Assessment of an application by Dow AgroSciences (EFSA-GMO-NL-2013-116) for placing on the market of genetically modified insect-resistant soybean DAS-81419-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003

Maes o ddiddordeb ymchwil: Novel and non-traditional foods, additives and processes
Statws y prosiect: Wedi'i gwblhau
Cod prosiect: RP1134
Awduron: Risk Assessment Unit FSA and Risk Assessment Team
Cynhaliwyd gan: Food Standards Agency and Food Standards Scotland
Dyddiad cyhoeddi: 11 Hydref 2022

1. Executive Summary

The FSA and FSS have undertaken an assessment of application RP1134 for the authorisation of genetically modified resistant soybean DAS-81419-2 for food and feed uses, import and processing.

A GM application has been received by Great Britain (GB) where 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 (footnote 1) and confirmed that it is sufficient for GB risk analysis and therefore was used this 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, as described in this application, is as safe and nutritious as its conventional counterpart and non-GM reference varieties tested with respect to potential effects on human and animal health and the environment in the context of its intended uses in GB.

2. Background and purpose of review

EFSA Journal 2016;14(12):4642

Question number: EFSA-Q-2013-00527

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1134 for the authorisation of genetically modified soybean DAS–81419–2, 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 opinion1 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. The EFSA GMO panel were not asked to review the labelling of this GMO or the requirements under the Cartagena protocol and therefore no consideration was given to these points in the assessment.

3.3 Source/organism

Soybean (*Glycine max L.*) containing a single insert expressing three new proteins.

3.4 Genetic modification step

- Cry1F and Cry1Ac proteins from Bacillus thuringiensis, to confer resistance to certain lepidopteran chewing pests.
- PAT protein from Streptomyces viridochromogenes, that confers tolerance to glufosinate ammonium-based herbicides and that was used as a selectable marker gene

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this event is DAS-81419-2. Soybean DAS-81419-2 was developed by Agrobacterium tumefaciens-mediated

transformation of cotyledonary nodes from germinated soybean (G. max) cv. Maverick seeds. It contains Cry1Fv3, Cry1Ac (synpro) and pat expression cassettes producing the Cry1F, Cry1Ac and PAT proteins, respectively. The genetic and phenotypic stability of the modifications was confirmed over several generations.

The newly expressed proteins did not give rise to safety issues. The nutritional value of food and feed derived from soybean DAS-81419-2 is not expected to differ from that of food and feed derived from non-GM soybean varieties.

Differences identified in forage, seed composition and the agronomic and phenotypic characteristics between soybean DAS-81419-2 and its conventional counterpart do not require further assessment regarding food and feed safety.

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, 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 safety assessment identified no concerns for human and animal health regarding the potential toxicity and allergenicity of the proteins Cry1F, Cry1Ac and PAT.
There is no evidence that the genetic modification might significantly change the overall allergenicity of soybean DAS-81419-2 when compared with that of its conventional counterpart and non-GM commercial reference soybean varieties.

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 DAS-81419-2 were previously validated, and declared fit for purpose. The previous assessment of the methodology remains appropriate and valid.

3.9 Post market environmental monitoring plans (PNEM)

FSA and FSS reviewed and accepted the GMO Panel conclusions about the PMEM plan proposed by the applicant for soybean DAS–81419–2 considering the scope consistent with the intended uses of soybean DAS–81419–2. PMEM plan provided by the applicant is in line the EFSA guidelines on the PMEM of GM plants. FSA and FSS accepted the proposed PMEM plan and did not require additional monitoring. No specific post market monitoring for food and feed was considered by the GMO panel in their opinion to be required.

4. EFSA assessment and conclusions

DAS-81419-2 is as safe and nutritious as its conventional counterpart and non-GM reference varieties tested with respect to potential effects on human and animal health and the environment in the context of the scope of the application. Soybean DAS-81419-2 would not raise safety concerns in the event of accidental release of viable GM soybean seeds into the environment.

No concern was identified in relation to the theoretically possible horizontal gene transfer (HGT) of the introduced genes to bacteria, as such recombinant genes would not introduce new properties to the environment due to the prevalence of cry and pat genes in environmental bacteria.

The likelihood of environmental effects from cross-pollination will not differ from that of conventional soybean varieties. The PMEM plan provided by the applicant is in line with the intended uses of soybean DAS-81419-2 and the EFSA guidelines on the PMEM of GM plants.

5. Caveats and uncertainties

No caveats and uncertainties were identified

6. FSA-FSS conclusion on applicability and reliability of the EFSA opinion for GB risk analysis

The application has been assessed in line with the applicable guidance (footnote 2) 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 EFSA 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.

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, as described in this application, is as safe and nutritious as its conventional counterpart and non-GM reference varieties tested with respect to potential effects on human and animal health and the environment in the context of the scope of the application.

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
- EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9(8):2316. [40 pp.] doi:10.2903/j.efsa.2011.2316
- European Food Safety Authority, 2013. EFSA guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003. EFSA Journal 2013; 11(12):3491, 133 pp., doi:10.2903/j.efsa.2013.3491
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H, Birch, AN, Casacuberta, J, De Schrijver, A, Gralak, MA, Guerche, P, Jones, H, Manachini, B, Messéan, A, Nielsen, EE, Nogué, F, Robaglia, C, Rostoks, N, Sweet, J, Tebbe, C, Visioli, F, Wal, J-M, Divéki, Z, Fernández-Dumont, A, Gennaro, A, Lanzoni, A, Neri, FM and Paraskevopoulos, K, 2016. Scientific Opinion on an application by Dow AgroSciences (EFSA-GMO-NL-2013-116) for placing on the market of genetically modified insect-resistant soybean DAS-81419-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016; 14(12):4642, 23 pp. doi:10.2903/j.efsa.2016.4642

1. EFSA Journal 2016;14(12):4642.

2. European Food Safety Authority, 2013. EFSA guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003. EFSA Journal 2013; 11(12):3491, 133 pp., doi:10.2903/j.efsa.2013.3491