Safety Assessment RP1123 Genetically Modified GMB151 Soybean

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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 RP1123 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 GMB151 soybean. 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 GMB151 soybean, 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 GMB151 soybean.

GMB151 soybean (Glycine max) is modified by the addition of the cry14Ab-1.b and hppdPf-4Pa gene cassettes. The Cry14Ab-1 protein is a member of the Cry (crystal)-type protein family produced by B. thuringiensis which are toxic towards insects and nematodes, and confers resistance to soybean cyst nematode (SCN). Bt Cry proteins have been used for 50 years as an alternative to synthetic pesticides and are very effective when expressed in genetically modified plants. Planting SCN resistant soybean reduces yield losses caused by SCN infestation. The HPPD-4 protein is a modified form of the 4-hydroxyphenylpyruvate dioxygenase gene from P. fluorescens, which confers tolerance to HPPD (4-hydroxyphenylpyruvate dioxygenase) inhibitor herbicides such as isoxaflutole. The hppdPf-4Pa gene was engineered by modifying the gene at four positions; E335P, G336W, K339A, and A340N. HPPD is involved in tyrosine catabolism in aerobic organisms, and the formation of isoprenoids in anaerobic organisms.

Soybeans have been domesticated for over three millennia and are now grown as a commercial crop in over 90 countries throughout the world. In 2021, over 129,000 hectares of soybeans were harvested producing over 370,000,000 tonnes of soybeans, and over 58,000,000 tonnes of oil. The major commodities of soybeans are the grain (used to make traditional soy foods such as miso, soy sauce and tofu as well as other products), oil, and meal, despite the known presence of allergens. The scope of the application is for the authorisation for import, processing, and food and feed use of cyst nematode resistant and herbicide tolerant GMB151 soybean. The application does not cover cultivation and therefore no GMB151 soybean will be grown in the UK.

In providing its scientific advice, the ACNFP considered data provided as part of application RP1123. The molecular characterisation of GMB151 soybean determined that there was a single, intact copy of the T-DNA at a single insertion locus, within the 3’ untranslated region of a putative endogenous gene with an unknown function in soybean. Genetic stability of the transgenic locus, and phenotypic stability of transgenic protein expression, were both confirmed over multiple

generations. Bioinformatics analyses of the newly expressed proteins. 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 GMB151 soybean 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. The studies were performed using bacterially-produced proteins, and the committee was satisfied these proteins were equivalent to plant-produced proteins. No safety concerns were raised during the 90-day feeding study. Bioinformatics analysis of the allergenicity potential of Cry14Ab-1 found one low identity match with Asp f 22 enolase from Aspergillus fumigatus, and a partial match with Hordein Barley peptide B03. Detailed analyses of these matches suggested they are not biologically relevant. No matches were found for the HPPD-4 protein. An independent outside contractor assessed the outcomes and methodologies of all bioinformatic analyses and were satisfied that the methods and results were adequate.

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 in application RP1123 that the import,
processing, and food and feed use of GMB151 soybean would raise any safety concerns. The ACNFP concludes that GMB151 soybean is as safe as its conventional counterpart.

Safety assessment

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