



VKM Report 2024:08

Assessment of genetically modified maize DP915635 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-172)

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

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Assessment of genetically modified maize DP915635 for food and feed uses, import and processing (application EFSA-GMO-NL-2020-172) 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.

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Summary

DP915635 is a genetically modified maize that expresses the insecticidal protein IPD079Ea for control of corn rootworm pests (*Diabrotica* spp.), the enzyme phosphinothricin acetyltransferase (PAT) for tolerance to glufosinate-ammonium herbicides, and the enzyme phosphomannose isomerase (PMI) that was used as a selectable marker. DP915635 was developed by site-specific integration using two sequential transformation steps. First, an integration site sequence (landing pad) was inserted at a specific location of the maize genome using microprojectile bombardment and a CRISPR-Cas9-mediated targeted insertion process. In the second step the transgene sequences required for expression were inserted into the landing pad in the maize genome by *Agrobacterium*-mediated transformation.

The scientific documentation provided in the application for DP915635 maize 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 DP915635 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 DP915635 maize was not performed by the VKM GMO Panel.

Sammendrag

DP915635 er en genmodifisert mais som uttrykker det insektsdrepende proteinet IPD079Ea som gir resistens mot enkelte skadegjørende billelarver (*Diabrotica* spp.), enzymet fosfinotricinacetyltransferase (PAT) for toleranse for ugressmiddelet glufosinat-ammonium, og enzymet fosfomannose isomerase (PMI) som ble brukt som seleksjonsmarkør. Mais DP915635 ble utviklet ved en to-trinns prosess for stedsspesifikk integrering av transgener i maisens genom. I første trinn ble det introdusert en DNA-sekvens som angir stedet i maisens genom hvor transgenene skal integreres ved hjelp av en kombinasjon av biolistikk (genkanon) og CRISPR-Cas9. I trinn to ble de aktuelle transgenene satt inn i det angitte stedet i genomet ved hjelp av *Agrobacterium*-mediert transformasjon.

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen er dekkende for risikovurdering, og i samsvar med EFSA's retningslinjer for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. De genetiske endringene i mais DP915635 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSA's risikovurdering er dermed tilstrekkelig også for norske forhold. Ettersom det ikke har blitt identifisert særnorske forhold vedrørende egenskaper ved mais DP915635, 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 DP915635 (application EFSA-GMO-NL-2020-172)

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-2020-172**Genetically modified maize
DP915635**2. Information related to the genetic modification:**

DP915635 maize expresses the insecticidal protein IPD079Ea for control of corn rootworm pests (*Diabrotica* spp.), the enzyme phosphinothricin acetyltransferase (PAT) for tolerance to glufosinate-ammonium herbicides, and the enzyme phosphomannose isomerase (PMI) that was used as a selectable marker. DP915635 was developed by site-specific integration using two sequential transformation steps. First, a landing pad was inserted at a specific location of the maize genome using microprojectile bombardment and a CRISPR-Cas9. In the second step the transgene sequences required for expression were inserted into the landing pad by *Agrobacterium*-mediated transformation.

Genes**Proteins***ipd079Ea*

IPD079Ea

mo-pat

PAT

pmi

PMI

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)**

11.06.2021

6. Deadline of EFSA's commenting period

13.09.2021

7. VKM's 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	NA	
10. Comment(s) to EFSA:		
11. If NO in item 8. – comments from VKM:		
VKM did not assess the application within the time frame of the EFSA scientific consultation		
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 DP915635 maize 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 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	17.01.2024
2. VKMs deadline for informing NFSA and EEA	17.02.2024
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 or NA in item 3 – Comment(s) and further considerations from VKM:	
VKM did not assess the application within the time frame of the EFSA scientific consultation	
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 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>The EFSA scientific Opinion (EFSA 2024) is adequate also for Norwegian conditions.</p>		
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		
<p>The VKM GMO Panel does not consider the introduced modifications in DP915635 maize 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	30.06.24	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize DP915635. DP915635 expresses the insecticidal protein IPD079Ea for control of corn rootworm pests (*Diabrotica* spp.), the enzyme phosphinothricin acetyltransferase (PAT) for tolerance to glufosinate-ammonium herbicides, and the enzyme phosphomannose isomerase (PMI) that was used as a selectable marker. DP915635 was developed by site-specific integration using two sequential transformation steps.

The scientific documentation provided in the application for DP915635 maize 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 DP915635 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 DP915635 maize 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>

EFSA (2024) Assessment of genetically modified maize DP915635 for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-172). <https://doi.org/10.2903/j.efsa.2024.8490>