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Assessment of genetically modified maize MON 95379 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-170)

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Assessment of genetically modified maize MON 95379 for food and feed uses, import and processing (application EFSA-GMO-NL-2020-170) 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

Event MON 95379 is a genetically modified maize developed by a two-step process. In the first step, immature embryos of maize inbred line LH244 were co-cultured with a disarmed *Agrobacterium tumefaciens* (also known as *Rhizobium radiobacter*) strain ABI containing the vector PV-ZMIR522223. In the second step, selected R2 lines were crossed with maize inbred LH244 line expressing *Cre* recombinase, which had been transformed with vector PV-ZMOO513642. In the resulting plants, the *CP4 EPSPS*-cassette (used for selection of transformed plants) was excised by the *Cre* recombinase, and the *Cre* gene was subsequently segregated away, through conventional breeding, to obtain maize MON 95379.

Maize MON 95379 expresses Cry1B.868, a chimeric protein containing domains from Cry1A, Cry1B and Cry1C naturally expressed in *Bacillus thuringiensis*, and Cry1Da_7, an optimised version of Cry1Da carrying four amino acids substitutions to increase its activity.

The two Cry proteins expressed in maize MON 95379 provide protection against targeted pests within the order of butterflies and moths (*Lepidoptera*) including fall armyworm (*Spodoptera frugiperda*), sugarcane borer (*Diatraea saccharalis*) and corn earworm (*Helicoverpa zea*).

The scientific documentation provided in the application for genetically modified maize MON 95379 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 event MON 95379 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 event MON 95379 was not performed by the VKM GMO Panel.

Sammendrag

MON 95379 er en genmodifisert mais utviklet ved en to-trinns prosess. I det første trinnet ble umodne embryoer av maislinje LH244 dyrket sammen med *Agrobacterium tumefaciens* (også kjent som *Rhizobium radiobacter*) stamme ABI som inneholder vektoren PV-ZMIR522223. I det andre trinnet ble utvalgte R2-linjer krysset med maislinje LH244 som uttrykker *Cre*-rekombinase, transformert med vektor PV-ZMOO513642. *CP4 EPSPS*-kassetten (kun brukt under seleksjon av transformerte planter) ble deretter klippet ut av *Cre*-rekombinasen, før *Cre*-genet ble segregert bort, gjennom konvensjonell avl, for å oppnå mais MON 95379.

Mais MON 95379 uttrykker Cry1B.868, et protein som inneholder domener fra Cry1A, Cry1B og Cry1C som naturlig uttrykkes i *Bacillus thuringiensis*, og Cry1Da_7, en optimalisert versjon av Cry1Da som bærer fire aminosyresubstitusjoner for å øke aktiviteten.

De to Cry-proteinene uttrykt i mais MON 95379 gjør planten motstandsdyktig mot enkelte planteskadegjørere innen ordenen sommerfugler (*Lepidoptera)*, inkludert Fall Armyworm (*Spodoptera frugiperda*), Sukkerrør borer (*Diatraea saccharalis*) og Maisøreorm (*Helicoverpa zea*).

Søkers vitenskapelige dokumentasjon for den genmodifiserte maisen MON 95379 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 maisen 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 mais MON 95379, har VKMs faggruppe for GMO – mat og fôr ikke utført en fullstendig risikovurdering av maisen.

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 maize MON 95379 (application EFSA-GMO-NL-2020-170)

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-2020-170** Genetically modified maize MON 95379

2. Information related to the genetic modification:

Event MON 95379 is a genetically modified maize developed by a two-step process. In the first step, immature embryos of maize inbred line LH244 were co-cultured with a disarmed *Agrobacterium tumefaciens* (also known as *Rhizobium radiobacter*) strain ABI containing the vector PV-ZMIR522223. In the second step, selected R2 lines were crossed with maize inbred LH244 line expressing *Cre* recombinase, which had been transformed with vector PV-ZMOO513642. In the resulting plants, the CP4 EPSPS cassette (used for selection of transformed plants) was excised by the *Cre* recombinase, and the *Cre* gene was subsequently segregated away, through conventional breeding, to obtain maize MON95379.

Maize MON 95379 expresses Cry1B.868, a chimeric protein containing domains from Cry1A, Cry1B and Cry1C naturally expressed in *Bacillus thuringiensis*, and Cry1Da_7, an optimised version of Cry1Da carrying four amino acids substitutions to increase its activity. The two Cry proteins expressed in maize MON 95379 provide protection against targeted *Lepidopteran* pests including fall armyworm (*Spodoptera frugiperda*), sugarcane borer (*Diatraea saccharalis*) and corn earworm (*Helicoverpa zea*).

Genes	**Proteins**
Cry1B.868	Cry1B.868
Cry1Da_7	Cry1Da_7

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)	29.03.21	
6. Deadline of EFSAs commenting period	01.07.21	
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: X
9. Date of submission from VKM	NA

10. Comment(s) to EFSA:

11. If NO in item 8. – comments from VKM:

VKM has not assessed the application during the EFSA scientific consultation-period 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 event MON 95379 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	15.11.22
2. VKMs deadline for informing NFSA and EEA	15.12.22
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 has not assessed the application during the EFSA scientific consultation-period 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 event MON 95379 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 or NA in item 4. – comments from VKM	
The VKM GMO Panel does not consider the introduced modifications in event MON 95379 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	30.03.2023

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified maize MON 95379.

Maize MON 95379 expresses Cry1B.868, a chimeric protein containing domains from Cry1A, Cry1B and Cry1C naturally expressed in *Bacillus thuringiensis*, and Cry1Da_7, an optimised version of Cry1Da carrying four amino acids substitutions to increase its activity.

The two Cry proteins expressed in maize MON 95379 provide protection against targeted *Lepidopteran* pests including fall armyworm (*Spodoptera frugiperda*), sugarcane borer (*Diatraea saccharalis*) and corn earworm (*Helicoverpa zea*).

The VKM GMO panel has assessed the documentation in application EFSA-GMO-NL-2020-170. 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 event MON 95379 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 event MON 95379 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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