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Assessment of genetically modified maize DP23211 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-163)

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 DP23211 for food and feed uses, import and processing (application EFSA-GMO-NL-2019-163) 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

DP23211 is a genetically modified maize that expresses the double-stranded ribonucleic acid (dsRNA) DvSSJ1, and the insecticidal protein IPD072Aa, both conferring resistance to corn rootworm pests. DP23211 maize also expresses the enzyme phosphinothricin acetyltransferase (PAT) for tolerance to glufosinate herbicide, and the enzyme phosphomannose isomerase (PMI) used as a selectable marker during development. DP23211 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 chromosome 1 with microprojectile bombardment. In the second step the transgene sequences required for expression were inserted into selected regenerated plants with a confirmed landing pad, by *Agrobacterium*-mediated transformation.

The DvSSJ1 dsRNA, is intended to down-regulate expression of the DvSSJ1 protein in the mid-gut of western corn rootworm (WCR; *Diabrotica virgifera virgifera* LeConte) via RNA interference (RNAi). The DvSSJ1 protein is important for maintaining the integrity of the paracellular pathway between epithelial cells, which separates the gut lumen from the interstitial space where metabolites and electrolytes are tightly regulated. The IPD072Aa protein is a non-pore forming protein that targets and disrupts midgut epithelial cells causing the breakdown of the epithelial lining. The IPD072Aa protein has activity limited to species within the order of Coleoptera (beetles).

The scientific documentation provided in the application for DP23211 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 DP23211 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 DP23211 maize was not performed by the VKM GMO Panel.

Sammendrag

DP23211 er en genmodifisert mais som uttrykker det dobbeltrådete RNAet (dsRNA) DvSSJ1, og det insektsdrepende proteinet IPD072Aa. Begge gir resistens mot enkelte skadegjørende billelarver (*Diabrotica* spp.). DP23211 uttrykker også enzymet fosfinotricinacetyltransferase (PAT) for toleranse for ugressmiddelet glufosinat, og enzymet fosfomannose isomerase (PMI) som ble brukt som seleksjonsmarkør under utvikling. Mais DP23211 ble utviklet ved en to-trinns prosess for stedsspesifikk integrering av transgener i maisens genom. I første trinn ble det introdusert (ved biolistikk/genkanon) en DNA-sekvens som angir stedet i maisens genom hvor transgenene skal integreres. I trinn to ble de aktuelle transgenene satt inn i planter med den angitte DNA-sekvensen ved hjelp av *Agrobacterium*-mediert transformasjon.

Hensikten med DvSSJ1 dsRNA, er å nedregulere uttrykket av proteinet DvSSJ1 («smooth septate junction protein 1») i tarmen på skadegjørende billelarver (*Diabrotica virgifera virgifera* LeConte), via RNA-interferens (RNAi). DvSSJ1-proteinet er viktig for transporten av metabolitter og elektrolytter over tarmepitelet (cellelaget som skiller tarm og bukhule).

Proteinet IPD072Aa er et ikke-poredannende protein som forårsaker nedbrytning av tarmepitelet hos arter innenfor insektsordenen Coleoptera (biller).

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen er dekkende for risikovurdering, og i samsvar med EFSAs retningslinjer for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. De genetiske endringene i mais DP23211 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAs risikovurdering er dermed tilstrekkelig også for norske forhold. Ettersom det ikke har blitt identifisert særnorske forhold vedrørende egenskaper ved mais DP23211, 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 DP23211 (application EFSA-GMO-NL-2019-163)

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-2019-163** Genetically modified maize DP23211
2. Information related to the genetic modification:	

Genes	**Proteins**
ipd072Aa	IPD072Aa
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)	16.04.2020	
6. Deadline of EFSAs commenting period	20.07.2020	
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 scientifc consultation	YES: X	NO:
9. Date of submission from VKM	17.07.2020	
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 residue levels, including relevant metabolites, in plant material from the field studies would support the assessment of food, feed, and environmental safety.*

The applicant has not described if the proteins are modified (accumulated or altered) upon processing. However, these proteins are easily degraded by enzymes (pepsin, pancreatin) upon consumption by humans and animals. Potential accumulation of IPD072Aa protein after processing would only affect the target organism or the genetically very near species and are not expected to be available to insect forage."

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 DP23211 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.
The VKM GMO Panel does not consider the introduced modifications in DP23211 maize to imply potential specific health or environmental risks in Norway, compared to EU-countries.

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 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	18.01.2024
2. VKMs deadline for informing NFSA and EEA	02.02.2024
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	Yes
4. If YES in item 3 – Comments from VKM:	
VKM is aware that herbicide residue levels are out of remit of the EFSA GMO-Panel.	
5. If NO or NA 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. The EFSA scientific Opinion is adequate also for Norwegian conditions.	
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 DP23211 maize 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 DP23211.

DP23211 is a genetically modified maize that expresses the double-stranded ribonucleic acid (dsRNA) DvSSJ1, and the insecticidal protein IPD072Aa, both conferring resistance to corn rootworm pests. DP23211 maize also expresses the enzyme phosphinothricin acetyltransferase (PAT) for tolerance to glufosinate herbicide, and the enzyme phosphomannose isomerase (PMI) used as a selectable marker during development.

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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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