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Assessment of genetically modified maize NK603 × T25 × DAS-40278-9 and sub-combinations, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-164)

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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 NK603 × T25 × DAS-40278-9 is a genetically modified maize developed via conventional crossing, combining the three single events: NK603, T25 and DAS-40278-9. NK603 expresses the *CP4epsps* and *CP4epspsl214p* genes encoding the CP4EPSPS and CP4EPSPSL214P proteins conferring tolerance to glyphosate-containing herbicides; T25 expresses the *pat* gene encoding the PAT protein conferring tolerance to glufosinate-ammonium containing herbicides; and DAS-40278-9 expresses the *aad-1* gene encoding the AAD-1 protein to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-D containing herbicides.

The scientific documentation provided in the application for genetically modified maize NK603 × T25 × DAS-40278-9 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 NK603 × T25 × DAS-40278-9 to 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 event NK603 × T25 × DAS-40278-9 was not performed by the VKM GMO Panel.

Sammendrag

NK603 × T25 × DAS-40278-9 er en genmodifisert mais utviklet ved konvensjonell krysning av de tre maisene NK603, T25 og DAS-40278-9. Mais NK603 × T25 × DAS-40278-9 uttrykker transgenene *CP4epsps*, *CP4epspsl214p*, *pat* og *aad-1*. Transgenene gjør maisen tolerant for ugressmidlene glyfosat og glufosinat-ammonium, og gjør maisen i stand til å bryte ned ugressmidler tilhørende klassen «aryloxy-phenoxy-propionates» (AOPP), som gir økt toleranse for ugressmidler som inneholder 2,4-diklorfenoksy-eddikesyre (2,4-D).

Den vitenskapelige dokumentasjonen i søknaden for den genmodifiserte maisen er dekkende for risikovurdering, og i samsvar med EFSAs veiledning for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. De genetiske endringene i mais NK603 × T25 × DAS-40278-9 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAs 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 NK603 × T25 × DAS-40278-9 and sub-combinations (application EFSA-GMO-NL-2019-164)

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 NK603 × T25 × DAS-40278-9 and sub-combinations

2. Information related to the genetic modification:

Stacked event NK603 × T25 × DAS-40278-9 is a genetically modified maize developed via conventional crossing to combine three single events: NK603, T25 and DAS-40278-9. NK603 expresses the *CP4epsps* and *CP4epsps l214p* genes encoding the CP4 EPSPS and CP4 EPSPS L214P proteins conferring tolerance to glyphosate-containing herbicides; T25 expresses the *pat* gene encoding the PAT protein conferring tolerance to glufosinate-ammonium containing herbicides; and DAS-40278-9 expresses the *aad-1* gene encoding the AAD-1 protein to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-D containing herbicides.

Genes	**Proteins**
CP4 epsps	CP4 EPSPS
CP4epsps l214p	CP4 EPSPS L214P
pat	PAT
aad-1	AAD-1

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)	26.03.20	
6. Deadline of EFSAs commenting period	26.06.20	
7. VKMs assessment of the documentation in the application		

Applicants' documentation:

Additional literature used by VKM:

Documentation in compliance with Regulation (EU) No. 503/2013:	YES: NO:
Documentation in accordance with EFSA guidance for risk assessment of genetically modified plants (EFSA 2010, 2011):	YES: 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 or NA in item 8. – comments from VKM:	
VKM has not assessed the application (in 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 has not assessed the application (in stage 1) in accordance with the assignment from NFSA and NEA, due to other pressing priorities.	
15. VKMs conclusion regarding the application:	
Additional comments:	

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	13.12.21	
2. VKMs deadline for informing NFSA and EEA	13.01.22	
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	YES:	NO:
4. If YES in item 3 – Comments from VKM:		
5. If NO in item 3 – Comment(s) and further considerations from VKM:		
6. Follow-up item 12 (table 1) – comments from VKM:		
VKM has not assessed the application (in stage 1) in accordance with the assignment from NFSA and NEA, due to other pressing priorities.		
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. The EFSA scientific opinion (EFSA, 2021) 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 modifications in stacked event NK603 × T25 × DAS-40278-9 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	14.02.22	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize NK603 × T25 × DAS-40278-9. The stacked event NK603 × T25 × DAS-40278-9 is a genetically modified maize developed via conventional crossing of the three single events: *i)* NK603, which expresses the *CP4epsps* and *CP4epspsl214p* genes encoding the CP4EPSPS and CP4EPSPS-L214P proteins conferring tolerance to glyphosate-containing herbicides; *ii)* T25, which expresses the *pat* gene encoding the PAT protein conferring tolerance to glufosinate-ammonium containing herbicides, and; *iii)* DAS-40278-9, which expresses the *aad-1* gene encoding the AAD-1 protein to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-D containing herbicides.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2019-164 and the EFSAs scientific opinion (EFSA, 2021) on genetically modified maize NK603 × T25 × DAS-40278-9. 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 NK603 × T25 × DAS-40278-9 to 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 NK603 × T25 × DAS-40278-9 was not performed by the VKM GMO Panel.

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

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