



VKM 2022:6

Assessment of genetically modified cotton GHB811 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-ES-2018-154)

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

14.02.2022

ISBN: 978-82-8259-381-6

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 cotton GHB811 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-ES-2018-154). Scientific Opinion of the Panel on genetically modified organisms (GMO) of the Norwegian Scientific Committee for Food and Environment. VKM Report 2022:6, ISBN: 978-82-8259-381-6, ISSN: 2535-4019. Norwegian Scientific Committee for Food and Environment (VKM), Oslo, Norway.

Assessment of genetically modified cotton GHB811 for food and feed uses, import and processing (application EFSA-GMO-ES-2018-154) 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

Cotton GHB811 is derived from the cotton variety Coker 312, which was transformed by *Agrobacterium*-mediated gene transfer technology. Cotton GHB811 was developed to confer tolerance to glyphosate-based herbicides and to HPPD (hydroxyphenylpyruvate dioxygenase) -inhibitor herbicides such as Isoxaflutole.

The two genes *2mepsps* and *hppdPFW336-1Pa* expressed by cotton GHB811, encode the modified proteins (enzymes) 2mEPSPS (5-enolpyruvyl-shikimate-3-phosphate synthase) and HPPD W336. Both enzymes are insensitive to (have low affinity for) their target herbicides, glyphosate and HPPD-inhibitors, respectively.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-ES-2018-154 and EFSA's scientific opinion on genetically modified cotton GHB811. 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 VKM GMO panel does not consider the introduced modifications in cotton GHB811 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 cotton event GHB811 was not performed by the VKM GMO Panel.

Sammendrag

Bomull GHB811 er avledet fra bomullssorten Coker 312, som ble transformert ved *Agrobacterium*-mediert genoverføring. Bomullen ble utviklet for å tolerere glyfosat-baserte ugressmidler, og ugressmidler som tilhører kategorien HPPD (hydroksyfenylpyruvat dioksygenase) -hemmere, f.eks. isoksaf lutol.

De to genene *hppdPFW336-1Pa* og *2mepsps* uttrykt i bomull GHB811 koder for de modifiserte proteinene (enzymene), 2mEPSPS (5-enolpyruvyl-shikimate-3-phosphate synthase) og HPPD W336. Begge enzymene er ufølsomme (har lav affinitet) for sine respektive ugressmidler, glyfosat (2mEPSPS) og HPPD-hemmere (HPPD W336).

VKMs GMO-panel har vurdert dokumentasjonen til søknad EFSA-GMO-ES-2018-154, og EFSAAs vurdering av genmodifisert bomull GHB811 (EFSA, 2021). Den vitenskapelige dokumentasjonen i søknaden er tilstrekkelig for risikovurdering, og i samsvar med EFSAAs veiledning for risikovurdering av genmodifiserte planter til bruk i mat eller fôr.

De genetiske endringene i bomull GHB811 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAAs vurdering (EFSA, 2021) er tilstrekkelig også for norske hensyn. VKMs GMO panel har derfor ikke utført en fullstendig risikovurdering av bomull GHB811.

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 GHB811 (application EFSA-GMO-ES-2018-154)

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-ES-2018-154**

Genetically modified cotton GHB811

2. Information related to the genetic modification:

Event GHB811 is a genetically modified cotton developed via *Agrobacterium tumefaciens* transformation. GHB811 plants contain the transgenes *2mepsps* and *hppdPFW336-1Pa*, that encode the modified proteins (enzymes) 2mEPSPS and HPPD W336. Both enzymes are insensitive to their target herbicides, glyphosate and HPPD-inhibitors, respectively.

2mepsps

The coding sequence of the wild-type gene (*epsps*) for maize 5-enol pyruvylshikimate-3-phosphate synthase was modified by the replacements of the amino acid at positions 102 (substitution of threonine by isoleucine) and position 106 (substitution of proline by serine). These modifications confer to the protein a decreased binding affinity for glyphosate, allowing it to maintain sufficient enzymatic activity in the presence of the herbicide.

hppdPFW336-1Pa

The coding sequence of the 4-hydroxyphenylpyruvate dioxygenase of *Pseudomonas fluorescens* strain A32 was modified by the replacement of the amino acid Glycine 336 with a Tryptophan.

Genes**Proteins***2mepsps*

2mEPSPS (5-enolpyruvyl-shikimate-3-phosphate synthase)

hppdPFW336-1Pa

HPPD W336 (4-hydroxyphenylpyruvate dioxygenase)

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 January 2019

6. Deadline of EFSA's commenting period

19 April 2019

7. VKM's 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
EFSA's public consultation**

YES: NO: X

9. Date of submission from VKM

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: 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 during EFSA's commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.

15. VKM's conclusion regarding the application:

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	16.08.2021		
2. VKMs deadline for informing NFSA and EEA	16.09.2021		
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 Stage 1. due to other pressing priorities.		
6. Follow-up item 10 (table 1) – comments from VKM	VKM has not assessed the application during Stage 1. 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 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 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 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 event GHB811 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 cotton GHB811.

Event GHB811 (application EFSA-GMO-ES-2018-154) is a genetically modified cotton developed via *Agrobacterium tumefaciens* transformation. GHB811 plants contain the transgenes *2mepsps* and *hppdPFW336-1Pa*, that encode the modified proteins (enzymes) 2mEPSPS and HPPDW336. Both enzymes are insensitive to (have low affinity for) their respective target herbicides: glyphosate (2mEPSPS) and HPPD-inhibitors (HPPDW336).

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-ES-2018-154 and EFSA's scientific opinion on genetically modified cotton GHB811. 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.

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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>

EFSA (2021) Scientific Opinion on the assessment of genetically modified cotton GHB811 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-ES-2018-154). EFSA Journal 2021;19(8):6781, 29 pp. <https://doi.org/10.2903/j.efsa.2021.6781>
ISSN: 1831-4732