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Assessment of genetically modified oilseed rape LBFLFK for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2019-157)

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Assessment of genetically modified oilseed rape LBFLFK for food and feed uses, import and processing (application EFSA-GMO-DE-2019-157) 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): Monica Sanden (Chair), Eirill Ager-Wick, Johanna Bodin, Nur Duale, Kristian Prydz, Volha Shapaval and Tage Thorstensen

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Summary

Oilseed rape LBFLFK was developed by *Agrobacterium rhizogenes-mediated* transformation. In total the following 13 genes were introduced, which would be expected to result in the expression of 11 new proteins: c-D12D(Ps) encoding a delta-12 desaturase (Ps); c-D6D(Ot) encoding a delta-6 desaturase (Ot); c-D6E(Tp) encoding a delta-6 elongase (Tp); c-D6E(Pp) encoding a delta-6 elongase (Pp); c-D5D(Tc), delta-5 desaturase (Tc); c-O3D(Pi) encoding a omega-3 desaturase (Pi); c-O3D(Pir) encoding a omega-3 desaturase (Pir); c-D5E(Ot) encoding a delta-5 elongase (Ot); c-D4D(Tc) encoding a delta-4 desaturase (Tc); c-D4D(Pl) encoding a delta-4 desaturase (Pl); and c-AHAS(At) encoding an acetohydroxy acid synthase (also named acetolactate synthase, (ALS)). These proteins impact the content of omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) in the seeds and also confers tolerance to imidazolinone herbicides. Two gene expression cassettes were introduced twice (O3D(Pir) and D5D(Tc) but have different seed-specific promotors to increase expression during seed maturation. Expression of the ten EPA and DHA biosynthesis genes results in the conversion of oleic acid (OA) to EPA and DHA in LBFLFK canola seeds.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-DE-2019-157. The VKM GMO panel has no additional observations regarding the limitations of the scientific documentation when considering the full scope of the application, as pointed out by EFSA: *"The GMO Panel is unable to conclude on the adequacy of the PMEM plan proposed by the applicant. The GMO Panel cannot conclude on the safety of oilseed rape LBFLFK when considering the full scope of the application. On the other hand, the GMO Panel concludes that the consumption of RBD LBFLFK oil is safe and does not represent any nutritional concern for humans under the conditions of use proposed by the applicant and considered during the pre-market risk assessment."* As no hazards specific to Norway have been identified, the VKM GMO panel supports EFSAs conclusions with the implied reservations regarding oilseed rape LBFLFK. Therefore, a full risk assessment of oilseed rape LBFLFK was not performed by the VKM GMO Panel.

Sammendrag

Raps LBFLFK ble utviklet ved *Agrobacterium rhizogenes*-mediert transformasjon. Totalt ble 13 gener introdusert, noe som resulterer i 11 nye proteiner: *c-D12D(Ps)* som koder for en delta-12 desaturase (Ps); *c-D6D(Ot)* som koder for en delta-6 desaturase (Ot); *c-D6E(Tp)* som koder for en delta-6 elongase (Tp); *c-D6E(Pp)* som koder for en delta-6 elongase (Pp); c-D5D(Tc), delta-5 desaturase (Tc); *c-O3D(Pi)* som koder for en omega-3 desaturase (Pi); *c-O3D(Pir)* som koder for en omega-3 desaturase (Pir); *c-D5E(Ot)* som koder for en delta-5 elongase (Ot); *c-D4D(Tc)* som koder for en delta-4 desaturase (Tc); *c-D4D(Pl)* som koder for en delta-4 desaturase (Pl); og *c-AHAS(At)* som koder for en acetohydroxy acidsyntase (også kalt acetolactate synthase (ALS)). Disse proteinene påvirker innholdet av langkjedede, flerumettede omega-3 fettsyrer (LC-PUFA) i frøene og gir også toleranse mot imidazolinon-ugressmidler To genkassetter ble introdusert to ganger (O3D(Pir) og D5D(Tc)), men har ulike frøspesifikke promotere for å øke uttrykket under frøutvikling. Uttrykk av de ti genene for biosyntese av EPA og DHA resulterer i endring av oljesyre (OA) til EPA og DHA i LBFLFK kanolafrø.

