Assessment of genetically modified cotton GHB614 x T304-40 x GHB119 for food and feed uses, import and processing

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Reference Number RP1205.

1.Executive summary

The FSA and FSS have undertaken an assessment of application RP1205 for the authorisation of genetically modified cotton GHB614 x T304-40 x GHB119 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 EFSA (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 cotton GHB614 x T304-40 x GHB119, as described in this application, is as safe as its comparator and the tested non-GM cotton reference varieties with respect to potential effects on human and animal health and the environment.

2. Background and purpose of review

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Question number: EFSA-Q-2014-00721

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1205 for the authorisation of genetically modified cotton GHB614 x T304-40 x GHB119 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 support 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 opinion 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. Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are and 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 adequate also for UK considerations. 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

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(on behalf of)
Name: Bayer CropScience LP

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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

Cotton (Gossypium hirsutum L.) containing three-event stack.

3.4 Genetic modification step

- GHB614 containing 2mepsps from Zea mays, expressing a double-mutated EPSPS to confer tolerance to glyphosate herbicide
- T304-40 containing cry1Ab from Bacillus thuringiensis, expressing Cry1Ab protein for selective resistance to lepidopteran pests and bar from Streptomyces hygroscopius to confer resistance to glufosinate herbicides
- GHB119 containing bar from Streptomyces hygroscopius to confer resistance to glufosinate herbicides and cry2Ae from Bacillus thuringiensis, expressing Cry2Ae protein for selective resistance to lepidopteran pests

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this event is BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS-GHØØ5-8.
Cotton events GHB614, T304-40 and GHB119 were combined by conventional crossing to produce the three-event stack cotton GHB614 x T304-40 x GHB119.

The molecular data establish that the events have retained their integrity. Protein expression analyses showed that the levels of the newly expressed proteins are similar in the three-event stack cotton and in the single events, the only foreseen interactions at the biological level are between the two Cry proteins.

The nutritional impact of cotton GHB614 x T304-40 x GHB119-derived food and feed is expected to be the same as those derived from the comparator and non-GM reference varieties. The three-event stack cotton, as described in this application, is nutritionally equivalent to and as safe as the comparator and the non-GM reference varieties tested.

None of the agronomic and phenotypic differences between GM cotton GHB614 x T304-40 x GHB119 and the comparator needed further assessment for its potential environmental impact, except the percentage of lint.

The change in lint was further assessed and found not to affect the ability of the cotton to survive until subsequent seasons or to establish feral plants under European environmental conditions.

The difference and the equivalence test on the three-event stack cotton with respect to its comparator and the non-GM reference varieties did not identify any need for further food/feed safety assessment except for total fat, dihydrosterculic acid and a-linolenic acid.

Upon further assessment, these changes were concluded to be of no concern for human and animal dietary consumption.

3.6 Exposure assessment

Not relevant

3.7 Toxicological data

The proteins 2mEPSPS, PAT, Cry1Ab and Cry2Ae newly expressed in cotton GHB614 x T304-40 x GHB119 do not raise safety concerns for human and animal health. No interactions between these newly expressed proteins relevant for food and feed safety were identified.

Similarly, there were no identified indications of safety concerns regarding allergenicity or adjuvanticity related to the presence of the newly expressed proteins, or regarding the overall allergenicity of the three-event stack cotton.

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 GHB119, GHB614 and T304-40 (footnote 2) were previously validated individually, and declared fit for purpose in detecting the stacked events.

3.9 Post Market Environmental Monitoring Plan (PMEM)

FSA and FSS reviewed and accepted the GMO Panel conclusions on the PMEM plan proposed by the applicant, considering the scope consistent with the intended uses of genetically modified cotton GHB614 x T304-40 x GHB119.

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 GHB614 x T304-40 x GHB119 cotton 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

Cotton GHB614 x T304-40 x GHB119, as described in this application is as safe as its comparator and the tested non-GM cotton reference varieties with respect to potential effects on human and animal health and the environment.

It is unlikely that cotton GHB614 x T304-40 x GHB119 would differ from conventional cotton varieties in its ability to persist under UK environmental conditions.

Interactions of occasional feral cotton GHB614 x T304-40 x GHB119 plants with the biotic and abiotic environment are not considered to be relevant issues. The analysis of HGT from the three-event stack cotton to bacteria does not indicate a safety concern.

Therefore, cotton GHB614 x T304-40 x GHB119 would not raise safety concerns in the event of accidental release of viable GM cotton seeds into the environment.

The scope of the PMEM plan provided by the applicant and the reporting intervals are in line with the intended uses of cotton GHB614 x T304-40 x GHB119.

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 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 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 genetically modified cotton GHB614 x T304-40 x GHB119 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 cotton GHB614 x T304-40 x GHB119 is as safe as its

comparator and the tested non-GM cotton reference varieties with respect to potential effects on human and animal health and the environment.

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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1. EFSA Journal 2018;16(7):5349

2. https://gmo-crl.jrc.ec.europa.eu/summaries/JRC101374_2016-06-21_eurlvl0910_VR.pdf

3. 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