



VKM Report 2022:23

Assessment of genetically modified maize MON 88017 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-014)

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 for food and feed uses, import and processing (application EFSA-GMO-RX-014) 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.

Table of Contents

Summary	5
Sammendrag	6
Background as provided by the Norwegian Food Safety Authority and the Norwegian Environment Agency	7
1 Assessment of genetically modified maize MON 88017 (application EFSA-GMO-RX-014)	8
1.1 Comments during the EFSA scientific consultation-period	8
1.2 Considerations after EFSAs publication of their scientific opinion – part 1.....	11
1.3 Considerations after EFSAs publication of their scientific opinion – part 2.....	12
2 Conclusions	13
3 References	14

Summary

Event MON 88017 (EFSA-GMO-RX-014) is a genetically modified maize developed via *Agrobacterium tumefaciens* transformation. MON 88017 plants contain the transgenes *cry3Bb1* and *cp4 epsps* which encode the proteins Cry3Bb1 and CP4 EPSPS. The proteins Cry3Bb1 and CP4 EPSPS provides protection against certain coleopteran pests and tolerance to glyphosate herbicides by the expression of Cry3Bb1 and CP4 EPSPS proteins, respectively.

The scientific documentation provided in the renewal application for genetically modified MON 88017 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 event MON 88017 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA opinion is adequate also for Norwegian considerations. Therefore, a full risk assessment of event MON 88017 was not performed by the VKM GMO Panel.

Sammendrag

MON 88017 (EFSA-GMO-RX-014) er en genmodifisert mais utviklet ved transformasjon av planteceller ved hjelp av *Agrobacterium tumefaciens*. MON 88017 uttrykker transgenene *cry3Bb1* og *cp4 epsps*, som koder henholdsvis for Cry3Bb1 og CP4 EPSPS. Transgenene gjør maisen resistent mot enkelte planteskadegjørende (coleoptera/biller), samt tolerant mot ugressmiddelet glyfosat. Søkers vitenskapelige dokumentasjon for mais MON 88017 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. EFSA's risikovurdering er derfor tilstrekkelig også for norske forhold. Ettersom det ikke ble identifisert særnorske forhold vedrørende egenskaper ved mais MON 88017, 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 (application EFSA-GMO-RX-014)

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-014**Genetically modified maize MON
88017**2. Information related to the genetic modification:**

Event MON 88017 (EFSA-GMO-RX-014) is a genetically modified maize developed via *Agrobacterium tumefaciens* transformation.

MON 88017 plants contain the transgenes *cry3Bb1* and *cp4 epsps* which encode the proteins Cry3Bb1 and CP4 EPSPS.

The proteins Cry3Bb1 and CP4 EPSPS provides protection against certain coleopteran pests and tolerance to glyphosate herbicides by the expression of Cry3Bb1 and CP4 EPSPS proteins, respectively.

Genes**Proteins***cry3Bb1*

Cry3Bb1

cp4 epsps

CP4 EPSPS

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 (EFSA/GMO/CZ/2005/27)

2008: Miljørisikovurdering av genmodifisert mais MON 88017 Monsanto Company (EFSA/GMO/CZ/2008/54)

2016: Final health- and environmental risk assessment of genetically modified maize MON 88017 (EFSA/GMO/CZ/2005/27)

2019: Comments to EFSA on the application for renewal of the authorisation of genetically modified maize MON 88017 (EFSA-GMO-RX-014)

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)

17.12.18

6. Deadline of EFSA's commenting period

16.03.19

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 EFSA's public consultation	YES: X	NO:
9. Date of submission from VKM	16.03.19	
10. Comment(s) to EFSA:		
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 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 event maize MON 88017 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 EFSA's 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	11.03.20
2. VKMs deadline for informing NFSA and EEA	11.04.20
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:	
VKM welcomed information on herbicide residue, and this is not in the remit of the EFSA GMO panel.	
5. If NO or NA 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 EFSA's 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 or NA in item 1. – comments from VKM:		
<p>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.</p> <p>Answers from EFSA to VKM comments were satisfactory.</p> <p>The EFSA opinion is adequate also for Norwegian considerations.</p>		
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		
<p>The VKM GMO Panel does not consider the introduced modifications in event maize MON 88017 to imply potential specific health or environmental risks in Norway, compared to EU-countries.</p>		
7. Need for a risk assessment	YES:	NO: X
8. Date of deadline for risk assessment	Not applicable	
9. Date of publication of assessment	13.06.22	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize MON 88017. Maize MON 88017 plants contain the transgenes *cry3Bb1* and *cp4 epsps* which encode the proteins Cry3Bb1 and CP4 EPSPS. The proteins Cry3Bb1 and CP4 EPSPS provide protection against certain *coleopteran* pests and tolerance to glyphosate herbicides by the expression of Cry3Bb1 and CP4 EPSPS proteins, respectively.

The VKM GMO panel has assessed the documentation in the renewal application EFSA-GMO-RX-014. 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 GMO panel does not consider the introduced modifications in event MON 88017 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA opinion is adequate also for Norwegian considerations.

3 References

EFSA (2010) Guidance on the environmental risk assessment of genetically modified plants. Scientific opinion 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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VKM (2019) Comments to EFSA on the application for renewal of the authorisation of genetically modified maize MON 88017 (EFSA-GMO-RX-014) <https://vkm.no/download/18.a898aed16af46563ac2824f/1559049241917/Innspill%20til%20h%C3%B8ring%20EFSA-GMO-RX-014.pdf>