FSA/FSS opinions of applications for nine genetically modified organisms for food and feed uses

Date of publication: 30 November 2021

Document subject and purpose

In this document we publish the finalised Food Standards Agency (FSA)/Food Standards Scotland (FSS) opinions, following the quality assurance of risk assessments conducted by the European Food Safety Authority (EFSA), of nine genetically modified organisms (GMO) for food and feed uses as outlined in the annexes.

The opinions will be considered by Ministers to inform decision making on whether to authorise the individual GMOs for use in England, Scotland and Wales.

This opinion is being published in parallel with FSS.

Comments and feedback

If you wish to comment on the FSA/FSS opinions, feedback should be sent to:

Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Chemical Safety Policy Unit

Please state, in your comment, whether you are commenting as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which country you are based.

Please indicate which application(s)/opinion(s) you are commenting on by using the following subject line for your response:

Comment on [insert RP number(s)] FSA/FSS opinion

Comments will be shared with FSS.

Comments will be published and made available to the public and Ministers.

Document details

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, the GMOs included in this document have been submitted for authorisation.

Nine GMOs have been submitted for authorisation in each nation of Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales. This is a function that was previously carried out at an EU level. Since the end of the transition period, assessing food and animal feed safety in the UK is the responsibility of FSA/FSS and the authorisation of regulated products is the responsibility of the relevant appropriate authority of each of the nations of GB.

In respect to Northern Ireland, EU Food Law on GMOs continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means GMOs require authorisation under the EU's authorisation procedures, before being placed on the market in Northern Ireland.

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in support of authorisations for regulated food and feed products. Since the end of the transition period, FSA/FSS has adopted the same technical guidance, governance, and quality assurance processes to make independent GB risk assessments. 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/FSS has decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion. Therefore, FSA/FSS risk assessors have reviewed the EFSA opinions for the products included in this document in the context of intended GB use and have concluded that the intended uses are safe. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion.

As the maize and soybean crops are not for cultivation in the UK or the EU, accidental release is considered in the EFSA assessment for the EU as a whole. The UK shares a similar climate to the countries that were considered by EFSA and is considerably colder than some of the European countries considered. Therefore, the accidental release considerations, including those looking at closely related wild relatives, would be relevant to the GB context.

The FSA/FSS opinion for each GMO is published within a separate annex, including the regulated product ID number and title of the application (Ctrl+Click to follow link):

Further information

If you require a more accessible format of this document, please send details to the email contact for comments and your request will be considered.

Yours,

Donal Griffin
Regulated Products Risk Assessment
Science, Evidence and Research Directorate

Annex A: RP476 – MIR604 maize (renewal)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed, in the EFSA Journal No.5846 (2019) (assessment of genetically modified maize MIR604 for renewal authorisation). Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

Following the submission of application EFSA-GMO-RX-013 under Regulation (EC) No 1829/2003, the EFSA Panel on Genetically Modified Organisms (GMO) risk assessed data submitted in the context of the renewal of authorisation application for genetically modified maize MIR604. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequence of the event in maize MIR604 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MIR604.

- Molecular characterisation (including comparative assessment): The risk assessment is based on the assumption the event sequence has remained the same.

- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Updated bioinformatics did not identify any relevant similarities to toxins, allergens or gluten related epitopes. No new publications were identified that would raise a safety concern for human or animal health.

- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. No adverse environmental risks were identified in 2009, no case specific environmental monitoring was required as part of authorisation. No safety concern identified for horizontal gene transfer. No publications were identified that would raise a safety concern for environmental risks.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Syngenta Crop Protection AG

   - Address: Rosentalstrasse 67, CH-4058 Basel, Switzerland

b) Designation and specification of the products:

   1. foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-IR6Ø4-5;
   2. feed containing, consisting of or produced from genetically modified maize SYN-IR6Ø4-5;
   3. products containing or consisting of genetically modified maize SYN-IR6Ø4-5 for uses other than those provided for in points (1) and (2), with the exception of cultivation.
      The genetically modified maize SYN-IR6Ø4-5 expresses the mcry3A gene, which confers protection against certain coleopteran pests, and the pmi gene, which was used as a selectable marker.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’.
2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize SYN-IR6Ø4-5, with the exception of products referred to in point (b)(1).

d) Method for detection:

1. Event specific real-time PCR based method for the detection of genetically modified maize SYN-IR6Ø4-5.
2. Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx
3. Reference Material: ERM®-BF423 is accessible via the Joint Research Centre (JRC) of the European Commission at https://ec.europa.eu/jrc/en/reference-materials/catalogue

e) Unique identifier:

SYN-IR6Ø4-5

f) Information required pursuant to Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required.

g) Conditions or restrictions on the placing on the market, use or handling of the products

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex B: RP526 – MZIR098 maize (new application)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.6171 (2020) (assessment of genetically modified maize MZIR098 for food and feed uses).

