MON 94100 oilseed rape

Herbicide-tolerant

Key facts

Bayer Agriculture BV[1]
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[1] Hereafter referred to as ‘Bayer’.

Oilseed rape, a little known but economically important crop

Oilseed rape[2] (*Brassica napus*) is the second most important source of vegetable oils in the world, after soybean oil[3]. Oilseed rape originates from the Mediterranean area but has been cultivated for thousands of years in Asia and India. It has been grown in Europe since the 13th century, initially as a source of fuel, then more recently as food and animal feed.

In 2021-2022, 74.03 million metric tons of oilseed rape were produced in the world, which represents approximately 38.08 million hectares of oilseed rape harvested globally[4]. Significant areas of production included EU, China, Canada and India representing 23.3%, 19.9%, 18.6% and 14.9% of the global oilseed rape production, respectively[4].

Today, oilseed rape is one of the few intensively cultivated crops in European agriculture, with a total volume of 5.3 million hectares[5]. The most significant areas of production in Europe (EU-27) for the 2020-2021 season include Germany, Poland, France, Romania and the Czech Republic representing 18.8%, 18.7%, 18.5%, 8.4% and 6.4% of total EU production, respectively. For the 2020-2021 season, the main suppliers of oilseed rape to the EU were Canada and Ukraine with 36.1% and 34.3% of imports, respectively.

As in other world areas, oilseed rape use in Europe is dominated by the demand for oil both for human consumption (salad oil, cooking oil and raw materials for the production of margarine and mayonnaise) and industrial purposes (lubricants for engines, slipping agents, plasticisers, cosmetics, pharmaceuticals, surfactants, soaps and detergents). Oilseed rape meal is fed to animals.

What is MON 94100?

MON 94100, developed by Monsanto Company through *Agrobacterium*-mediated transformation of oilseed rape hypocotyls, contains the *dmo* gene from *Stenotrophomonas maltophilia* that expresses the DMO protein to confer tolerance to dicamba herbicide.

Worldwide plantings and regulatory status of MON 94100

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide[6]. Of the 190.4 million hectares of global biotech crops planted in 2019, 5.3% or 10.1 million hectares were biotech oilseed rape.

MON 94100 oilseed rape received regulatory approval for cultivation in Canada. It has also received regulatory approval for food and/or feed uses in Australia/New Zeeland, Canada, the European Union, Japan, Philippines and Taiwan.

MON 94100 single product is not and will not be commercialised on its own, instead stacked products, made via traditional breeding, are the aimed commercial products.

A stringent regulatory system for GM crops in the EU

In the EU, the regulatory system for GM crops comprises several regulations and directives, including Directive 2001/18/EC for deliberate release of genetically modified organisms (GMOs) in the environment, Regulation (EC) No 1829/2003 on GM Food and Feed and Commission Implementing Regulation (EU) No 503/2013.

Directive 2001/18/EC includes procedures for the authorisation of deliberate release into the environment of GMOs, whereas Regulation (EC) No 1829/2003 includes procedures for the authorisation of deliberate release (cultivation and/or import, processing and, food and feed use), according to the "one door, one key" principle. Commission Implementing Regulation (EU) No 503/2013 includes requirements for applications for authorisation of GM food and feed in accordance with Regulation (EC) No 1829/2003.

A regulation on traceability and labelling of GMOs and products produced from GMOs (Regulation (EC) No 1830/2003) entered into enforcement on 18 April 2004.

Furthermore, a regulation laying down the methods of sampling and analysis for the official control of feeding as regards to the presence of GM material for which an authorisation procedure is pending or the authorisation of which has expired (Commission regulation (EU) No 619/2011) entered into force on 24 June 2011.

Regulatory status of MON 94100 in the EU

On 29 October 2020 Bayer CropScience LP submitted an application for import and food and feed uses of MON 94100 oilseed rape as any other oilseed rape (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Dutch Competent Authority. This application received the reference number EFSA-GMO-NL-2020-169 and was declared valid on 25 March 2021.

