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

VKM Report 2023:10

Assessment of genetically modified soybean MON 87701 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (renewal application EFSA-GMO-RX-022)

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 soybean MON 87701 × MON 89788 for food and feed uses, import and processing (application EFSA-GMO-RX-022) 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), Eirill Ager-Wick, Johanna Bodin, Nur Duale, Kristian Prydz, Volha Shapaval and Tage Thorstensen

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Summary

MON 87701 × MON 89788 is developed via conventional crossing, combining the two single GM-soybean events MON 87701 and MON 89788. MON 87701 × MON 89788 plants contain the transgenes *cry1Ac* and *cp4 epsps* which encode the proteins Cry1Ac and CP4 EPSPS. The protein Cry1Ac provides resistance against specific Lepidopteran (order of butterflies and moths) pests, and the protein CP4 EPSPS provides tolerance against herbicides containing glyphosate.

The scientific documentation provided in the renewal application EFSA-GMO-RX-022 for soybean MON 87701 × MON 89788 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 MON 87701 × MON 89788 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 MON 87701 × MON 89788 was not performed by the VKM GMO Panel.

Sammendrag

MON 87701 × MON 89788 er en genmodifisert soya utviklet ved hjelp av konvensjonell krysning av de to GM-soyaene MON 87701 og MON 89788. MON 87701 og MON 89788 uttrykker transgenene *cry1Ac* og *cp4 epsps* som koder for proteinene Cry1Ac og CP4 EPSPS. Transgenene gjør MON 87701 × MON 89788 resistent mot enkelte planteskadegjørere i ordenen Lepidoptera (sommerfugler og møll) og tolerante for ugressmidler med virkestoffet glyfosat.

Søkers vitenskapelige dokumentasjon i fornyelsessøknaden EFSA-GMO-RX-022 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 MON 87701 × MON 89788 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 MON 87701 × MON 89788, har VKMs GMO panel ikke utført en fullstendig risikovurdering av soyaen.

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 soybean MON 87701 × MON 89788 (renewal application EFSA-GMO-RX-022)

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-022** Genetically modified soybean MON 87701 × MON 89788

2. Information related to the genetic modification:

MON 87701 × MON 89788 was developed via conventional crossing, combining the two single GM-soybean events MON 87701 and MON 89788. MON 87701 × MON 89788 plants contain the transgenes *cry1Ac* and *cp4 epsps* which encode the proteins Cry1Ac and CP4 EPSPS. The protein Cry1Ac provides resistance against specific lepidopteran pests, and the protein CP4 EPSPS provides tolerance against herbicides containing glyphosate.

Genes	**Proteins**
cry1Ac	Cry1Ac
cp4 epsps	CP4 EPSPS

3. Previously assessed by VKM	YES:	X	NO:

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

VKM performed a risk assessment of MON 87701 × MON 89788 in 2010 (application EFSA-GMO-NL-2009-73).

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	04.05.21
6. Deadline of EFSAs commenting period	04.08.21
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 public consultation	YES:	NO:	NA: X
9. Date of submission from VKM	NA		
10. Comment(s) to EFSA:			
11. If NO or NA in item 8. – comments from VKM:			
VKM did not assess the application during EFSAs scientific consultation 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 MON 87701 × MON 89788 to imply potential specific health or environmental risks in Norway, compared to EU-countries.			
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 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	19.12.22
2. VKMs deadline for informing NFSA and EEA	19.01.23
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 did not assess the application during EFSAs scientific consultation 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 does not consider the introduced modifications in MON 87701 × MON 89788 to imply potential specific health or environmental risks in Norway, compared to EU-countries.	
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 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 in item 4. – comments from VKM		
The VKM GMO Panel does not consider the introduced modifications in MON 87701 × MON 89788 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	30.04.23	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified soybean MON 87701 × MON 89788.

MON 87701 × MON 89788 plants contain the transgenes *cry1Ac* and *cp4 epsps* which encode the proteins Cry1Ac and CP4 EPSPS. The protein Cry1Ac provides resistance against specific Lepidopteran pests, and the protein CP4 EPSPS provides tolerance against herbicides containing glyphosate.

The VKM GMO panel has assessed the documentation in renewal application EFSA-GMO-RX-022. 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 MON 87701 × MON 89788 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA opinion is adequate also for Norwegian considerations.

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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