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Assessment of genetically modified oilseed rape GT73 for placing on the market of isolated seed protein for food under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-026/2)

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Abstract

Genetically modified oilseed rape GT73 was developed to confer herbicide tolerance; this property was achieved by introducing the single insert containing one copy of *goxv247* and the *CP4 epsps* expression cassettes. The scope of the application EFSA-GMO-RX-026/2 is for the modification of the terms of the authorisation regarding the placing on the market of isolated seed protein from oilseed rape GT73 for food. Considering previous opinions on this event of the GMO Panel, the molecular characterisation data do not identify issues requiring additional food safety assessment. Based on previous assessments, no biologically relevant differences were identified in the compositional, agronomic and phenotypic characteristics of oilseed rape GT73 compared with its conventional counterpart, except for the newly expressed proteins. No new agronomic, phenotypic and compositional data in support of the comparative analysis were considered necessary in the context of this application. The GMO Panel did not identify indications of safety concern regarding toxicity, allergenicity or adjuvanticity related to the presence of the newly expressed proteins CP4 EPSPS and GOXv247 in oilseed rape GT73. Therefore, the GMO Panel concludes that in the context of this application, the consumption of oilseed rape GT73 does not represent any nutritional concern and is as safe as the conventional counterpart. No post-market monitoring of food/feed is considered necessary. In the case of accidental release of viable oilseed rape GT73 into the environment, this would not raise environmental safety concerns. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of oilseed rape GT73. The GMO Panel concludes that oilseed rape GT73 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment. These conclusions also apply to the placing on the food market of isolated seed protein produced from oilseed rape GT73.

Keywords: GM, genetic engineering, oilseed rape (*Brassica napus*), GT73, GOXv247, CP4 EPSPS, isolated seed protein

Requestor: European Commission

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Summary

Following the submission of application EFSA-GMO-RX-026/2 under Regulation (EC) No 1829/2003 from Bayer Group (referred to hereafter as 'the applicant'), the Panel on Genetically Modified Organisms of the European Food Safety Authority (referred to hereafter as 'GMO Panel') was asked to deliver a Scientific Opinion on the safety of the herbicide tolerant genetically modified (GM) oilseed rape GT73 according to Regulation (EU) No 503/2013 in the context with the scope of this application. The scope of the application EFSA-GMO-RX-026/2 is for the modification of the terms of the authorisation regarding the placing on the market of isolated seed protein from GT73 oilseed rape for food in the European Union, pursuant Regulation (EC) No 1829/2003.

The molecular characterisation data previously assessed by the GMO Panel established that oilseed rape GT73 contains a single insert consisting of one copy of the *goxv247* and the *CP4 epsps* expression cassettes. Updated bioinformatics analyses of the sequences encoding the newly expressed proteins (NEPs) and other ORFs within the insert or spanning the junctions between the insert and genomic DNA provided in the context of this application do not raise concerns.

Based on previous assessments, no biologically relevant differences were identified in the compositional, agronomic and phenotypic characteristics of oilseed rape GT73 compared with its conventional counterpart, except for the NEPs. No new agronomic, phenotypic and compositional data in support of the comparative analysis were considered necessary in the context of this application.

The GMO Panel did not identify indications of safety concerns regarding toxicity, allergenicity or adjuvanticity related to the presence of the NEPs CP4 EPSPS and GOXv247 in oilseed rape GT73. Therefore, the GMO Panel concludes that in the context of this application the consumption of oilseed rape GT73 does not represent any nutritional concern and is as safe as the conventional counterpart. No post-market monitoring of food/feed is considered necessary.

Considering the introduced traits, the outcome of the agronomic and phenotypic analysis and the routes and levels of exposure, oilseed rape GT73 does not raise safety concerns in the case of an accidental release of viable GM oilseed rape GT73 into the environment. The post-market environmental monitoring (PMEM) plan and reporting intervals are in line with the intended uses of oilseed rape GT73.

The GMO Panel considered the overall quality of the performed literature searches acceptable. The literature searches identified six relevant peer-reviewed publications on oilseed rape GT73. Based on the relevant publications identified through the literature searches, the GMO Panel does not identify any safety issues pertaining to the intended uses of oilseed rape GT73.

