Position papers

ACNFP advice on the safety of genetically modified soybean A5547-127 for renewal of authorisation

Reference Number RP188

Regulated Product Dossier Assessment

Assessment finalised: 5th of April 2024

Summary

Following the submission of application RP188 to the Food Standards Agency (FSA) under assimilated Regulation (EC) No. 1829/2003 from BASF Plc (United Kingdom), FSA/FSS (Food Standards Scotland) were required to undertake a safety assessment on genetically modified soybean A5547-127. 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 A5547-127, as outlined in this document.

Soybean A5547-127 is modified to express the PAT (phosphinothricin acetyltransferase) protein from the soil bacteria Streptomyces viridochromogenes to confer resistance to glufosinate ammonium herbicide. The PAT protein prevents glufosinate ammonium herbicide from inhibiting the glutamate synthase enzyme, which is essential for nitrogen metabolism in plants.

Soybean A5547-127 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 products containing, consisting of, or produced from genetically modified soybean A5547-127. This includes food, feed, and products other than food or feed. The application does not cover cultivation and therefore no soybean A5547-127 will

be grown in the UK.

In providing its advice on the safety of soybean A5547-127 for food and feed, the ACNFP considered data provided as part of application RP188 (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 (EFSA GMO Panel 2011).

The ACNFP concludes that there is no evidence in the renewal application RP188 of new hazards, modified exposures, or new scientific uncertainties that would change the conclusions of the original risk assessment of genetically modified soybean A5547-127 (EFSA GMO Panel 2011).

1. Introduction

1.1 Background

On February 3rd 2021, the Food Standards Agency (FSA) received application RP188 for the renewal of the authorisation of genetically modified soybean A5547-127 (unique identifier: ACS-GMØØ6-4), submitted by BASF Agricultural Solutions Seed US LLC (New Jersey, USA) (hereafter referred to as “the applicant”) according to Regulation (EC) No. 1829/2003, as assimilated into UK law.

FSA checked the application for compliance with the relevant requirements of Regulation (EC) No. 1829/2003, and assimilated Regulation (EU) No. 503/2013, and on 2nd November 2022, declared the application valid.

Following the submission of application EFSA-GMO-NL-2008-52 and the publication of the EFSA (European Food Safety Authority) scientific opinion (EFSA GMO Panel 2011), the placing on the market of genetically modified soybean A5547-127 for products containing, consisting of, or produced from soybean A5547-127, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/81/EU. A copy of Commission Implementing Decision 2012/81/EU was provided by the applicant.

FSA and FSS would like to thank the following members of the ACNFP committee who participated in the assessment: Dr Camilla Alexander White, Dr Andy Greenfield, Dr Anton Alldrick, Alison Austin, Dr Mark Berry, Prof Dimitris

Charalampopoulos, Prof Susan Fairweather-Tait, Prof Paul Fraser, Dr Hamid Ghouddusi, Prof Wendy Harwood, Prof Huw Jones, Dr Ray Kemp, Dr Elizabeth Lund, Emeritus Prof Harry McArdle, Rebecca McKenzie, Prof Clare Mills, Dr Lesley Stanley, Prof Hans Verhagen, Dr Maureen Wakefield, Prof Bruce Whitelaw, and Emeritus Prof Pete Lund (co-opted member of ACNFP-PGT Subcommittee).

1.2 Terms of Reference

According to Articles 6 and 18 of assimilated Regulation (EC) No. 1829/2003, the FSA/FSS were requested to carry out a scientific risk assessment of genetically modified soybean A5547-127 for the renewal of authorisation for placing on the market of products containing, consisting of, or produced from soybean A5547-127 in the context of its scope as defined in application RP188.

FSA/FSS sought safety advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on A5547-127 soybean, which will inform the FSA/FSS safety assessment. The FSA/FSS safety assessment is to be seen as the opinion requested under Articles 6(6) and 18(6) of assimilated Regulation (EC) No. 1829/2003.

