Assessment of genetically modified maize 1507 x MIR162 x MON810 x NK603 for food and feed uses

Assessment of genetically modified maize 1507 x MIR162 x MON810 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003. Reference Number RP1184.

1. Executive summary

The FSA and FSS have undertaken an assessment of application RP1184 for the authorisation of genetically modified maize 1507 x MIR162 x MON810 x NK603 and subcombinations, for food and feed uses, import and processing under Regulation (EC) No 1829/2003.

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 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 maize 1507 x MIR162 x MON810 x NK603 and subcombinations, as described in this application, are as safe as the non-GM comparator and the selected non-GM reference varieties with respect to potential effects on human and animal health and the environment.

2. Background and purpose of review

EFSA Journal 2021;19(1):6348 Question number: EFSA-Q-2015-00841

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1184 for the authorisation of genetically modified maize 1507 x MIR162 x MON810 x NK603 and subcombinations, for food and feed uses, 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 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.

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

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Belgium
(on behalf of)
Name: Pioneer Hi-Bred International, Inc.
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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

Maize (Zea mays) containing four-event stack.

3.4 Genetic modification step

- 1507 containing cry1Fa2 from Bacillus thuringiensis, expressing modified Cry1F protein for selective resistance to lepidopteran pests and pat from Streptomyces viridochromogenes, expressing PAT for glufosinate herbicide resistance
- MIR162 containing vip3Aa20 from Bacillus thuringiensis, expressing Vip3Aa to confer selective resistance to lepidopteran pests and pmi from Escherichia coli, expressing PMI to metabolise mannose as a selection marker
- Mon810 containing cry1Ab from Bacillus thuringiensis, expressing modified Cry1Ab protein to confer selective resistance to lepidopteran pests
- NK603 containing cp4 esps (aroA:CP4) from Agrobacterium tumefaciens, expressing CP4 ESPS to confer tolerance to glyphosate herbicide.

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this event is DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYN-IR162-4 x MON-ØØ6Ø3-6.

The four-event stack was produced by conventional crossbreeding to combine four single events 1507, MIR162, MON810 and NK603 previously assessed and considered safe (EFSA Journal 2009, 1149, 1–85), (EFSA Journal 2004, 124, 1–18), (EFSA Journal 2009, 1137, 1–50), (EFSA Journal 2012; 10(6): [27 pp.]).

The four-event stack as well as four of ten subcombinations were assessed in this application (EFSA Journal 2021;19(1):6348) and considered safe. No novel genetic modifications were performed.

PCR and sequence analysis confirmed the integrity of all events in the four-event stack and expression levels of all newly expressed proteins in the four-event stack were similar to expression levels in the corresponding single events in all tissues.

There is no indication of interactions that may affect the integrity of the events or levels of newly expressed protein in this four-event stack maize.

3.6 Exposure assessment

Not relevant

3.7 Toxicological data

All four single events 1507 x MON810 x MIR162 x NK603 were previously assessed and considered safe, as well as six subcombinations (EFSA Journal 2017;15(11):5000), (EFSA Journal 2018;16(7):5309), (EFSA Journal 2019;17(7):5734). No novel genetic modifications were performed.

Four of the 10 subcombinations included in this application have not been previously assessed therefore no experimental data were provided. In this case, the risk was assessed using data generated for the four-event stack as well as all the additional data available on subcombinations previously assessed.

The possibility of interactions among the events in the four subcombinations was assessed concluding that these subcombinations are expected to be as safe as and nutritionally equivalent to the single maize events, the previously assessed subcombinations and the four-event stack maize.

The four-event stack maize 1507 x MON810 x MIR162 x NK603 is nutritionally equivalent to the non-GM comparator and non-GM reference varieties, with no differences in composition of the four-event stack maize identified that would require further safety assessment.

The newly expressed Cry1F, PAT, Cry1Ab, Vip3Aa20, PMI and CP4 EPSPS proteins do not raise safety concerns for human and animal health and no interactions between the newly expressed proteins are expected that would raise food and feed safety concerns in terms of toxicity, allergenicity and adjuvanticity.

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 four-event stack maize 1507 x MON810 x MIR162 x NK603 were 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 for considering the scope consistent with the intended uses of maize 1507 x MON810 x MIR162 x NK603. 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.

3.10 Proposed labelling

The applicant proposed no additional labelling of maize 1507 x MON810 x MIR162 x NK603. The FSA and FSS accept the applicant's conclusion and does not require specific or additional labelling.

4. EFSA assessment and conclusions

The EFSA GMO panel have previously assessed all four single maize events, the two-event stacks MON810 x 1507, MON810 x NK603, 1507 x NK603, 1507 x MIR162 and NK603 x MIR162, and the three-event stack MON810 x 1507 x NK603. No safety concerns were identified. The previous assessments of the single events and six of the subcombinations provided a basis for the assessment of the four-event stack maize and the remaining four subcombinations.

Four of the 10 subcombinations included in the scope of this application have not been previously assessed, and no experimental data were provided for these maize stacks. Since no new safety concerns were identified for the 6 previously assessed subcombinations, previous conclusions on these maize subcombinations remain valid. For the remaining 4 subcombinations the possibility of interactions between the events was assessed, concluding that these combinations would not raise safety concerns.

These subcombinations are therefore expected to be as safe as the single maize events, the previously assessed subcombinations and the four-event stack maize.

The genetically modified maize 1507 x MIR162 x MON810 x NK603 is not for cultivation in the UK/ EU. Accidental release of viable GM maize would not cause an environmental concern and as with conventional maize varieties, would be unlikely to persist under European environmental conditions. 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 of the EFSA opinion for GB risk analysis

The application has been assessed in line with the applicable guidance 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 maize 1507 x MIR162 x MON810 x NK603 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 maize 1507 x MIR162 x MON810 x NK603, as described in this application, are as safe as the non-GM comparator and the selected non-GM 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

Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds, The EFSA Journal (2004) 124, 1–18.

Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-NL-2005-22 and EFSA-GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses and import and processing, and for renewal of the authorisation of maize NK603 as existing product. The EFSA Journal (2009) 1137, 1–50.

Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-RX-MON810) for the renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal (2009) 1149, 1–85.

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