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

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Assessment of genetically modified maize MON 87429 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-161)

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Assessment of genetically modified maize MON 87429 for food and feed uses, import and processing (application EFSA-GMO-NL-2019-161) 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.

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Summary

Event MON 87429 is a genetically modified maize developed via Agrobacterium tumefaciens transformation. MON 87429 plants contain the transgenes pat, dmo, ft_t and cp4 epsps. Maize MON 87429 encodes the DMO, PAT and FT_T proteins. In addition, maize MON 87429 encodes the CP4 EPSPS protein and utilises an endogenous maize RNAi regulatory element to suppress its expression in pollen. This results in a lack of viable pollen and thus male sterility when MON 87429 plants are exposed to glyphosate-containing herbicides at growth stages ranging from V8 to V13. This is part of a hybridisation system to be used in inbred lines to facilitate the hybrid seeds production. This is not considered an agronomic trait since the application of glyphosate outside the specific growth stages does not lead to male sterile plants but reduces plant yield compared to plants not expressing the same trait.

The scientific documentation provided in the application for genetically modified maize MON 87429 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 87429 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 event MON 87429 was not performed by the VKM GMO Panel.

Sammendrag

MON 87429 er en genmodifisert mais utviklet ved transformasjon av planteceller ved hjelp av *Agrobacterium tumefaciens*. MON 87429 planter utrykker transgenene *pat*, *dmo*, *ft_t* og *cp4 epsps*. Mais MON 87429 uttrykker DMO, PAT og FT_T proteiner. I tillegg uttrykker mais MON 87429 proteinet CP4 EPSPS og et endogent regulerende element (RNAi) i pollen. RNAi maskineriet som nedregulerer uttrykket av proteinet i pollen. Dette resulterer i mangel på levedyktig pollen, og dermed hannsterilitet, når MON 87429 planter blir sprøytet med ugressmidler med virkestoffet glyfosat i vekststadier fra V8 til V13. Dette er en del av et hybridiseringssystem som skal brukes i innavlede linjer for å lette produksjonen av hybridfrø. Dette regnes ikke som et agronomisk trekk siden bruken av glyfosat utenfor de spesifikke vekststadiene ikke fører til hannsterile planter, men reduserer utbyttet sammenlignet med planter som ikke uttrykker samme egenskap.

Søkers vitenskapelige dokumentasjon for den genmodifiserte mais MON 87429 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 MON 87429, 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 MON 87429 (application EFSA-GMO-NL-2019-161)

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-2019-161** Genetically modified maize MON 87429

2. Information related to the genetic modification:

Event MON 87429 is a genetically modified maize developed via *Agrobacterium tumefaciens* transformation. MON 87429 plants contain the transgenes *pat*, *dmo*, *ft_t* and *cp4 epsps*. Maize MON 87429 encodes the DMO, PAT and FT_T proteins. In addition, maize MON 87429 encodes the CP4-EPSPS protein and utilises an endogenous maize RNAi regulatory element to suppress its expression in pollen. This results in a lack of viable pollen and thus male sterility when MON 87429 plants are exposed to glyphosate-containing herbicides at growth stages ranging from V8 to V13. This is part of a hybridisation system to be used in inbred lines to facilitate the hybrid seeds production. This is not considered an agronomic trait since the application of glyphosate outside the specific growth stages does not lead to male sterile plants but reduces plant yield compared to plants not expressing the same trait.

Genes	**Proteins**
pat	PAT
dmo	DMO
ft_t	FT_T
cp4 epsps	CP4 EPSPS

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)	16.01.20	
6. Deadline of EFSAs commenting period	16.04.20	
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	14.04.20	

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 glufosinate, dicamba, quizalofop, glyphosate and 2,4-D herbicide residue levels, including relevant metabolites, in plant material from the field studies would support the assessment of food, feed, and environmental safety.

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 or NA in item 12. – comments from VKM:

The VKM GMO Panel does not consider the introduced modifications in event MON 87429 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	18.11.22	
2. VKMs deadline for informing NFSA and EEA	18.12.22	
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:		
Herbicide residue levels are not within the remit of the EFSA GMO Panel and are covered by other regulations (EC 396/2005).		
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 event MON 87429 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 87429 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	NA	
9. Date of publication of assessment	06.01.23	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize MON 87429. MON 87429 plants contain the transgenes *pat*, *dmo*, *ft_t* and *cp4 epsps*. Maize MON 87429 encodes the DMO, PAT and FT_T proteins. In addition, maize MON 87429 encodes the CP4 EPSPS protein and utilises an endogenous maize RNAi regulatory element to suppress its expression in pollen. This results in a lack of viable pollen and thus male sterility when MON 87429 plants are exposed to glyphosate-containing herbicides at growth stages ranging from V8 to V13. This is part of a hybridisation system to be used in inbred lines to facilitate the hybrid seeds production. This is not considered an agronomic trait since the application of glyphosate outside the specific growth stages does not lead to male sterile plants but reduces plant yield compared to plants not expressing the same trait.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2019-161. 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 event MON 87429 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA opinion is adequate also for Norwegian considerations.

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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