In addition to the present advice on the safety of genetically modified soybean A5547-127, the ACNFP were also asked to report on the particulars listed under Articles 6(5) and 18(5) of assimilated Regulation (EC) No. 1829/2003.

2. Applicant details

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue

Florham Park

New Jersey, 07932

USA

(represented by)

Name: BASF Plc

Address: 2 Stockport Exchange

Railway Road

Stockport

Cheshire

England, SK1 3GG

3. Data and assessment

3.1 Data

The data for application RP188 submitted according to legal requirements contained in Regulation (EC) 1829/2003 and provided by the applicant at the time of submission are specified below. To inform the FSA/FSS safety assessment of the application for renewal of the authorisation of genetically modified soybean A5547-127 for food and feed uses in accordance with Articles 11 and 23 of Regulation (EC) No. 1829/2003, the ACNFP was asked to provide safety advice. They considered the requirements described in applicable guidance for the risk assessment of renewal applications of GM food and feed authorised under assimilated Regulation (EC) No. 1829/2003. The comments raised by the ACNFP were taken into consideration during the scientific risk assessment.

Contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing sequencing and bioinformatic analyses.

3.2 Methodologies

The ACNFP conducted its assessment in accordance with the principles described in assimilated Regulation (EU) No. 503/2013, applicable guidance, explanatory notes, and statements (EFSA GMO Panel, 2015; EFSA, 2019). Independent contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing sequencing and bioinformatics analyses.

4. Assessment

4.1 Post-market environmental monitoring reports

The implementation of a PMEM (post-market environmental monitoring) plan was a condition of the authorisation, however since the previous environmental risk assessment of genetically modified soybean A5547-127 identified no potential adverse environmental effects, and the application did not cover cultivation, case-specific post-market environmental monitoring was not required.

The assessment of the PMEM reports provided in the renewal application are within the remit of Advisory Committee on Releases to the Environment (ACRE), and their assessment of the PMEM reports forms part of the final scientific assessment published by FSA/FSS.

4.2 Systematic searches and evaluation of literature

A systematic literature search and review is required for renewal applications to identify new information relevant to the risk assessment of the GM food and feed that has become available since the previous authorisation. This includes information relating to molecular characterisation, food and feed safety, and the environment.

In addition to the separate searches provided as part of the annual PMEM reports, the applicant also performed updated literature searches in accordance with the recommendations on literature searches outlined in EFSA guidance (2010, 2019). Searches in websites of relevant organisations were also performed.

In total, 889 unique publications were identified and assessed to exclude irrelevant publications, resulting in 20 publications that were further assessed in a detailed review. One publication was identified as relevant (and was provided); however, this publication did not have any implication for the risk assessment as no new hazards, modified exposures, or scientific uncertainties were reported.

The ACNFP assessed the applicant’s literature searches on genetically modified soybean A5547-127 and the newly expressed protein (PAT) and found the overall quality of the performed literature searches to be acceptable.

The ACNFP acknowledged that no relevant publications raising a safety concern for human and animal health and the environment, which would change the original risk assessment conclusions on genetically modified soybean A5547-127, were identified by the applicant.

4.3 Updated bioinformatic data

The bioinformatics assessment of renewal applications for GM food and feed is focused on demonstrating that the conclusions of the original risk assessment remain applicable when considering information from up-to-date methods of bioinformatics analysis. This includes analysis of the DNA sequence of the insertion site and flanking sequences to identify:

- disruption of endogenous genes

- open reading frames (ORFs) that potentially encode peptides with amino acid sequence similarities to known toxins or allergenic proteins
- similarity to microbial DNA sequences that may facilitate horizontal gene transfer

The amino acid sequence of the newly expressed protein(s) is also assessed, including for sequence similarity to known toxins and allergenic proteins, and their capacity to trigger coeliac disease.

