

STATEMENT

Assessment of the 2024 post-market monitoring report of genetically modified oilseed rape 73496

European Food Safety Authority (EFSA) | Michele Ardizzone | Thomas Frenzel | José Ángel Gomez Ruiz | Tilemachos Goumperis | Giovanni Savoini | Robin Ornsrud | Elena Sánchez-Brunete | Reinhilde Schoonjans

Correspondence: nif@efsa.europa.eu

The declarations of interest of all scientific experts active in EFSA's work are available at <https://open.efsa.europa.eu/experts>

Abstract

Following a request from the European Commission (EC), the European Food Safety Authority (EFSA) analysed the 2024 post-market monitoring (PMM) report of genetically modified oilseed rape (OSR) 73496 and the additional information provided during the assessment. EFSA concluded that the assumptions for consumption and for the intended uses considered during the pre-market risk assessment (human and animal dietary exposure) remain valid. The authorisation holder did not provide consumption data for humans and animals of OSR 73496 and of products derived from OSR 73496 as requested in the authorisation. However, EFSA concluded that the methodology used and the information provided is sufficient to conclude that the conditions considered during the pre-market risk assessment are still applicable.

KEY WORDS

GMO, oilseed rape 73496, post-market monitoring (PMM)

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

© 2025 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

CONTENTS

Abstract.....	1
1. Introduction	3
1.1. Background and Terms of Reference as provided by the requestor.....	3
1.2. EFSA GMO Panel pre-market risk assessment	3
2. Data and Methodologies.....	3
3. Assessment.....	3
3.1. Contents of the 2024 PMM report.....	3
3.1.1. Methodology used in the 2024 PMM report	3
3.1.2. Data provided in the 2024 PMM report.....	4
3.2. EFSA's assessment of the 2024 PMM report	5
3.2.1. Post-market monitoring for food	5
3.2.2. Post-market monitoring for feed	6
4. Conclusions.....	6
5. Recommendations for future monitoring	7
6. Documentation as provided to EFSA	7
Abbreviations	7
Requestor	7
Question number	7
Copyright for non-EFSA content.....	7
Legal notice	7
References.....	7

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

On 16 December 2024, the European Commission (EC) received from Corteva the post-market monitoring (PMM) report of genetically modified oilseed rape (OSR) 73496 in accordance with Commission Decision (EU) 2022/529¹ for the reporting period June 2023 – July 2024.

EFSA is requested to evaluate the findings of these monitoring activities. EFSA is also requested to assess the appropriateness of the methodology used for the monitoring.²

1.2 | EFSA GMO Panel pre-market risk assessment

OSR 73496 confers tolerance to the herbicidal active substance glyphosate through the expression of the glyphosate acetyltransferase protein GAT4621. During the pre-market risk assessment of OSR 73496, the compositional analysis in seeds showed an alteration of the N-acetylated amino acids as compared to its conventional counterpart. This alteration was characterised mainly by an increase of the levels of N-acetylaspartate (NAA), but also of N-acetylglutamate (NAG) and N-acetylthreonine (NAT) (EFSA GMO Panel, 2021).

As part of the pre-market risk assessment, the dietary exposure assessment in humans was focused on NAA. Dietary estimations were considered to assess the toxicological relevance of the compositional changes, using different dietary scenarios assuming the consumption of protein isolates and OSR powder produced from OSR 73496. The GMO Panel concluded that the human dietary exposure to NAA as estimated from the combined consumption of conventional food and considering the processed food from OSR 73496 is unlikely to present a risk to health in humans.

The dietary exposure assessment in farmed and companion animals considered NAA, NAG and NAT. Dietary intake estimations were considered to assess the toxicological relevance of the compositional changes, using different dietary scenarios assuming the consumption of OSR 73496 toasted defatted meal, protein isolates and solubles (whey fractions). Considering these scenarios, margins of exposures (MoEs) and estimated exposures to NAA, NAG and NAT were calculated for ruminants and monogastric animals (e.g. swine and horses based on feed incorporating defatted toasted meal from OSR 73496). While overall acceptable for NAG and NAT, further refinement of risk characterisation was considered for NAA (Section 3.3.3.2, pp. 24–27 of EFSA GMO Panel, 2021).

In conclusion, no safety concerns were identified with regards to the increased levels of the N-acetyl amino acids NAA, NAG and NAT in food and feed derived from OSR 73496 as considered during this risk assessment. Nonetheless, the GMO Panel recommended implementing a PMM plan to confirm the predicted consumption of OSR 73496 and/or its food and feed products and the application of conditions of uses considered during the pre-market risk assessment.

