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Assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111)

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Assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing (application EFSA-GMO-DE-2012-111) 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 SYHT0H2 (EFSA-GMO-DE-2012-111) is a genetically modified soybean developed via *Agrobacterium tumefaciens* transformation. SYHT0H2 plants contain the transgenes *avhppd-03* and *pat* which encode the proteins AvHPPD-03 and PAT. The proteins AvHPPD-03 and PAT provide tolerance to HPPD-inhibiting herbicides, such as mesotrione, and herbicides containing glufosinate ammonium, respectively.

The scientific documentation provided in the application for genetically modified soybean SYHT0H2 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 SYHT0H2 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 SYHT0H2 was not performed by the VKM GMO Panel.

Sammendrag

SYHT0H2 (EFSA-GMO-DE-2012-111) er en genmodifisert soya utviklet ved transformasjon av planteceller ved hjelp av *Agrobacterium tumefaciens*. SYHT0H2 uttrykker transgenene *avhppd-03* og *pat*, som koder henholdsvis for proteinene AvHPPD-03 og PAT. Transgenene gjør SYHT0H2 tolerant mot HPPD-inhiberende ugressmidler, som f.eks. mesotrione, og ugressmidler som inneholder glufosinate ammonium. Søkers vitenskapelige dokumentasjon for den genmodifiserte soya SYHT0H2 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 SYHT0H2 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 vedrørende egenskaper ved soyaen, har VKMs GMO panel ikke utført en fullstendig risikovurdering av SYHT0H2.

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 SYHT0H2 (application EFSA-GMO-DE-2012-111)

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-DE-2012-111** Genetically modified soybean SYHT0H2

2. Information related to the genetic modification:

Event SYHT0H2 (EFSA-GMO-DE-2012-111) is a genetically modified soybean developed via *Agrobacterium tumefaciens* transformation.

SYHT0H2 plants contain the transgenes *avhppd-03* and pat which encode the proteins AvHPPD-03 and PAT.

The proteins AvHPPD-03 and PAT provide tolerance to HPPD-inhibiting herbicides, such as mesotrione, and herbicides containing glufosinate ammonium, respectively.

Genes	**Proteins**
avhppd-03	AvHPPD-03
pat	PAT

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)	09.01.13	
6. Deadline of EFSAs commenting period	09.04.13	
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	09.04.13	

10. Comment(s) to EFSA:

HDDP is involved in a metabolic pathway where disturbances of enzymatic activities give rise to a number of severe metabolic disorders, among others alkaptonuria (Moran, 2005). In addition, the intermediate homogentisic acid has been shown to have some mutagenic effect (Gatt, 1990; Hiraku et al. 1998). The applicant has quantified some of the molecules (alpha-tocopherol, tyrosine and phenylalanine) associated with this pathway, and found these not to be significant different from the control plant. However, as homogentisic acid is a key intermediate in this pathway, and the molecule with potential deleterious effect if accumulated, the concentration of this compound should also have been measured and compared between SYHT0H2 and the control soybean.

For the toxicity studies, the applicant has tested the recombinant proteins AvHPPD-03 and PAT. However, related to the genetic modifications, it would have been more relevant to test whole food/feed of herbicide treated and untreated plants, and measured more specific the level of the metabolic intermediated related to homogentisic acid in the animals.

Reference**s**:

Moran GR. 4-Hydroxyphenylpyruvate dioxygenase. Arch Biochem Biophys. 2005 Jan 1;433(1):117-28.

Hiraku Y; Yamasaki M; Kawanishi S Oxidative DNA damage induced by homogentisic acid, a tyrosine metabolite. FEBS Lett. 1998, Jul 31; 432(1-2):13-6.

Glatt H, Endogenous mutagens derived from amino acids. Mutat Res. 1990, May; 238(3):235-43

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 or NA in item 12. – comments from VKM:

The VKM GMO Panel does not consider the introduced modifications in event SYHT0H2 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	20.01.20
2. VKMs deadline for informing NFSA and EEA	20.02.20
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:	
According to EFSA, the applicant provided sufficient information on the catabolism of tyrosine according to the guidelines, indicating that homogentisic acid is not accumulating in the plant. Furthermore, 90-day study is not required if there is no difference in nutritional content compared to non-GM counterpart or sequence homology to known toxins or allergens.	
5. If NO or NA in item 3 – Comment(s) and further considerations from VKM:	
6. Follow-up item 12 (table 1) – comments from VKM	
The comments from VKM were acknowledged by EFSA and no follow-up is needed.	
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 SYHT0H2 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	13.06.22

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified soybean SYHT0H2 (EFSA-GMO-DE-2012-111). SYHT0H2 plants contain the transgenes *avhppd-03* and *pat* which encode the proteins AvHPPD-03 and PAT. The proteins AvHPPD-03 and PAT provide tolerance to HPPD-inhibiting herbicides, such as mesotrione, and herbicides containing glufosinate ammonium, respectively.

The VKM GMO panel assessed the documentation in application EFSA-GMO-DE-2012-111. 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 event SYHT0H2 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 SYHT0H2 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

VKM (2013) Førebels helserisikovurdering av genmodifisert soya SYHT0H2 (EFSA/GMO/DE/2012/111) https://vkm.no/risikovurderinger/allevurderinger/forebelshelserisikovurderingavgenmodifisertsoyasyht0h2efsagmode2012111.4.175083d415c86c573b5d909f.html

EFSA (2020) Assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111) EFSA Journal 2020;18(1):5946 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.5946