



VKM Report 2022:13

Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139)

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

VKM Report 2022:13

Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139)

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

ISBN: 978-82-8259-388-5

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](mailto:vkm@vkm.no)

[vkm.no](http://vkm.no)

Cover photo: Colourbox

Suggested citation: VKM, Johanna Bodin (Chair), Nur Duale, Anne Marthe Jevnaker, Monica Sanden, Ville Erling Sipinen, Tage Thorstensen and Rose Vikse (2022). Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139). Scientific Opinion of the Panel on genetically modified organisms (GMO) of the Norwegian Scientific Committee for Food and Environment. VKM Report 2022:13, ISBN: 978-82-8259-388-5, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

**Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations, for food and feed uses, import and processing (application EFSA-GMO-NL-2017-139) 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 before chair of the Panel): Johanna Bodin (chair), Nur Duale, Monica Sanden, Tage Thorstensen and Rose Vikse.

# Table of Contents

<b>Summary</b> .....	<b>5</b>
<b>Sammendrag</b> .....	<b>6</b>
<b>Background as provided by the Norwegian Food Safety Authority and the Norwegian Environment Agency</b> .....	<b>7</b>
<b>1 Assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations (application EFSA-GMO-NL-2017-139)</b> .....	<b>8</b>
1.1 Comments during the EFSA scientific consultation-period .....	8
1.2 Considerations after EFSA's publication of their scientific opinion – part 1.....	12
1.3 Considerations after EFSA's publication of their scientific opinion – part 2.....	13
<b>2 Conclusions</b> .....	<b>14</b>
<b>3 References</b> .....	<b>15</b>

# Summary

Stacked event MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is a genetically modified maize developed via conventional crossing, combining the six single maize events: MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122.

Transgenes of each single maize event is present in the stacked maize. The transgenes encode the following: CP4 EPSPS (glyphosate-herbicide tolerance); CspB (drought tolerance); NptII (selection marker/kanamycin-resistance); Cry1A.105, Cry2Ab2 and Cry1F (resistance to lepidopteran insect pests); PAT (glufosinat-ammonium herbicide tolerance); Cry3Bb1, Cry34Ab1, Cry35Ab1 and DvSnf7-dsRNA (resistance to coleopteran insect pests).

The scientific documentation provided in the application for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 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 concludes that the introduced modifications in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 do not imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion (EFSA, 2021) is adequate also for Norwegian considerations. Therefore, a full risk assessment of stacked maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was not performed by the VKM GMO Panel.

# Sammendrag

Mais MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 er en genmodifisert mais utviklet ved konvensjonell krysning av de seks maisene: MON 87427, MON 87460, MON 89034, 1507, MAN 87411 og 59122.

Transgenene fra hver av de seks maisene er også uttrykt i den kryssede maisen. Transgenene koder for følgende: CP4 EPSPS (glyfosattoleranse, ugressmiddel); CspB (tørketoleranse); NptII (seleksjonsmarkør/kanamycinresistens); Cry1A.105, Cry2Ab2 og Cry1F (insektsresistens, lepidoptera); PAT (glufosinat-ammonium -toleranse, ugressmiddel); Cry3Bb1, Cry34Ab1, Cry35Ab1 og DvSnf7-dsRNA (insektsresistens, coleoptera).

Den vitenskapelige dokumentasjonen i søknaden for den genmodifiserte maisen MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 er dekkende for risikovurdering, og i samsvar med EFSA's veiledning for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. VKMs GMO-panel konkluderer at de genetiske endringene i mais MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 ikke tilsier en økt helse- eller miljørisiko i Norge, sammenliknet med EU-land. EFSA's vurdering er tilstrekkelig også for norske forhold. VKMs GMO-panel har derfor 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 MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations (application EFSA-GMO-NL-2017-139)

## 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-2019-164**

Genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and sub-combinations

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

The stacked event MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is a genetically modified maize developed via conventional crossing, combining the six single maize events: MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122.

Transgenes of each single maize event is present in the stacked maize. The transgenes encode the following: CP4 EPSPS (glyphosate-herbicide tolerance); CspB (drought tolerance); NptII (selection marker/kanamycin-resistance); Cry1A.105, Cry2Ab2 and Cry1F (resistance to lepidopteran insect pests); PAT (glufosinat-ammonium herbicide tolerance); Cry3Bb1, Cry34Ab1, Cry35Ab1 and DvSnf7-dsRNA (resistance to coleopteran insect pests).