Conclusions from EFSA Risk Assessment:

The GMO Panel was asked to carry out a scientific assessment of maize MZIR098 for import, processing and food and feed uses in accordance with Regulation (EC) No 1829/2003, considering the scope of the application EFSA-GMO-DE-2017-142.

Maize MZIR098 was developed to confer tolerance to glufosinate-ammonium-containing herbicides and resistance to certain coleopteran pests. The molecular characterisation

data and bioinformatic analyses do not identify issues requiring food/feed safety assessment. None of the identified differences in the agronomic/phenotypic and compositional characteristics tested between maize MZIR098 and its conventional counterpart needs further assessment, except for neutral detergent fibre (NDF) in grains, which does not raise nutritional and safety concerns.

The GMO Panel does not identify safety concerns regarding the toxicity and allergenicity of the eCry3.1Ab, mCry3A and PAT proteins as expressed in maize MZIR098, and finds no evidence that the genetic modification would change the overall allergenicity of maize MZIR098. In the context of this application, the consumption of food and feed from maize MZIR098 does not represent a nutritional concern in humans and animals. The GMO Panel concludes that maize MZIR098 is as safe as the conventional counterpart and non-GM maize reference varieties tested, and no post-market monitoring of food/feed is considered necessary.

In the case of accidental release of viable maize MZIR098 grains into the environment, maize MZIR098 would not raise environmental safety concerns. The post-market environmental monitoring plan (PMEM) and reporting intervals are in line with the intended uses of maize MZIR098.

In conclusion, the GMO Panel considers that maize MZIR098, as described in this application, is as safe as its conventional counterpart and the non-GM maize reference varieties tested with respect to potential effects on human and animal health and the environment.

- Molecular characterisation (including comparative assessment): MZIR098 contains a single insert with 1 copy of the expression cassettes. Stability of the DNA insert and traits was confirmed over several generations.
- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): No concerns relating to allergenicity or toxicity of MIR098 were identified, consumption of MZIR098 does not represent a nutritional concern in humans or animals. No significant differences in safety from the conventional non-GM counterpart were identified.
- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. MZIR098 would not raise safety concerns in the event of accidental

release of viable GM maize grains into the environment. The PMEM plan did not need any additional monitoring to the proposed plan.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

- Name: Syngenta Crop Protection AG
- Address: Rosentalstrasse 67, CH-4058 Basel, Switzerland

b) Designation and specification of the products:

1. foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-ØØØ98-3;
2. feed containing, consisting of or produced from genetically modified maize SYN-ØØØ98-3;
3. products containing or consisting of genetically modified maize SYN-ØØØ98-3 for uses other than those provided for in points (1) and (2), with the exception of cultivation.
4. The genetically modified maize SYN-ØØØ98-3 expresses the ecry3.1Ab gene and the mcry3A gene, which confer protection against certain coleopteran pests and the pat gene, which confers tolerance to glufosinate-ammonium based herbicides.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’.
2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize SYN-ØØØ98-3, with the exception of products referred to in point (b)(1).

d) Method for detection:

1. Event specific real-time quantitative PCR based method for detection of the genetically modified maize SYN- ØØØ98-3;

2. Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx;

3. Reference Material: AOCS 1114-B2 is accessible via the American Oil Chemists Society (AOCS) at https://www.aocs.org/crm.

e) Unique identifier:

SYN-ØØØ98-3

f) Information required pursuant to Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required.

g) Conditions or restrictions on the placing on the market, use or handling of the products

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex C: RP535 – MON 87427 × MON 89034 × MIR162 × NK603 maize and its sub-combinations (new application)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.5734 (2019) (assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and sub-combinations, for food and feed uses).

