



VKM Report 2022: 27

Assessment of renewal application for genetically modified Soybean A5547-127 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-020)

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

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Assessment of renewal application for genetically modified soybean A5547-127 for food and feed uses, import and processing (application EFSA-GMO-RX-020) 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

Event A5547-127 is a genetically modified soybean derived from the conventional soybean variety A5547, which was transformed using particle bombardment. Soybean A5547-127 expresses the *phosphinothricin-N-acetyltransferase (pat)* gene, from the soil bacterium *Streptomyces viridochromogenes*. The encoded PAT protein (enzyme) confers tolerance to glufosinate-ammonium based herbicides.

The scientific documentation provided in the renewal application for soybean A5547-127 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 soybean A5547-127 to imply potential specific health or environmental risks in Norway, compared to EU-countries. The EFSA scientific opinion (EFSA, 2022) is adequate also for Norwegian considerations. Therefore, a full risk assessment of soybean event A5547-127 was not performed by the VKM GMO Panel.

Sammendrag

A5547-127 er en genmodifisert soya avledet ved biolistisk transformasjon av celler fra den konvensjonelle soyasorten A5547. A5547-127 uttrykker genet *fosphinothricin-N-acetyltransferase (pat)* fra jordbakterien *Streptomyces viridochromogenes*. Det kodede PAT-proteinet (enzym) gir økt toleranse for glufosinat-ammoniumbaserte ugressmidler.

Den vitenskapelige dokumentasjonen i fornyelsessøknaden for den genmodifiserte soyaen er dekkende for risikovurdering, og i samsvar med EFSAAs veiledning for risikovurdering av genmodifiserte planter til bruk i mat eller fôr. De genetiske endringene i soya A5547-127 tilsier ingen økt helse- eller miljørisiko i Norge sammenlignet med EU-land. EFSAAs vurdering (EFSA, 2020) er tilstrekkelig også for norske forhold. VKMs GMO-panel har derfor 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 A5547-127 (application EFSA-GMO-RX-020)

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-020

2. Information related to the genetic modification:

Event A5547-127 is a genetically modified soybean derived from the conventional soybean variety A5547, which was transformed using particle bombardment. Soybean A5547-127 expresses the gene *phosphinothricin-N-acetyltransferase (pat)*, from the soil bacterium *Streptomyces viridochromogenes*. The encoded PAT protein confers tolerance to glufosinate-ammonium based herbicides.

Genes

Proteins

pat

phosphinothricin-N-acetyltransferase (PAT)

3. Previously assessed by VKM

YES: X

NO:

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

Health and environmental risk assessments of soybean A5547-127 were performed by the VKM GMO-Panel in 2008 (VKM 2008) and 2015 (VKM 2015).

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)

07.05.2021

6. Deadline for submitting comments during EFSA's scientific consultation

07.08.2021

7. VKM's 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:

The conducted 90-day toxicological whole food feeding study for the single event MON 87705 was not in line with regulation No. 503/2013. The study did not use test material treated with the target herbicide, Glyphosate.

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 EFSA's scientific consultation

YES: NO: X

9. Date of submission from VKM

10. Comment(s) to EFSA:

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

VKM has not assessed the application during EFSA's scientific consultation in accordance with the assignment from NFSA and NEA, due to other pressing priorities.

12. Need for national consideration(s)

YES: NO: NA: X

13. If YES in item 12. – comments from VKM:

14. If NO or NA in item 12. – comments from VKM:

VKM has not assessed the application during EFSA's scientific consultation in accordance with the assignment from NFSA and NEA, due to other pressing priorities.

15. VKM's conclusion regarding the application:

1.2 Considerations after EFSA's 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	20.06.2022
2. VKMs deadline for informing NFSA and EEA	20.07.2022
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 Stage 1. due to other pressing priorities.	
6. Follow-up item 12 (table 1) – comments from VKM:	
VKM has not assessed the application during Stage 1. due to other pressing priorities.	
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 EFSA's 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 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 Soybean A5547-127 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		
9. Date of publication of assessment		

2 Conclusions

The VKM GMO Panel has performed an assessment of a renewal application for genetically modified Soybean event A5547-127.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-RX-020 and the EFSA's scientific opinion (EFSA, 2022) on genetically modified Soybean A5547-127. 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 Soybean A5547-127 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 soybean event A5547-127 was not performed by the VKM GMO Panel.

3 References

EFSA (2010) Guidance on the environmental risk assessment of genetically modified plants. Scientific opinion 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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VKM (2008) Helse- og miljørisikovurdering av genmodifisert soyalinje A5547-127 fra Bayer CropScience (EFSA/GMO/NL/2008/52)

VKM (2015) Endelig helse- og miljørisikovurdering av genmodifisert soya A5547-127 (EFSA/GMO/NL/2008/52)