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Assessment of genetically modified oilseed rape Ms8, Rf3 and Ms8xRf3 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (renewal application EFSA-GMO-RX-024)

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Assessment of genetically modified oilseed rape Ms8, Rf3 and Ms8xRf3 for food and feed uses, import and processing (Renewal application EFSA-GMO-RX-024) 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 before chair of the Panel): Johanna Bodin (chair), Nur Duale, Monica Sanden, Tage Thorstensen and Rose Vikse.

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Summary

The oilseed rape Ms8xRf3, developed by BASF Agricultural Solutions Seed US LLC, is a fertile hybrid tolerant to glufosinate-ammonium containing herbicides. The hybrid is derived through conventional breeding of the male sterile oilseed rape event Ms8 and the oilseed rape event Rf3, called the fertility restorer. Ms8 and Rf3 were produced by *Agrobacterium tumefaciens* mediated transformation of cells from a conventional oilseed cultivar. The dominant gene for male sterility in event Ms8 is *barnase*, and the dominant gene for fertility restoration in event Rf3 is *barstar.* The *bar* gene, conferring tolerance to glufosinate-ammonium, is found in both Ms8 and Rf3.

The scientific documentation provided in the renewal application for the genetically modified oilseed rape events Ms8, Rf3 and Ms8 x Rf3 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 events Ms8, Rf3 and Ms8 x Rf3 to imply potential specific health or environmental risks in Norway, compared to EU-countries.

Ms8, Rf3 and Ms8 x Rf3, were previously assessed by VKM in 2008, 2013 and 2014.

Sammendrag

Rapsen Ms8 x Rf3, utviklet av BASF Agricultural Solutions Seed US LLC, er en forplantningsdyktig hybrid, tolerant for ugressmidler basert på glufosinat-ammonium. Hybriden er en konvensjonell krysning av den hannsterile rapsen Ms8 og rapsen Rf3. Rf3 gjenoppretter forplantningsevnen i hybriden. Ms8 og Rf3 er begge utviklet ved *Agrobacterium tumefaciens* -mediert transformasjon av celler fra en konvensjonell rapssort. Det dominante genet som gir hannsterilitet i raps Ms8 er *barnase*, og det dominante genet som gjenoppretter fertiliteten i hybriden er *barstar*. Genet *bar,* som gir toleranse for glufosinat-ammonium, finnes i både Ms8 og Rf3.

Den vitenskapelige dokumentasjonen som følger fornyelsessøknaden for de genmodifiserte rapsene Ms8, Rf3 og Ms8 x Rf3 er tilstrekkelig for risikovurdering, og i samsvar med EFSA veiledning for risikovurdering av genmodifiserte planter til bruk i mat og fôr. VKMs GMO-panel anser ikke at genmodifiseringene i Ms8, Rf3 og Ms8 x Rf3 vil innebære en særegen helse- eller miljørisiko i Norge, sammenlignet med EU-land.

Ms8, Rf3 og Ms8 x Rf3, har tidligere blitt vurdert av VKM i 2008, 2013 og 2014.

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 Ms8, Rf3 and Ms8 x RF3 (renewal application EFSA-GMO-RX-024)

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-024**

Genetically modified oilseed rape Ms8, Rf3 and Ms8 x Rf3

2. Information related to the genetic modification:

The oilseed rape Ms8 x Rf3 hybrid, is derived through conventional breeding of the male sterile oilseed rape event Ms8 and the oilseed rape event Rf3, called the fertility restorer. The dominant gene for male sterility in event Ms8 is *barnase*, and the dominant gene for fertility restoration in event Rf3 is *barstar*. They encode two small single-chain proteins, designated as Barnase and Barstar. Under the control of a specific plant promoter that exclusively expresses these genes in the tapetal cell-layer during anther development, the barnase and barstar genes are the basis of a well-characterised hybridisation system in oilseed rape.

The *bar* gene, encoding the enzyme phosphinothricin acetyl transferase (PAT) conferring tolerance to glufosinate-ammonium, is found in both Ms8 and Rf3. The *barnase* and *barstar* genes have both been isolated from the bacterium *Bacillus amyloliquefaciens*. The *bar* gene was isolated from the bacterium *Streptomyces hygroscopicus.*

Genes	**Proteins**
barnase	Barnase (small single-chain protein)
barstar	Barstar (small single-chain protein)
bar	PAT (phosphinothricin acetyl transferase)

3. Previously assessed by VKM YES: X NO:

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

Ms8, Rf3 and Ms8 x Rf3, was assessed by VKM in 2008, 2013 and 2014.

The overall conclusion by VKM in 2014 was:

"Based on current knowledge, the VKM GMO Panel has not identified toxic, allergenic or altered nutritional properties of oilseed rape MS8, RF3 and MS8 x RF3 or its processed products compared to conventional oilseed rape.

The VKM GMO Panel likewise concludes that oilseed rape MS8, RF3 and MS8 x RF3, are unlikely to have any adverse effect on the environment and agriculture in Norway in the context of its intended usage."

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	09.11.21
6. Deadline of EFSAs commenting period	22.02.22
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: X NO:
9. Date of submission from VKM	10.02.22
10. Comment(s) to EFSA:	
"VKM would have liked to see the inclusion of the database SCOPUS in the systematic literature search, to further strengthen the search."	
11. If NO in item 8. – comments from VKM:	
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 the oilseed rape events Ms8, Rf3 and Ms8 x Rf3, 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	26.04.23
2. VKMs deadline for informing NFSA and EEA	26.05.23
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:	
EFSA took note of the comment and has also requested a more detailed search strategy.	
5. If NO in item 3 – Comment(s) and further considerations from VKM:	
6. Follow-up item 12 (table 1) – comments from VKM	
The VKM GMO Panel does not consider the introduced modifications in the oilseed rape events Ms8, Rf3 and Ms8 x Rf3, 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. Answers from EFSA to VKM comments were satisfactory. 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 or NA in item 4. – comments from VKM	
The VKM GMO Panel does not consider the introduced modifications in event Ms8, Rf3 and Ms8 x Rf3 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	12.06.23

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize Ms8 x Rf3.

The oilseed rape event Ms8 x Rf3, developed by BASF Agricultural Solutions Seed US LLC, is a fertile hybrid tolerant to glufosinate-ammonium containing herbicides. The hybrid is derived through conventional breeding of the male sterile oilseed rape event Ms8 and the oilseed rape event Rf3, called the fertility restorer. Ms8 and Rf3 were produced by Agrobacterium tumefaciens mediated transformation of cells from a conventional oilseed cultivar. The dominant gene for male sterility in event Ms8 is *barnase*, and the dominant gene for fertility restoration in event Rf3 is *barstar*. The bar gene, conferring tolerance to glufosinate-ammonium, is found in both Ms8 and Rf3.

The scientific documentation provided in the renewal application for the genetically modified oilseed rape events Ms8, Rf3 and Ms8 x Rf3 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 events Ms8, Rf3 and Ms8 x Rf3 to imply potential specific health or environmental risks in Norway, compared to EU-countries.

Ms8, Rf3 and Ms8 x Rf3, were previously assessed by VKM in 2008, 2013 and 2014.

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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