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Assessment of application for the authorisation of soy leghemoglobin produced from genetically modified *Komagataella phaffii* for food use in the European Union under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-162)

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): Monica Sanden (chair), Eirill Ager-Wick, Johanna Bodin, Nur Duale, Kristian Prydz, Volha Shapaval, and Tage Thorstensen.

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Summary

This application is submitted to gain authorisation for the use of soy leghemoglobin (the liquid preparation is referred to as "LegH Prep") produced from genetically modified *Komagataella phaffii (*yeast) as a flavouring ("meaty taste") in meat analogue products that will be marketed in the European Union (EU). Soy leghemoglobin is intended for addition to meat analogue products that are for use in foods such as burgers, meatballs, and sausages.

The *Komagataella phaffii* MXY054-strain employed in the production of soy leghemoglobin contains genetic modifications which allow it to express this protein. Following fermentation, the cells are lysed, and the soy leghemoglobin is concentrated by physical means. The soy leghemoglobin is delivered in a liquid preparation (LegH Prep) that is standardised to contain up to 9% soy leghemoglobin on a wet weight basis and a soy leghemoglobin protein purity of at least 65%. The remainder of the protein fraction in the LegH Prep is accounted for by residual proteins from the *Komagataella phaffii* production strain. These residual proteins are all endogenous to *Komagataella phaffii* as the gene coding for the expression of soy leghemoglobin is the only gene from a different organism.

Sammendrag

Søknaden gjelder godkjenning for bruk av soya leghemoglobin (ekstraktet/preparatet er referert til som "LegH Prep") produsert av en genmodifisert gjærsopp, *Komagataella phaffii*, som smakstilsetning ("kjøttaktig smak") i kjøtterstattere som vil bli markedsført i EU. Soya leghemoglobin er tiltenkt for plantebaserte matvarer brukt i analoger til burgere, kjøttboller og pølser.

Komagataella phaffii-stammen som brukes i produksjon av soya leghemoglobin inneholder genetiske endringer som gjør det mulig å uttrykke proteinet. Etter en gjæringsperiode og lysering av cellene, oppkonsentreres et ekstrakt (LegH Prep) med opptil 9% soya leghemoglobin med en proteinrenhet på minst 65%. Den resterende proteinfraksjonen i LegH Prep er gjenværende proteiner fra *Komagataella phaffii*. Disse gjenværende proteinene finnes naturlig i *Komagataella phaffii*. Det er kun leghemoglobinet som kommer fra en annen organisme.

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 soy leghemoglobin produced from genetically modified *Komagataella phaffii* for food use in the European Union (application EFSA-GMO-NL-2019-162)

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-2019-162** Soy leghemoglobin produced from genetically modified *Komagataella phaffii* (yeast) for food use in the European Union under Regulation (EC) No 1829/2003
2. **Information related to the genetic modification:**	
Genes	**Proteins**
Multiple copies of *LGB2*-gene from soybean (*Glycine max*)	Soy leghemoglobin c2 (in extract 'LegH Prep', 9% soy leghemoglobin protein content. Soy leghemoglobin protein purity of ~ 65%) Soy leghemoglobin is a small 16 kDa holoprotein (protein + haem cofactor) expressed within the nitrogen-fixing root nodule of the soybean plant (Glycine max).
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)**	15.12.21
6. **Deadline of EFSAs commenting period**	28.06.22
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 microorganisms and their products intended for food and feed use (EFSA 2011):	YES: X	NO:
8. Comments submitted from VKM during EFSAs public consultation	YES:	NO:X
9. Date of submission from VKM		
10. Comment(s) to EFSA:		
11. If NO in item 8. – comments from VKM:		
Application is in accordance with the EFSA guidance on genetically modified microorganisms (GMM)		
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 Leghemoglobin from genetically modified *Komagataella phaffii* to imply potential specific health 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 microorganisms 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**	15.11.24	
2. **VKMs deadline for informing NFSA and EEA**	15.12.24	
3. **If YES in item 8. (table 1)– Answer from EFSA has been considered by VKM as satisfactory (Annex G)**	YES:	NO:
4. **If YES in item 3 – Comments from VKM:**		
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 Leghemoglobin from genetically modified Komagataella phaffii to imply potential specific health 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 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 microorganisms 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 in item 4. – comments from VKM		
The VKM GMO Panel does not consider Leghemoglobin from genetically modified Komagataella phaffii to imply potential specific health risks in Norway, compared to EU-countries.		
7. Need for a risk assessment	YES:	NO: X
8. Date of deadline for risk assessment	NA	
9. Date of publication of assessment	NA	

2 Conclusions

The VKM GMO Panel has performed an assessment of an application for authorisation for the use of soy leghemoglobin (the liquid preparation is referred to as "LegH Prep") produced from genetically modified Komagataella phaffii as a flavouring ("meaty taste") in meat analogue products that will be marketed in the European Union (EU).

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 microorganisms for use in food or feed. The VKM GMO Panel does not consider leghemoglobin from genetically modified *Komagataella phaffii* to imply potential specific health risks in Norway, compared to EU-countries. The EFSA opinion is adequate also for Norwegian considerations. Therefore, a full risk assessment was not performed by VKM.

3 References

EFSA (2011) EFSA guidance for risk assessment of genetically modified microorganisms and their products intended for food and feed use EFSA Journal 2011;9(6):2193 EFSA Journal - 2011 - - Guidance on the risk assessment of genetically modified microorganisms and their products intended.pdf

EFSA (2024) Assessment of soy leghemoglobin produced from genetically modified Komagataella phaffii, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2019-162) EFSA Journal. 2024; 22:e9060 EFSA Journal - 2024 - - Assessment of soy leghemoglobin produced from genetically modified Komagataella phaffii under.pdf