The GMO Panel concludes that oilseed rape GT73 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment. These conclusions also apply to the placing on the food market of isolated seed protein produced from oilseed rape GT73.

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1. Introduction

The scope of the application EFSA-GMO-RX-026/2 is for the modification of the terms of the authorisation regarding the placing on the market of isolated seed protein[1] from genetically modified GT73 oilseed rape for food, pursuant Regulation (EC) No 1829/2003.[2]

1.1. Background

On 22 March 2021, the European Food Safety Authority (EFSA) received from the European Commission the application EFSA-GMO-RX-026/2 for the modification of the terms of authorisation regarding the placing on the market of isolated seed protein from genetically modified GT73 oilseed rape for food, pursuant Regulation (EC) No 1829/2003, submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP. Following receipt of application EFSA-GMO-RX-026/2, EFSA informed EU Member States (MS) and the European Commission (EC) and made the application available to them. Simultaneously, EFSA published a summary of the application.[3]

In the context of the scope with this application, EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013[4], with the EFSA guidance documents, and, when needed, asked the applicant to supplement the initial application. On 6 January 2022, EFSA declared the application valid.

From validity date, EFSA and the Panel on Genetically Modified Organisms of the European Food Safety Authority (referred to hereafter as 'GMO Panel') endeavoured to respect a time limit of six months to issue a scientific opinion on application EFSA-GMO-RX-026/2. Such time limit was extended whenever EFSA and/or GMO Panel requested supplementary information to the applicant. According to Regulation (EC) No 1829/2003, any supplementary information provided by the applicant during the risk assessment was made available to the EU Member States and European Commission (for further details, see the section 'Documentation', below).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of EU Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC.[5] The EU Member States had three months to make their opinion known on application EFSA-GMO-RX-026/2 as of date of validity.

1.2. Terms of Reference as provided by the requestor

According to Article 6 of Regulation (EC) No 1829/2003, which applies *mutatis mutandis*, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of oilseed rape GT73 in the context of its scope as defined in application EFSA-GMO-RX-026/2.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Article 6(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Article 6(5). In addition to the present scientific opinion, EFSA was also asked to report on the particulars listed under Article 6(5) of Regulation (EC) No 1829/2003, but not to give an opinion on them because they pertain to risk management.[6]

2. Data and methodologies

2.1. Data

The GMO Panel based its scientific assessment of oilseed rape GT73 on the valid application EFSA-GMO-RX-026/2, additional information provided by the applicant during the risk assessment, relevant scientific comments submitted by EU MS, relevant peer-reviewed scientific publications and previous scientific opinions on this event by the GMO Panel. As part of this information package, the applicant

[1] Isolated seed protein is defined here as highly concentrated protein fractions of a crop.
[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.
[3] Available online: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2021-00283
[4] Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L157, 8.6.2013, p. 1–48.
[5] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.
[6] These particulars are available online at: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2021-00283

also performed a search for additional documents or studies performed by or on behalf of the applicant.

Considering that this application is for the modification of the terms of the authorisation regarding the placing on the market of isolated seed protein from genetically modified oilseed rape GT73, the data newly produced in the context of this dossier included: (i) updated bioinformatics analyses (disruption of known coding sequences or regulatory elements, expression of potential fusion proteins in junctions, presence of ORFs within the insert, toxicity, allergenicity and celiac analysis of NEPs, potential for horizontal gene transfer); (ii) dietary exposure estimates to NEPs; (iii) a post-market environmental monitoring (PMEM) plan; and (iv) literature searches on oilseed rape GT73 and the NEPs.

2.2. Methodologies

The GMO Panel conducted the assessment of the new information (Section 2.1) in line with the principles described in Regulation (EU) No 503/2013, the applicable guidelines (i.e. EFSA GMO Panel, 2010a, 2011a,b, 2017) and explanatory notes and statements (i.e. EFSA GMO Panel, 2010b; EFSA, 2010, 2019a,b) for the risk assessment of GM plants.

In the frame of the contract OC/EFSA/GMO/2018/04, the contractor performed preparatory work and delivered reports on the methods applied by the applicant in performing literature search.

