Assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003

Area of research interest: Novel and non-traditional foods, additives and processes
Project status: Completed
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Conducted by: Food Standards Agency and Food Standards Scotland
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1. Executive Summary

The FSA and FSS have undertaken an assessment of application RP1138 for the authorisation of genetically modified soybean SYHT0H2 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 (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 SYHT0H2, as described in this application, is as safe as its conventional counterpart and the tested non-GM soybean reference varieties 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 2020;18(1):5946

Question number: EFSA-Q-2012-00753
In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1138 for the authorisation of genetically modified soybean SYHT0H2 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 own independent 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 EFSA assessment

3.1 Applicant

Name: Syngenta Crop Protection AG, Basel Switzerland and all affiliated companies

Address: Schwarzwaldallee 215, CH 4058, Basel, Switzerland

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 a single insert consisting of two genes.

3.4 Genetic modification step

- avhppd-03 gene from Oat (Avena sativa) to confer tolerance to the herbicidal active substances mesotrione and other p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides.
- pat gene from Streptomyces viridochromogenes to confer tolerance to glufosinate ammonium-based herbicides.

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this event is SYN-???H2-5. Soybean SYHT0H2, obtained by Agrobacterium tumefaciens-mediated plant transformation, contains avhppd-03 gene and pat gene. None of the agronomic/phenotypic and compositional differences identified between soybean SYHT0H2 and the conventional counterpart needed further assessment except for seed levels of ?-tocopherol and ?-tocopherol. These differences were further assessed for their safety and nutritional relevance and found not to raise concerns.

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 AvHPPD-03 and PAT proteins were not identified as toxicological and allergenicity concerns. Soybean SYHT0H2 is as safe as and nutritionally equivalent to the conventional counterpart and the tested non-GM soybean reference varieties, and no post-market monitoring of food/feed is considered necessary.

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 AvHPPD-03 and PAT proteins were previously validated, and declared fit for purpose. The previous assessment of the methodology remains appropriate and valid.

3.9 Post market environmental monitoring plan

FSA and FSS reviewed and accepted GMO Panel conclusions on the PMEM plan proposed by the applicant for soybean SYHT0H2, considering the scope consistent with the intended uses of soybean SYHT0H2. The 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 SYHT0H2 soybean for the renewal of the authorisation. The FSA and FSS accept the applicant's conclusion and do not require specific or additional labelling.

4. EFSA assessment and conclusions

Soybean SYHT0H2, as described in this application, is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment. There is a very low likelihood of environmental effects resulting from the accidental release of viable seeds from soybean SYHT0H2 into the environment. The analysis of HGT from soybean SYHT0H2 to bacteria does not indicate a safety concern. The scope of the PMEM plan provided is consistent with the intended uses of soybean SYHT0H2.

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 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 the UK. 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 soybean SYHT0H2 have been well characterised by the applicant under the Annex II to the Cartagena Protocol.

Following the principles outlined in the background for making use of the EFSA opinion, the FSA and FSS conclude that genetically modified soybean SYHT0H2, as described in this application, is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and 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.
- 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, Bresson, J-L, Dalmay, T, Dewhurst, IC, Epstein, MM, Firbank, LG, Guerche, P, Hejatko, J, Moreno, FJ, Mullins, E, Nogué, F, Rostoks, N, Sánchez Serrano, JJ, Savoini, G, Veromann, E, Veronesi, F, Álvarez, F, Ardizzone, M, Dumont, AF, Devos, Y, Gennaro, A, Gómez Ruiz, JÁ, Lanzoni, A, Neri, FM and Paraskevopoulos, K, 2020. Scientific Opinion on the assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111). EFSA Journal 2020;18(1):5946, 29 pp. https://doi.org/10.2903/j.efsa.2020.5946

1. EFSA Journal 2020;18(1):5946.

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