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2 Also known as canola, rapeseed or colza.

3 SoyStats® 2022 - http://soystats.com/international-world-oilseed-production/ (Accessed on 08 March 2023).

4 https://apps.fas.usda.gov/psdonline/app/index.html#/app/downloads (Accessed on 08 March 2023).

5 European Commission - https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en (Accessed on 08 March 2023).

6 ISAAA, 2019 - http://www.isaaa.org/resources/publications/ (Accessed on 08 March 2023).

The EFSA evaluated the application as well as additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications.

On 22 July 2022, the EFSA published a positive Scientific Opinion on the safety of MON 94100 oilseed rape (EFSA, 2022). The EFSA GMO panel concluded that "*oilseed rape MON 94100 is as safe as its conventional counterpart and the tested non-GM oilseed rape reference varieties with respect to potential effects on human and animal health and the environment*".

On 14 December 2022, the European Commission (EC) presented the Draft Commission Implementing Decision of the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote. After this vote, since no qualified majority was reached, the draft decision was passed to the Appeal Committee (AC) who met for a vote on 24 January 2023, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 22 February 2023 (European Commission, 2023).

Traceability, labelling, unique identifier

Operators handling or using GM products and derived food and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products, laid down in Regulations (EC) No 1829/2003 and 1830/2003. MON 94100 single product is not and will not be commercialised on its own. The unique identifier for this product is MON-941ØØ-2.

In September 2020, MON 94100 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF). The validated method, as well as the validation report for MON 94100, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), are available at the EURL website [7].

Food, feed and environmental safety of MON 94100

Food and feed safety

The food and feed safety assessment of MON 94100 was established based on:

- A detailed molecular characterisation of the inserted DNA confirming that a single copy of the DMO expression cassette was integrated at a single locus within the oilseed rape genome;
- The long history of safe use of the DMO protein;
- The compositional and nutritional equivalence of the grains derived from MON 94100 with those of conventional oilseed rape;
- The rapid digestibility of the DMO protein by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of the DMO protein as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies;
- A large margin of safety resulting from the low dietary exposure to the DMO protein in MON 94100.

Further details on the safety of MON 94100 are available in the EFSA scientific opinion adopted on 20 June 2022 (EFSA, 2022).

Environmental safety

Extensive field trials as well as laboratory experiments demonstrated that MON 94100 poses negligible risk to human and animal health or the environment.

The agronomic and phenotypic analyses confirmed that MON 94100 does not possess characteristics that would confer a plant pest risk compared to conventional oilseed rape. Data on the environmental interaction also confirmed that MON 94100 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of unintended environmental effects due to the adventitious release and spread of MON 94100 oilseed rape will not be different from that of traditionally bred oilseed rape. Moreover, the scope of the authorisation covers the import, processing and all uses as any other oilseed rape, but excludes cultivation from MON 94100 oilseed rape in the EU. Also, MON 94100 single product is not and will not be commercialised on its own. Therefore, no deliberate release of the viable plant material in the EU environment is expected.

Contact point for further information

MON 94100 single product is not and will not be commercialised on its own.

Operators in the food and feed supply chain and/or any other person wishing to report a potential adverse effect associated with the import or use of Bayer products, can refer to the CropLife Europe website at:

https://croplifeeurope.eu/product-information/

If required, additional comments or questions relative to MON 94100 can also be addressed to Bayer at:

https://www.cropscience.bayer.com/en/support/contact-us

[7] EURL - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 08 March 2023).

References

EFSA, 2022. Assessment of genetically modified oilseed rape MON 94100 for food and feed uses, under regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-169). EFSA journal, 20, e07411.

European Commission, 2023. Commission Implementing Decision (EU) 2023/416 of 22 February 2023 authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 (MON-941ØØ-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union, L 59/25, 1-5.