2 | DATA AND METHODOLOGIES

In delivering this statement, EFSA considered the information provided in the 2024 annual PMM report³ for OSR 73496 for the period July 2023–June 2024 received from the EC as provided by Corteva, the terms of reference of the mandate, the Commission Decision (EU) 2022/529 and the EFSA GMO Panel scientific opinion on application EFSA-GMO-NL-2012-109 (EFSA GMO Panel, 2021). Additional information was provided by the authorisation holder upon EFSA's request.

3 | ASSESSMENT

3.1 | Contents of the 2024 PMM report

3.1.1 | Methodology used in the 2024 PMM report

According to the Commission Decision (EU) 2022/529 (Section 1.1), the authorisation holder shall collect import data and, in case of imports, to collect consumption data for humans and animals on OSR 73496 and on products derived from OSR 73496 for food and for feed.

¹Commission Implementing Decision (EU) 2022/529 of 31 March 2022 authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape 73496 (DP-Ø73496-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

²Mandate for the assessment of the 2024 PPM report of GM oilseed rape 73,496 available on: <https://open.efsa.europa.eu/questions/EFSA-Q-2025-00197>.

³The GM oilseed rape 73,496 2024 PMM report is publicly available at https://food.ec.europa.eu/plants/genetically-modified-organisms/post-authorisation/monitoring-plans-and-reports_en#pmm_gmff.

The authorisation holder provided European Union (EU) import data from Eurostat⁴ for both OSR seed and OSR meal (both from non-GM and GM sources) for the period July 2023 to June 2024.

In addition, an estimate of OSR 73496 seed and meal that may be imported into the EU was presented together with the results of searches for potential new food and feed products in the EU using the following methodology:

- Information on the EU production, supply and distribution of OSR seed and OSR meal (USDA, 2024).⁵
- OSR cultivation and trade trends from USA Canola Association,⁶ Canola Council,⁷ USDA⁴ and Australian Oilseeds Federation.⁸
- Internal commercial information regarding the estimated percentage of OSR 73496 out of: (1) the total OSR harvested area in Australia, Canada and the USA in 2023; (2) the OSR 73496 seed units sold for sowing; (3) the OSR planting rates (seeds per surface).
- A literature search and review using Web of Science, Food Science and Technology Abstracts, Chemical Business NewsBase and Chemical Industry Notes from 2021 to 2024.
- Searches in the EU list of novel foods⁹ and EFSA website.¹⁰
- Consultation with sector's experts (EU trade associations COCERAL, FEDIOL and FEFAC).

Collection of consumption data for food and feed was not reported.

3.1.2 | Data provided in the 2024 PMM report

EU OSR imports and production

EU import data for both OSR seeds and OSR meal (both from non-GM and GM sources) were provided for the period July 2023 to June 2024, as well as information on the EU production, supply and distribution. The EU is the largest global producer of OSR, but imports are still required in order to meet the demand. Apart from food and feed uses, OSR is used for biodiesel production.

In the period July 2023 to June 2024, EU produced approximately 20 million metric tons and 14 million metric tons of OSR seeds and OSR meal respectively, whereas imports accounted for 4.4 million tonnes and 814 thousand tonnes respectively.

Estimation of OSR 73496 that may be imported into the EU

The authorisation holder declared that they were not an operator directly involved in the import of OSR into the EU for food/feed and processing. Therefore, they were not in a position to report directly on globally traded volumes of seed and meal of the OSR 73496. However, estimations of the amount of OSR 73496 seed and meal that could possibly be imported into the EU were provided. OSR 73496 is expected to be imported as a commodity with no nutritional or post-harvest value-added traits. Therefore, there is no anticipated segregation of OSR 73496 in the OSR chain for food and feed products.

Commercial production of OSR 73496 was harvested for the first time in three countries, namely Australia, Canada and United States of America (USA) and in 2023. The extent of OSR 73496 cultivation was rather low in these countries, between [REDACTED] of the total OSR harvested area.

Imports of OSR seeds from Australia, Canada and the USA represented about 37% of the imports from all countries outside the EU, whereas no OSR meal was imported. Data on OSR harvested area in these three countries were considered. Internal information on the OSR 73496 seed units sold for sowing and OSR planting rates (seeds per surface) was also provided by the authorisation holder.