Conclusions from EFSA Risk Assessment:

The GMO Panel was asked to carry out a scientific assessment of maize MON 87427 × MON 89034 × MIR162 × NK603 and sub-combinations for import, processing and food and feed uses in accordance with Regulation (EC) No 1829/2003, considering the scope of the application EFSA-GMO-NL-2016-131.

Maize MON 87427 × MON 89034 × MIR162 × NK603 (four-event stack maize) was produced by conventional crossing to combine four single events: MON 87427, MON 89034, MIR162 and NK603. The GMO Panel previously assessed the four single maize events and four of the sub-combinations did not identify safety concerns. No new data on the single maize events or the four sub-combinations that could lead to modification of the original conclusions on their safety were identified. The molecular characterisation, comparative analysis (agronomic, phenotypic and compositional characteristics) and the

outcome of the toxicological, allergenicity and nutritional assessment indicate that the combination of the single maize events and of the newly expressed proteins in the four-event stack maize does not give rise to food and feed safety and nutritional concerns.

The GMO Panel concludes that the four-event stack maize, as described in this application, is as safe as and nutritionally equivalent to its non-GM comparator and the non-GM reference varieties tested. In the case of accidental release of viable grains of the four-event stack maize into the environment, this would not raise environmental safety concerns. The GMO Panel assessed the likelihood of interactions among the single events in the six maize sub-combinations not previously assessed and concludes that these are expected to be as safe as and nutritionally equivalent to the single events, the previously assessed sub-combinations and the four-event stack maize.

The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of the four-event stack maize. Post-market monitoring of food/feed is not considered necessary. The GMO Panel concludes that the four-event stack maize and its sub-combinations are as safe as its non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.

- Molecular characterisation (including comparative assessment): None of the differences identified in the agronomic and phenotypic characteristics tested between the four-event stack maize and the non-GM comparator required further assessment for environmental or food/feed safety.
- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Herbicide residues were assessed by EFSA pesticides 2018. The newly expressed proteins in the four-event stack do not raise concerns for human and animal health. Interactions between these proteins and toxins, or allergens are not expected, and the four-event stack is nutritionally equivalent to the non-GM comparator.
- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. It is unlikely that the four-event stack maize differs from conventional maize varieties, feral plants would not persist better than conventional varieties. No safety concerns were identified relating to accidental release of maize grain

into the environment. No post market monitoring of food and feed is necessary. The proposed PMEM plan was acceptable and did not require extra monitoring.

- Risk assessment of sub-combinations: The 10 alternative sub-combinations of stacked transgenes (4 x three-event stacks and 6 x two-event stacks) which could have been produced by conventional crossing through targeted breeding approaches, and which could be bred, produced and marketed independently of the four-event stack maize, were assessed separately. These sub-combinations are expected to be as safe and nutritionally equivalent to the single and four stack maize.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Bayer CropScience LP
   - Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

b) Designation and specification of the products:

   1. foods and food ingredients containing, consisting of or produced from genetically modified maize (Zea mays L.) as referred to in point (e);
   2. feed containing, consisting of or produced from genetically modified maize (Zea mays L.) as referred to in point (e);
   3. products containing or consisting of genetically modified maize (Zea mays L.) as referred to in point (e) for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-87427-7 expresses the CP4 epsps gene, which confers tolerance to glyphosate- based herbicides.

The genetically modified maize MON-89Ø34-3 expresses the cry1A.105 and cry2Ab2 genes, which confer protection against certain lepidopteran pests.

The genetically modified maize SYN-IR162-4 expresses a modified vip3Aa20 gene, which provides protection against certain lepidopteran pests. In addition, the

pmi gene coding for the PMI protein was used as a selection marker in the genetic modification process.

The genetically modified maize MON-ØØ6Ø3-6 expresses the CP4 epsps and the CP4 epsps L214P genes, which confer tolerance to glyphosate-based herbicides.

c) Labelling:

1. for the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize specified in point (e), with the exception of products referred to in point (b)(1).

d) Method for detection:

1. The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-87427-7, MON-89Ø34-3, SYN-IR162-4 and MON-ØØ6Ø3-6 and further verified on maize MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6.