3. Assessment

3.1. Introduction

Oilseed rape GT73 has previously been risk assessed by the EFSA GMO Panel. Briefly, the initial scope of the evaluations of the GMO Panel involved the (i) import and processing of oilseed rape GT73 for feed use (EFSA GMO Panel, 2004), and (ii) renewal of the authorisation for continued marketing of existing food and food ingredients produced from oilseed rape GT73, and feed materials, feed additives and food additives produced from oilseed rape GT73 (EFSA GMO Panel, 2009). The EFSA GMO Panel concluded in its scientific opinions that GM oilseed rape GT73 is unlikely to have an adverse effect on human and animal health and on the environment, in the context of its proposed uses.

Subsequently, a scientific opinion for the placing on the market of genetically modified herbicide tolerant oilseed rape GT73 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape GT73 (with the exception of refined oil and food additives) was published (EFSA GMO Panel, 2013). In such opinion, no indication of potential concerns over the safety of the newly expressed CP4-EPSPS and GOXv247 proteins or the occurrence of unintended effects were identified in either oilseed rape GT73 pollen/pollen-containing dietary supplements or trace levels of seeds when adventitiously present in human foods. An equivalent assessment with isolated seed protein[1] from oilseed rape GT73 could not be made because of the lack of availability of relevant consumption and safety data (EFSA GMO Panel, 2013).

More recently, a renewal application covering feed containing or consisting of GM oilseed rape GT73, and products other than food and feed containing or consisting of it, excluding cultivation was evaluated by the GMO Panel. The applicant provided a 28-day repeated dose toxicity study in mice on the GOXv247 protein, to complement the assessment of oilseed rape GT73 products other than those with trace levels of GOXv247 protein (e.g. oil, toasted meal). The GMO Panel concluded that this new information does not raise any concern for human and animal health and the environment (EFSA GMO Panel, 2020).

Finally, a renewal for the placing on the market of foods and food ingredients containing, consisting of, or produced from oilseed rape GT73 with the exception of isolated seed protein, and feed produced from this GM oilseed rape, excluding cultivation in the EU was adopted by the GMO Panel. The GMO Panel concluded that there is no evidence in this renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape GT73 (EFSA GMO Panel, 2022).

3.2. Systematic literature review[7]

The GMO Panel assessed the applicant's literature searches on oilseed rape GT73 and the NEPs GOXv247 and CP4 EPSPS. The overall quality of the performed literature searches is acceptable.

[7] Dossier: Part II – Section 7; additional information: 31/03/2022 and 24/08/2022.

In the original application, the applicant performed a systematic literature search covering the period from January 2010 until December 2020 in accordance with the recommendations on literature search outlined in EFSA (2010, 2019b). In the context of this application, the literature review was updated covering the period until June 2022. Six peer-reviewed publications were identified as relevant for food and feed safety or for environment assessment. The relevant publications are listed in Appendix A.

None of the relevant records identified through the literature searches reported information pointing to safety issues associated with oilseed rape GT73 relevant to the scope of this application.

3.3. Molecular characterisation[8]

As previously described (EFSA GMO Panel, 2004, 2013, 2020, 2022), the molecular characterisation data establish that oilseed rape GT73 contains a single insert consisting of one copy of the *goxv247* and the *CP4 epsps* expression cassettes. Bioinformatics analyses of the sequences encoding the NEPs and other ORFs within the insert or spanning the junctions between the insert and genomic DNA do not raise concerns. The stability of the inserted DNA and of the introduced trait (herbicide tolerant phenotype) is confirmed over several generations. The methodology used to quantify the levels of the GOXv247 and CP4 EPSPS proteins is considered adequate. The protein characterisation data comparing the biochemical, structural and functional properties of plant and microbe-produced GOXv247 and CP4 EPSPS proteins, indicate that these proteins are equivalent and the microbial derived proteins can be used in the safety studies.

3.4. Comparative analysis[9]

In its previous opinions, the GMO Panel concluded that no biologically relevant differences were identified in the compositional, agronomic and phenotypic characteristics of oilseed rape GT73 compared with its conventional counterpart, except for the NEPs (EFSA GMO Panel, 2004, 2013). The scope of the application EFSA-GMO-RX-026/2 is for the placing on the market of isolated seed protein from oilseed rape GT73 for food in the EU. The EFSA GMO Panel considers that the modification of the terms of the authorisation does not require to produce new agronomic, phenotypic and compositional data in support of the comparative analysis.

