Vitenskapskomiteen for mat og miljø
Norwegian Scientific Committee for Food and Environment

VKM Report 2022:12

Assessment of genetically modified maize MON 88017 x MON 810 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-017)

Scientific Opinion of the Panel on genetically modified organisms of the Norwegian Scientific Committee for Food and Environment

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Assessment of genetically modified maize MON 88017 x MON 810 for food and feed uses, import and processing (application EFSA-GMO-RX-017) under regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and **feed**

Authors of the opinion

The authors have contributed to the opinion in a way that fulfils the authorship principles of VKM (VKM, 2019). The principles reflect the collaborative nature of the work, and the authors have contributed as members of the VKM Panel on genetically modified organisms.

Members of the Panel on genetically modified organisms (in alphabetical order before chair of the Panel): Johanna Bodin (chair), Nur Duale, Monica Sanden, Tage Thorstensen and Rose Vikse.

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Summary

Stacked event maize MON 88017 × MON 810 is produced by crossing single-trait inbred plants of MON 88017 and MON 810 using traditional breeding methods. Genetically modified maize MON 88017 x MON 810 plants contain the transgenes *cp4 epsps*, *cry3Bb1 and cry1Ab* which encode the proteins CP4 EPSPS, Cry3Bb1 and Cry1Ab. CP4 EPSPS provides tolerance to glyphosate. Cry3Bb1 protein provides protection against certain coleopteran insect pests. Cry1Ab protein which provides protection from certain lepidopteran insect pests.

The scientific documentation provided in the application for genetically modified MON 88017 × MON 810 is adequate for risk assessment, and in accordance with EFSA guidance on risk assessment of genetically modified plants for use in food or feed. The VKM GMO panel does not consider the introduced modifications in stacked event MON 88017 x MON 810 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA Scientific opinion (EFSA 2021) is adequate also for Norwegian considerations. Therefore, a full risk assessment of stacked event MON 88017 x MON 810 was not performed by the VKM GMO Panel.

Sammendrag

MON 88017 × MON 810 (EFSA-GMO-RX-017) er en genmodifisert mais utviklet ved konvensjonelle krysning av genmodifisert mais MON88017 og mais MON 810. MON 88017 × MON 810 uttrykker transgenene *cp4 epsps*, *cry3Bb1* og *cry1Ab*, som koder henholdsvis for CP4 EPSPS, Cry3Bb1 og Cry1Ab. Transgenene gjør MON 88017 × MON 810 resistent mot enkelte planteskadegjørende, samt tolerant mot ugressmiddelet glyfosat. Cry3Bb1-proteinet beskytter mot angrep fra arter i billeslekten Diabrotica, mens Cry1Ab beskytter mot skadegjørere i sommerfuglordenen Lepidoptera. Søkers vitenskapelige dokumentasjon for den genmodifiserte MON 88017 × MON 810 er dekkende for risikovurdering, og i samsvar med EFSA retningslinjer for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. De genetiske endringene i maisen tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAs vitenskapelige vurdering (EFSA 2021) er derfor tilstrekkelig også for norske forhold. Ettersom det ikke har blitt identifisert særnorske forhold vedrørende egenskaper ved MON 88017 × MON 810, har VKMs GMO panel ikke utført en fullstendig risikovurdering av maisen.

Background as provided by the Norwegian Food Safety Authority and the Norwegian Environment Agency

The Norwegian Food Safety Authority (NFSA) and the Norwegian Environment Agency (NEA), have assigned VKM to perform assessments of genetically modified organisms (GMOs) and derived products thereof, for which there are sought approval of authorisation to the European market under the Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. VKM is requested to perform assessments for all GMO applications made accessible through the EFSA Document Management System (DMS), where the main focus should be on potential health or environmental risks specific to Norway compared to the EU.

1 Assessment of genetically modified maize MON 88017 × MON 810 (application EFSA-GMO-RX-017)

1.1 Comments during the EFSA scientific consultation-period

When EFSA submits an application for scientific consultation with a three-month commenting deadline, VKM shall initiate the scientific assessment. From the application is submitted for scientific consultation until EFSA has published its Scientific Opinion (6.5 months + the period when 'the clock stops') VKM should:

• Use this period to assess the scientific quality of the documentation presented in the application. Possible lack of essential information and other relevant scientific literature should be addressed. The application must be in compliance with Regulation (EU) No. 503/2013 and adhere to EFSA guidance (EFSA 2010, 2011) for risk assessment of genetically modified organisms.

• Provide comments to EFSA within the deadline and inform The Norwegian Food Safety Authority (NFSA) and the Norwegian Environment Agency (NEA) no later than two weeks before the deadline. If no comments are provided to EFSA, VKM notifies the NFSA and NEA for the reasons why no comment was submitted.

• Assess whether there are considerations specific to Norway that need to be addressed. If such considerations are identified VKM should immediately inform the NFSA and NEA.

Stage 1

1. Application	**EFSA-GMO-RX-017** Genetically modified maize MON 88017 × MON 810

2. Information related to the genetic modification:

Stacked event maize MON 88017 × MON 810 is produced by crossing single-trait inbred plants of MON 88017 and MON 810 using traditional breeding methods. Genetically modified maize MON 88017 x MON 810 plants contain the transgenes *cp4 epsps*, *cry3Bb1* and *cry1Ab* which encode the proteins CP4 EPSPS, Cry3Bb1 and Cry1Ab. CP4 EPSPS provides tolerance to glyphosate. Cry3Bb1 protein provides protection against certain coleopteran insect pests. Cry1Ab protein which provides protection from certain lepidopteran insect pests.

