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# Summary

Cotton GHB614 is derived from the cotton variety Coker 312 which was transformed by *Agrobacterium*-mediated gene transfer technology. Cotton GHB614 expresses a modified *epsps* (*2mepsps*) maize gene leading to the production of a modified 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS) enzyme. The enzyme is insensitive to glyphosate and thereby confers tolerance in cotton GHB614 to glyphosate-based herbicides.

A risk assessment of cotton GHB614 was first performed by the VKM GMO Panel in connection with the original application, EFSA-GMO-NL-2008-51, in 2009 (VKM 2009). An updated risk assessment was published in 2016 (VKM 2016).

The scientific documentation provided in the original application for genetically modified cotton GHB614 was adequate for risk assessment, and in accordance with EFSA guidance on risk assessment of genetically modified plants for use in food or feed (EFSA 2011; VKM 2016).

VKM did not assess the renewal application EFSA-GMO-RX-018 during EFSA's commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.

However, the VKM GMO panel has assessed the documentation in the application EFSA-GMO-RX-018 and EFSA's scientific opinion on genetically modified cotton GHB614. 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 GHB614 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion is, therefore, adequate also for Norwegian considerations.

# Sammendrag

Bomull GHB614 er avledet fra bomullssorten Coker 312 som ble transformert ved *Agrobacterium*-mediert genoverføring. Bomull GHB614 uttrykker et modifisert *epsps* gen (*2mepsps*) fra mais som fører til produksjon av et modifisert 5-enolpyruvyl-shikimate-3-fosfatsyntase (2mEPSPS) enzym. Enzymet hemmes ikke av glyfosat og gir dermed bomull GHB614 økt toleranse for glyfosatbaserte ugressmidler.

Bomull GHB614 ble første gang risikovurdert av VKMs faggruppe for GMO i 2009 (VKM, 2009) i forbindelse med EFSA's offentlige høring av den opprinnelige søknaden EFSA-GMO-NL-2008-51. En oppdatert risikovurdering ble publisert i 2016 (VKM, 2016).

Søkers vitenskapelige dokumentasjon i den originale søknaden for den genmodifiserte bomullen GHB614 er dekkende for risikovurdering, og er i samsvar med EFSA retningslinjer for risikovurdering av genmodifiserte planter til bruk i mat eller fôr (EFSA, 2011; VKM, 2016).

VKM vurderte ikke fornyelsessøknaden EFSA-GMO-RX-018 under EFSA's høringsperiode i henhold til oppdraget fra NFSA og NEA, på grunn av andre prioriteringer.

VKM faggruppe for GMO har imidlertid vurdert dokumentasjonen i søknad EFSA-GMO-RX-018 og EFSA's vitenskapelige vurdering av genmodifisert bomull GHB614. Den vitenskapelige dokumentasjonen i søknaden er tilstrekkelig for risikovurdering, og i samsvar med EFSA veiledning om risikovurdering av genmodifiserte planter til bruk i mat eller fôr. VKMs GMO faggruppe for GMO anser ikke de genetiske endringene i bomull GHB614 for å innebære potensiell helse- eller miljørisiko i Norge, sammenlignet med EU-land. EFSA's vitenskapelige vurdering er tilstrekkelig også for norske hensyn.

# 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 GHB614 (renewal application EFSA-GMO-RX-018)

## 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 plants.
- 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-018**

Genetically modified cotton GHB614

**2. Information related to the genetic modification:**

Event GHB614 is a genetically modified cotton developed via *Agrobacterium tumefaciens* transformation.

GHB614 plants contain the transgene *2mepsps*, a modified version of the *epsps* gene derived from maize, which encodes the enzyme 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS). 2mEPSPS differs from the wild type maize enzyme EPSPS by two amino acid substitutions (Threonine102 replaced by Isoleucine, and Proline106 replaced by Serine), resulting in unchanged enzymatic properties, with the exception of the insensitivity to glyphosate. This provides the plants tolerance to glyphosate-based herbicides.

**Genes**

*2mepsps*

**Proteins**

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

**3. Previously assessed by VKM**

YES: X

NO:

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

A risk assessment of cotton GHB614 was first performed by the VKM GMO Panel in connection with the original application, EFSA-GMO-NL-2008-51, in 2009 (VKM 2009). An updated risk assessment was published in 2016 (VKM 2016).

