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# Assessment of genetically modified maize MON 95275 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2022-173 (GMFF-2022-5890))

**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 MON 95275 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (Application EFSA-GMO-NL-2022-173 (GMFF-2022-5890)). EFSA-Q-2022-00330

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# Assessment of genetically modified maize MON 95275 for food and feed uses, import and processing Application EFSA-GMO-NL-2022-173 (GMFF-2022-5890)) 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.

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# Summary

MON 95275 is a genetically modified maize developed via *Agrobacterium tumefaciens* transformation. MON 95275 plants contain the transgenes *mpp75Aa1.1* and *vpb4Da2* which encode the proteins Mpp75Aa1.1 (Cry) and Vpb4Da2 (Vip), and a double-stranded RNA transcript *DvSnf7*. The proteins Mpp75Aa1.1 and Vpb4Da2, and the double-stranded RNA transcript *DvSnf7*, provide protection against feeding damage caused by targeted coleopteran insect pests.

According to the applicant maize MON 95275 as a single product is not, and will not be, commercialised on its own, instead stacked products, made via traditional breeding, are the aimed commercial products. Therefore, the hypothetical import of the product in the EU is considered in the application.

The scientific documentation provided in the application for genetically modified maize MON 95275 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 MON 95275 to imply potential specific health or environmental risks in Norway, compared to EU-countries. Therefore, a full risk assessment of maize MON 95275 was not performed by VKM.

# Sammendrag

MON 95275 er en genmodifisert mais utviklet ved transformasjon av planteceller ved hjelp av *Agrobacterium tumefaciens*. MON 95275 uttrykker transgenene *mpp75Aa1.1* og *vpb4Da2*, som henholdsvis koder for proteinene Mpp75Aa1.1 (Cry) og Vpb4Da2 (Vip), og et dobbelttrådet RNA transkript *DvSnf7*. Transgenene gjør MON 95275 resistent mot enkelte planteskadegjørere i insektordenen *Coleoptera* (biller).

Ifølge produsenten (søker) vil mais MON 95275 som enkeltprodukt ikke bli kommersialisert på egen hånd, i stedet vil MON 95275 inngå i genmodifisert mais laget via tradisjonell avl. Søker vurderer derfor hypotetisk import av MON 95275 i søknaden til EU.

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen MON 95275 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 MON 95275.

# 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 MON 95275 (application EFSA-GMO-NL-2022-173 (GMFF-2022-5890))

## 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-2022-173 (GMFF-2022-5890)**<br><br>Genetically modified maize MON 95275 |

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

MON 95275 is a genetically modified maize developed via transformation with *Agrobacterium tumefaciens*. MON 95275 plants contain the transgenes *mpp75Aa1.1* and *vpb4Da2* which encode the proteins Mpp75Aa1.1 and Vpb4Da2, and a double-stranded RNA transcript *DvSnf7*. The proteins Mpp75Aa1.1 and Vpb4Da2, and the double-stranded RNA transcript *DvSnf7*, provide protection against feeding damage caused by targeted coleopteran insect pests.

| ***Genes*** | **Proteins/product** |
|---|---|
| *mpp75Aa1.1* | Mpp75Aa1.1 (Cry) |
| *vpb4Da2* | Vpb4Da2 (Vip) |
| *DvSnf7* | *double-stranded RNA* |

| | | |
|---|---|---|
| **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)** | 29.08.22 | |
| **6. Deadline of EFSAs commenting period** | 01.12.22 | |
| **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 public consultation** | YES: X | NO: |
| **9. Date of submission from VKM** | 30.11.22 | |
| **10. Comment(s) to EFSA:** | | |

VKM gave a comment to EFSA in the scientific hearing of EFSA-GMO-NL-2017-139 (Maize MON 87411, also containing *DvSnf7*):

*"VKM questions whether there is sufficient knowledge on the safe use of RNAi in GM-plants"*

EFSA replied:

"*EFSA is aware of the particularities that the risk assessment of RNAi-based GMPs can pose. EFSA has taken several actions to determine whether the existing risk assessment approaches for GMPs are appropriate for the risk assessment of RNAi based GMPs or require complementary or alternative approaches. An overview of EFSA's activities on the risk assessment of RNAi-based GMPs is given in Papadopoulou et al. (2020)".*

Regarding EFSA-GMO-NL-2022-173, maize MON 95275, the applicant has performed a bioinformatic evaluation of the *DvSnf7* sequence against the *Zea Mays* transcriptome. No potential off-target effects were identified.

In general, VKM finds this type of bioinformatic evaluation necessary for the risk assessment of GMPs containing RNAi.

VKM therefore recommends EFSA to include specific considerations in the guidance regarding different properties of GMPs containing RNAi, e.g., sequence screening for off-targets in the modified plant. This would be beneficial to ensure a common understanding between product developers and risk assessors regarding the type and extent of data needed to perform a risk assessment.

| | | |
|---|---|---|
| **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 MON 95275 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 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** | 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)** | YES: X NO: |
| **4. If YES in item 3 – Comments from VKM:** | |
| EFSAs answer is adequate. | |
| **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** | |
| The VKM GMO Panel does not consider the introduced modifications in maize MON 95275 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 maize MON 95275 to imply potential specific health or environmental risks in Norway, compared to EU-countries. | |
| **7. Need for a risk assessment** | YES: X NO: |
| **8. Date of deadline for risk assessment** | Not applicable |
| **9. Date of publication of assessment** | XX.XX.2024 |

# 2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize MON 95275.

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.

In general, VKM finds bioinformatic evaluations necessary for the risk assessment of GMPs containing RNAi. VKM has therefore recommended EFSA to include specific considerations in the guidance regarding different properties of GMPs containing RNAi, e.g., sequence screening for off-targets in the modified plant. This would be beneficial to ensure a common understanding between product developers and risk assessors regarding the type and extent of data needed to perform a risk assessment.

The GMO panel does not consider the introduced modifications in MON 95275 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 MON 95275 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