2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003

3. Reference Material: AOCS 0512 (for MON-87427-7), AOCS 0906 (for MON-89Ø34-3) and AOCS 1208 (for SYN- IR162-4) are accessible via the American Oil Chemists Society and ERM®- BF415 (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre (JRC) of the European Commission.

e) Unique identifiers:

- MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4;
- MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6;

- MON-87427-7 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-87427-7 × MON-89Ø34-3;
- MON-87427-7 × MON-ØØ6Ø3-6;
- MON-87427-7 × SYN-IR162-4;
- MON-89Ø34-3 × MON-ØØ6Ø3-6;
- MON-89Ø34-3 × SYN-IR162-4;
- SYN-IR162-4 × MON-ØØ6Ø3-6.

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex D: RP606 – MON 87427 × MON 89034 × MIR162 × MON 87411 maize and its sub-combinations (new application)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion , therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.5848 (2019) (assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and sub-combinations, for food and feed uses).

Conclusions from EFSA Risk Assessment:

The GMO Panel was asked to carry out a scientific assessment of maize MON 87427 × MON 89034 × MIR162 × MON 87411 and sub-combinations for import, processing and food and feed uses in accordance with Regulation (EC) No 1829/2003, considering the scope of the application EFSA-GMO-NL-2017-144.

Maize MON 87427 × MON 89034 × MIR162 × MON 87411 (four-event stack maize) was produced by conventional crossing to combine four single events: MON 87427, MON 89034, MIR162 and MON 87411. The genetically modified organism (GMO) Panel previously assessed the four single maize events and four of the sub-combinations and did not identify safety concerns. No new data on the single maize events or the four sub-combinations that could lead to modification of the original conclusions on their safety

were identified. The molecular characterisation, comparative analysis (agronomic, phenotypic and compositional characteristics) and the outcome of the toxicological, allergenicity and nutritional assessment indicate that the combination of the single maize events and of the newly expressed proteins and dsRNA in the four-event stack maize does not give rise to food and feed safety and nutritional concerns.

The GMO Panel concludes that the four-event stack maize, as described in this application, is as safe as and nutritionally equivalent to its non-GM comparator and the non-GM reference varieties tested. In the case of accidental release of viable grains of the four-event stack maize into the environment, this would not raise environmental safety concerns.

The GMO Panel assessed the likelihood of interactions among the single events in the six maize sub-combinations not previously assessed and concludes that these are expected to be as safe as and nutritionally equivalent to the single events, the previously assessed sub-combinations and the four-event stack maize. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of the four-event stack maize. Post-market monitoring of food/feed is not considered necessary.

The GMO Panel concludes that the four-event stack maize and its sub-combinations are as safe as its non-GM comparator and tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.

- Molecular characterisation (including comparative assessment): The four-event stack was produced by conventional crossing of the single lines, each of the single lines have been independently assessed as have a number of the sub combinations. Off-target bioinformatics did not identify any off-targets for the RNAi (DvSnf7 dsRNA). The only potential interaction of newly expressed proteins is between Cry and Vip proteins in susceptible insects.

- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Updated bioinformatics showed no significant similarities to toxins or allergens. No safety concerns for human or animal heath were identified including allergenicity, toxicity and adjuvanticity. The four-event stack maize is nutritionally equivalent to the non GM comparator varieties tested.

- Environmental risk assessment (including PMEM): Not for cultivation in the UK/ EU. It is unlikely that the four-event stack maize differs from conventional maize varieties, feral plants would not persist better than conventional varieties. No safety concerns were identified relating to accidental release of maize grain into the environment. No additional post market monitoring of food and feed is necessary. The proposed PMEM plan was acceptable and did not require extra monitoring.

- Risk assessment of sub-combinations: The initial four-event stack was considered as well as the possible 10 sub combinations. 4 x three-event stacks and 6 x two-event stacks. No unintended effects were identified in the sub combinations and there is no expectation of interactions in these combinations that would raise safety concerns.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Bayer CropScience LP
   - Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 6t3167, United States of America

b) Designation and specification of the products:

1. foods and food ingredients containing, consisting of or produced from genetically modified maize (Zea mays L.) as referred to in point (e);
2. feed containing, consisting of or produced from genetically modified maize (Zea mays L.) as referred to in point (e);
3. products containing or consisting of genetically modified maize (Zea mays L.) as referred to in point (e) for uses other than those provided for in points (1) and (2), with the exception of cultivation.
4. The genetically modified maize MON-87427-7 expresses the cp4 epsps gene, which confers tolerance to glyphosate- based herbicides.

