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

VKM Report 2023:1

Assessment of genetically modified maize DP41143 x MON890343 x MON 874113 x DAS-40278-9 and sub-combinations for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-171)

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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), 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

Genetically modified maize DP41149 x MON 890349 x MON 874119 x DAS-40278-9 was developed by crossing to combine four single events: DP4114, MON 89034, MON 87411 and DAS-40278-9.

DP4114 express the Cry1F protein to confer protection against certain lepidopteran pests, the Cry34Ab1 and Cry35Ab1 proteins to confer protection against certain coleopteran pests and PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides. MON 89034 express the Cry1A.105 and Cry2Ab2 proteins to confer protection against certain lepidopteran pests. MON 87411 express the Cry3Bb1 protein to confer protection against certain coleopteran larvae and the DvSnf7 dsRNA confer protection against western corn rootworm, and the CP4 EPSPS protein for tolerance to glyphosate containing herbicides. DAS-40278-9 express the AAD-1 protein to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) herbicides.

The scientific documentation provided in the application for genetically modified maize DP41149 x MON 890349 x MON 874119 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 DP41149 x MON 890349 x MON 874119 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 was not performed by the VKM GMO Panel.

Sammendrag

Genmodifisert mais DP41149 x MON 890349 x MON 874119 x DAS-40278-9 ble utviklet ved kryssing for å kombinere fire enkelt eventer: DP4114, MON 89034, MON 87411 og DAS-40278-9.

DP4114 uttrykker Cry1F-proteinet som gir resistens mot planteskadegjørere i slekten lepidopteran, Cry34Ab1 og Cry35Ab1 proteinene som gir resistens mot planteskadegjører i insektordenen Coleoptera (biller) og PAT-protein for å gi toleranse mot ugressmidlet glufosinat-ammonium. MON 89034 uttrykker proteinene Cry1A.105 ogCry2Ab2 som gir resistens mot planteskadegjørere i insektordenen lepidopterra (sommerfugler). MON 87411 uttrykker Cry3Bb1-proteinet som gir resistens mot planteskadegjørere i insektordenen Coleoptera (biller), og DvSnf7 dsRNA gir resistens mot rotorm, og CP4 EPSPS-proteinet som gjør planten tolerant mot ugressmiddelet glyfosat. DAS-40278-9 uttrykker proteinet AAD-1 som katalysere nedbrytningen av klassen av herbicider kjent som aryloxyphenoxypropionates (AOPP) og gir planten toleranse mot ugressmidlet 2,4-diklorfenoksyeddiksyre (2,4-D).

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen DP41149 x MON 890349 x MON 874119 x DAS-40278-9 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 DP41149 x MON 890349 x MON 874119 x DAS-40278-9 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 vedrørende egenskaper ved mais DP41149 x MON 890349 x MON 874119 x DAS-40278-9, 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 DP41143 x MON890343 x MON 874113 x DAS-40278-9 and sub-combinations (application EFSA GMO-NL-2020-171)

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-2020-171** Genetically modified maize DP41143 x MON890343 x MON 874113 x DAS-40278-9 and sub-combinations

2. Information related to the genetic modification:

Genetically modified maize DP41149 x MON 890349 x MON 874119 x DAS-40278-9 was developed by crossing to combine four single events: DP4114, MON 89034, MON 87411 and DAS-40278-9.

DP4114 express the Cry1F protein to confer protection against certain lepidopteran pests, the Cry34Ab1 and Cry35Ab1 proteins to confer protection against certain coleopteran pests and PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides. MON 89034 express the Cry1A.105 and Cry2Ab2 proteins to confer protection against certain lepidopteran pests. MON 87411 express the Cry3Bb1 protein to confer protection against certain coleopteran larvae and the DvSnf7 dsRNA confer protection against western corn rootworm, and the CP4 EPSPS protein for tolerance to glyphosate containing herbicides. DAS-40278-9 express the AAD-1 protein to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) herbicides.

Genes	**Proteins**
Cry1F	Cry1F
Cry34Ab1	Cry34Ab1
Cry35Ab1	Cry35Ab1
pat	PAT
Cry1A.105	Cry1A.105
Cry2Ab2	CryAb2
Cry3Bb1	Cry3Bb1
DvSnf7	dsRNA
cp4 epsps	CP4 EPSPS
add-1	ADD-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)	26.04.21
6. Deadline of EFSAs commenting period	26.07.21
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: NO: X
9. Date of submission from VKM	NA
10. Comment(s) to EFSA:	
11. If NO in item 8. – comments from VKM:	
VKM has not assessed the application during EFSAs commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.	
12. Need for national consideration(s)	YES: NO: X
13. If YES in item 12. – comments from VKM:	
14. If NO or NA in item 12. – comments from VKM:	

The VKM GMO Panel does not consider the introduced modifications in maize DP41143 x MON890343 x MON 874113 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 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	09.11.22
2. VKMs deadline for informing NFSA and EEA	09.12.22
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	YES: NO: NA: X
4. If YES in item 3 – Comments from VKM:	
5. If NO or NA in item 3 – Comment(s) and further considerations from VKM:	
VKM has not assessed the application during Stage 1. due to other pressing priorities.	
6. Follow-up item 12 (table 1) – comments from VKM	
The VKM GMO panel concludes that the introduced modifications in maize DP41143 x MON890343 x MON 874113 x DAS-40278-9 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 or NA 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 DP41143 x MON890343 x MON 874113 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 DP41149 x MON 890349 x MON 874119 x DAS-40278-9. Genetically modified maize DP41149 x MON 890349 x MON 874119 x DAS-40278-9 was developed by conventional crossing to combine the four single events: DP4114, MON 89034, MON 87411 and DAS-40278-9.

DP4114 expresses the Cry1F protein to confer protection against certain lepidopteran pests, the Cry34Ab1 and Cry35Ab1 proteins to confer protection against certain coleopteran pests and PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides. MON 89034 expresses the Cry1A.105 and Cry2Ab2 proteins to confer protection against certain lepidopteran pests. MON 87411 expresses the Cry3Bb1 protein to confer protection against certain coleopteran larvae and the DvSnf7 dsRNA confer protection against Western corn rootworm, and the CP4 EPSPS protein for tolerance to glyphosate containing herbicides. DAS-40278-9 expresses the AAD-1 protein to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) herbicides.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2020-171. 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 DP41149 x MON 890349 x MON 874119 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.

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) Assessment of genetically modified maize DP4114 x MON89034 x MON 87411 x DAS-40278-9 and sub-combinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA GMO-NL-2020-171). EFSA Journal 2022;20(11):7619 https://www.efsa.europa.eu/en/efsajournal/pub/7619