Vitenskapskomiteen for mat og miljø
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Assessment of genetically modified maize DP202216 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-159)

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Assessment of genetically modified maize DP202216 for food and feed uses, import and processing (application EFSA-GMO-NL-2019-159) 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 maize was produced by *Agrobacterium*-mediated transformation of maize cells. DP202216 maize has 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.

The scientific documentation provided in the application for genetically modified maize DP202216 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 DP202216 maize to imply potential specific health or environmental risks in Norway, compared to EU-countries.

The EFSA scientific Opinion is adequate also for Norwegian conditions. Therefore, a full risk assessment of DP202216 maize was not performed by the VKM GMO Panel.

Sammendrag

Mais DP202216 ble produsert ved *Agrobacterium*-mediert transformasjon av maisceller. Mais DP202216 har 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.

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 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAs risikovurdering er dermed tilstrekkelig også for norske forhold. VKMs GMO panel har derfor 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 DP202216 (application EFSA-GMO-NL-2019-159)

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-2019-159** **Genetically modified maize DP202216**

2. Information related to the genetic modification:

DP202216 maize was produced by *Agrobacterium*-mediated transformation of maize cells. DP202216 maize expresses genes encoding the proteins ZMM28 and PAT. The two proteins enhance grain yield potential and confere tolerance to the herbicide glufosinate-ammonium, respectively.

Genes	**Proteins**
zmm28	ZMM28
mo-pat	PAT

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)	23.09.2019	
6. Deadline of EFSAs commenting period	03.01.2020	
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 scientific consultation	YES: X NO:
9. Date of submission from VKM	Dec. 2019
10. Comment(s) to EFSA:	
"VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-plants. Data on glufosinate-ammonium residue levels, 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 DP202216 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 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	20.03.2024
2. VKMs deadline for informing NFSA and EEA	04.04.2024
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 outside the remit 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	
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. Answers from EFSA to VKM comments were satisfactory. The EFSA opinion (EFSA 2024) 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 event maize DP202216 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	XX.XX.XX

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize DP202216.

DP202216 maize expresses genes encoding the proteins ZMM28 and PAT. The two proteins enhance grain yield potential and confere tolerance to the herbicides glufosinate-ammonium, respectively.

The scientific documentation provided in the application for genetically modified maize DP202216 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 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion is adequate also for Norwegian conditions. Therefore, a full risk assessment of maize DP202216 was not performed by the VKM GMO Panel.

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

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