



VKM Bulletin 2026:03

Assessment of genetically modified maize DP202216 x NK603 x DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application GMFF-2022-6232 (AP183) / EFSA-Q-2023-00197 (183))

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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Assessment of genetically modified maize DP202216 x NK603 x DAS-40278-9 for food and feed uses, import and processing (application GMFF-2022-6232 (AP183) / EFSA-Q-2023-00197 (183)) 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 after chair of the Panel): Monica Sanden (Chair), 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

DP202216 x NK603 x DAS-40278-9 maize was produced by crossing the GM-maize events DP202216, NK603 and DAS-40278-9 by traditional breeding methods.

DP202216 maize was developed to have an increased and extended expression of the *zmm28* gene relative to the native *zmm28* expression. The gene encodes the ZMM28 protein, a MADS-box transcription factor, which enhances grain yield potential. DP202216 maize also expresses the *mo-pat* gene encoding the enzyme phosphinothricin acetyltransferase (PAT) which confers tolerance to glufosinate-ammonium herbicides. NK603 maize was developed to express the gene *cp4 epsps* encoding the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) which confers tolerance to glyphosate herbicides. DAS-40278-9 maize was developed to express the gene *aad-1* encoding the enzyme aryloxyalkanoate dioxygenase (1AAD-1) which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) herbicide and aryloxyphenoxypropionate (AOPP) herbicides.

The scientific documentation provided in the application for genetically modified maize DP202216 x NK603 x DAS-40278-9 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 DP202216 x NK603 x 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. Therefore, a full risk assessment of maize DP202216 x NK603 x DAS-40278-9 was not performed by the VKM GMO Pane

Sammendrag

Mais DP202216 x NK603 x DAS-40278-9 ble produsert ved å krysse de genmodifiserte maisene DP202216, NK603 og DAS-40278-9 ved hjelp av tradisjonelle avlsmetoder.

Mais DP202216 ble utviklet til å ha et forhøyet og forlenget uttrykk av genet *zmm28* sammenliknet med det naturlige uttrykket av *zmm28*. Genet koder for proteinet ZMM28, en MADS-boks transkripsjonsfaktor, som gir økt avlingspotensial. Mais DP202216 uttrykker også genet *mo-pat*, som koder for enzymet fosfinotricin acetyltransferase (PAT), som gir økt toleranse for ugressmiddelet glufosinat-ammonium.

Mais NK603 uttrykker genet *cp4 epsps*, som koder for enzymet 5-enolpyruvulshikimat-3-fosfat syntase (CP4 EPSPS), som gir økt toleranse for ugressmiddelet glyfosat.

Mais DAS-40278-9 uttrykker genet *aad-1*, som koder for enzymet aryloksyalkanoat dioksygenase (AAD-1), som gir økt toleranse for ugressmiddelet 2,4-diklorfenoksyeddiksyre (2,4-D), og ugressmidler i gruppen av sprøytemidler (aryloksyfenoksypropionat (AOPP)), som hemmer enzymet acetyl-CoA-karboksylase.

Den vitenskapelige dokumentasjonen i søknaden 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 mais DP202216 x NK603 x DAS-40278-9 tilsier ingen økt helse- eller miljørisiko i Norge sammenliknet med EU-land. Ettersom det ikke har blitt identifisert særnorske forhold vedrørende egenskaper ved mais DP202216 x NK603 x DAS-40278-9, har VKMs GMO panel ikke utført en fullstendig risikovurdering av soyaen.

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 DP202216 x NK603 x DAS-40278-9 (application GMFF-2022-6232 (AP183) / EFSA-Q-2023-00197 (183))

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****GMFF-2022-6232 (AP183) /
EFSA-Q-2023-00197 (183)**Genetically modified maize
DP202216 x NK603 x DAS-40278-9**2. Information related to the genetic modification:**

DP202216 x NK603 x DAS-40278-9 maize was produced by crossing the GM-maize events DP202216, NK603 and DAS-40278-9 by traditional breeding methods.

DP202216 x NK603 x DAS-40278-9 maize expresses genes encoding the proteins ZMM28, PAT, CP4 EPSPS and AAD-1. These transgenes enhance grain yield potential, and confere tolerance to the herbicides glufosinate-ammonium, glyphosate, 2,4-dichlorophenoxyacetic acid, and aryloxyphenoxypropionate (AOPP) herbicides.

Genes**Proteins***zmm28*

ZMM28

mo-pat

PAT

cp4 epsps

CP4 EPSPS

aad-1

AAD-1

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)**

20.06.23

6. Deadline of EFSA's commenting period

09.05.24

**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 scientific consultation	YES:	NO: X
9. Date of submission from VKM		
10. Comment(s) to EFSA:		
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 DP202216 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:		
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 two weeks 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	05.12.25
2. VKMs deadline for informing NFSA and EEA	05.01.26
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	NA
4. If YES in item 3 – Comments from VKM:	
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 DP202216 x NK603 x DAS-40278-9 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 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. 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 maize DP202216 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	25.02.26	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize DP202216 x NK603 x DAS-40278-9.

DP202216 x NK603 x DAS-40278-9 maize was produced by crossing the GM-maize events DP202216, NK603 and DAS-40278-9 by traditional breeding methods.

DP202216 x NK603 x DAS-40278-9 maize expresses genes encoding the proteins ZMM28, PAT, CP4 EPSPS and AAD-1. These transgenes enhance grain yield potential, and confer tolerance to the herbicides glufosinate-ammonium, glyphosate, 2,4-dichlorophenoxyacetic acid, and aryloxyphenoxypropionate (AOPP) herbicides.

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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>

EFSA (2025) Assessment of genetically modified maize DP202216 × NK603 × DAS-40278-9 (application GMFF-2022-6232) EFSA Journal. 2025;23:e9746
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