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

VKM Report 2022:19

Assessment of genetically modified maize DP4114 x MON810 x MIR604 x NK603 and sub-combinations, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-150)

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

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Summary

Stacked event DP4114 x MON810 x MIR604 x NK603 is a genetically modified maize developed via conventional crossing of the four single maize events DP4114, MON810, MIR604, and NK603.

The stacked event expresses genes for the following proteins and enzymes: Cry1F and Cry1Ab to confer resistance to lepidopteran pests; Cry34Ab1, Cry35Ab1 and mCry3A to confer resistance to coleopteran pests; PAT, CP4 EPSPS and CP4 EPSPS L214P providing tolerance to glufosinate-ammonium and glyphosate containing herbicides, respectively; and finally, the enzyme phosphomannose isomerase (PMI) as a selectable marker.

The scientific documentation provided in the application for genetically modified maize DP4114 x MON810 x MIR604 x NK603 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 concludes that the introduced modifications in DP4114 x MON810 x MIR604 x NK603 do not 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. The VKM GMO-panel has therefore not performed a full risk assessment of the maize.

Sammendrag

DP4114 x MON810 x MIR604 x NK603 er en genmodifisert mais utviklet ved konvensjonell krysning av de fire maisene DP4114, MON810, MIR604 og NK603.

Transgenene fra hver av de fire maisene er også uttrykt i den kryssede maisen. Transgenene koder for følgende proteiner og enzymer: Cry1F og Cry1Ab (insektsresistens, lepidoptera/sommerfugler); Cry34Ab1, Cry35Ab1 og mCry3A (insektsresistens, coleoptera/biller); PAT (glufosinat-ammonium toleranse), CP4 EPSPS and CP4 EPSPS L214P (glyfosat toleranse); og enzymet fosfomannoseisomerase (PMI, seleksjonsmarkør).

Den vitenskapelige dokumentasjonen i søknaden for den genmodifiserte maisen DP4114 x MON810 x MIR604 x NK603 er dekkende for risikovurdering, og i samsvar med EFSAs veiledning for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. VKMs GMO-panel konkluderer at de genetiske endringene i mais DP4114 x MON810 x MIR604 x NK603 ikke tilsier en økt helse- eller miljørisiko i Norge, sammenliknet med EU-land. EFSAs vurdering (EFSA, 2022) er tilstrekkelig også for norske forhold. VKMs GMO-panel har derfor ikke utført en full 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 DP4114 x MON810 x MIR604 x NK603 and sub-combinations (application EFSA-GMO-NL-2018-150)

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-2018-150** Genetically modified maize DP4114 x MON810 x MIR604 x NK603 and sub-combinations

2. Information related to the genetic modification:

Stacked event DP4114 x MON810 x MIR604 x NK603 is a genetically modified maize developed via conventional crossing of the four single maize events DP4114, MON810, MIR604, and NK603. The stacked event expresses genes for the following proteins and enzymes: Cry1F and Cry1Ab to confer resistance to lepidopteran pests; Cry34Ab1, Cry35Ab1 and mCry3A to confer resistance to coleopteran pests; PAT, CP4 EPSPS and CP4 EPSPS L214P providing tolerance to glufosinate-ammonium and glyphosate containing herbicides, respectively; and finally, the enzyme phosphomannose isomerase (PMI) as a selectable marker.

Genes	**Proteins**
cry1F	Cry1F
cry34Ab1	Cry34Ab1
cry35Ab1	Cry35Ab1
pat	PAT
cry1Ab	Cry1Ab
mcry3A	mCry3A
pmi	PMI
CP4 epsps	CP4 EPSPS
CP4 epsps l214p	CP4 EPSPS L214P

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)	10.08.2018	

6. Deadline of EFSAs commenting period	12.11.2018
7. VKMs assessment of the documentation in the application	
Applicants' documentation:	The scientific documentation provided in the application is adequate for risk assessment, and in accordance with EFSA guidance on risk assessment of genetically modified plants for use in food or feed.
Additional literature used by VKM:	
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	7.11.2018
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 DP4114 x MON810 x MIR604 x NK603 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	07.03.22
2. VKMs deadline for informing NFSA and EEA	07.04.22
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:	
VKM is aware that herbicide residue levels are out of scope of the mandate of 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:	
The VKM GMO panel concludes that the introduced modifications in DP4114 x MON810 x MIR604 x NK603 do not 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. The EFSA scientific opinion (EFSA, 2022) 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 in item 4. – comments from VKM		
The VKM GMO Panel does not consider the modifications in stacked event DP4114 x MON810 x MIR604 x NK603 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	13.06.22	

2 Conclusions

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2018-150 and the EFSAs scientific opinion (EFSA, 2022) on genetically modified maize DP4114 x MON810 x MIR604 x NK603.

The scientific documentation provided in the application 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 concludes that the introduced modifications in DP4114 x MON810 x MIR604 x NK603 do not 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.

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

EFSA (2022) Scientific Opinion on the assessment of genetically modified maize DP4114 x MON 810 x MIR604 x NK603 and sub-combinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSAGMO-NL-2018-150). EFSA Journal 2022;20(3):7134, 38 pp. https://doi.org/10.2903/j.efsa.2022.7134. ISSN: 1831-4732