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Assessment of genetically modified cotton COT102 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2017-141)

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

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Assessment of genetically modified cotton COT102 for food and feed uses, import and processing (application EFSA-GMO-DE-2017-141) 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 (in alphabetical order after chair of the Panel): Monica Sanden (Chair), Johanna Bodin, Nur Duale, Kristian Prydz, Volha Shapaval and Tage Thorstensen

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Summary

COT102 is a genetically modified cotton developed by *Agrobacterium tumefaciens* -mediated transformation. COT102 expresses the insecticidal protein Vip3Aa19 which confers resistance to insect pests within the order of butterflies and moths (Lepidoptera). COT102 also expresses the enzyme APH4, used as a selectable marker during development. The enzyme inactivates the antibiotic hygromycin B.

The scientific documentation provided in the application for cotton COT102 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 COT102 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific Opinion is adequate also for Norwegian conditions. Therefore, a full risk assessment of cotton COT102 was not performed by the VKM GMO Panel.

Sammendrag

COT102 er en genmodifisert bomull utviklet ved *Agrobacterium tumefaciens* -mediert transformasjon. COT102 uttrykker det insektdrepende proteinet Vip3Aa19 som gir resistens mot skadegjørende insekter innen ordenen for sommerfugler og møll (Lepidoptera). COT102 uttrykker også enzymet APH4, som ble brukt som seleksjonsmarkør under utvikling. Enzymet inaktiverer antibiotikumet hygromycin B.

Den vitenskapelig dokumentasjonen i søknaden for COT102 er dekkende for risikovurdering, og i samsvar med EFSAs retningslinjer for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. De genetiske endringene i bomull COT102 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAs risikovurdering er dermed tilstrekkelig også for norske forhold. Ettersom det ikke har blitt identifisert særnorske forhold vedrørende egenskaper ved COT102, 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 COT102 (application EFSA-GMO-DE-2017-141)

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-DE-2017-141** Genetically modified cotton COT102

2. Information related to the genetic modification:

COT102 was developed by *Agrobacterium tumefaciens* -mediated transformation. COT102 expresses the insecticidal protein Vip3Aa19 which confers resistance to insect pests within the order of butterflies and moths (Lepidoptera). COT102 also expresses the enzyme APH4, used as a selectable marker during development.

Genes	**Proteins**
vip3Aa19	Vip3Aa19
aph4	APH4

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)	24.07.2017	
6. Deadline of EFSAs commenting period	30.10.2017	
7. VKMs 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 EFSAs scientifc 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 did not assess the application within the time frame of the EFSA scientifc consultation	
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:	
15. VKMs conclusion regarding the application:	

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 two weeks 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	26.06.2023
2. VKMs deadline for informing NFSA and EEA	10.07.2023
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	NA
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 did not assess the application within the time frame of the EFSA scientifc consultation	
6. Follow-up item 12 (table 1) – comments from VKM	
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 or NA 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 conditions.	
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 introduced modifications in COT102 cotton 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	30.06.24

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified cotton COT102.

The scientific documentation provided in the application for cotton COT102 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 COT102 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific Opinion is adequate also for Norwegian conditions. Therefore, a full risk assessment of cotton COT102 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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