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

VKM 2022:14

Assessment of genetically modified maize Bt11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (renewal application EFSA-GMO-RX-016)

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

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

ISBN: 978-82-8259-389-2
ISSN: 2535-4019
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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 Bt11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (renewal application EFSA-GMO-RX-016). Scientific Opinion of the Panel on genetically modified organisms (GMO) of the Norwegian Scientific Committee for Food and Environment. VKM Report 2022:14, ISBN: 978-82-8259-389-2, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

Assessment of genetically modified maize Bt11 for food and feed uses, import and processing (renewal application EFSA-GMO-RX-016) 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: Johanna Bodin (Chair), Monica Sanden, Nur Duale, Rose Vikse og Tage Thorstensen.

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Summary

Maize Bt11 was generated by protoplast transformation of a conventional maize line, introducing two new genes: the *cry1ab* gene from *Bacillus thuringiensis* subsp *kurstaki* HD-1, and a *pat* gene derived from *Streptomyces viridochromogenes* strain Tu494. The encoded proteins Cry1Ab and phosphinothricine acetyl-transferase (PAT), confer resistance to certain lepidopteran insect pests and tolerance to glufosinate-ammonium based herbicides, respectively.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-RX-016 and EFSAs scientific opinion on genetically modified maize Bt11. 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 and/or feed.

The VKM GMO panel concludes that the introduced modifications in maize Bt11 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 maize event Bt11 was not performed by the VKM GMO Panel.

Sammendrag

Maize Bt11 ble utviklet ved protoplasttransformasjon av en konvensjonell maislinje, for å introdusere to nye gener: *cry1ab-genet* fra *Bacillus thuringiensis* subsp *kurstaki* HD-1, og et *pat*-gen fra *Streptomyces viridochromogenes* stamme Tu494. Proteinene som genene koder for, Cry1Ab og fosphinothricine acetyl-transferase (PAT), gir henholdsvis motstand mot visse skadegjørende insekter (arter av Lepidoptera/sommerfugler) og toleranse for glufosinat-ammonium baserte ugressmidler.

VKMs GMO-panel har vurdert dokumentasjonen til søknad EFSA-GMO-RX-016, og EFSAs vurdering av genmodifisert mais BT11 (EFSA, 2021). Den vitenskapelige dokumentasjonen i søknaden er tilstrekkelig for risikovurdering, og i samsvar med EFSAs veiledning for risikovurdering av genmodifiserte planter til bruk i mat og/eller fôr.

VKMs GMO-panel konkluderer at de genetiske endringene i mais BT11 ikke tilsier en økt helse- eller miljørisiko i Norge, sammenlignet med EU-land. EFSAs vurdering (EFSA, 2021) er tilstrekkelig også for norske hensyn. VKMs GMO-panel har derfor ikke utført en fullstendig risikovurdering av mais BT11.

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 Bt11 (application EFSA-GMO-RX-016)

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-RX-016** Genetically modified maize Bt11

2. Information related to the genetic modification:

Maize Bt11 was developed by protoplast transformation of a conventional maize line, introducing two new genes: the *cry1ab* gene from *Bacillus thuringiensis* subsp *kurstaki* HD-1, and a *pat* gene derived from S*treptomyces viridochromogenes* strain Tu494. The encoded proteins Cry1Ab and phosphinothricine acetyl-transferase (PAT), confer resistance to certain lepidopteran insect pests and tolerance to glufosinate-ammonium based herbicides, respectively.

Genes	**Proteins**
cry1ab	Cry1Ab
pat	phosphinothricine acetyl-transferase

3. Previously assessed by VKM	YES:X	NO:

4. If yes in item 3. – comments from VKM:

Bt11 has previously been risk assessed by the VKM GMO panel (VKM 2005, VKM 2007, VKM 2014). Bt11 has also been evaluated by the VKM GMO Panel as a component of several stacked GM maize events (VKM 2008, VKM 2009a,b,c,d,e VKM 2012a,b, 2013a,b,c). These assessments are available at https://vkm.no/

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	26 November 2018
6. Deadline of EFSAs commenting period	4 March 2019

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: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	4 March 2019
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-ammonium 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 in item 12. – comments from VKM:	
The VKM GMO panel concludes that the introduced modifications in maize Bt11 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 is adequate for risk assessment, and in accordance with the EFSA guidance on risk assessment of genetically modified plants for use in food and/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:	
Herbicide residue levels is not part of the mandate of the EFSA GMO Panel. The answer from the EFSA GMO panel is therefore considered adequate.	
5. If NO in item 3 – Comment(s) and further considerations from VKM:	
6. Follow-up item 12 (table 1) – comments from VKM	
The EFSA scientific opinion is adequate also for Norwegian considerations.	
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 uncertainties and knowledge gaps. It shall be stated within which areas there are knowledge gaps, and whether uncertainties, quality of 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 maize event BT11 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	29.04.2022	

2 Conclusions

Maize Bt11 was generated by protoplast transformation of a conventional maize line, introducing two new genes: the *cry1ab* gene from *Bacillus thuringiensis* subsp *kurstaki* HD-1, and a *pat* gene derived from *Streptomyces viridochromogenes* strain Tu494. The encoded proteins Cry1Ab and phosphinothricine acetyl-transferase (PAT), confer resistance to certain lepidopteran insect pests and tolerance to glufosinate-ammonium based herbicides, respectively.

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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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