Assessment of application EFSA-GMO-NL-2016-132 for authorisation of genetically modified, insect-resistant and herbicide-tolerant soybean DAS–81419–2 x DAS–44406–6 for food and feed uses, import and processing submitted in accordance with Regulation (EC)

Area of research interest: Novel and non-traditional foods, additives and processes
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Authors: Risk Assessment Unit
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1. Executive Summary

The FSA and FSS have undertaken an assessment of application RP1133 for the authorisation of genetically modified insect-resistant and herbicide-tolerant soybean DAS–81419–2 x DAS–44406–6 for food and feed uses, import and processing.

A GM application has been received by Great Britain (GB) where the European Food Safety Authority (EFSA), prior to the end of the transition period, evaluated an application for the product. FSA and FSS have reviewed the EFSA opinion and confirmed that it is sufficient for GB risk analysis and therefore was used to form the basis of the UK opinion.

The FSA and FSS risk assessors conclude that the EFSA opinion is sufficient and relevant for GB risk analysis and therefore genetically modified soybean DAS–81419–2 x DAS–44406–6, as described in this application, is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses in GB.

2. Background and purpose of review

EFSA Journal 2020;18(11):6302 Question number: EFSA-Q-2016-00195

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1133 for the authorisation of genetically modified soybean DAS–81419–2 x DAS–44406–6, has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA and FSS have adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application is now made to GB, FSA and FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its opinion. Therefore, FSA and FSS risk assessors have reviewed the EFSA opinion (footnote 1) for the application below in the context of intended GB use and have concluded that the intended uses are safe.

In reviewing the EFSA risk assessment opinion, the reviewers have verified that the standard approach as outlined in the relevant guidance has been followed and the arguments made are consistent with the data summarised in the opinion. Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are any aspects that would require further review such as specific issues for the countries of the UK. The result of the assessment is that the EFSA scientific opinion is sufficient also for GB risk analysis.

3. Details of the EFSA assessment

3.1 Applicant

Name: Dow AgroSciences LLC
Address: European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom
(on behalf of)

Name: Dow AgroSciences
Address: LLC9330 Zionsville Road, Indianapolis, IN 46268-1054, USA
And

Name: M.S. Technologies LLC

Address: M.S. Technologies LLC, 103 Avenue D, West Point, IA 52656, USA

3.2 Methodology applied in the EFSA opinion

EFSA Genetically Modified Organisms (GMO) Panel guidance: Guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003 (2013) and principles in Regulation (EC) No 1829/2003.

3.3 Source/organism

Soybean (*Glycine max L*.) containing two-event stack.

3.4 Genetic modification step

- DAS-81419-2 (expressing the proteins Cry1F, Cry1Ac and PAT) to confer protection against specific lepidopteran pests and tolerance to glufosinate ammonium-based herbicides

- DAS–44406–6 (expressing the proteins 2mEPSPS, AAD–12 and PAT), to confer tolerance to glyphosate-containing herbicides and 2,4- dichlorophenoxyacetic acid (2-4-D) and other related phenoxy herbicides.

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for DAS-81419-2 x DAS-44406-6 soybean is DAS-81419-2 x DAS-444Ø6-6. DAS-81419-2 x DAS-44406-6 soybean provides two distinct sources for insect resistance combined with three distinct modes of herbicide tolerance, 2,4-D, glufosinate, and glyphosate, supporting broad spectrum weed and grass control within a single field.

The two-event stack soybean was produced by conventional crossing combining two single soybean events DAS–81419–2 and DAS–44406–6 previously assessed (EFSA Journal 2016;14(12):4642), (EFSA Journal 2017;15(3):4738) and considered safe. No new genetic modifications were performed.

Molecular data show that the events stacked in soybean DAS–81419–2 x DAS–44406–6 have retained their integrity. Expression levels of newly expressed proteins in the two-event stack are comparable to the single soybean events, with higher levels of PAT as expected due to both events producing PAT.
Based on the known biological function of the newly expressed proteins, there is no indication of interactions that may affect the integrity of the events and the levels of the newly expressed proteins in this two-event stack soybean.

