



VKM Report 2023:2

Assessment of genetically modified cotton 281-24-236 × 3006-210-23 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-019)

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

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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.

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Summary

The genetically modified cotton 281-24-236 x 3006-210-23 was produced by conventional crossing between lines of the genetically modified cotton events 281-24-236 and 3006-210-23 to combine resistance to certain lepidopteran insect pests. Cotton 281-24-236 x 3006-210-23 contains the *cry1F* gene from event 281-24-236, the *cry1Ac* gene from event 3006-210-23 and the *pat* genes from both events encoding the Cry1F, Cry1Ac and PAT proteins. The proteins Cry1F and Cry1Ac provide the plant resistance against certain lepidopteran pests. The PAT protein was used as a selectable marker during transformation processes.

The scientific documentation provided in the application for genetically modified cotton 281-24-236 x 3006-210-23 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 cotton 281-24-236 x 3006-210-23 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 cotton was not performed by the VKM GMO Panel.

Sammendrag

Den genmodifiserte bomullen 281-24-236 x 3006-210-23 ble produsert ved konvensjonell kryssing mellom de genmodifiserte bomulls linjene 281-24-236 og 3006-210-23. Bomull 281-24-236 x 3006-210-23 uttrykker genet *cry1F* fra den genmodifiserte bomullen 281-24-236, *cry1Ac* genet fra den genmodifiserte bomullen 3006-210-23 og *pat* genene fra begge linjene. Disse genene koder for henholdsvis Cry1F, Cry1Ac og PAT proteinene.

Proteinene Cry1F og Cry1Ac gir planten resistent mot planteskadegjørere i insektordenen lepidoptera (sommerfugler). PAT proteinet gjør plantene tolerante for ugressmidlet glufosinate ammonium, og ble benyttet som en markør under transformasjonsprosesser.

Søkers vitenskapelige dokumentasjon for den genmodifiserte bomullen 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 bomull 281-24-236 x 3006-210-23 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 bomull 281-24-236 x 3006-210-23, har VKMs GMO panel ikke utført en fullstendig risikovurdering av bomullen.

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 cotton 281-24-236 × 3006-210-23 (application EFSA-GMO-RX-019)

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-019**

Genetically modified cotton 281-24-236 × 3006-210-23

2. Information related to the genetic modification:

The genetically modified cotton 281-24-236 x 3006-210-23 was produced by conventional crossing between lines of the genetically modified cotton events 281-24-236 and 3006-210-23 to combine resistance to certain lepidopteran insect pests. Cotton 281-24-236 x 3006-210-23 contains the cry1F gene from event 281-24-236, the cry1Ac gene from event 3006-210-23 and the pat genes from both events encoding the Cry1F, Cry1Ac and PAT proteins. The proteins Cry1F and Cry1Ac provide the plant resistance against certain lepidopteran pests. The PAT protein was used as a selectable marker during transformation processes.

Genes**Proteins***cry1F*

Cry1F

cry1Ac

Cry1Ac

pat

PAT

3. Previously assessed by VKM

YES: X

NO:

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

Application EFSA-GMO-NL-2005-16 (cotton 281-24-236 x 3006-210-23) was assessed by VKM in 2005.

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)

21.05.21

6. Deadline of EFSA's commenting period

21.08.21

7. VKM's 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 EFSA's public consultation	YES:	NO: X
9. Date of submission from VKM	NA	
10. Comment(s) to EFSA:		
11. If NO in item 8. – comments from VKM:	VKM has not assessed the application during EFSA's commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.	
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 does not consider the introduced modifications in cotton 281-24-236 × 3006-210-23 to imply potential specific health or environmental risks in Norway, compared to EU-countries.	
15. VKM's 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 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	
1. Date of publication of EFSA opinion	10.11.22
2. VKMs deadline for informing NFSA and EEA	10.12.22
3. If YES in item 8. (Table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	YES: NO: NA: X
4. If YES in item 3 – Comments from VKM:	
5. If NO or NA in item 3 – Comment(s) and further considerations from VKM:	
VKM has not assessed the application during EFSA's commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.	
6. Follow-up item 12 (table 1) – comments from VKM	
The VKM GMO panel concludes that the introduced modifications in cotton 281-24-236 x 3006-210-23 do not imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion (EFSA, 2022) 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 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		
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:		
<p>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.</p> <p>Answers from EFSA to VKM comments were satisfactory.</p> <p>The EFSA opinion is adequate also for Norwegian considerations.</p>		
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		
<p>The VKM GMO Panel does not consider the introduced modifications in cotton 281-24-236 × 3006-210-23 to imply potential specific health or environmental risks in Norway, compared to EU-countries.</p>		
7. Need for a risk assessment	YES:	NO: X
8. Date of deadline for risk assessment	Not applicable	
9. Date of publication of assessment	06.01.23	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified cotton 281-24-236 x 3006-210-23. The genetically modified cotton 281-24-236 x 3006-210-23 was produced by conventional crossing of the genetically modified cotton events 281-24-236 and 3006-210-23 to combine resistance to certain lepidopteran insect pests. Cotton 281-24-236 x 3006-210-23 contains the *cry1F* gene from event 281-24-236, the *cry1Ac* gene from event 3006-210-23 and the *pat* genes from both events encoding the Cry1F, Cry1Ac and PAT proteins. The proteins Cry1F and Cry1Ac provide the plant resistance against certain lepidopteran pests. The PAT protein was used as a selectable marker during transformation processes.

The VKM GMO panel has assessed the documentation in the renewal application EFSA-GMO-RX-019. 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 cotton 281-24-236 x 3006-210-23 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The modifications present in cotton 281-24-236 x 3006-210-23 have no practical uses in Norway. The EFSA opinion is adequate also for Norwegian considerations.

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>

VKM (2005) UTTALELSE OM DOW AGROSCIENCES GENMODIFISERTE BOMULL 281-24-236 x 3006-210-23 (EFSA/GMO/NL/2005/16)
<https://www.vkm.no/download/18.13dd6752161d1e853a1140cb/1519726279508/Risikovurdering%20av%20genmodifisert%20bomull%20281-24-236%203006-210-23.pdf>

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