The amounts of OSR 73496 seeds that might have been imported in the EU from Australia, Canada and the USA in the period July 2023 to June 2024 and potentially available for processing and for food and feed uses were estimated to be [REDACTED] tonnes, respectively. During the same period, considering that there were no imports of OSR meal from these countries, is expected that no OSR 73496 meal was imported into the EU.

Monitoring for new OSR food or feed uses in the EU

The authorisation holder performed a literature search using Web of Science, Food Science and Technology Abstracts, Chemical Business NewsBase and Chemical Industry Notes for the period 2021 to June 2024 seeking for information on

⁴GM oilseed rape 73,496 2024 PMM report; Annex 1: EU Oilseed rape Imports and Exporters; Source Eurostat (2024): <https://ec.europa.eu/eurostat/en/>.

⁵USDA FAS GAIN report April 8, 2024; https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Oilseeds%20and%20Products%20Annual_Vienna_European%20Union_E42024-0009.

⁶<https://www.uscanola.com/crop-production/spring-and-winter-canola/>.

⁷<https://www.canolacouncil.org/markets-stats/production/>.

⁸<https://australianoilseeds.com/resources/fact-sheets/>.

⁹https://food.ec.europa.eu/food-safety/novel-food/authorisations/union-list-novel-foods_en#updates-to-the-union-list-of-novel-foods.

¹⁰<https://open.efsa.europa.eu/>.

new processing methods and new food or feed uses of OSR. After reviewing the retrieved information, the authorisation holder concluded that, while there is research investigating new processing methods or new food or feed uses of OSR other than those already considered during the pre-market risk assessment, none were identified that are currently in commercial use.

The authorisation holder searched for OSR novel foods authorised since the adoption of the EFSA GMO Panel opinion of OSR 73496. The search identified none in the EU list for novel foods⁸. Although two new applications for OSR protein-fibre concentrate as novel food have been submitted to EFSA,⁹ one is still under risk assessment and the second under intake phase by EFSA. Therefore, neither product is authorised in the EU.

Lastly, other sources were consulted for gathering information regarding OSR food and feed uses and trends, namely, USA Canola Association,⁵ Canola council,⁶ USDA⁴ and a recent EFSA external scientific report (Martinez et al., 2024). No new OSR food and feed uses were identified.

Consultation with sector's experts

The authorisation holder stated that they consulted EU trade associations¹¹ (COCERAL, FEDIOL, FEFAC) to collect data and information regarding trends in the trade of OSR, processing technologies, and food and feed uses of OSR.

According to the information gathered, the primary use of OSR seeds is crushing for oil and meal production. In general, the non-GM OSR seeds provide oil to the food, feed and the oleochemical (biodiesel and energy) industries, while the meal is used in animal feed. No other new uses were identified. As for GM OSR seeds, they deliver oil to the oleochemical industry for biodiesel and energy production, whereas the meal is utilised in animal feed. No OSR food product labelled as GM has been identified on the EU market. The use of OSR oil for biodiesel in the EU has increased from 5.54 million tonnes in 2019 to 6.35 million tonnes in 2023. The expanded use of OSR oil for biodiesel has led to an equivalent increase in the use of OSR meal for feed. Furthermore, information about the use of OSR meal as feed for different animals was also provided in the 2024 PMM report. The average OSR meal uses in animal diets is impacted by the trend in OSR production, however, the level of incorporation is very stable.

Overall conclusions as provided in the 2024 PMM report

According to the authorisation holder, the availability of OSR 73496 (seed and meal) and derived products in the EU is expected to be limited compared to the assumptions made during the pre-market risk assessment. No new products from OSR were introduced in the EU market. Therefore, no changes in the consumption and feeding patterns were identified with respect to those considered in the risk assessment performed by the EFSA GMO Panel. Hence, according to the authorisation holder, the conclusions of the pre-market risk assessment are still applicable and valid.

3.2 | EFSA's assessment of the 2024 PMM report

Although exact figures are not available, the authorisation holder confirmed that imports of OSR 73496 seeds into EU are possible, based on the cultivation of this GM crop in three countries that are suppliers of OSR to the EU (Australia, Canada and USA).