3.6 Exposure assessment

EFSA undertook an exposure assessment as part of their opinion. In order to verify if it was still relevant for GB, data from NDNS databases were reviewed by FSA and FSS, showing UK soy consumption has increased in the last few years but remains lower than several European countries. These data confirm the suitability of the risk assessment for GB use.

3.7 Toxicological data

The increase of lectin content in soybean DAS-81419-2 x DAS-44406-6 (footnote 2) as compared with its conventional counterpart does not raise concerns for allergenicity. In the context of human nutrition, the relatively small decrease in glutamic acid does not represent nutritional concerns.
The newly expressed proteins Cry1Ac, Cry1F, PAT, AAD-12 and 2mEPSPS do not raise safety concerns for human and animal health.

3.8 Analytical method review

FSA and FSS accepted the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF)report, showing that the detection methods for the single events DAS-81419-2 and DAS-44406-6 were previously validated individually, and declared fit for purpose.

3.9 Post Market Environmental monitoring plan (PMEM)

FSA and FSS reviewed and accepted the GMO Panel conclusions about the PMEM plan proposed by the applicant for soybean DAS–81419–2 x DAS–44406–6, considering the scope consistent with the intended uses of soybean DAS–81419–2 x DAS–44406–6. FSA and FSS accepted the proposed PMEM plan and did not require additional monitoring.

3.10 Proposed labelling

The applicant proposed no additional labelling of DAS-81419-2 x DAS-44406-6 soybean on the basis that it is equivalent to the conventional counterparts, and its intended uses is the same as for conventional soybean. The FSA and FSS accept the applicant's conclusion and do not require specific or additional labelling.

4. EFSA assessment and conclusions

Soybean DAS–81419–2 x DAS–44406–6 is as safe as the conventional counterpart and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.

Soybean DAS–81419–2 x DAS–44406–6 is not for cultivation in the UK/ EU. Accidental release of viable GM soybean would not cause an environmental safety concern and as with conventional soybean varieties, would be unlikely to persist under European environmental conditions. No post market monitoring of food and feed is necessary. The proposed PMEM plan was acceptable and did not require extra monitoring.

5. Caveats and uncertainties

No caveats and uncertainties were identified.

6. FSA-FSS conclusion on applicability and reliability

The application has been assessed in line with the applicable guidance (footnote 3) and is partially based on considerations of detailed proprietary information available to the Panel, whilst this is only briefly summarised this description is consistent with the conclusions. The conclusions of the opinion have been reviewed by FSA and FSS and are considered appropriate and consistent within the identified caveats and uncertainties identified in the opinion and would be applicable to GB. As such the opinion forms the basis of this opinion.

7. Outcome of assessment

FSA and FSS have reviewed the EFSA opinion and consider it sufficient and relevant for GB risk analysis. Therefore, the opinion was used to form the basis of the UK opinion.

FSA and FSS had access to all supporting documentation that was provided to the EFSA Panel by the applicant, and subsequently used to form the EFSA opinion. FSA and FSS agree with the safety conclusions outlined in the EFSA opinion.

The environmental and human safety of the Cry1F, Cry1Ac, AAD-12, PAT and 2mEPSPS proteins have been well characterised by the applicant under the Annex II to the Cartagena Protocol. It is therefore accepted by FSA and FSS the conclusion that DAS-81419-2 × DAS-44406-6 poses no increased risk to conservation and sustainable use of biodiversity, or to human or animal health in terms of allergenicity or toxicity compared to conventional soybean.

Following the principles outlined in the background for making use of the EFSA opinion, the FSA and FSS conclude that genetically modified soybean DAS–81419–2 x DAS–44406–6, as described in this application, is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses.

8. References

Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

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