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Assessment of genetically modified maize 1507 x MIR162 x MON810 x NK603 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-127)

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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.

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Summary

Stacked event 1507 x MON810 x MIR162 x NK603 (EFSA-GMO-NL-2015-127) is a genetically modified maize obtained by traditional breeding between genetically modified 1507, MON810, MIR162 and NK603 maize. Maize 1507 x MON810 x MIR162 x NK603 maize confers herbicide tolerance to glyphosate and glufosinate-ammonium herbicides due to the presence of the CP4 EPSPS and PAT proteins, respectively, and protection against lepidopteran target pests based on the presence of the Cry1F, Cry1Ab and Vip3Aa20 proteins, conferring independent modes of action for insect protection. Maize 1507 contains the *cry1F* and *pat* genes, maize MON810 contains the *cry1Ab* gene, maize MIR162 contains the *vip3Aa20* gene, and maize NK603 the *cp4 epsps* gene.

The scientific documentation provided in the application for genetically modified maize 1507 x MON810 x MIR162 x NK603 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 stacked event 1507 x MON810 x MIR162 x NK603 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 stacked event 1507 x MON810 x MIR162 x NK603 was not performed by the VKM GMO Panel.

Sammendrag

Mais 1507 x MON810 x MIR162 x NK603 (EFSA-GMO-NL-2015-127) er en genmodifisert mais utviklet ved konvensjonell krysning av genmodifisert mais 1507, MON810, MIR162 og NK603. Mais 1507 x MON810 x MIR162 x NK603 utrykker proteinene CP4 EPSPS and PAT som gjør planten tolerant mot ugressmidlene glufosinat-ammonium og glyfosat. Videre utrykker mais 1507 x MON810 x MIR162 x NK603 proteinene Cry1F, Cry1Ab og Vip3Aa20 som gjør planten resistent mot enkelte planteskadegjørende. Mais 1507 uttrykker transgenene *cry1F* og *pat*, mais MON810 uttrykker transgenet *cry1Ab*, mais MIR162 uttrykker transgenet *vip3Aa20*, and mais NK603 uttrykker transgenet *cp4 epsps*.

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen 1507 x MON810 x MIR162 x NK603 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 1507 x MON810 x MIR162 x NK603 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 vedrørende egenskaper ved maisen, har VKMs GMO panel ikke utført en fullstendig risikovurdering av mais 1507 x MON810 x MIR162 x NK603.

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 1507 x MIR162 x MON810 x NK603 (application EFSA-GMO-NL-2015-127)

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-2015-127** Genetically modified 1507 x MON810 x MIR162 x NK603

2. Information related to the genetic modification:

Stacked event 1507 x MON810 x MIR162 x NK603 (EFSA-GMO-NL-2015-127) is a genetically modified maize obtained by traditional breeding between genetically modified 1507, MON810, MIR162 and NK603 maize. Maize 1507 x MON810 x MIR162 x NK603 maize confers herbicide tolerance to glyphosate and glufosinate-ammonium herbicides due to the presence of the CP4 EPSPS and PAT proteins, respectively, and protection against lepidopteran target pests based on the presence of the Cry1F, Cry1Ab and Vip3Aa20 proteins, conferring independent modes of action for insect protection.

Maize 1507 contains the *cry1F* and *pat* genes, maize MON810 contains the *cry1Ab* gene, maize MIR162 contains the *vip3Aa20* gene, and maize NK603 the *cp4 epsps* gene.

Genes	**Proteins**
cry1F	Cry1F
pat	PAT
cry1Ab	*Cry1Ab*
vip3Aa20	Vip3Aa20
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)	09.02.2016	
6. Deadline of EFSAs commenting period	09.05.2016	
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	09.05.2016		
10. Comment(s) to EFSA:			

Comparative assessments

A, 3.3. For compositional analysis: Based on the scientific information and tables given by the applicant for parameters required in OECD and EFSA guidelines using the analytical methods described, the VKM GMO Panel has the opinion that 1507 x MON810 x MIR162 NK603 maize grain and forage are compositionally similar to those of its conventional counterpart, and/or other conventional maize varieties.

A, 3.5. For effect of processing: The conclusions drawn by the applicant that "there are no metabolic pathways affected or new metabolites produced in 1507 x MON810 x MIR162 x NK603 maize" are not supported by the parameters provided using the targeted analyses described. Untargeted assays such as transcriptomics, proteomics and/or metabolomics are needed to support such statements. Although OECD and EFSA guidelines at present do not require such analyses, the conclusions, as they are currently worded, are misleading and the applicant should consider rephrasing or removing them.

Furthermore, maize gluten meal (MGM) is a commonly used protein-rich ingredient in feeds for companion animals and fish. Processing steps to produce MGM are quite mild and the newly expressed proteins, such as Cry1F, Cry1Ab and Vip3Aa20, will possibly be present in MGM at considerably higher concentrations than in unprocessed maize. Especially Vip3Aa20 is present at relatively high levels in unprocessed maize grain (mg per kg level) and the Norwegian VKM's GMO panel considers that documentation regarding levels expected in MGM would be of value for considerations regarding hazard identification for untested non-target animals such as dogs and cats, as well as salmon, trout and other carnivorous farmed fish species.

Food and feed safety assessment

A, 4. For toxicological assessment: Based on data provided by the applicant, the GMO panel is of the opinion that sufficient data are provided on the toxicological properties of the newly expressed proteins. No hazard indicating toxicity has been identified in any of the single event maize lines. However, information on synergistic/antagonistic interactions between the proteins in non-target organisms is lacking, especially at higher levels presumably present in processed maize products such as MGM (see above).

A, 5. For allergenicity and adjuvanticity: The applicant claims that insecticidal-proteins have not been identified as allergens or adjuvants. However, various studies indicate that effects due to Cry1Ac's adjuvant properties cannot be ruled out. Relevant levels of the insecticidal Bt proteins in processed maize products such as MGM (see above) should also be taken into consideration for allergenicity and adjuvanticity development in untested non-target animals.

A, 6. For nutritional assessment: Data provided did not reveal performance differences between feeding groups in the broiler study conducted with maize 1507 x MON810 x MIR162 x NK603 and its conventional counterpart and other commercial maize varieties. However, The VKM GMO panel is of the opinion that data on residues levels of the intended herbicides glyphosate and glufosinate should have been provided.

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 stacked event 1507 x MON810 x MIR162 x NK603 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	13.01.2021	
2. VKMs deadline for informing NFSA and EEA	13.02.2021	
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:		
The VKM GMO Panel considers the EFSA answers acceptable		
5. If NO in item 3 – Comment(s) and further considerations from VKM:		
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 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. Answers from EFSA to VKM comments were acceptable The EFSA scientific 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 stacked event 1507 x MON810 x MIR162 x NK603 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	29.04.22	

2 Conclusions

Stacked event 1507 x MON810 x MIR162 x NK603 (EFSA-GMO-NL-2015-127) is a genetically modified maize obtained by traditional breeding between genetically modified 1507, MON810, MIR162 and NK603 maize. Maize 1507xMON810xMIR162xNK603 maize confers herbicide tolerance to glyphosate and glufosinate-ammonium herbicides due to the presence of the CP4 EPSPS and PAT proteins, respectively, and protection against lepidopteran target pests based on the presence of the Cry1F, Cry1Ab and Vip3Aa20 proteins, conferring independent modes of action for insect protection. Maize 1507 contains the *cry1F* and *pat* genes, maize MON810 contains the *cry1Ab* gene, maize MIR162 contains the *vip3Aa20* gene, and maize NK603 the *cp4 epsps* gene.

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3 References

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