The genetically modified maize MON-89Ø34-3 expresses the cry1A.105 and cry2Ab2 genes, which confer protection against certain lepidopteran pests.

The genetically modified maize SYN-IR162-4 expresses the vip3Aa20 gene, which provides protection against certain lepidopteran pests. In addition, the pmi gene, coding for the PMI protein, was used as selection marker in the genetic modification process.

The genetically modified maize MON-87411-9 expresses the cp4 epsps gene, which confers tolerance to glyphosate- based herbicides, the cry3Bb1 gene and the DvSnf7 dsRNA, which confer protection against corn rootworm (Diabrotica spp.)

c) Labelling:

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’;

2. The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of the maize specified in point (e), with the exception of products referred to in point (b)(1).

d) Method for detection:

1. The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-87427-7, MON-89Ø34-3 , SYN-IR162-4 and MON-87411-9 and further verified on maize stack MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9;

2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003.

3. Reference Material: AOCS 0512 (for MON-87427-7), AOCS 0906 (for MON-89Ø34-3), AOCS 1208 (for SYN-IR162-4) and AOCS 0215 (for MON-87411-9) are accessible via the American Oil Chemists Society.

e) Unique identifier:

- MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9;
- MON-87427-7 × MON-89Ø34-3 × MON-87411-9;
- MON-87427-7 × SYN-IR162-4 × MON-87411-9;
- MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9;
- MON-87427-7 × MON-87411-9;
- MON-89Ø34-3 × MON-87411-9;
- SYN-IR162-4 × MON-87411-9.

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex E: RP607 – MON 87751 × MON 87701 × MON 87708 × MON 89788 soybean (new application)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.5847 (2019) (assessment of genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 for food and feed uses).

Conclusions from EFSA Risk Assessment:

The GMO Panel was asked to carry out a scientific assessment of soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 for import, processing and food and feed uses in accordance with Regulation (EC) No 1829/2003, considering the scope of application EFSA-GMO-NL-2016-128.

Soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 (four-event stack soybean) was produced by conventional crossing to combine four single events: MON 87751, MON 87701, MON 87708 and MON 89788. The GMO Panel previously assessed the four single events and did not identify safety concerns. No new data on the single events have been identified that would lead to modification of the original conclusions on their safety. The molecular characterisation, comparative analysis (agronomic, phenotypic and compositional characteristics) and the outcome of the toxicological and

allergenicity assessment indicate that the combination of the single soybean events and of the newly expressed proteins in the four-event stack soybean does not give rise to food and feed safety and nutritional concerns.

The GMO Panel concludes that the four-event stack soybean, as described in this application, is as safe as and nutritionally equivalent to the non-GM comparator and the non-GM reference varieties tested. In the case of accidental release of viable seeds of the four-event stack soybean into the environment, this would not raise environmental safety concerns.

The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of the four-event stack soybean. Post-market monitoring of food/feed is not considered necessary. The GMO Panel concludes that the four-event stack soybean is as safe as the non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.

- Molecular characterisation (including comparative assessment): Protein expression analysis showed the four-event stack to have comparable expression of novel proteins to the singles. The only potential interactions between the novel proteins are between the cry proteins and susceptible insects. Comparative assessment required further assessment for Gly levels in seed in terms of food or feed.

- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Allergen Gly levels were significantly different to comparator lines but were decreased in the four-event stack. Allergenicity of the novel proteins did not identify any safety concerns. The four-event stack is nutritionally equivalent to and as safe as comparator varieties tested.

- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. Accidental release of viable GM soybean would not cause an environmental safety concern. No post market monitoring of food and feed is necessary. The proposed PMEM plan was acceptable and did not require extra monitoring.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

- Name: Bayer CropScience LP
- Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

b) Designation and specification of the products:

1. foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1;
2. feed containing, consisting of or produced from genetically modified soybean MON-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1;
3. products containing or consisting of genetically modified soybean MON-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-87751-7 × MON 877Ø1-2 × MON–877Ø8-9 × MON-89788-1 expresses the dmo gene, which confer tolerance to dicamba based herbicides, the cp4 epsps gene which confers tolerance to glyphosate based herbicides, the cry1Ac, cry2Ab2 and cry1A.105 genes, which confer protection against certain lepidopteran pests.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘soybean’.
2. The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified soybean MON-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1, with the exception of products referred to in point (b)(1).

d) Method for detection:

1. The quantitative event-specific PCR detection methods are those individually validated for genetically modified soybean events MON-87751-7, MON 877Ø1-2, MON-877Ø8-9 and MON-89788-1 and further verified on soybean stack MON-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1;

2. Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003.

3. Reference Material: AOCS 0215(for MON-87751-7), AOCS 0809 (for MON 877Ø1-2), AOCS 0311 (for MON-877Ø8-9) and AOCS 0906 (for MON-89788-1) are accessible via the American Oil Chemists Society (AOCS).

e) Unique identifier:

MON-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1.

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex F: RP620 – Bt11 maize (renewal)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.6347 (2021) (assessment of genetically modified maize Bt11 for renewal authorisation). Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

Following the submission of application EFSA-GMO-RX-016 under Regulation (EC) No 1829/2003 from Syngenta the GMO Panel was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant and herbicide-tolerant genetically modified maize Bt11, for food and feed uses, excluding cultivation within the European Union.

The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequences of the event in maize Bt11 considered for renewal is identical to the sequence of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-016 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize Bt11.

- Molecular characterisation (including comparative assessment): The risk assessment is based on the assumption the event sequence has remained the same.
- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Updated bioinformatics and literature searches did not identify any new safety concerns relating to toxins, or allergens on the assumption that the sequence has not changed from the original assessment.
- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. Existing monitoring is acceptable and did not identify any concerns.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Syngenta Crop Protection AG
   - Address: Rosentalstrasse 67, CH-4058 Basel, Switzerland

b) Designation and specification of the products:

   1. foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;
   2. feed containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;
   3. products containing or consisting of genetically modified maize SYN-BTØ11-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize SYN-BTØ11-1, as described in the application, expresses the Cry1Ab protein, which confers resistance against certain lepidopteran

pests and the PAT protein, which confers tolerance to the glufosinate- ammonium herbicide.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’.

2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize SYN-BTØ11-1, with the exception of products referred to in point (b)(1).

d) Method for detection:

1. Event specific real-time PCR based method for the detection of genetically modified maize SYN-BTØ11-1.

2. Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003.

3. Reference material: ERM®-BF412 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM).

e) Unique identifier:

SYN-BTØ11-1

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex G: RP714 – MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations (new application)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.5774 (2019) (assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and sub-combinations, for food and feed uses).

Conclusions from EFSA Risk Assessment:

The GMO Panel was asked to carry out a scientific assessment of maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and sub-combinations for import, processing and food and feed uses in accordance with Regulation (EC) No 1829/2003, considering the scope of application EFSA-GMO-NL-2016-134.

Maize MON 87427 ×MON 87460 × MON 89034 × MIR162 × NK603 (five-event stack maize) was produced by conventional crossing to combine five single events: MON 87427, MON 87460, MON 89034, MIR162 and NK603. The GMO Panel previously assessed the five single maize events and eleven of the sub-combinations and did not

identify safety concerns. No new data on the single maize events or the 11 sub-combinations that could lead to modification of the original conclusions on their safety were identified. The molecular characterisation, comparative analysis (agronomic, phenotypic and compositional characteristics) and the outcome of the toxicological, allergenicity and nutritional assessment indicate that the combination of the single maize events and of the newly expressed proteins in the five-event stack maize does not give rise to food and feed safety and nutritional concerns.

The GMO Panel concludes that the five-event stack maize, as described in this application, is as safe as and nutritionally equivalent to its non-GM comparator and the non-GM reference varieties tested. In the case of accidental release of viable grains of the five-event stack maize into the environment, this would not raise environmental safety concerns.

The GMO Panel assessed the likelihood of interactions among the single events in the 14 maize sub-combinations not previously assessed and concludes that these are expected to be as safe as and nutritionally equivalent to the single events, the previously assessed sub-combinations and the five-event stack maize. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of the five-event stack maize. Post-market monitoring (PMEM) of food/feed is not considered necessary.

