Assessment of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 for food and feed uses

Assessment of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003.

Reference Number RP1180

1. Executive summary

The FSA and FSS have undertaken an assessment of application RP1180 for the authorisation of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and subcombinations, for food and feed uses.

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 maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 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

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP 1180 for authorisation of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and subcombinations 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. 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: Monsanto Europe S.A./N.V.

Address: Avenue de Tervueren 270-272
Tervurenlaan 270-272
B-1150 Brussels
Belgium

(on behalf of)
Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
US

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 L.) produced by combining six single maize events.

3.4 Genetic modification step

- MON 87427 containing cp4 epsps (aroA:CP4) from Agrobacterium tumefaciens, expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein to confer tolerance to glyphosate-containing herbicides.
- MON 87460 containing cspB from Bacillus subtilis, expressing the cold shock protein B (CspB) to confer drought tolerance and the neomycin phosphotransferase II protein (NPTII) used as a selectable marker.
- MON 89034 containing cry1A.105 and cry2Ab2 from Bacillus thuringiensis, expressing the Cry1A.105 and Cry2Ab2 proteins for protection against certain lepidopteran pests.
- 1507 containing cry1Fa2 from Bacillus thuringiensis and pat from Streptomyces viridochromogenes, expressing the Cry1F protein for protection against certain lepidopteran pests and the PAT protein for tolerance to glufosinate-ammonium containing herbicides.
- MON 87411 containing cry3Bb1 from Bacillus thuringiensis, dvsnf7 from Western Corn Rootworm (Diabrotica virgifera virgifera), cp4 epsps (aroA:CP4) from Agrobacterium tumefaciens, expressing the Cry3Bb1 protein and the DvSnf7 dsRNA for protection against

certain coleopteran pests and the CP4 EPSPS protein for tolerance to glyphosate containing herbicides.
- 59122 containing cry34Ab1 and cry35Ab1 from Bacillus thuringiensis and pat from Streptomyces viridochromogenes, expressing the Cry34Ab1 and Cry35Ab1 proteins for protection against certain coleopteran pests and the PAT protein for tolerance to glufosinate-ammonium containing herbicides.

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this six-stack event is MON-87427-7 x MON-8746Ø-4 x MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-87411-9 x DAS-59122-7.

The six-event stack maize was produced by conventional crossing to combine six single events (MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122) previously assessed and considered safe (EFSA Journal 2004, 124, 1-18), (EFSA Journal 2007, 470, 1-25), (EFSA Journal 2008, 909, 1-30), (EFSA Journal 2009, 1074, 1-28), (EFSA Journal 2012; 10(11):2936), (EFSA Journal 2015;13(6):4130), (EFSA Journal 2018;16(6):5310).

The six-event stack as well as 39 of 56 subcombinations were assessed in this application (EFSA Journal 2021;19(1):6351) and considered safe.

The molecular data establish that the events stacked in maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 have retained their integrity. Protein expression analyses showed that the levels of the newly expressed proteins are similar in the six-event stack maize and in the single events. Based on the known biological function of the newly expressed proteins, the only foreseen interactions at the biological level are between the Cry proteins in susceptible insects. Information provided on the identity, composition and specifications of the GMO does not raise safety concerns.

3.6 Exposure assessment

Not relevant

3.7 Toxicological data

The newly expressed proteins do not raise safety concerns for human and animal health. No interactions between the newly expressed proteins relevant for food and feed safety were identified, and no overall toxicological concerns on the six-event stack maize were identified. Similarly, there were no identified indications of safety concerns regarding allergenicity or adjuvanticity related to the presence of the newly expressed proteins in the six-stack maize, or regarding the overall allergenicity of this six-event stack maize.

Based on the outcome of the comparative and nutritional assessment, as well as previous assessment of six single events and 17 subcombinations (EFSA Journal 2010; 8(9):1781), (EFSA Journal 2017;15(8):4921), (EFSA Journal 2017;15(8):4922), (EFSA Journal 2019;17(8):5774), (EFSA Journal 2019;17(11):5848), along with the remaining 39 subcombinations evaluated in this application (EFSA Journal 2021;19(1):6351), the consumption of maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and its subcombinations does not represent any nutritional concern.

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 MON 87427 x MON

87460 x MON 89034 x 1507 x MON 87411 x 59122 (footnote 2) were validated, and declared fit for purpose.

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 MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122. 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 MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122. The FSA and FSS accept the applicant's conclusion and do not require specific or additional labelling.

4. EFSA assessment and conclusions

Maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and its 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.

Thirty-nine of the 56 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 17 previously assessed subcombinations, previous conclusions on these maize subcombinations remain valid. For the remaining 39 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 six-event stack maize.

It is unlikely that the six-event stack maize would differ from conventional maize varieties in its ability to persist under UK environmental conditions. Occasional feral six–event stack maize plants within the biotic and abiotic environment are not considered to be relevant issues and analysis of the possibility for horizontal gene transfer from the GM maize to bacteria raises no concerns. Therefore, the six-event stack maize would not raise safety concerns in the event of accidental release of viable GM maize grains into the environment.

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 guidance3 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 EFSA opinion forms the basis of this opinion.

7. Outcome of assessment

FSA (footnote 3) 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 MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and subcombinations 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 MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and subcombinations 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.

EFSA Panel on Genetically Modified Organisms, 2007. Opinion of the Scientific Panel on genetically modified organisms [GMO]on an application (Reference EFSA-GMO-NL-2005-12) for the placing on the market of insect-resistant genetically modified maize 59122, for food and feed uses, import and processing under Regulation (EC)

No 1829/2003, from Pioneer Hi-Bred International, Inc. and Mycogen Seeds, c/o Dow Agrosciences LLC, EFSA Journal 2007; 5(4):470, 25 pp. doi:10.2903/j.efsa.2007.470

Scientific Opinion of the Panel on Genetically Modified Organisms on application (Reference EFSA-GMO-NL-2007-37) for the placing on the market of the insect-resistant genetically modified maize MON 89034, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal (2008) 909, 1–30

EFSA Panel on Genetically Modified Organisms, 2009. Application (Reference EFSA-GMO-NL-2005-15) for the placing on the market of the insect-resistant and herbicide-tolerant genetically modified maize 1507 × 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Mycogen Seeds, c/o Dow AgroSciences LLC and Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation. EFSA Journal 2009; 7(5):1074, 28 pp. doi:10.2903/j.efsa.2009.1074

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