An updated sequence analysis was performed to compare the DNA sequence of the A5547-127 event (both insert and flanking sequences) to previously determined sequences for the A5547-127 event. The DNA sequences of the insert and flanking DNA regions were identical to those sequences previously reported. The updated bioinformatics analyses for the A5547-127 event also found no DNA sequences that could provide sufficient length and identity to facilitate horizontal gene transfer.

The updated bioinformatics analyses of the newly created ORFs within the insert, or spanning the junctions with the genomic DNA, did not indicate sequence similarities to toxins or allergens, nor did analysis of the amino acid sequence of the newly expressed protein. In addition, the amino acid sequence of the newly expressed protein did not have significant similarities with proteins known to cause coeliac disease.

The ACNFP reviewed the updated bioinformatics data and analyses provided by the applicant as part of the risk assessment process and concluded that the bioinformatics analyses performed using updated methodologies and tools identified no new information that would change the conclusions on the safety of soybean A5547-127, or change the parameters of the previous authorisations.

4.4 Additional documents or studies provided by the applicant

The applicant stated that no prohibitions or restrictions have been placed on genetically modified soybean A5547-127 in any country, and that no inconclusive scientific opinions have been issued by any regulatory agency.

Unpublished studies performed by, or on behalf of the applicant, since genetically modified soybean A5547-127 was authorised were screened, and the relevance of the studies for molecular characterisation, human and animal safety, and the environment, was assessed by the applicant.

During the risk assessment, the ACNFP concluded that the new additional documents or studies provided by the applicant do not raise any concerns for human and animal health and do not change the previous risk assessment conclusions on genetically modified soybean A5547-127.

4.5 Overall assessment as provided by the applicant

The applicant provided an overall assessment concluding that the results of the monitoring reports and of the new information (including independent peer-reviewed literature and updated bioinformatic analyses) provided in the application for renewal of authorisation of genetically modified soybean A5547-127 for food and feed uses does not lead to the identification of new hazards, modified exposures, or uncertainties, and therefore does not change the outcome of the previous risk assessment (EFSA GMO Panel 2011).

The ACNFP evaluated the overall assessment provided by the applicant and confirmed that there is no evidence in the renewal application that would indicate new hazards, relevant changes in exposure, or scientific uncertainties that would change the previous conclusions on genetically modified soybean A5547-127.

4.6 Environmental monitoring plan and proposal for improving the conditions of the original authorisation

The post-market environmental monitoring plan does not need revision as no adverse effects were reported during the authorisation period, nor was any literature identified that changes the conclusions of the previous assessment.

Assessing any proposals to change the PMEM plan is within the remit of ACRE, and their assessment forms part of the final safety assessment published by FSA/FSS.

ACRE’s advice is available at GOV.UK.

5. Overall conclusions and recommendations

The ACNFP concludes that there is no evidence in renewal application RP188 for new hazards, modified exposure, or scientific uncertainties that would change the conclusion of the original risk assessment on genetically modified soybean A5547-127.

6. References

Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

Commission Implementing Regulation (EU) No. 503/2013 of 3rd April 2013 on application for authorisation of genetically modified food and feed in accordance with Regulation (EC) No. 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No. 641/2004 and (EC) No. 1981/2006.

Commission Implementing Decision (2012/81/EU) of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 40/10 14/2/2012.

EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on application (EFSA-GMO-NL-2008-52) for the placing on the market of herbicide tolerant genetically modified soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. The EFSA Journal (2011); 9(5):2147, 1-28. [27 pp.] https://doi.org/10.2903/j.efsa.2011.2147.

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637.

EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Alvarez F and Glanville J, 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publications 2019:EN-1614. 62 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1614.

Abbreviations

Acronym	Definition
ACNFP	Advisory Committee on Novel Foods and Processes
ACRE	Advisory Committee on Releases to the Environment

DNA	Deoxyribonucleic acid
EC	European Commission
EU	European Union
FSA	Food Standards Agency
FSS	Food Standard Scotland
GM	Genetically modified
GMO	Genetically modified organism
ORFs	Open reading frames
PMEM	Post-market environmental monitoring