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

VKM Report 2023:4

# Assessment of genetically modified maize MIR162 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (renewal application EFSA-GMO-RX-025) and assessment of updated additional information

**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 MIR162 for food and feed uses, import and processing (renewal application EFSA-GMO-RX-025) under regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and assessment of updated additional information

## 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**: Monica Sanden (chair), Johanna Bodin, Nur Duale, Kristian Prydz, Volha Shapaval, Tage Thorstensen and Eirill Ager-Wick.

**VKM staff**: Anne Marthe Jevnaker and Ville Erling Sipinen

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# Summary

Event MIR162 is a genetically modified maize developed via *Agrobacterium tumefaciens* mediated transformation of maize embryos. MIR162 plants contain the transgenes *vip3Aa20,* a modified version of the native *vip3Aa1* from *Bacillus thuringiensis,* and the *pmi* gene from *Escherichia coli*. *Vip3Aa20* encodes the insecticidal Vip3Aa20-protein, conferring MIR162 with resistance to several species of lepidopteran (order of butterflies and moths) insect pests. *Pmi* encodes the enzyme phosphomannose isomerase (PMI) which catalyses the isomerization of mannose-6-phosphate to fructose-6-phosphate. PMI was used as a selectable marker during development of MIR162.

The scientific documentation provided in the renewal application (EFSA-GMO-RX-025) for maize MIR162 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 event MIR162 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 event MIR162 was not performed by the VKM GMO Panel.

**June 2023 update. Assessment of new information.**

VKM has assessed new information on maize MIR162 to determine whether the conclusions on the safety of maize MIR162 as a single event and as a part of stacked events remain valid. The new information is included in a European patent that reports a decrease in male fertility in some MIR162 inbred lines, pointing to a potential link between such decrease and the Vip3 protein expressed by maize MIR162.

The EFSA GMO Panel has published an evaluation of the data provided by the patent owner (EFSA 2023). EFSA found scarce support for a causal link between Vip3 and decreased fertility. The general hypothesis of an association between event MIR162 and altered fertility could not be confirmed. The EFSA GMO Panel conducted the safety assessment based on the conservative assumption that such an association exists. The EFSA GMO Panel concluded that a decrease in male fertility would have no impact on the previous conclusions on maize MIR162 and stacked events containing MIR162. The updated EFSA opinion is adequate also for Norwegian considerations.

# Sammendrag

MIR162 er en genmodifisert mais utviklet via *Agrobacterium tumefaciens* mediert transformasjon av maisembryoer. MIR162-planter inneholder transgenene *vip3Aa20,* en modifisert versjon av det opprinnelige genet *vip3Aa1* fra *Bacillus thuringiensis,* og et *pmi*-gen fra *Escherichia coli*. *Vip3Aa20* koder for det insekticide Vip3Aa20-proteinet, som gir plantene resistens mot flere arter av skadegjørere innen ordenen Lepidoptera (sommerfugler og møll). *Pmi* koder for enzymet fosfomannoseisomerase (PMI), som katalyserer isomerisering av mannose-6-fosfat til fruktose-6-fosfat. PMI ble brukt som transformasjonsmarkør i utviklingen av MIR162.

Den vitenskapelige dokumentasjonen i fornyelsessøknaden (EFSA-GMO-RX-025) for MIR162 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. EFSAs risikovurdering er derfor tilstrekkelig også for norske forhold. Ettersom det ikke har blitt identifisert særnorske forhold som gjelder egenskaper ved mais MIR162, har VKMs GMO panel ikke utført en fullstendig risikovurdering av maisen.

**Juni 2023, oppdatering. Vurdering av ny informasjon.**

VKM har vurdert ny informasjon om mais MIR162 for å avgjøre om konklusjonene om risiko knyttet til mais MIR162, i seg selv og som del av kryssede hybrider, fortsatt er gyldige. Den nye informasjonen er en del av et europeisk patent som rapporterer om redusert fertilitet hos hannplanter av MIR162 i innavlede maislinjer, og peker på en potensiell sammenheng mellom en slik reduksjon og Vip3-proteinet i mais MIR162.

EFSAs GMO panel har publisert en vurdering av dataene fra patentholder (EFSA 2023).

EFSAs vurdering er at det er lite støtte i dataene for antakelsen av en forbindelse mellom Vip3 og redusert fertilitet, og at hypotesen for en slik assosiasjon ikke kunne bekreftes. EFSAs vurdering ble utført ut ifra en konservativ antakelse om en reel assosiasjon. EFSAs konklusjon er at en redusert fertilitet hos hannplanter av MIR162 ikke vil endre tidligere konklusjoner om helse- eller miljørisiko ved MIR162 og kryssede hybrider der den inngår.

EFSAs oppdaterte risikovurdering er tilstrekkelig også for norske forhold.

