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

VKM Report 2023:5

Assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-151)

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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): Monica Sanden (chair), Johanna Bodin, Nur Duale and Tage Thorstensen

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Summary

Stacked event MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 (EFSA-GMO-NL-2018-151) is a genetically modified maize developed via conventional breeding. MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 plants contain the transgenes *cry1A.105, cry2Ab2, cry1F, Vip3Aa20, cp4 epsps, pat, aad-1* and the phosphomannose isomerase (PMI) used as a selectable marker in the production of MIR162.

MON89034 x 1507 x MIR162 x NK603 x DAS-40278-9 maize provides distinct sources for insect resistance combined with three distinct modes of herbicide tolerance: 2,4-D, glufosinate, and glyphosate.

The scientific documentation provided in the application for genetically modified maize 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 maize 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 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 was not performed by the VKM GMO Panel.

Sammendrag

MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 (EFSA-GMO-NL-2018-151) er en genmodifisert mais utviklet ved konvensjonell kryssing av genmodifiserte mais MON 89034, 1507, MIR162, NK603 og DAS-40278-9. Maisen uttrykker transgenene *cry1A.105, cry2Ab2, cry1F, Vip3Aa20, cp4 epsps, pat, aad-1* og phosphomannose isomerase (PMI). PMI benyttes som seleksjonsmarkør i produksjonen av MIR162.

Transgenene gjør maisen resistent mot planteskadegjørende, samt tolerant mot ugressmiddelene 2,4-D, glufosinate og glyfosat.

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen 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 risikovurdering er derfor tilstrekkelig også for norske forhold. Ettersom det ikke har blitt identifisert særnorske forhold som gjelder egenskaper til maisen, har VKMs GMO panel ikke utført en fullstendig risikovurdering av genmodifisert mais MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9.

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 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 (application EFSA-GMO-NL-2018-151)

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-NL-2018-151** Genetically modified maize MON 89034×1507×MIR162×NK603×DAS-40278-9

2. Information related to the genetic modification:

Stacked event MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 (EFSA-GMO-NL-2018-151) is a genetically modified maize developed via conventional breeding.

MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 plants contain the transgenes *cry1A.105, cry2Ab2, cry1F, Vip3Aa20, cp4 epsps, pat, aad-1* and the phosphomannose isomerase (PMI) used as a selectable marker in the production of MIR162.

MON89034 x 1507 x MIR162 x NK603 x DAS-40278-9 maize provides distinct sources for insect resistance combined with three distinct modes of herbicide tolerance: 2,4-D, glufosinate, and glyphosate.

Genes	**Proteins**
cry1A.105	CRY1A.105
cry2Ab2	CRY2Aa2
cry1F	CRY1F
Vip3Aa20	VIP3Aa20
cp4 epsps	CP4 EPSPS
pat	PAT
aad-1	AAD-1
pmi	PMI

3. Previously assessed by VKM	YES:	NO: X
4. If yes in item 3. – comments from VKM:		
5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	18.10.18	

6. Deadline of EFSAs commenting period	26.01.19	
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 EFSAs public consultation	YES: X	NO:
9. Date of submission from VKM	26.01.19	
10. Comment(s) to EFSA:		

In the Main text (Dossier page 51): Section 1.2.2.2 b) "organisation and sequence of the inserted genetic material at each insertion site", the applicant compares the MIR162 insert to a 'DAS stack B maize' without clarifying why. Here the applicant should have used the maize stack MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9.

General information about the maize stack tolerance to the herbicide haloxyfop (herbicide family AOPP) in the application is insufficient. The use of haloxyfop is first mentioned on page 56 of the Main text. The applicant should further explain this herbicide tolerance trait.

VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-plants. Data on glyphosate, glufosinate-ammonium, 2,4-D and haloxyfop residue levels, including relevant metabolites, in plant material from the field studies would support the assessment of food, feed, and environmental safety.

Generally, the application contains some inconsistencies and many typing errors that may lead to misinterpretations.

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 MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9 to imply potential specific health or environmental risks in Norway, compared to EU-countries.

15. VKMs conclusion regarding the application:

Despite the uncertainties reflected in the comments to EFSA (10. Comments to EFSA), the scientific documentation provided in the application is adequate for risk assessment.

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	12.08.22	
2. VKMs deadline for informing NFSA and EEA	12.09.22	
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:		
EFSA has given an adequate reply to the VKM comments		
5. If NO in item 3 – Comment(s) and further considerations from VKM:		
6. Follow-up item 12 (table 1) – comments from VKM		
The VKM GMO Panel does not consider the modifications in stacked event MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9 to imply potential specific health or environmental risks in Norway compared to EU-countries. The EFSA scientific opinion (EFSA, 2022) is adequate also for Norwegian considerations.		
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 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 stacked event MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9 to 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	06.01.23	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9. MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 plants contain the transgenes *cry1A.105, cry2Ab2, cry1F, Vip3Aa20, cp4 epsps, pat, aad-1* and the phosphomannose isomerase (PMI) used as a selectable marker in the production of MIR162.

MON89034 x 1507 x MIR162 x NK603 x DAS-40278-9 maize provides distinct sources for insect resistance combined with three distinct modes of herbicide tolerance: 2,4-D, glufosinate, and glyphosate.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2018-151. 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 stacked event MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 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 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

EFSA (2011) Guidance for risk assessment of food and feed from genetically modified plants. The EFSA Journal 9(5): 2150. http://www.efsa.europa.eu/en/efsajournal/doc/2150.pdf

VKM (2019) Comments from The Norwegian Scientific Committee for Food and Environment (VKM) on the stacked maize event MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9 (Application EFSA-GMO-NL-2018-151)

https://www.vkm.no/download/18.2247e3031686ea532e033a49/1548250950939/Innspill%20til%20EFSAs%20offentlige%20h%C3%B8ring%20EFSA-GMO-NL-2018-151.pdf