3.5. Food/feed safety assessment[10]

The GMO Panel did not identify indications of safety concerns regarding toxicity, allergenicity or adjuvanticity related to the presence of the newly expressed CP4 EPSPS and GOXv247 proteins in oilseed rape GT73. The GMO Panel considered previous opinions on oilseed rape GT73 (EFSA GMO Panel, 2004, 2009, 2013, 2020, 2022), which comprised the outcome of a 28-day oral repeated dose toxicity study in mice on GOXv247 (EFSA GMO Panel, 2020). The GMO Panel also considered new information provided in the context of this application (see Section 2) that included updated bioinformatics analyses of the NEPs, recently assessed by the GMO Panel (EFSA GMO Panel, 2022), and human dietary exposure to CP4 EPSPS and GOXv247 proteins.

In line with Regulation (EU) No 503/2013, the applicant was asked to provide dietary exposure estimates to CP4 EPSPS and GOXv247 proteins in oilseed rape GT73. It is noted that isolated seed protein produced from oilseed rape might enter the market via different food products such as meat imitates, protein supplements, etc. To estimate human dietary exposure to CP4 EPSPS and GOXv247 proteins, the available consumption data in the EFSA consumption database on meat imitates and protein supplements were used, assuming they are all derived from oilseed rape GT73.[11] Levels of CP4 EPSPS and GOXv247 proteins in meat imitates and protein supplements were derived using different factors[11] applied to the concentrations reported in seeds in the 2013 scientific opinion[12] (EFSA GMO Panel, 2013). Across the different European countries, the highest chronic dietary exposure estimates (high consumers) were 2,793 and 559 μg/kg body weight (bw) per day for GOXv247 and CP4 EPSPS, respectively, while the highest acute dietary exposure estimates (high consumers) were 4,297 and 859 μg/kg bw per day for GOXv247 and CP4 EPSPS, respectively. For both, chronic and acute dietary

[8] Dossier: Part II – Section 1.2.
[9] Dossier: Part II – Section 1.3.
[10] Dossier: Part II – Sections 1.4, 1.5, 1.6, 2, 3, 4; additional information: 16/9/22.
[11] https://www.efsa.europa.eu/en/applications/gmo/tools. Data accessed: August 2022.
[12] Mean levels in seeds: 34 μg/g (fresh weight, fw) for CP4 EPSPS, and 170 μg/g fw for GOXv247 (EFSA GMO Panel, 2013).

exposure, the highest estimates were in 'Adults' via the consumption of 'Protein and protein components for sports people'.

The GMO Panel concludes that in the context of this application the consumption of oilseed rape GT73 does not represent any nutritional concern and is as safe as the conventional counterpart. No post-market monitoring of food/feed is considered necessary. These conclusions also apply to the placing on the food market of isolated seed protein produced from oilseed rape GT73.

3.6. Environmental risk assessment and monitoring plan[13]

3.6.1. Environmental risk assessment

The scope of the application EFSA-GMO-RX-026/2 is for modifying the terms of the authorisation regarding the placing on the market of isolated seed protein from oilseed rape GT73 for food in the EU. The EFSA GMO Panel considers that the modification of the terms of the authorisation has no impact on the environmental risk assessment (ERA) of oilseed rape GT73 and confirms its previous conclusions (EFSA GMO Panel, 2013, 2020, 2022).

3.6.2. Post-market environmental monitoring

The objectives of a PMEM plan, according to Annex VII of Directive 2001/18/EC, are: (1) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO, or its use, in the ERA are correct; and (2) to identify the occurrence of adverse effects of the GMO, or its use, on human health or the environment that were not anticipated in the ERA.

Monitoring is related to risk management, and thus a final adoption of the PMEM plan falls outside the mandate of EFSA. However, the GMO Panel gives its opinion on the scientific rationale of the PMEM plan provided by the applicant (EFSA GMO Panel, 2011b).

As the ERA did not identify potential adverse environmental effects from oilseed rape GT73, no case-specific monitoring is required.