The GMO Panel concludes that the five-event stack maize and its sub-combinations are as safe as its non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.

- Molecular characterisation (including comparative assessment): The single events were assessed including updated bioinformatics and no safety concerns were identified. The five stack was produced through the conventional crossing of the singles. No interactions between the newly expressed proteins were identified, with the exception of cry and vip3Aa20 and susceptible insects.
- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): No safety concerns were identified relating to toxins, allergens or adjuvanticity. The nutritional content of the 5 stack is equivalent to that of the non-GM comparator and reference varieties.

- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. The five stack was not identified in posing safety concerns viable GM maize grains were accidentally released into the environment. The proposed PMEM plan is sufficient, no extra monitoring is required.
- Risk assessment of sub-combinations: For this application, a sub combination may contain up to 4 events , the possible sub combinations are 5 x four-event stacks, 10 x three-event stacks and 10 x two-event stacks. These sub-combinations are expected to be as safe and nutritionally equivalent to the single and five stack maize.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Bayer CropScience LP
   - Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

b) Designation and specification of the products:

   1. foods and food ingredients containing, consisting of or produced from genetically modified maize (Zea mays L.) as referred to in point (e);
   2. feed containing, consisting of or produced from genetically modified maize (Zea mays L.) as referred to in point (e);
   3. products containing or consisting of genetically modified maize (Zea mays L.) as referred to in point (e) for uses other than those provided for in points (1) and (2), with the exception of cultivation.

   The genetically modified maize MON-87427-7 expresses the CP4 epsps gene, which confers tolerance to glyphosate- based herbicides.

   The genetically modified maize MON-8746Ø-4 expresses a Bacillus subtilis modified cspB gene, which aims to reduce yield loss caused by drought stress. In addition, the nptII gene, conferring kanamycin and neomycin resistance, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-89Ø34-3 expresses the cry1A.105 and cry2Ab2 genes, which confer protection against certain lepidopteran pests.

The genetically modified maize SYN-IR162-4 expresses a modified vip3Aa20 gene, which provides protection against certain lepidopteran pests. In addition, the pmi gene, coding for the PMI protein, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-ØØ6Ø3-6 expresses the CP4 epsps and the CP4 epsps L214P genes, which confers tolerance to glyphosate-based herbicides.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize specified in point (e), with the exception of products referred to in point (b)(1).

d) Method for detection:

1. The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-87427-7, MON-8746Ø-4, MON-89Ø34-3, SYN-IR162-4 and MON-ØØ6Ø3-6 and further verified on maize MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6.

2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003.

3. Reference Material: AOCS 0512 (for MON-87427-7), AOCS 0709 (for MON-8746Ø-4) AOCS 0906 (for MON- 89Ø34-3) and AOCS 1208 (for SYN-IR162-4) are accessible via the American Oil Chemists Society and ERM®-BF415 (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre (JRC) of the European Commission.

e) Unique identifiers:

- MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4;
- MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6;
- MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3;
- MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4;
- MON-87427-7 × MON-8746Ø-4 × MON-ØØ6Ø3-6;
- MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6;
- MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4;
- MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6;
- MON-87427-7 × MON-8746Ø-4;
- MON-8746Ø-4 × MON-89Ø34-3;
- MON-8746Ø-4 × SYN-IR162-4;
- MON-8746Ø-4 × MON-ØØ6Ø3-6;

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex H: RP715 – MON 88017 maize (renewal)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.6008 (2020) (assessment of genetically modified maize MON 88017 for renewal authorisation). Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

Following the submission of application EFSA-GMO-RX-014 under Regulation (EC) No 1829/2003 from Monsanto Company the GMO Panel was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant and herbicide-tolerant genetically modified maize MON 88017, for food and feed uses, excluding cultivation within the EU. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant.

The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA

sequence of the event in maize MON 88017 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-014 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017.