VKMs faggruppen for GMO har vurdert dokumentasjonen i søknaden EFSA-GMO-DE-2019-157. VKMs faggruppen for GMO har ingen ytterligere kommentarer angående begrensningene i den vitenskapelige dokumentasjonen som er påpekt av EFSA: *«GMO-panelet kan ikke konkludere angående PMEM-planen som er foreslått av søkeren. GMO-panelet kan heller ikke konkludere hvorvidt raps LBFLFK trygt kan brukes til alle bruksområder dekket av søknaden. Men GMO-panelet konkluderer med at konsum av RBD LBFLFK-olje er ernæringsmessig trygt for mennesker med tanke på bruken som er foreslått av søkeren, og vurdert i forkant av markedsføring.»* Siden ingen spesifikke farer for Norge er identifisert, støtter VKMs faggruppen for GMO derfor EFSAs konklusjoner i risikovurderingen av raps LBFLFK med de forbeholdene som er presentert. Ettersom det ikke har blitt identifisert særnorske forhold vedrørende egenskaper ved rapsen, har VKMs faggruppe for GMO ikke utført en fullstendig risikovurdering.

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 LBFLFK (application EFSA-GMO-DE-2019-157)

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-2019-157**

Genetically modified oilseed rape LBFLFK

2. Information related to the genetic modification:

Oilseed rape LBFLFK was developed by Agrobacterium rhizogenes-mediated transformation. In total the following 13 genes were introduced, which would be expected to result in the expression of 11 new proteins: c-D12D(Ps) encoding a delta-12 desaturase (Ps); c-D6D(Ot) encoding a delta-6 desaturase (Ot); c-D6E(Tp) encoding a delta-6 elongase (Tp); c-D6E(Pp) encoding a delta-6 elongase (Pp); c-D5D(Tc), delta-5 desaturase (Tc); c-O3D(Pi) encoding a omega-3 desaturase (Pi); c-O3D(Pir) encoding a omega-3 desaturase (Pir); c-D5E(Ot) encoding a delta-5 elongase (Ot); c-D4D(Tc) encoding a delta-4 desaturase (Tc); c-D4D(Pl) encoding a delta-4 desaturase (Pl); and c-AHAS(At) encoding an acetohydroxy acid synthase. These proteins impact the content of omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) in the seeds and also confers tolerance to imidazolinone herbicides. Two gene expression cassettes were introduced twice (O3D(Pir) and D5D(Tc) but have different seed-specific promotors to increase expression during seed maturation. Expression of the ten EPA and DHA biosynthesis genes results in the conversion of oleic acid (OA) to EPA and DHA in LBFLFK canola seeds.

Genes	**Proteins**
D12D(Ps)	D12D(Ps)
D6D(Ot)	D6D(Ot)
D6E(Tp)	D6E(Tp)
D6E(Pp)	D6E(Pp)
D5D(Tc) x2	D5D(Tc)
O3D(Pir) x2	O3D(Pir)
O3D(Pi)	O3D(Pi)
D5E(Ot)	D5E(Ot)
D4D(Pl)	D4D(Pl)
D4D(Tc)	D4D(Tc)

AHAS(At)	AHAS(At)	
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)	27.11.19	
6. Deadline of EFSAs commenting period	27.02.20	
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:	NO: X
8. Comments submitted from VKM during EFSAs public consultation	YES: X	NO:
9. Date of submission from VKM	13.02.20	
10. Comment(s) to EFSA:		

Food and feed safety assessment

VKM welcomes information on herbicide residue levels and their relevant metabolites in applications for herbicide tolerant GM-plants. Data on imazamox residue levels, including relevant metabolites (hydroxymethyl metabolite CL 263284 and its glucose conjugate CL 189215), in plant material from the field studies would support the assessment of food, feed, and environmental safety.

