Assessment of genetically modified oilseed rape GT73 for renewal authorisation

Assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003. Reference Number RP1263.

1. Executive summary

The FSA and FSS have undertaken an assessment of application RP1263 for the renewal of authorisation of genetically modified oilseed rape GT73 for feed and products other than food and feed containing or consisting of it, excluding cultivation.

A GM application has been received by Great Britain (GB) where the European Food Safety Authority (EFSA), prior to the end of the transition period, evaluated an application for the product. FSA and FSS have reviewed the EFSA opinion (footnote 1) and confirmed that it is sufficient for GB risk analysis and therefore was used this to form the basis of the UK opinion.

The FSA and FSS risk assessors conclude that the EFSA opinion is sufficient and relevant for GB risk analysis and therefore genetically modified oilseed rape GT73, as described in this application, poses no new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape GT73.

2. Background and purpose of review

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Question number: EFSA-Q-2016-00478

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1263 for the renewal of the authorisation of genetically modified oilseed rape GT73 has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA and FSS have adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application is now made to GB, FSA and FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

Therefore, FSA and FSS risk assessors have reviewed the EFSA opinion1 for the application below in the context of intended GB use and have concluded that the intended uses are safe.

In reviewing the EFSA risk assessment opinion the reviewers have verified that the standard approach as outlined in the relevant guidance has been followed and the arguments made are consistent with the data summarised in the EFSA opinion.

Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are any aspects that would require further review such as specific issues for the countries of the UK.

The result of the assessment is that the EFSA scientific opinion is sufficient also for GB risk analysis.

3. Details of the EFSA assessment

3.1 Applicant

Name: Bayer Agriculture BV

Address: Jan Emiel Mommaertslaan, 14
1831 Diegem
Belgium

(on behalf of)

Name: Bayer CropScience LP, United States

3.2 Methodology applied in the EFSA opinion

EFSA Genetically Modified Organisms (GMO) Panel guidance: Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 (2015) and principles in Regulation (EC) No 1829/2003.

3.3 Source/organism

Brassica napus containing two transgenes.

3.4 Genetic modification step

- cp4 epsps (aroA:CP4) (from Agrobacterium tumefaciens) to confer glyphosate tolerance
- goxv247 (from Ochrobactrum anthropic) to confer glyphosate tolerance.

3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this event is MON-ØØØ73-7.

Information provided on the identity, composition and specifications of the plant does not raise safety concerns. In the context of this renewal application, no new sequencing data were provided by the applicant.

Updated bioinformatics analyses were therefore performed using the original sequence data provided, on the basis that the GT73 event sequence is the same as the sequence of the originally assessed event (The EFSA Journal (2004) 29, 1-19).

3.6 Exposure assessment

Not relevant

3.7 Toxicological data

Updated bioinformatics analyses did not identify any similarities with known toxins or allergens. No new safety concerns were identified from the literature review.

3.8 Analytical Method Review

FSA and FSS accepted the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) report, showing that the detection methods for the Oilseed rape GT73 (footnote 2) were previously validated, and declared fit for purpose.

3.9 Post Market Environmental Monitoring Plan (PMEM)

FSA and FSS reviewed and accepted the GMO Panel conclusions on the PMEM plan proposed by the applicant for genetically modified oilseed rape GT73 considering the scope consistent with the intended uses of genetically modified oilseed rape GT73.

PMEM plan provided by the applicant is in line the EFSA guidelines on the PMEM of GM plants. FSA and FSS accepted the proposed PMEM plan and did not require additional monitoring. However, it was noted that the GMO panel highlighted that the monitoring of GMOs is a risk management measure.

3.10 Proposed labelling

The applicant proposed no additional labelling of oilseed rape GT73 for the renewal of the authorisation. The FSA and FSS accept the applicant's conclusion and do not require specific or additional labelling.

4. EFSA assessment and conclusions

There is no evidence in renewal application EFSA–GMO–RX–002 for new hazards or modified exposure that would change the conclusions of the original risk assessment on oilseed rape GT73 (The EFSA Journal (2004) 29, 1-19).

5. Caveats and uncertainties

No caveats and uncertainties were identified

6. FSA- FSS Conclusion on applicability and reliability of the EFSA opinion for GB risk analysis

The application has been assessed in line with the applicable guidance (footnote 3) and is partially based on considerations of detailed proprietary information available to the Panel, whilst this is only briefly summarised this description is consistent with the conclusions.

The conclusions of the opinion have been reviewed by FSA and FSS and are considered appropriate and consistent within the identified caveats and uncertainties and would be applicable to the UK. As such the opinion forms the basis of this opinion.

The Advisory Committee on Releases to the Environment (ACRE) have considered the environmental risk assessment and find that GT73 oilseed rape does not pose a greater risk to

the environment than non-GM counterparts.

Oilseed rape is imported and crushed in HACCP (Hazard Analysis and Critical Control Point) compliant facilities at certain ports and the monitoring plan is acceptable to mitigate the risk of GM seed growth at or near these facilities, including minimising spillage, prompt disposal of spilled material and proper removal of germinating plants within the facility.

7. Outcome of assessment

FSA and FSS have reviewed the EFSA opinion and consider it sufficient and relevant for GB risk analysis. Therefore, the opinion was used to form the basis of the UK opinion.

FSA and FSS had access to all supporting documentation that was provided to the EFSA Panel by the applicant, and subsequently used to form the EFSA opinion. FSA and FSS agree with the safety conclusions outlined in the EFSA opinion.

The environmental and human safety of the genetically modified oilseed rape GT73 have been well characterised by the applicant under the Annex II to the Cartagena Protocol.

Following the principles outlined in the background for making use of the EFSA opinion, the FSA and FSS conclude that genetically modified oilseed rape GT73, as described in this application, poses no new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape GT73.

8. References

Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of glyphosate-tolerant oilseed rape event GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto, The EFSA Journal (2004) 29, 1–19.

EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9(8):2316. [40 pp.] doi: 10.2903/j.efsa.2011.2316

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2. https://gmo-crl.jrc.ec.europa.eu/summaries/RT73_val_report.pdf

3. European Food Safety Authority, 2013. EFSA guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003. EFSA Journal 2013; 11(12):3491, 133 pp., doi:10.2903/j.efsa.2013.3491