- Molecular characterisation (including comparative assessment): The risk assessment is based on the assumption the event sequence has remained the same.
- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Updated bioinformatics did not identify any relevant similarities to toxins, allergens or gluten related epitopes. No new publications were identified that would raise a safety concern for human or animal health.
- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. No adverse environmental risks were identified in earlier assessment, no case specific environmental monitoring was required as part of renewing authorisation. No safety concern identified for horizontal gene transfer. No publications were identified that would raise a safety concern for environmental risks.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Bayer CropScience LP
   - Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

b) Designation and specification of the products:

   1. foods and food ingredients containing, consisting of or produced from genetically modified maize (Zea mays L.) MON-88Ø17-3;
   2. feed containing, consisting of or produced from genetically modified maize (Zea mays L.) MON-88Ø17-3;

3. products containing or consisting of genetically modified maize (Zea mays L.) MON-88Ø17-3 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-88Ø17-3 expresses a modified cry3Bb1 gene, which provides protection to certain coleopteran pests and the cp4 epsps gene, which confers tolerance to glyphosate-based herbicides.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize MON-88Ø17-3 , with the exception of products referred to in point (b)(1).

d) Method for detection:

1. Event specific real-time quantitative PCR based method for detection of the genetically modified maize MON- 88Ø17-3.

2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003.

3. Reference Material: AOCS 0406-D2 accessible via the American Oil Chemists Society..

e) Unique identifier:

MON-88Ø17-3

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.

Annex I: RP716 – MON 89034 maize (renewal)

FSA/FSS has reviewed the EFSA opinion and confirm that FSA/FSS agree with the safety conclusions outlined. FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. Therefore, the information on which this opinion is based can be found in the EFSA opinion as detailed below. There has been no additional information received by FSA/FSS since the publication date of the EFSA opinion, therefore, the appropriateness of the EFSA opinion is maintained. Following the principles outlined in the introduction for making use of the EFSA opinion, the FSA/FSS opinion is that the GMO, as described in this application, is safe. FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions.

EFSA Risk Assessment:

EFSA has published its risk assessment and opinion, which FSA/FSS has reviewed in the EFSA Journal No.5845 (2019) (assessment of genetically modified maize MON 89034 for renewal authorisation). Since this concerns a renewal application, the EFSA opinion refers to the original EFSA risk assessment that FSA/FSS has also reviewed where necessary.

Conclusions from EFSA Risk Assessment:

Following the submission of application EFSA-GMO-RX-015 under Regulation (EC) No 1829/2003 from Bayer Agriculture BVBA, the GMO Panel was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorization application for the insect-resistant genetically modified maize MON 89034, for food and feed uses, excluding cultivation within the EU.

The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

Under the assumption that the DNA sequence of the event in maize MON 89034 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-015 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034.

- Molecular characterisation (including comparative assessment): The risk assessment is based on the assumption the event sequence has remained the same.

- Food and feed safety assessment (toxicity, allergenicity and dietary exposure): Updated bioinformatics and literature searches did not identify any new safety concerns relating to toxins, or allergens on the assumption that the sequence has not changed from the original assessment.

- Environmental risk assessment (including PMEM): Not cultivated in UK or EU, import only. No adverse environmental risks were identified in earlier assessment, no case specific environmental monitoring was required as part of authorisation. No safety concern identified for horizontal gene transfer. No publications were identified that would raise a safety concern for environmental risks.

Proposed terms of authorisation:

a) Applicant and authorisation holder:

   - Name: Bayer CropScience LP

   - Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

b) Designation and specification of the products:

   1. foods and food ingredients containing, consisting of or produced from genetically modified maize (Zea mays L.) MON-89Ø34-3;

   2. feed containing, consisting of or produced from genetically modified maize (Zea mays L.) MON-89Ø34-3;

3. products containing or consisting of genetically modified maize (Zea mays L.) MON-89Ø34-3 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-89Ø34-3 expresses the cry1A.105 gene and the cry2Ab2 gene, which confer protection against certain lepidopteran pests.

c) Labelling:

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified maize MON-89Ø34-3, with the exception of products referred to in point (b)(1) of this Annex.

d) Method for detection:

1. Event specific real-time PCR based method for the quantification of genetically modified maize MON-89Ø34-3.

2. Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003.

3. Reference Material: AOCS 0906-E accessible via the American Oil Chemists Society.

e) Unique identifier:

MON-89Ø34-3

f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not required

g) Conditions or restrictions on the placing on the market, us or handling of the products:

Not required

h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC

i) Post-market monitoring requirements for the use of the food for human consumption:

Not required

Return to top of document.