3.2.1 | Post-market monitoring for food

EFSA confirmed the information provided by the authorisation holder that currently in the Union list of Novel foods¹² there are no new OSR novel foods apart from the two that were considered in 2021 at the time of the pre-market risk assessment. These two novel foods are partially defatted OSR powder and OSR protein isolates:

- For OSR powder the authorised uses remain the same as those considered in 2021.
- For the OSR protein isolates EFSA agrees with the confirmation by the authorisation holder that although there is ongoing research investigating for new food uses of OSR, no commercial uses were identified. The scenario conducted during the pre-market risk assessment assuming the use of protein isolates from OSR 73496 as protein supplements is overly conservative and covers any minor dietary exposure that could eventually result from niche foods containing OSR protein isolates.

A full replacement scenario was used to estimate the dietary exposure to NAA. This scenario assumes that the foods containing or produced from OSR 73496 considered in the assessment would replace 100% of the conventional counterpart foods in the market. Therefore, if no new protein-containing OSR novel foods enter the market, the increase in the amounts

¹¹GM oilseed rape 73496 2024 PMM report, Section 6; Additional information 23/6/2025.

¹²https://food.ec.europa.eu/food-safety/novel-food/authorisations/union-list-novel-foods_en#updates-to-the-union-list-of-novel-foods.

of OSR 73496 imported into EU per se will have no impact on the human dietary exposure estimations conducted at the pre-market risk assessment.

The information provided in the PMM report for the period June 2023 – July 2024 shows that the scenario assumed for consumption and for the intended uses during the pre-market risk assessment (human dietary exposure) was overly conservative. Therefore, the conclusions of the pre-market risk assessment of OSR 73496 remain applicable.

3.2.2 | Post-market monitoring for feed

It is noted that OSR meal is a protein and fibre-rich feed ingredient that can be used in animal nutrition. It is suitable for inclusion in feed for ruminants, monogastric animals and fish, provided that diets are appropriately formulated to account for its nutritional composition and the presence of natural antinutritional factors. Processing methods and dietary strategies can enhance its digestibility and nutritional value across different animal species. Whilst no imports of OSR 73496 meal were expected (Section 3.1.2), meal could be produced from OSR 73496 seeds imported. The amount of meal potentially produced from OSR 73496 might be up to 60% of the seed imported.¹³

The EFSA GMO Panel Scientific Opinion (2021) on OSR 73496 applied a conservative approach, assuming full replacement scenarios of conventional OSR with OSR 73496 in feed.

In the 2024 PMM report provided by the authorisation holder, no new feed products or consumption trends were identified and imports of OSR 73496 seeds were reported to be limited in comparison to the overall availability of OSR in the EU. No feed consumption data for OSR 73496 were provided. As reported in Pinotti et al. (2024), obtaining harmonised feed consumption data poses several challenges, particularly when it involves specific GM feed materials.

Based on the information provided by the authorisation holder in the 2024 PMM report, even in the absence of feed consumption data, EFSA considers that the conclusions of the pre-market risk assessment of OSR 73496 remain applicable.

Additional considerations

Unlike novel foods, which require specific authorisation under EU law, new feed materials do not follow a harmonised approval process. Feed materials are listed in the EU catalogue of Feed Materials. Its use by the feed business operators shall be voluntary. Regulation (EC) No 767/2009 on the placing on the market and use of feed states in article 24(6): *'the person who, for the first time, places on the market a feed material that is not listed in the Catalogue shall immediately notify its use to the representatives of the European feed business sectors. The representatives of the European feed business sectors shall publish a register of such notifications on the Internet and update the register on a regular basis'*.

EFSA acknowledges that obtaining reliable feed consumption data poses several challenges:

- (i) When it involves specific GM feed materials, this is likely due to the practical challenges as these materials are often used in relatively small volumes compared to non-GM or more commonly used GM feed ingredients, necessitating knowledge on inclusion rate at product level.
- (ii) As highlighted by Pinotti et al. (2024), the lack of harmonised and transparent data on the use of feed ingredients across animal species remains a major limitation for exposure assessments in regulatory contexts. Stakeholders such as national and EU feed industry associations, large feed manufacturers and species-specific producer groups could be engaged to support voluntary data sharing or the development of sector-wide consumption estimates. Without access to such data, it is challenging to verify real-world exposure levels or confirm assumptions made during pre-market evaluations.

4 | CONCLUSIONS

The information provided in the PMM report for the period June 2023 – July 2024 shows that the assumptions for consumption and for the intended uses considered during the pre-market risk assessment (human and animal dietary exposure) were overly conservative. Therefore, the conclusions of the pre-market risk assessment of OSR 73496 remain applicable.

