to plant-produced proteins. No safety concerns were identified in the 90-day feeding study. Bioinformatics analysis of allergenicity potential found no relevant homology with known allergenic proteins. An independent, outside contractor assessed the outcomes and methodologies of all bioinformatic analyses and was satisfied that the methods and results were satisfactory.

The ACNFP concludes that considering the nature of the introduced traits, the lack of differences in the agronomic and compositional analyses, and the proposed levels of exposure, there is no evidence that the import, processing, and food and feed use of GHB811 cotton would raise any safety concerns. The ACNFP concludes that GHB811 cotton is as safe as its conventional counterpart.

## **Safety assessments**

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