Vitenskapskomiteen for mat og miljø
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VKM Report 2022:5

Assessment of genetically modified oilseed rape 73496, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2012-109)

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.

Members of the Panel on genetically modified organisms (in alphabetical order before chair of the Panel): Johanna Bodin (chair), Nur Duale, Monica Sanden, Tage Thorstensen and Rose Vikse.

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Summary

Event 73496 (application EFSA-GMO-NL-2012-109) is a genetically modified oilseed rape developed for tolerance towards glyphosate-containing herbicides via expression of the synthetic glyphosate N-acetyltransferase gene *gat4621*. The *gat4621* gene was achieved by a gene shuffling process involving three glyphosate acetyltransferase genes from *Bacillus licheniformis.* Oilseed rape event 73496 was produced by biolistic transformation.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-NL-2012-109, and the EFSA scientific opinion (EFSA, 2021) on genetically modified oilseed rape 73496. 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 oilseed rape 73496 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion is adequate also for Norwegian considerations. Therefore, a full risk assessment of oilseed rape 73496 was not performed by the VKM GMO Panel.

Sammendrag

Oljeraps 73496 (søknad EFSA-GMO-NL-2012-109) er en genmodifisert raps utviklet for toleranse mot glyfosatholdige ugressmidler via uttrykk av et syntetisk glyfosat N-acetyltransferase gen, *gat4621*. *Gat4621*-genet ble utviklet ved en prosess som involverte tre gener for glyfosat-N-acetyl transferase fra bakterien *Bacillus licheniformis*. Oljeraps 73496 ble utviklet ved biolistisk transformasjon.

VKMs GMO-panel har vurdert dokumentasjonen til søknad EFSA-GMO-NL-2012-109, og EFSAs vurdering av genmodifisert oljeraps 73496 (EFSA, 2021). Den vitenskapelige dokumentasjonen i søknaden er tilstrekkelig for risikovurdering, og i samsvar med EFSA veiledning for risikovurdering av genmodifiserte planter til bruk i mat eller fôr.

De genetiske endringene i oljeraps 73496 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAs vurdering (EFSA, 2021) er tilstrekkelig også for norske hensyn. VKMs GMO panel har derfor ikke utført en fullstendig risikovurdering av oljeraps 73496.

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 oilseed rape 73496(application EFSA-GMO-NL-2012-109)

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-NL-2012-109** Genetically modified oilseed rape 73496

2. Information related to the genetic modification:

Event 73496 is a genetically modified oilseed rape (Canola) developed via biolistic transformation to express the synthetic glyphosate N-acetyltransferase gene *gat4621,* conferring tolerance towards glyphosate-containing herbicides. The inserted DNA fragment/expression cassette in oilseed rape 73496 also contains the polyubiquitin (UBQ10) promoter of *Arabidopsis thaliana,* and a terminator sequence of a gene encoding the proteinase inhibitor II (*pin*II-terminator) of *Solanum tuberosum*. The *gat4621* gene is a shuffled variant of three *gat* genes, isolated from *Bacillus licheniformis* strains 401, B6 and DS3.

Genes	**Proteins**
UBQ10	polyubiquitin (UBQ10) promoter
gat4621	synthetic glyphosate N-acetyltransferase
*pin*II	proteinase inhibitor II

3. Previously assessed by VKM	YES: X	NO:
4. If yes in item 3. – comments from VKM:		

During EFSA hearing 2013

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	04.12.12
6. Deadline of EFSAs commenting period	04.03.13
7. VKMs 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 EFSAs public consultation	YES: X NO:
9. Date of submission from VKM	04.03.2013
10. Comment(s) to EFSA:	
Due to the increased use of plant based ingredients in feeds for farmed fish in Norway (14.6 % rapeseed oil and 5 - 10 % rapeseed meal in salmon feed, reported by Skretting Norway in 2010), the Norwegian Scientific Committee for Food Safety would like the applicant to consider performing additional feeding studies in e.g. salmonids.	
11. If NO in item 8. – comments from VKM:	
12. Need for national consideration(s)	YES: NO:
13. If YES in item 12. – comments from VKM:	
14. If NO or NA in item 12. – comments from VKM:	
The current VKM GMO Panel has not assessed the application during Stage 1. The assessment of the application including written comments sent to EFSA in 2013 was performed by the VKM GMO Panel at that time.	
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 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	17.06.2021
2. VKMs deadline for informing NFSA and EEA	17.07.2021
3. If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)	YES: X NO:
4. If YES in item 3 – Comments from VKM:	
The current VKM GMO Panel has not assessed the application during stage 1 but considers the answers from EFSA to VKM as satisfactory.	
5. If NO in item 3 – Comment(s) and further considerations from VKM:	
6. Follow-up item 12 (table 1) – comments from VKM:	
The current VKM GMO Panel has not assessed the application in stage 1.	
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 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 (EFSA, 2021) 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 modifications in oilseed rape event 73496 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	14.02.2022	

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified oilseed rape 73496 (application EFSA-GMO-NL-2012-109), developed for tolerance towards glyphosate-containing herbicides via expression of the synthetic glyphosate N-acetyltransferase gene *gat4621*. The *gat4621* gene was achieved by a gene shuffling process involving three glyphosate acetyl N-transferase genes from *Bacillus licheniformis.* Oilseed rape event 73496 was produced by biolistic transformation.

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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

EFSA (2021) Scientific Opinion on the assessment of genetically modified oilseed rape 73496 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2012-109). EFSA Journal 2021;19(6):6610, 57pp. https://doi.org/10.2903/j.efsa.2021.6610. ISSN:1831-4732