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## Assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-026/1)

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### Abstract

Following the submission of application EFSA-GMO-RX-026/1 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV on behalf of Bayer CropScience LP, the Panel on Genetically Modified Organisms of EFSA was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for 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. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and a search for additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequences of the events in oilseed rape GT73 considered for renewal are identical to the sequences of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-026/1 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape GT73.

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## Summary

Following the submission of application EFSA-GMO-RX-026/1 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV on behalf of Bayer CropScience LP, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the herbicide-tolerant genetically modified oilseed rape GT73. The scope of the renewal application EFSA-GMO-RX-026/1 is for the renewal of 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. In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-026/1, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-026/1 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, additional studies performed by or on behalf of the applicant and updated bioinformatics analyses. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequences of the events in oilseed rape GT73 considered for renewal are identical to the sequences of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-026/1 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, 2013).

## Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background .....	5
1.2. Terms of Reference as provided by the requestor .....	5
2. Data and Methodologies .....	6
2.1. Data.....	6
2.1.1. Post-market monitoring reports .....	6
2.1.2. Systematic search and evaluation of literature .....	6
2.1.3. Updated bioinformatic data .....	7
2.1.4. Additional documents or studies provided by the applicant .....	7
2.1.5. Overall assessment as provided by the applicant .....	7
2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation .....	7
2.2. Methodologies.....	7
3. Assessment.....	7
3.1. Evaluation of the post-market monitoring reports .....	7
3.2. Evaluation of the systematic search and evaluation of literature.....	7
3.3. Evaluation of the updated bioinformatic data.....	8
3.4. Evaluation of the additional documents or studies provided by the applicant.....	8
3.5. Evaluation of the overall assessment as provided by the applicant .....	8
3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation.....	8
4. Conclusions.....	8
5. Documentation as provided to EFSA .....	8
References.....	9
Abbreviations.....	9
Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2010 – June 2022).....	10

## 1. Introduction

### 1.1. Background

On 23 March 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-026/1 for the renewal of the authorisation of oilseed rape GT73 (Unique Identifier MON-ØØØ73-7), submitted by Bayer Agriculture BV on behalf of Bayer CropScience LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.<sup>1</sup>

Following receipt of application EFSA-GMO-RX-026/1, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.<sup>2</sup>

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013<sup>3</sup> and, when needed, asked the applicant to supplement the initial application. On 17 July 2021, EFSA declared the application valid and made the valid application available to the MS and the EC.

Following the submission of application EFSA-GMO-NL-2010-87 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2013), 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 authorised by Commission Implementing Decision 2015/701/EU<sup>4</sup> and Commission Implementing Decision (EU) 2019/1579 amending Decision 2015/701/EU.<sup>5</sup> A copy of the original authorisation was provided by the applicant.<sup>6</sup>

From the validity date, EFSA and its scientific Panel on Genetically Modified Organisms (hereafter referred to as 'the GMO Panel') endeavoured to respect a time limit of 6 months to issue a scientific opinion on application EFSA-GMO-RX-026/1. Such time limit was extended whenever EFSA and/or its 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 MS and EC (for further details, see the section 'Documentation', below).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of the MS, including national Competent Authorities within the meaning of Directive 2001/18/EC.<sup>7</sup> The MS had 3 months to make their opinion known on application EFSA-GMO-RX-026/1 as of the date of validity.

### 1.2. Terms of Reference as provided by the requestor

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of oilseed rape GT73 for the renewal of authorization for placing on the market of food containing or consisting of, or food and feed produced from, oilseed rape GT73 as defined in application EFSA-GMO-RX-026/1.

<sup>1</sup> 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.

<sup>2</sup> Available online: <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00164>

<sup>3</sup> 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 L 157, 8.6.2013, p. 1–48.

<sup>4</sup> 2015/701/EU: Commission Implementing Decision (EU) 2015/701 of 24 April 2015 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape GT73, or food and feed produced from that genetically modified organism pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 112/86, 24.4.2015.

<sup>5</sup> Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union. Official Journal of the European Union L 244/8, 18.9.2019.

<sup>6</sup> Dossier: Oilseed rape GT73 – Annex I.

<sup>7</sup> 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.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation including the opinions of the nominated risk assessment bodies of the MS.<sup>8</sup>

In addition to the present scientific opinion on oilseed rape GT73, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003. The relevant information is made available in Open EFSA,<sup>9</sup> including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a post-market environmental monitoring (PMEM) plan as provided by the applicant; the method(s), validated by the Community reference laboratory, for detection, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it and the appropriate reference materials.

## 2. Data and Methodologies

### 2.1. Data

The data for application EFSA-GMO-RX-026/1 submitted according to EFSA requirements (EFSA GMO Panel, 2015; EFSA, 2019a) and provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

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.

#### 2.1.1. Post-market monitoring reports<sup>10</sup>

Based on the outcome of the initial food and feed risk assessment, a case-specific post-market monitoring plan for monitoring of GM food and feed was not required by the authorisation decision. The implementation of a PMEM plan, consisting of a general surveillance plan to check for any unanticipated adverse effects on the environment arising from oilseed rape GT73, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of oilseed rape GT73 (EFSA GMO Panel, 2013), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided 11 annual PMEM reports covering a reporting period from July 2010 till July 2021. The annual PMEM plans submitted by the applicant included (1) commodity crop (GM and non GM) imports into the EU by country of origin and destination; (2) the description of a centralised system established by EuropaBio<sup>11</sup> for the collection of information recorded by various operators (federations involved in oilseed rape import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of oilseed rape GT73; (3) the reports of the surveillance activities conducted by such operators; and (4) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

#### 2.1.2. Systematic search and evaluation of literature<sup>12</sup>

In addition to the separate searches provided as part of the annual PMEM reports, 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). The literature review was updated covering the period until June 2022.

