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

VKM Bulletin 2024: 21

# Assessment of genetically modified maize DP910521 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (GMFF-2021-2473(#174))

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

VKM Bulletin 2024:21
Assessment of genetically modified maize DP910521 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (GMFF-2021-2473)

Scientific Opinion of the Panel on genetically modified organisms of the Norwegian Scientific Committee for Food and Environment
12.09.2024

ISSN: 2535-4019
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

Cover photo: Colourbox

Suggested citation: VKM, Monica Sanden, Eirill Ager-Wick, Johanna Bodin, Nur Duale, Anne Marthe Ganes Jevnaker, Kristian Prydz, Volha Shapaval, Ville Erling Sipinen and Tage Thorstensen (2024). Assessment of genetically modified maize DP910521 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (GMFF-2021-2473). Scientific Opinion of the Panel on genetically modified organisms – food and feed. VKM Bulletin 2024:21, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

# Assessment of genetically modified maize DP910521 for food and feed uses, import and processing (application GMFF-2021-2473) 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), 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

# Table of Contents

# Summary

DP910521 is a genetically modified maize created by site-specific integration (SSI) of transgenes into the maize genome. Maize DP910521 contains the transgenes *cry1B.34*, *pat* and *pmi*, which encode the proteins Cry1B.34, phosphinothricin acetyltransferase (PAT) and phosphomannose isomerase (PMI), respectively. Cry1B.34 is an insecticidal protein providing protection against certain Lepidopteran (order of butterflies and moths) pests, PAT is an enzyme that provides tolerance to glufosinate-ammonium herbicides, and PMI is an enzyme used as a selectable marker during development.

The scientific documentation provided in the application for genetically modified maize DP910521 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 DP910521 to imply potential specific health or environmental risks in Norway, compared to EU-countries. Therefore, a full risk assessment of maize DP910521 was not performed by VKM.

# Sammendrag

DP910521 er en genmodifisert mais utviklet ved stedsspesifikk integrering (SSI) av transgener i maisens genom/arvestoff. Mais DP910521 uttrykker transgenene *cry1B.34*, *pat* og *pmi*, som koder for henholdsvis proteinene Cry1B.34, phosphinothricin acetyltransferase (PAT) og phosphomannose isomerase (PMI). Cry1B.34 er et insekticid som gir resistens mot enkelte planteskadegjørere i insektordenen Lepidoptera (sommerfugler og møll), PAT er et enzym som gir økt toleranse for glufosinat-ammonium baserte ugressmidler, og PMI er et enzym benyttet som seleksjonsmarkør under utvikling av planten.

Søkers vitenskapelige dokumentasjon for genmodifisert mais DP910521 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 maisen tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. VKM har derfor ikke gjort en fullstendig risikovurdering av mais DP910521.

# 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 DP910521 (application GMFF-2021-2473)

## 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** | **GMFF-2021-2473**<br><br>Genetically modified maize DP910521 |

**2. Information related to the genetic modification:**

DP910521 is a genetically modified maize created by site-specific integration (SSI) of transgenes into the maize genome. Maize DP910521 contains the transgenes *cry1B.34*, *pat* and *pmi*, which encode the proteins Cry1B.34, phosphinothricin acetyltransferase (PAT) and phosphomannose isomerase (PMI), respectively. Cry1B.34 is an insecticidal protein providing protection against certain Lepidopteran (order of butterflies and moths) pests, PAT is an enzyme that provides tolerance to glufosinate ammonium herbicides, and PMI is an enzyme used as a selectable marker during development.

| ***Genes*** | **Proteins** |
|---|---|
| *cry1B.34* | Cry1B.34 |
| *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)** | 04.01.23 | |
| **6. Deadline of EFSAs commenting period** | 04.04.23 | |
| **7. VKMs assessment of the documentation in the application** | | |
| Applicants' documentation: | The VKM Panel on genetically modified organisms finds the documentation provided 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:** | | |
| 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 event maize DP910521 to imply potential specific health or environmental risks in Norway, compared to EU-countries. | | |
| **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 event maize DP910521 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 two weeks inform the NFSA and EEA on the following:

• Are EFSA's answer(s) to the Norwegian comments satisfactorily answered, or does 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** | 01.08.2024 |
| **2. VKMs deadline for informing NFSA and EEA** | 15.08.2024 |
| **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 in item 3 – Comment(s) and further considerations from VKM:** | |
| | |
| **6. Follow-up item 12 (table 1) – comments from VKM** | |
| The VKM GMO Panel does not consider the introduced modifications in event maize DP910521 to imply potential specific health or environmental risks in Norway, compared to EU-countries. | |
| **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 event maize DP910521 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.24 | |

# 2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize DP910521.

The scientific documentation provided in the application for maize DP910521 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 DP910521 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 DP910521 was not performed by VKM.

# 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