<i>Genes</i>	<b>Proteins</b>	<b>dsRNA</b>
<i>CP4 epsps</i>	CP4 EPSPS	
<i>cspb</i>	CspB	
<i>nptII</i>	NptII	
<i>cry1a.105</i>	Cry1A.105	
<i>cry2ab2</i>	Cry2Ab2	
<i>cry1f</i>	Cry1F	
<i>pat</i>	PAT	
<i>cry3bb1</i>	Cry3Bb1	
<i>cry34ab1</i>	Cry34Ab1	
<i>cry35ab1</i>	Cry35Ab1	
<i>snf 7</i>		DvSnf7

**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)**

31.05.2017

**6. Deadline of EFSA's commenting period**

26.09.2018

**7. VKM's assessment of the documentation in the application**

Applicants' documentation:

Additional literature used by VKM:

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 public consultation**

YES: X NO:

**9. Date of submission from VKM**

03.09.2018

**10. Comment(s) to EFSA:****Food and feed safety assessment**

1. VKM questions whether there is sufficient knowledge on the safe use of RNAi in GM-plants.
2. The applicant states: *"The CP4 EPSPS, CspB, NptII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and the DvSnf7 dsRNA have no synergistic or antagonistic effects to each other. The modes of biological activity are different for these proteins and there is no known or conceivable mechanism of interaction between all proteins which could lead to adverse health effects in animals or humans."* VKM opposes since this statement is not supported by any experimental data. Different modes of action do not necessarily exclude interaction.
3. VKM would have preferred that the applicant performed a nutritional feeding study on the stacked event with animals fed a high inclusion of maize gluten in their diets.

4. VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-plants. Data on glyphosate and glufosinate-ammonium residue levels, including their relevant metabolites, in plant material from field studies would support the assessment of food and feed safety.

**11. If NO or NA 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 concludes that the introduced modifications in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 do not imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion (EFSA, 2021) is adequate also for Norwegian considerations.

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

The scientific documentation provided in the application for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 is adequate for risk assessment, and in accordance with 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 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	
<b>1. Date of publication of EFSA opinion</b>	19.01.21
<b>2. VKMs deadline for informing NFSA and EEA</b>	19.02.21
<b>3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)</b>	YES: X    NO:
<b>4. If YES in item 3 – Comments from VKM:</b>	
The VKM GMO Panel considers the answers adequate	
<b>5. If NO or NA in item 3 – Comment(s) and further considerations from VKM:</b>	
<b>6. Follow-up item 12 (table 1) – comments from VKM:</b>	
The VKM GMO panel concludes that the introduced modifications in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 do not imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion (EFSA, 2021) is adequate also for Norwegian considerations.	
<b>7. Considerations from VKM regarding comments from EU member states and other countries under Annex G:</b>	
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		
<b>1. Need for further assessment(s)</b>	YES:	NO: X
<b>2. If YES in item 1. – Further considerations from VKM:</b>		
<b>3. If NO in item 1. – comments from VKM:</b>		
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 (EFSA, 2021) is adequate also for Norwegian considerations.		
<b>4. Need for national considerations</b>	YES:	NO: X
<b>5. If YES in item 4. – comments from VKM:</b>		
<b>6. If NO in item 4. – comments from VKM</b>		
The VKM GMO Panel does not consider the modifications in stacked event MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 to imply potential specific health or environmental risks in Norway compared to EU-countries.		
<b>7. Need for a risk assessment</b>	YES:	NO: X
<b>8. Date of deadline for risk assessment</b>	Not applicable	
<b>9. Date of publication of assessment</b>	29.04.22	

## 2 Conclusions

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2017-139 and the EFSA's scientific opinion (EFSA, 2021) on genetically modified stacked event maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122.

The stacked maize was developed via conventional crossing, combining the six single maize events: MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122. Transgenes of each single maize event is present in the stacked maize. The transgenes encode the following: CP4 EPSPS (glyphosate herbicide tolerance); CspB (drought tolerance); NptII (selection marker/kanamycin-resistance); Cry1A.105, Cry2Ab2 and Cry1F (resistance to lepidopteran insect pests); PAT (glufosinat-ammonium herbicide tolerance); Cry3Bb1, Cry34Ab1, Cry35Ab1 and DvSnf7-dsRNA (resistance to coleopteran insect pests).

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 concludes that the introduced modifications in maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 do not imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion is adequate also for Norwegian considerations. Therefore, a full risk assessment of stacked maize event MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 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 (2021) Scientific Opinion on the assessment of genetically modified maize MON 874279/MON 874609/MON 890349/15079/MON 874119/59122 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139). EFSA Journal 2021;19(1):6351, 45 pp. <https://doi.org/10.2903/j.efsa.2021.6351>. ISSN:1831-4732