Genes	**Proteins**
cp4 epsps	CP4 EPSPS
cry3Bb1	Cry3Bb1
cry1Ab	Cry1Ab

3. Previously assessed by VKM	YES: X	NO:

4. If yes in item 3. – comments from VKM:

2007: UTTALELSE OM MONSANTOS GENMODIFISERTE MAIS MON 88017 x MON 810 (EFSA/GMO/CZ/2006/33)

2016: Final health- and environmental risk assessment of genetically modified maize MON 88017 x MON 810 (EFSA/GMO/CZ/2006/33)

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	24.10.2019
6. Deadline of EFSAs commenting period	24.11.2019
7. VKMs assessment of the documentation in the application	
Applicants documentation:	The VKM Panel on genetically modified organisms finds the documentation provided as satisfactory for risk assessment.
Additional literature used by VKM:	No

Documentation in compliance with Regulation (EU) No. 503/2013:	YES: X	NO:
Documentation in accordance with EFSA guidance for risk assessment of genetically modified plants (EFSA 2010, 2011):	YES: X	NO:
8. Comments submitted from VKM during EFSAs public consultation	YES: X	NO:
9. Date of submission from VKM	25.01.2020	
10. Comment(s) to EFSA:		

Food and feed safety assessment

VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-plants. Data on glyphosate residue levels, including relevant metabolites, in plant material from the field studies would support the assessment of food, feed, and environmental safety.

11. If NO in item 8. – comments from VKM:		
12. Need for national consideration(s)	YES:	NO: X
13. If YES in item 12. – comments from VKM:		
14. If NO in item 12. – comments from VKM:		

The VKM GMO Panel does not consider the introduced modifications in stacked event MON88017 x MON810 to imply potential specific health or environmental risks in Norway, compared to EU-countries.

15. VKMs conclusion regarding the application:

The scientific documentation provided in the application is adequate for risk assessment, and in accordance with the EFSA guidance on risk assessment of genetically modified plants for use in food or feed.

1.2 Considerations after EFSAs publication of their scientific opinion – part 1

When EFSA publishes their scientific opinion together with the comments from the member states, VKM shall within a month inform the NFSA and EEA on the following:

• Are EFSA's answer(s) to the Norwegian comments satisfactorily answered, or do VKM still have scientific objections to EFSA's conclusions

• Do EFSA's answers to comments from member states indicate need for follow-up by VKM

• Considerations specific to Norway

Stage 2		
1. Date of publication of EFSA opinion	09.12.2020	
2. VKMs deadline for informing NFSA and EEA	09.01.2021	
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	YES: X	NO:
4. If YES in item 3 – Comments from VKM:		
The VKM GMO Panel is aware that herbicide residue levels are out of scope of the mandate for the EFSA GMO Panel.		
5. If NO in item 3 – Comment(s) and further considerations from VKM:		
6. Follow-up item 12 (table 1) – comments from VKM		
7. Considerations from VKM regarding comments from EU member states and other countries under Annex G:		
No member state comments imply the need for follow-up by VKM.		

1.3 Considerations after EFSAs publication of their scientific opinion – part 2

If VKM's comments regarding health and environmental risk are not considered to be satisfactorily answered by EFSA, VKM shall within three months carry out a risk assessment of these conditions, as well as conditions specific to Norway. VKM shall highlight uncertainty and knowledge gaps. It shall be stated in what area there are knowledge gaps, and whether the uncertainty, quality of the data, and knowledge gaps will affect the conclusion.

Stage 3		
1. Need for further assessment(s)	YES:	NO: X
2. If YES in item 1. – Further considerations from VKM:		
3. If NO in item 1. – comments from VKM:		
The scientific documentation provided in the application is adequate for risk assessment, and in accordance with the EFSA guidance on risk assessment of genetically modified plants for use in food or feed. Answers from EFSA to VKM comments were satisfactory. The EFSA scientific opinion is adequate also for Norwegian considerations.		
4. Need for national considerations	YES:	NO: X
5. If YES in item 4. – comments from VKM:		
6. If NO or NA in item 4. – comments from VKM		
The VKM GMO Panel does not consider the introduced modifications in genetically modified maize MON 88017 × MON 810to imply potential specific health or environmental risks in Norway, compared to EU-countries.		
7. Need for a risk assessment	YES:	NO: X
8. Date of deadline for risk assessment	Not applicable	
9. Date of publication of assessment	29.04.22	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize MON 88017 x MON 810. Maize MON 88017 x MON 810 plants contain the transgenes *cp4 epsps*, *cry3Bb1* and *cry1Ab* which encode the proteins CP4 EPSPS, Cry3Bb1 and Cry1Ab. CP4 EPSPS provides tolerance to glyphosate. Cry3Bb1 protein provides protection against certain coleopteran insect pests. Cry1Ab protein provides protection from certain lepidopteran insect pests.

The VKM GMO panel has assessed the documentation in application EFSA-GMO-RX-017. The scientific documentation provided in the application is adequate for risk assessment, and in accordance with the EFSA guidance on risk assessment of genetically modified plants for use in food or feed.

The VKM GMO panel concludes that the introduced modifications in stacked event MON 88017 x MON 810 do not imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion (2021) is adequate also for Norwegian considerations.

3 References

EFSA (2010) Guidance on the environmental risk assessment of genetically modified plants. Scientific option from the EFSA Panel on Genetically Modified Organisms (GMO). The EFSA Journal 8 (11):1-111 http://www.efsa.europa.eu/en/efsajournal/doc/1879.pdf

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