VKM concluded in 2016:

*"Cotton is not cultivated in Norway, and there are no cross-compatible wild or weedy relatives of cotton in Europe.*

*Based on current knowledge and except for the introduced trait, the VKM GMO Panel concludes that cotton GHB614 is nutritionally, compositionally, phenotypically and agronomically equivalent to and as safe as its conventional counterpart and other cotton cultivars.*

*Considering the intended uses, which exclude cultivation, the VKM GMO Panel concludes that GHB614 does not represent an environmental risk in Norway."*

<b>5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)</b>	11.08.2020
<b>6. Deadline of EFSAs commenting period</b>	14.11.2020
<b>7. VKMs assessment of the documentation in the application</b>	
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:
<b>8. Comments submitted from VKM during EFSAs public consultation</b>	YES: NO: X
<b>9. Date of submission from VKM</b>	
<b>10. Comment(s) to EFSA:</b>	
<b>11. If NO in item 8. – comments from VKM:</b>	
VKM has not assessed the application during EFSAs commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.	
<b>12. Need for national consideration(s)</b>	YES: NO: NA: X
<b>13. If YES in item 12. – comments from VKM:</b>	
<b>14. If NO or NA in item 12. – comments from VKM:</b>	
VKM has not assessed the application during EFSAs commenting period in accordance with the assignment from NFSA and NEA, due to other pressing priorities.	
<b>15. VKMs conclusion regarding the application:</b>	

## 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			
<b>1. Date of publication of EFSA opinion</b>		07.07.21	
<b>2. VKMs deadline for informing NFSA and EEA</b>		07.08.21	
<b>3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)</b>	YES:	NO:	NA: X
<b>4. If YES in item 3 – Comments from VKM:</b>			
<b>5. If NO or NA in item 3 – Comment(s) and further considerations from VKM:</b>	VKM has not assessed the application during Stage 1. due to other pressing priorities.		
<b>6. Follow-up item 10 (table 1) – comments from VKM</b>	VKM has not assessed the application in accordance with the assignment from NFSA and NEA, due to other pressing priorities.		
<b>7. Considerations from VKM regarding comments from EU member states and other countries under Annex G:</b>	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		
<b>1. Need for further assessment(s)</b>	YES:	NO: X
<b>2. If YES in item 1. – Further considerations from VKM:</b>		
<b>3. If NO in item 1. – comments from VKM</b>		
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 opinion is adequate also for Norwegian considerations.		
<b>4. Need for national considerations</b>	YES:	NO: X
<b>5. If YES in item 4. – comments from VKM:</b>		
<b>6. If NO or NA in item 4. – comments from VKM</b>		
The VKM GMO Panel does not consider the modifications in event GHB614 to imply potential specific health or environmental risks in Norway, compared to EU-countries.		
<b>7. Need for a risk assessment</b>	YES:	NO: X
<b>8. Date of deadline for risk assessment</b>	NA	
<b>9. Date of publication of assessment</b>	14.02.22	

## 2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified cotton GHB614.

Event GHB614 (application EFSA-GMO-RX-018) is a genetically modified cotton developed via *Agrobacterium tumefaciens* transformation. GHB614 plants contain the transgene *2mepsps*, a modified version of the *epsps* gene derived from maize, which encodes the enzyme 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS). 2mEPSPS differs from the wild type maize enzyme EPSPS by two amino acid substitutions (Threonine102 replaced by Isoleucine, and Proline106 replaced by Serine), resulting in unchanged enzymatic properties, with the exception of the insensitivity to glyphosate. This provides the plants tolerance to glyphosate-based herbicides.

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The VKM GMO panel does not consider the introduced modifications in cotton GHB614 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion is adequate also for Norwegian considerations.

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*Considering the intended uses, which exclude cultivation, the VKM GMO Panel concludes that GHB614 does not represent an environmental risk in Norway."*

### 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 GHB614 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA–GMO–RX–018). EFSA Journal 2021;19(7):6671, 12 pp. <https://doi.org/10.2903/j.efsa.2021.6671>

VKM (2009) Helse- og miljørisikovurdering av genmodifisert bomull GHB614 fra Bayer CropScience (EFSA/GMO/NL/2008/51). <https://vkm.no/risikovurderinger>

VKM (2016) Final health and environmental risk assessment of genetically modified cotton GHB614 (Application EFSA/GMO/NL/2008/51). <https://vkm.no/>