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 4,545 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, 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.

<sup>8</sup> Opinions of the nominated risk assessment bodies of EU Member States can be found at <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00164>

<sup>9</sup> Available online: <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00164>

<sup>10</sup> Dossier: Oilseed rape GT73 – Annex II, additional information: 15/3/2022.

<sup>11</sup> The responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops were taken over by CropLife Europe as of 1st January 2021.

<sup>12</sup> Dossier: Oilseed rape GT73 – Annex III; additional information: 31/3/2022; 22/8/2022.

### 2.1.3. Updated bioinformatic data<sup>13</sup>

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for oilseed rape GT73 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of the newly expressed proteins: GOXv247 and CP4 EPSPS regarding their capacity to trigger celiac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

### 2.1.4. Additional documents or studies provided by the applicant<sup>14</sup>

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019), the applicant provided an overview on the worldwide approvals of oilseed rape GT73 and searched for any available full reports of studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU.

### 2.1.5. Overall assessment as provided by the applicant<sup>15</sup>

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of oilseed rape GT73 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2013).

### 2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation<sup>16</sup>

The applicant indicated in the dossier that the environmental post-market monitoring plan is appropriate and does not need any changes.

## 2.2. Methodologies

The GMO Panel assessed the application for renewal of the authorisation of oilseed rape GT73 for food and feed uses in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015). The comments raised by the nominated risk assessment bodies of EU Member States were taken into consideration during the scientific risk assessment.

## 3. Assessment

### 3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of oilseed rape GT73, no adverse effects were reported by the applicant.

### 3.2. Evaluation of the systematic search and evaluation of literature

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

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on oilseed rape GT73 (EFSA GMO Panel, 2013) have been identified by the applicant.

<sup>13</sup> Dossier: Oilseed rape GT73 – Annex III; additional information: 31/3/2022.

<sup>14</sup> Dossier: Oilseed rape GT73 – Annex III; additional information: 08/06/2022.

<sup>15</sup> Dossier: Oilseed rape GT73 – Annex III.

<sup>16</sup> Dossier: Oilseed rape GT73 – Part III – Summary.

### 3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses to assess the interruption of oilseed rape endogenous genes confirm previous results indicating that no endogenous genes have been interrupted by event GT73 (EFSA GMO Panel, 2013, 2020).

Analyses of the amino acid sequence of the newly expressed GOXv247 and CP4 EPSPS proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. The updated bioinformatic analyses of the newly created ORFs within the insert do not indicate sequence similarities to toxins or allergens in oilseed rape GT73. In addition, the updated bioinformatic analysis of the newly created ORFs spanning the junctions with genomic DNA confirms previous results which did not indicate sequence similarities to toxins or allergens in oilseed rape GT73 (EFSA GMO Panel, 2013, 2020).

The updated bioinformatic analysis for oilseed rape event GT73 does not reveal any DNA sequence that could provide sufficient length and identity which could facilitate double homologous recombination (HR), confirming the previous conclusions (EFSA GMO Panel, 2013, 2020). Given the results of this analysis and that the recombinant DNA in oilseed rape GT73 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible horizontal gene transfer.

### 3.4. Evaluation of the additional documents or studies provided by the applicant

Taking into account (i) the relevance for molecular characterisation, human and animal safety and the environment; and (ii) the scope of this renewal application, there are no unpublished studies available performed by or on behalf of the applicant and not previously submitted to the EU since oilseed rape GT73 was authorised.

### 3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal application EFSA-GMO-RX-026/1 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on oilseed rape GT73.

### 3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM plant material, including oilseed rape GT73. This general surveillance is coordinated by CropLife Europe and implemented by selected operators (federations involved in oilseed rape grains import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of application EFSA-GMO-RX-026/1, but reminds that monitoring is related to risk management, and thus the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

## 4. Conclusions

Under the assumption that the DNA sequences of the events in oilseed rape GT73 considered for renewal are identical to the sequences of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-026/1 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, 2013).

## 5. Documentation as provided to EFSA

- 1) Letter from the European Commission to EFSA received on 23 March 2021 for the continued marketing of genetically modified oilseed rape GT73 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture BV on behalf of Bayer CropScience LP (EFSA-GMO-RX-026/1)
- 2) Application EFSA-GMO-RX-026/1 validated by EFSA, 16 July 2021



- 3) Request for supplementary information to the applicant, 3 September 2021
- 4) Receipt of supplementary information from the applicant, 3 November 2021
- 5) Request for supplementary information to the applicant, 22 December 2021
- 6) Receipt of supplementary information from the applicant, 31 March 2022
- 7) Request for supplementary information to the applicant, 20 May 2022
- 8) Receipt of supplementary information from the applicant, 8 June 2022
- 9) Request for supplementary information to the applicant, 28 June 2022
- 10) Receipt of supplementary information from the applicant, 22 August 2022

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## Abbreviations

CP4 EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
GOXv247	glyphosate oxidase
ORFs	open reading frames
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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