Assessment of genetically modified MS8, RF3, and MS8 × RF3 canola for food and feed uses, import and processing submitted for renewal of authorisation under assimilated Regulation (EC) No. 1829/2003

Reference Number RP1585

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Regulated Product Dossier Assessment

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1. Executive summary

FSA/FSS have reviewed an assessment of application RP1585 for the renewal of authorisation of genetically modified (GM) MS8, RF3, and MS8 × RF3 oilseed rape (canola) for food and feed uses, import and processing.

This GM application has been made to renew the authorisation in Great Britain (GB) as it is 10 years since the product was authorised and placed on the market in the EU. The same events have been authorised for food and/or feed use in 10 or more other territories worldwide as the information and data demonstrate that the regulatory science and safety criteria are satisfied according to the regulatory requirements in those territories. This Genetically Modified Organism (GMO) had its authorisation renewed by the European Food Safety Authority (EFSA) in 2023.

FSA/FSS have reviewed the information provided by the applicant and the EFSA renewal Opinion[1] and confirmed that MS8, RF3, and MS8 × RF3 canola, as described in this application, is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses in GB.

2. Background and purpose of review

In accordance with assimilated EU Regulation 1829/2003 on genetically modified food and feed[2], the application RP1585 for the renewal of authorisation of genetically modified MS8, RF3, and MS8 × RF3 canola, 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. When GB left the EU, it retained the same regulations for food and feed regulated products; FSA/FSS also adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

To ensure our regulatory systems are risk proportionate and resources are used effectively, FSA/FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA Scientific Opinion, to provide a summary assessment of the evidence of safety presented in this report.

Specifically, in reviewing the risk assessment that EFSA have recently completed, the reviewers have verified that the standard approach taken, when compared to the relevant guidance, is appropriate for GB and the conclusions made are consistent with the data summarised in the Opinion. Consideration has been given to the processes undertaken by EFSA to ensure that the 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 conclusion of the assessment is that there is sufficient evidence of safety to conclude without requiring further risk assessment activities at this time.

2.1 Applicant

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USA

(represented by)

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2.2 Source/organism

Oilseed rape/canola (*Brassica napus*).

2.3 Genetic modification step

This renewal application comprises two GM events and a stacked event; MS8, RF3, and MS8 × RF3. MS8 canola is a male sterile line modified to express Barnase in the tapetum cells during anther development resulting in a lack of viable pollen and consequently male sterility. RF3 is the fertility restorer line which expresses Barstar in the tapetum cells to inhibit the activity of Barnase. The stacked MS8 × RF3 event is a fully fertile hybrid, benefitting from hybrid vigour. All events also contain the *bar* gene which confers tolerance to glufosinate-ammonium herbicides.

3. Details of other Regulators' opinions

These events (either MS8 × RF3, or both individual events) have been authorised for food and/or feed use in 15 or more other territories worldwide (Australia, Canada, China, Colombia, Iran, Japan, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa, South Korea, Taiwan, and USA).

Specifically, reviewing the EFSA risk assessment[1] and renewal data provided by the applicant, it was found that there is no evidence for new hazards, modified exposure, or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape MS8, RF3, and MS8 × RF3, which were that MS8, RF3, and MS8 × RF3 oilseed rape is "unlikely to have an adverse effect on human and animal health or on the environment, in the context of their intended uses".

3.1 Methodology applied in the EFSA Opinion

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015; 13(6):4129, 8 pp. https://doi:10.2903/j.efsa.2015.4129.[3]

3.2 Specification

In accordance with Commission Regulation (EC) No 65/2004[4], the unique identifiers for MS8, RF3, and MS8 × RF3 oilseed rape are:

- MS8: ACS-BNØØ5-8
- RF3: ACS-BNØØ3-6
- MS8 × RF3: ACS-BNØØ5-8 × ACS-BNØØ3-6

Information provided on the identity, composition and specification of the plant does not raise safety concerns. In the context of this renewal application, new bioinformatics analyses were provided to assess the potential interruption of endogenous oilseed rape genes. Results confirmed previous conclusions which did not identify interruption of endogenous genes.

3.3 Exposure assessment

EFSA undertook an exposure assessment as part of their Scientific Opinion. In order to verify if it was still relevant for GB, data from National Diet and Nutrition Survey databases were reviewed by FSA/FSS. This showed UK oilseed rape consumption is similar to that of other EU countries during the time period of the previous authorisation, with no significant changes over that time period. These data confirm the suitability of the risk assessment for GB use.

3.4 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.

3.5 Analytical Method Review

FSA/FSS accepted the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) report, showing that the detection methods for MS8[5], RF3[6], and MS8 × RF3[7] oilseed rape were previously validated and declared fit for purpose.

