Safety Assessment RP212 Genetically Modified Soybean 40-3-2

Area of research interest: Research projects
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Project code: RP212
Conducted by: Regulated Products Risk Assessment Unit FSA and Risk Assessment Team FSS
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Summary

Following the submission of application RP212 to the Food Standards Agency (FSA) under assimilated Regulation (EC) No. 1829/2003 from Bayer CropScience Ltd, FSA/FSS (Food Standards Scotland) have undertaken a safety assessment on genetically modified soybean 40-3-2. 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 renewal of authorisation for the genetically modified soybean 40-3-2, 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 soybean 40-3-2.

Soybean 40-3-2 is modified to express the CP4 EPSPS (5-enolpyruvylshikimate 3-phosphate synthase) protein from the CP4 strain of Agrobacterium tumefaciens, which has a lower binding affinity with glyphosate, conferring tolerance to glyphosate herbicides.
Soybean 40-3-2 has previously been authorised for food and feed uses and is most commonly used as a source of protein in animal feed. The scope of this application is for the renewal of the authorisation for placing on the market of food and feed products containing, consisting of, or produced from genetically modified soybean 40-3-2. This also includes products other than food or feed. The application does not cover cultivation and therefore no soybean 40-3-2 will be grown in the UK.

In providing its advice on the safety of soybean 40-3-2 for food and feed, the ACNFP considered data provided as part of application RP212 (post-market environmental monitoring reports, evaluation of systematic literature searches, additional studies performed by or on behalf of the applicant, and updated bioinformatics analyses), additional information provided by the applicant, and analyses and reports from outside contractors. The ACNFP assessed these data for possible new hazards, modified exposures, or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application (or the first renewal in 2012).

FSA/FSS concludes, based on ACNFP advice, that there is no evidence in the renewal application RP212 for new hazards, modified exposures, or new scientific uncertainties that would change the conclusions of the original risk assessments on genetically modified soybean 40-3-2 (EFSA GMO Panel 2010, UK-ACNFP 1995).

Safety assessment

PDF
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