Monitoring

Given the scope of the application, accidental spillage and loss of viable seeds of genetically modified EPA+DHA canola event LBFLFK during transport, storage, handling, and processing into derived products cannot be precluded. Oilseed rape can establish feral

populations outside cultivated areas (e.g. roadsides, railway ground, ports) and escaped populations of herbicide-tolerant oilseed rape have been reported along transportation routes, ports and close to processing plants in Japan, Canada and USA (Yoshimura et al.,2006; Knispel et al., 2008; Nishizawa et al., 2009, 2016; Schafer et al., 2011). Feral transgenic oilseed rape is also detected along railway lines in Switzerland (Hecht et al., 2014) and near oil mills in Germany (Franzaring et al., 2016).

Germination and establishment of volunteer LBFLFK plants may result in gene flow into cultivated and feral Brassica napus as well as into closely related wild relatives (Knispel et al., 2008; Schafer et al., 2011). The magnitude of establishment, dissemination and gene flow depends among others on the level of LBFLFK canola in the imported oilseed rape commodities. Therefore, case-specific monitoring must focus on pathways where viable LBFLFK canola enters the environment.

The applicant is requested to provide an appropriate case-specific monitoring plan comprising: i) spillage or loss of LBFLFK canola during transport, storage, packaging, processing and use, ii) spread and persistence of LBFLFK canola, if spillage or loss of viable LBFLFK canola occurs, iii) out-crossing of LBFLFK canola to cultivated and feral/naturalized oilseed rape populations and wild relatives resulting from spillage or loss of viable LBFLFK canola.

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 oilseed rape LBFLFK to imply potential specific health or environmental risks in Norway, compared to EU-countries.

15. VKMs conclusion regarding the application:

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	05.11.25
2. VKMs deadline for informing NFSA and EEA	05.12.25
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:	
Answers from EFSA to VKM comments were satisfactory.	
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 oilseed rape LBFLFK 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 in item 1. – comments from VKM:	
The VKM GMO panel has no additional observations regarding the limitations of the scientific documentation when considering the full scope of the application, as pointed out by EFSA: *"The (EFSA) GMO Panel is unable to conclude on the adequacy of the PMEM plan proposed by the applicant. The GMO Panel cannot conclude on the safety of oilseed rape LBFLFK when considering the full scope of the application. On the other hand, the GMO Panel concludes that the consumption of RBD LBFLFK oil is safe and does not represent any nutritional concern for humans under the conditions of use proposed by the applicant and considered during the pre-market risk assessment"*. 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 in item 4. – comments from VKM	
The VKM GMO Panel does not consider the introduced modifications in oilseed rape LBFLFK 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	21.12.26

2 Conclusions

Oilseed rape LBFLFK was developed by Agrobacterium rhizogenes-mediated transformation. In total the following 13 genes were introduced, which would be expected to result in the expression of 11 new proteins: *c-D12D(Ps)* encoding a delta-12 desaturase (Ps); *c-D6D(Ot)* encoding a delta-6 desaturase (Ot); *c-D6E(Tp)* encoding a delta-6 elongase (Tp); *c-D6E(Pp)* encoding a delta-6 elongase (Pp); *c-D5D(Tc)*, delta-5 desaturase (Tc); *c-O3D(Pi)* encoding a omega-3 desaturase (Pi); *c-O3D(Pir)* encoding a omega-3 desaturase (Pir); *c-D5E(Ot)* encoding a delta-5 elongase (Ot); *c-D4D(Tc)* encoding a delta-4 desaturase (Tc); *c-D4D(Pl)* encoding a delta-4 desaturase (Pl); and *c-AHAS(At)* encoding an acetohydroxy acid synthase. These proteins impact the content of omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs) in the seeds and also confers tolerance to imidazolinone herbicides. Two gene expression cassettes were introduced twice (O3D(Pir) and D5D(Tc) but have different seed-specific promotors to increase expression during seed maturation. Expression of the ten EPA and DHA biosynthesis genes results in the conversion of oleic acid (OA) to EPA and DHA in LBFLFK canola seeds.

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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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