3.6 Post Market Environmental Monitoring Plan (PMEM)

FSA/FSS reviewed and accepted the EFSA GMO Panel conclusions about the PMEM plan proposed by the applicant for MS8, RF3, and MS8 × RF3 oilseed rape, considering the scope consistent with the intended uses. FSA/FSS accepted the proposed PMEM plan and did not require additional monitoring.

3.7 Proposed labelling

The applicant proposed no additional labelling of MS8, RF3, and MS8 × RF3 oilseed rape on the basis that it is equivalent to the conventional counterparts, and its intended use is the same as for conventional oilseed rape. The FSA/FSS accept the applicant's conclusion and do not require specific or additional labelling.

4. Other regulators' opinions and conclusions

EFSA[1] found that there is "no evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment" for these events, herein denoted as MS8, RF3, and MS8 × RF3 oilseed

rape. The conclusions of the original EFSA risk assessment, that MS8, RF3, and MS8 × RF3 oilseed rape is “unlikely to have an adverse effect on human and animal health or on the environment, in the context of their intended uses”, therefore remain unchanged.

It is noted that MS8, RF3, and MS8 × RF3 oilseed rape are not authorised for cultivation in the UK/EU. No post market monitoring of food and feed is necessary. The proposed PMEM plan was acceptable and did not require extra monitoring.

5. Caveats and uncertainties

No caveats and uncertainties were identified.

6. FSA/FSS conclusion for GB risk analysis

The application has been assessed in line with the applicable guidance[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 EFSA Opinion have been reviewed in detail by FSA/FSS and are considered appropriate and applicable to GB.

7. Outcome of assessment

FSA/FSS have reviewed the applicant’s renewal application, supporting documentation, and other regulators risk assessments, most notably, the EFSA risk assessment opinion (2023) and consider sufficient evidence has been demonstrated to conclude without further questions or risk assessment activities.

The environmental and human safety of MS8, RF3, and MS8 × RF3 oilseed rape has been well characterised by the applicant under the Annex II to the Cartagena Protocol. It is therefore accepted by FSA/FSS the conclusion that MS8, RF3, and MS8 × RF3 oilseed rape pose no increased risk to conservation and sustainable use of biodiversity, or to human or animal health in terms of allergenicity or toxicity compared to conventional oilseed rape.

The FSA/FSS conclude that genetically modified MS8, RF3, and MS8 × RF3 oilseed rape, as described in this application, poses no new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment.

In making this assessment the following principles have been applied:

1) There is no legal duty to perform a separate risk assessment for GB and there was sufficient scientific evidence to make a conclusion on safety with no further questions to the applicant, and therefore no further risk assessment activities are necessary.
2) The application is for a renewal or authorisation where the UK/GB already has accepted the established risk of the products on the market.
3) Sufficient evidence was available in the literature, for example, where other National food safety authorities had positively assessed the application using the same risk assessment guidance in principle and legal requirements in GB with the exception to changes in the General Food Law.
4) Applicants provided sufficient relevant information as requested by FSA/FSS.
5) FSA/FSS review did not find any issues of divergence from guidance or mutual approaches or new scientific issues for consideration.
6) There were no other specific issues that would require an assessment for the UK or the nations of the UK.

8. References

1. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2023. Scientific Opinion on the assessment of genetically modified oilseed rape MS8, RF3 and MS8xRF3 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-024). EFSA Journal 2023;21(4):7934, 14 pp. https://doi.org/10.2903/j.efsa.2023.7934
2. Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
3. EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. *EFSA Journal* 2015; 13(6):4129, 8 pp.
4. 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
5. Joint Research Centre, Institute for Health and Consumer Protection, Savini, C., Bogni, A., Mazzara, M., 2007. Event-specific method for the quantification of oilseed rape line Ms8 using real-time PCR validation report, Publications Office, 2007a, https://data.europa.eu/doi/10.2788/33880
6. Joint Research Centre, Institute for Health and Consumer Protection, Mazzara, M., Savini, C., Bogni, A. et al., 2013. Event-specific method for the quantification of oilseed rape line Rf3 using real-time PCR v. 1.01 – Validation report, validated method, seeds sampling and DNA extraction, Publications Office, 2013, https://data.europa.eu/doi/10.2788/22600
7. Joint Research Centre, Institute for Health and Consumer Protection, Savini, C., Grazioli, E., Mazzara, M., 2007. Verification of performance of Ms8 and Rf3 event-specific methods on the hybrid Ms8xRf3 using real-time PCR validation report, Publications Office, 2007b, https://data.europa.eu/doi/10.2788/31713