# 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 MIR162 (renewal application EFSA-GMO-RX-025)

## 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-RX-025** |
| | Genetically modified maize MIR162 |

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

Maize MIR162 was developed via *Agrobacterium tumefaciens* mediated transformation of maize embryos. MIR162 plants contain the transgenes *vip3Aa20*, a modified version of the native *vip3Aa1* from *Bacillus thuringiensis*, and a *pmi*-gene from *Escherichia coli*. *Vip3Aa20* encodes the insecticidal Vip3Aa20 protein, conferring resistance to several species of lepidopteran (order of butterflies and moths) insect pests. *Pmi* encodes the enzyme phosphomannose isomerase (PMI) which catalyses the isomerization of mannose-6-phosphate to fructose-6-phosphate. PMI was used as a selectable marker during development of MIR162.

| ***Genes*** | **Proteins** |
|---|---|
| *vip3Aa20* | Vip3Aa20, insecticidal protein |
| *pmi* | PMI, phosphomannose isomerase |

| | | |
|---|---|---|
| **3. Previously assessed by VKM** | YES: X | NO: |

**4. If yes in item 3. – comments from VKM:**

Maize MIR162 was assessed by VKM as a single event in the application

EFSA/GMO/DE/2010/82.

And, on several occasions as part of different stacked maize events:

Bt11 x MIR162 x MIR604 x GA21 (EFSA/GMO/DE/2009/66)
Bt11 x MIR162 x GA21 (EFSA/GMO/DE/2009/67)
Bt11 x MIR162 x 1507 x GA21 (EFSA/GMO/DE/2010/86)
Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 (EFSA/GMO/DE/2011/103)
1507 x MON 810 x MIR162 x NK603 (EFSA/GMO/NL/2015/127)
MON 87427 x MON 89034 x MIR162 x NK603 (EFSA/GMO/NL/2016/131)
MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 (EFSA/GMO/NL/2016/134)
MON 87427 × MON 89034 × MIR162 × MON 87411 (EFSA/GMO/NL/2017/144)
Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 (EFSA/GMO/DE/2018/149)
MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9 (EFSA/GMO/NL/2018/151)

| | |
|---|---|
| **5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)** | 16.07.21 |
| **6. Deadline of EFSAs commenting period** | 16.10.21 |

**7. VKMs assessment of the documentation in the application**

| | |
|---|---|
| Applicants documentation: | The scientific documentation provided in the renewal application (EFSA-GMO-RX-025) for maize MIR162 is adequate 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**

**10. Comment(s) to EFSA:**

**11. If NO in item 8. – comments from VKM:**

VKM did not assess the application during the EFSA scientific consultation-period (stage 1) in accordance with the assignment from NFSA and NEA, due to other pressing priorities.

**12. Need for national consideration(s)** YES: NO: NA: X

**13. If YES in item 12. – comments from VKM:**

**14. If NO or NA in item 12. – comments from VKM:**

VKM did not assess the application during the EFSA scientific consultation-period (stage 1) in accordance with the assignment from NFSA and NEA, due to other pressing priorities.

**15. VKMs conclusion regarding the application:**

## 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** | 22.09.22 |
| **2. VKMs deadline for informing NFSA and EEA** | 22.10.22 |
| **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 did not assess the application during Stage 1. due to other pressing priorities. | |
| **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.<br><br>No member state comments regarding the application imply the need for follow-up by VKM.<br><br>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 in item 4. – comments from VKM** | |
| The VKM GMO Panel does not consider the introduced modifications in event maize MIR162 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** | 06.01.2023 |

# 2 Conclusions

The VKM GMO Panel has performed an assessment of the genetically modified maize MIR162. MIR162 plants contain the transgenes *vip3Aa20* and *pmi* which encode the proteins Vip3Aa20 and phosphomannose isomerase (PMI). Vip3Aa20 confers MIR162-plants with resistance to species of lepidopteran insect pests. PMI is an enzyme used as a selectable marker during the development of maize MIR162.

The VKM GMO panel has assessed the documentation in application EFSA-GMO-RX-025. 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 MIR162 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The insect resistance of maize MIR162 has no practical uses in Norway. The EFSA opinion is adequate also for Norwegian considerations.

**June 2023 update. Assessment of new information.**

VKM assessment of new information indicating a potential reduction in fertility of male plants in some MIR162 inbred lines, and possible link to the Vip3- protein.

VKM agrees with the EFSA conclusion that a potential reduction in fertility of male plants in single event maize MIR162 has no implications for the risk assessment of hybrid maize, containing MIR162, for food or feed uses. Nor would a reduced fertility in male MIR162-plants increase the likelihood of persistence or invasiveness of the crop in the case of accidental release of viable seeds into the environment.

# 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 MIR162 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-025). EFSA Journal 2022;20(9):7562. DOI: https://doi.org/10.2903/j.efsa.2022.7562

EFSA (2023) Risk assessment of additional information on maize MIR162. https://doi.org/10.2903/j.efsa.2023.7935