The authorisation holder did not provide consumption data for humans and animals of OSR 73496 and of products derived from OSR 73496 as requested in the authorisation. However, EFSA concluded that the methodology used and the information provided is sufficient to conclude that the conditions considered during the pre-market risk assessment are still applicable.

¹³<https://www.canolacouncil.org/markets-stats/>.

5 | RECOMMENDATIONS FOR FUTURE MONITORING

As part of the pre-market risk assessment, the EFSA GMO Panel performed a risk characterisation concerning the occurrence of NAA, NAG and NAT in processed foods and feeds from OSR 73496 which resulted in acceptable MoEs for humans and animals. This was conducted following human and animal dietary exposure assessments to N-acetylated amino acids and based on toxicological reference values for these compounds derived from animal toxicity studies. In the context of a renewal application for the authorisation of OSR 73496 (10 years after the initial approval), EFSA recommends that updated data on the concentration of N-acetylated amino acids (NAA, NAG and NAT) in seeds should be provided to inform the post-market dietary exposure assessment and the risk characterisation for these compounds in humans and animals.

Literature search and review should be conducted (10 years after the initial approval) according to EFSA's updated guidance on systematic literature review methodology to ensure that all relevant scientific and technical publications are captured and evaluated appropriately in the renewal application for authorisation of OSR 73496.

While the 2024 PMM report concluded that imports of OSR 73496 were limited, this situation may change in the future. If the volume of imports increases, robust consumption data will become more important for evaluating dietary exposure in animals.

Monitoring of new uses for feed and new feed products derived from OSR is also warranted.

6 | DOCUMENTATION AS PROVIDED TO EFSA

- Mandate from the European Commission (EC) received on 4 February 2025 requesting EFSA to assess the 2024 post-market monitoring report of GM oilseed rape 73496.
- The mandate was accepted on 4 March 2025.
- Request for supplementary information to the authorisation holder, 26 May 2025.
- Receipt of supplementary information from the authorisation holder, 23 June 2025.

ABBREVIATIONS

EFSA GMO Panel	EFSA Panel on Genetically Modified Organisms
GM	Genetically modified
GMO	Genetically modified organism
MoE	margin of exposure
NAA	N-acetylaspartate
NAG	N-acetylglutamate
NAT	N-acetylthreonine
OSR	oilseed rape
PMM	Post-market monitoring

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2025-00197

COPYRIGHT FOR NON-EFSA CONTENT

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.

LEGAL NOTICE

Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by EFSA. The full output has been shared with the European Commission, EU Member States (if applicable) and the applicant. The blackening may be subject to review once the decision on the confidentiality requests is adopted by EFSA and in case it rejects some of the confidentiality requests.

REFERENCES

- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Mullins, E., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., Devos, Y., ... Lanzoni, A. (2021). Scientific Opinion on the assessment of genetically modified oilseed rape 73496 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2012-109). *EFSA Journal*, 19(6), 6610. <https://doi.org/10.2903/j.efsa.2021.6610>
- Martinez, J. M., Gutiérrez, M., Moreno, B., Calvo, M., Fondevila, M., Belanche, A., Raso, J., Moreno, J., Álvarez, I., & Cebrián, G. (2024). Investigating technological processing supporting the assessment of novel proteins in food and feed risk assessment scientific report. *EFSA Supporting Publications*, EN-9113. <https://doi.org/10.2903/sp.efsa.2024.EN-9113>

Pinotti, L., Pastorelli, G., Varese, G., Cheli, F., Di Lorenzo, M. S., Landolfi, C., Mangano, G., Gazerro, C., Perricone, V., Ottoboni, M., Moradei, A., Abbate, R., Luciano, A., & Mercogliano, F. (2024). A proposal for the development of a feed consumption database using a standardised feed classification system. *EFSA Supporting Publications*, 21(9), EN-9036. <https://doi.org/10.2903/sp.efsa.2024.EN-9036>

How to cite this article: EFSA (European Food Safety Authority), Ardizzone, M., Frenzel, T., Gomez Ruiz, J. Á., Goumperis, T., Savoini, G., Ornsrud, R., Sánchez-Brunete, E., & Schoonjans, R. (2025). Assessment of the 2024 post-market monitoring report of genetically modified oilseed rape 73496. *EFSA Journal*, 23(7), e9579. <https://doi.org/10.2903/j.efsa.2025.9579>