The PMEM plan proposed by the applicant for oilseed rape GT73 includes: (1) the description of a monitoring approach involving operators (federations involved in import and processing), reporting to the applicant, via a centralised system, any observed adverse effect(s) of GMOs on human health and the environment; (2) a coordinating system established by CropLife Europe for the collection of information recorded by the various operators; and (3) the review of relevant scientific publications retrieved from literature searches (Lecoq et al., 2007; Windels et al., 2008). The applicant proposes to submit a PMEM report on an annual basis for the duration of the authorisation period.

The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of oilseed rape GT73. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan.

3.6.2.1. Conclusion of the environmental risk assessment and monitoring plan

The GMO Panel concludes that it is unlikely that oilseed rape GT73 would differ from conventional oilseed rape varieties in its ability to persist under European environmental conditions. Considering the scope of application EFSA-GMO-RX-026/2, interactions of occasional feral oilseed rape GT73 plants with the biotic and abiotic environment are not considered to be relevant issues. The analysis of potential HGT from oilseed rape GT73 to bacteria does not indicate a safety concern. Therefore, considering the introduced trait, the outcome of the agronomic and phenotypic analysis, and the routes and levels of exposure, the GMO Panel concludes that oilseed rape GT73 would not raise safety concerns in the event of accidental release of viable GM oilseed seeds into the environment.

The scope of the PMEM plan provided by the applicant and the reporting intervals are in line with the intended uses of oilseed rape GT73.

4. Overall conclusions

The GMO Panel was asked to carry out a scientific assessment of oilseed rape GT73 for the modification of the terms of authorisation regarding the placing on the market of isolated seed protein from genetically modified GT73 oilseed rape for food, pursuant Regulation (EC) No 1829/2003.

[13] Dossier: Part II – Section 5, 6; additional information: 24/8/2022.

The molecular characterisation data previously assessed by the GMO Panel established that oilseed rape GT73 contains a single insert consisting of one copy of the *goxv247* and the *CP4 epsps* expression cassettes. The updated bioinformatic analyses do not identify issues requiring additional food safety assessment. Based on previous assessments, no biologically relevant differences were identified in the compositional, agronomic and phenotypic characteristics of oilseed rape GT73 compared to its conventional counterpart, except for the NEPs. No new agronomic, phenotypic and compositional data in support of the comparative analysis were considered necessary in the context of this application. The GMO Panel did not identify indications of safety concerns regarding toxicity, allergenicity or adjuvanticity related to the presence of the NEPs CP4 EPSPS and GOXv247 in oilseed rape GT73. Therefore, the GMO Panel concludes that in the context of this application, the consumption of oilseed rape GT73 does not represent any nutritional concern and is as safe as the conventional counterpart. No post-market monitoring of food/feed is considered necessary. In the case of accidental release of viable oilseed rape GT73 into the environment, this would not raise environmental safety concerns. The PMEM plan and reporting intervals are in line with the intended uses of oilseed rape GT73.

The GMO Panel concludes that oilseed rape GT73 is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment. These conclusions also apply to the placing on the food market of isolated seed protein produced from oilseed rape GT73.

5. Documentation as provided to EFSA

- Letter from the European Commission to EFSA received on 22 March 2021 for the renewing of the authorisation for the placing on the market of food products containing or consisting of genetically modified oilseed rape GT73 and food and feed products produced from genetically modified oilseed rate GT73 authorised under Regulation 1829/2003 (Commission Implementing Decision (EU) 2015/701) and for modifying the terms of the authorisation regarding the placing on the market of isolated seed protein from genetically modified oilseed rape GT73 for food pursuant to Regulation 1829/2003 submitted by Bayer CropScience.
- Letter from EFSA to the European Commission, dated 5 May 2021, requesting the split of the assessment process of the original request to two procedures.
- Letter from the European Commission to EFSA, dated 11 May 2021 consenting the split.
- EFSA made the application EFSA-GMO-RX-026/2; EFSA-Q-2021-00283 valid on 6 January 2022.
- Additional information (1) was requested on 17 February 2022.
- Additional information (1) was received on 31 March 2022.
- Additional information (2) was requested on 30 June 2022.
- Additional information (2) was received on 24 August 2022.
- Additional information (3) was requested on 18 July 2022.
- Additional information (3) was received on 15 September 2022.

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Abbreviations

EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organisms
GMO Panel	EFSA Panel on genetically modified organisms
NEP	newly expressed protein
PMEM	post-market environmental monitoring

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2010 – June 2022)

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