



VKM Report 2023:21

Assessment of genetically modified maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2018-149)

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

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Norwegian Scientific Committee for Food and Environment (VKM)

Postboks 222 Skøyen

0213 Oslo

Norway

Phone: +47 21 62 28 00

Email: vkm@vkm.no

vkm.no

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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 after chair of the Panel): Monica Sanden (Chair), Eirill Ager-Wick, Johanna Bodin, Nur Duale, Kristian Prydz, Volha Shapaval and Tage Thorstensen

VKM staff (in alphabetical order): Anne Marthe Ganes Jevnaker and Ville Erling Sipinen

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Summary

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21.

Accordingly, Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize produces the transgenic proteins in the individual GM maize events (Cry1Ab, PAT, Vip3Aa20, PMI, mCry3A, MIR604 PMI, Cry1A.105, Cry2Ab2, eCry3.1Ab and mEPSPS).

Event Bt11 maize expresses the insecticidal protein Cry1Ab that protects against feeding damage caused by certain lepidopteran pests and the phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.

Event MIR162 maize expresses the insecticidal protein Vip3Aa20 that protects against feeding damage caused by certain lepidopteran pests and the PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the MIR162 maize.

Event MIR604 maize expresses the insecticidal protein mCry3A that protects against feeding damage caused by certain coleopteran pests and the MIR604 PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the MIR604 maize.

Event MON 89034 maize expresses the insecticidal proteins Cry1A.105 and Cry2Ab2 that protect against feeding damage caused by certain lepidopteran pests.

Event 5307 maize expresses the insecticidal protein eCry3.1Ab that protects against feeding damage caused by certain coleopteran pests and the PMI protein which enables transformed plant cells to utilise mannose as a primary carbon source and therefore used as a selectable marker in the development of the 5307 maize.

Event GA21 expresses the double-mutated 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) for weed control by providing tolerance to herbicide products containing glyphosate.

The scientific documentation provided in the application for genetically modified maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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 maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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 maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was not performed by the VKM GMO Panel.

Sammendrag

Genmodifisert mais Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 ble utviklet ved konvensjonell avl ved å krysse de genmodifiserte maisene Bt11, MIR162, MIR604, MON 89034, 5307 and GA21. Den kryssede maisen har økt toleranse overfor ugrasmidler med virkestoffene glufosinat-ammonium og glyfosat, og er motstandsdyktig mot enkelte skadeinsekter i ordenen Lepidoptera (sommerfugler) og Coleoptera (biller).

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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 mais Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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 har blitt identifisert særnorske forhold vedrørende egenskaper ved mais Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21, 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 (application EFSA-GMO-DE-2018-149)

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-DE-2018-149**Genetically modified maize Bt11 x
MIR162 x MIR604 x MON 89034 x
5307 x GA21**2. Information related to the genetic modification:**

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21.

Accordingly, Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize produces the transgenic proteins in the individual GM maize events (Cry1Ab, PAT, Vip3Aa20, PMI, mCry3A, MIR604 PMI, Cry1A.105, Cry2Ab2, eCry3.1Ab and mEPSPS).

Genes**Proteins***cry1Ab*

Cry1Ab

pat

PAT

vip3Aa20

Vip3Aa20

pim

PMI

mcry3A

mCry3A

MIR604 pim

MIR604 PMI

cry1A.105

Cry1A.105

cry2Ab2

Cry2Ab2

ecry3.1Ab

eCry3.1Ab

mepsps

mEPSPS

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)**

06.07.18

6. Deadline of EFSAs commenting period	15.10.18	
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	15.10.18	
10. Comment(s) to EFSA:		
VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-crops. Data on residue levels of glyphosate and glufosinate-ammonium, 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 maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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	23.06.23
2. VKMs deadline for informing NFSA and EEA	23.07.23
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:	
Herbicide residue levels are out of remit of the EFSA GMO Panel. Adequately addressed by EFSA in their response.	
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 introduced modifications in maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 to imply potential specific health or environmental risks in Norway, compared to EU-countries.	
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 in item 4. – comments from VKM		
<p>The VKM GMO Panel does not consider the introduced modifications in stacked event maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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	XX.09.23	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21. Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was produced by conventional breeding of the GM maize events Bt11, MIR162, MIR604, MON 89034, 5307 and GA21.

Accordingly, Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize produces the transgenic proteins in the individual GM maize events (Cry1Ab, PAT, Vip3Aa20, PMI, mCry3A, MIR604 PMI, Cry1A.105, Cry2Ab2, eCry3.1Ab and mEPSPS).

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-DE-2018-149. 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 maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 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 maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was not performed by the VKM GMO Panel.

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>

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 (2018) Comments from The Norwegian Scientific Committee for Food and Environment (VKM) on the stacked maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 (Application EFSA-GMO-DE-2018-149) <https://www.vkm.no/download/18.3533fa35166534fbf7cde912/1539950616245/Innspill%20til%20h%C3%B8ring%20EFSA-GMO-DE-2018-149.pdf>