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Assessment of genetically modified oilseed rape GT73 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-002)

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Assessment of genetically modified oilseed rape GT73 for food and feed uses, import and processing (application EFSA-GMO-RX-002) 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 GT73 was developed using *Agrobacterium tumefaciens*-mediated transformation, to introduce the *goxv247* and the *cp4 epsps* expression cassettes into the oilseed rape genome. Oilseed rape GT73 produces the glyphosate oxidoreductase (GOXv247) protein, derived from the bacterium *Ochrobactrum anthropi* strain LBAA, and the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from *Agrobacterium sp.* strain CP4 (CP4 EPSPS), which confer tolerance to glyphosate.

The scientific documentation provided in the application for genetically modified oilseed rape GT73 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 GT73 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 GT73 was not performed by the VKM GMO Panel.

Sammendrag

Event GT73 ble utviklet ved transformasjon av planteceller ved hjelp av *Agrobacterium tumefaciens*. GT73 uttrykker transgenene *goxv247* og *cp4 epsps* som koder for henholdsvis glyfosatoksidoreduktase (GOXv247) proteinet, fra bakterien Ochrobactrum anthropi-stamme LBAA, og 5-enolpyruvylshikimate-3-fosfatsyntase (EPSPS) proteinet fra Agrobacterium sp. stamme CP4 (CP4 EPSPS), som gir toleranse for glyfosat.

Søkers vitenskapelige dokumentasjon for den genmodifiserte rapsen GT73 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 GT73 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 rapsen, har VKMs GMO panel ikke utført en fullstendig risikovurdering av event GT73.

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 GT73 (application EFSA-GMO-RX-002)

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-002** Genetically modified oilseed rape GT73

2. Information related to the genetic modification:

Event GT73 was developed using Agrobacterium tumefaciens-mediated transformation, to introduce the *goxv247* and the *cp4 epsps* expression cassettes into the oilseed rape genome. Oilseed rape GT73 produces the glyphosate oxidoreductase (GOXv247) protein, derived from the bacterium Ochrobactrum anthropi strain LBAA, and the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from *Agrobacterium sp*. strain CP4 (CP4 EPSPS), which confer tolerance to glyphosate.

Genes	**Proteins**
goxv247	GOXv247
cp4 epsps	EPSPS

3. Previously assessed by VKM YES: X NO:

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

2012: Foreløpig helse- og miljørisikovurdering av genmodifisert oljeraps GT73 fra Monsanto Company (EFSA/GMO/NL/2010/87)

2006: UTTALELSE OM MONSANTOS GENMODIFISERTE RAPS GT73 (C/NL/98/11)

5. Date when EFSA declared the application as valid in accordance with Articles 6(1) and 18(1)	15.12.2016
6. Deadline of EFSAs commenting period	10.04.2017
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	10.04.17	
10. Comment(s) to EFSA:		

D. 12.02 Case-specific GM plant monitoring

Given the scope of the application, accidental spillage and loss of viable seeds of GT73 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 GT73 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). In Norway glyphosate may be used for weed control in non-agricultural environments including traffic areas, and therefore spilled GT73 might have a selective advantage over conventional oilseed rape along some transport routes.

The magnitude of establishment, dissemination and gene flow depends among others on the level of GT73 oilseed rape in the imported oilseed rape commodities. Therefore, case-specific monitoring has to focus on pathways where viable GT73 oilseed rape enters into the environment.

The applicant is requested to provide an appropriate case-specific monitoring plan, comprising: i) spillage or loss of GT73 oilseed rape during transport, storage, packaging, processing and use, ii) spread and persistence of GT73 oilseed rape, if spillage or loss of viable GT73 oilseed rape occurs, iii) out-crossing of GT73 oilseed rape to cultivated and feral/naturalized oilseed rape populations and wild relatives resulting from spillage or loss of viable GT73 oilseed rape.

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 GT73 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	29.07.2020	
2. VKMs deadline for informing NFSA and EEA	29.08.2020	
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:		
Since the GMO Panel concluded that no new hazards or modified exposure and no new scientific uncertainties were identified in the application for renewal that would change the conclusions of the original risk assessment on oilseed rape GT73 no case-specific monitoring would be considered necessary.		
5. If NO in item 3 – Comment(s) and further considerations from VKM:		
6. Follow-up item 12 (table 1) – comments from VKM		
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 in item 4. – comments from VKM		
The VKM GMO Panel does not consider the introduced modifications in event GT73 oilseed rape 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		

2 Conclusions

The VKM GMO Panel has performed an assessment of genetically modified oilseed rape GT73. GT73 contains the transgenes *goxv247* and *cp4 epsps*, which encode the enzymes GOXv247 and CP4 EPSPS, conferring tolerance to glyphosate-based herbicides.

The VKM GMO panel has assessed the documentation in the application EFSA-GMO-RX-002. 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 GT73 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 new full risk assessment of event GT73 was not performed by the VKM GMO Panel.

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