

GT73 oilseed rape

Roundup Ready®

Herbicide-tolerant

Key facts



Bayer Agriculture BV¹
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¹ Hereafter referred to as 'Bayer'

Roundup Ready® is a registered trademark of Bayer Group.

Oilseed rape, a little known but economically important crop

Oilseed rape² (*Brassica napus*) is the second most important source of vegetable oils in the world, after soybean oil³. 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.

Total oilseed rape production in 2023/24 reached approximately 87 million metric tonnes⁴. The main oilseed rape producing regions globally are EU (22.9% of global production), Canada (21.5%), China (17.9%) and India (13.7%). Today, oilseed rape is one of the few intensively cultivated crops in European agriculture, with a total volume of more than 5 300 thousand hectares⁵. The most significant areas of production in Europe (EU-27) for the 2022 include France (19% of total EU production), Romania (14%), Germany (10%), Poland (9.5%), Bulgaria (8.7%) and Spain (8.5%)⁶. For the 2023-2024 season, the main suppliers of oilseed rape to the EU are Ukraine and Australia⁷.

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 GT73?

GT73 oilseed rape (or Roundup Ready[®] canola) plants have been developed to enable farmers to effectively control weeds during the growing season by using Roundup[®] agricultural herbicides.

Glyphosate tolerance

Roundup[®] herbicides contain the active ingredient glyphosate, a broad spectrum herbicide that acts via inhibition of the protein 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS). EPSPS is found naturally in all plants, fungi and bacteria and is important in the production of essential aromatic amino acids. Inhibition of EPSPS by glyphosate blocks the production of these amino acids, interfering with growth and ultimately leading to plant death.

GT73 oilseed rape plants contain a glyphosate tolerant EPSPS, isolated from the CP4 strain of the common soil bacterium *Agrobacterium tumefaciens*, as well as a glyphosate metabolising protein, glyphosate oxidoreductase (GOX), derived from the bacterium *Ochrobactrum anthropi*. The presence of the glyphosate tolerant EPSPS ensures the continued function of the aromatic amino acid pathway, even in the presence of the herbicide glyphosate, while the GOX protein catalyses the breakdown of glyphosate.

Worldwide plantings and regulatory status of GT73

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide⁸. Of the 190.4 million hectares of global biotech crops planted in 2019, 5.3% or 10.1 million hectares were biotech oilseed rape.

GT73 oilseed rape received regulatory approval for cultivation in Australia, Canada, and United States. GT73 has also received regulatory approvals for food and/or feed uses in Australia/New Zealand, China, the EU, Great Britain, Japan, Korea, Malaysia, Mexico, Philippines, Singapore, Taiwan and Vietnam⁹.

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.

² Also known as canola, rapeseed or colza.

³ <http://soystats.com/international-world-oilseed-production/> (Accessed on 15 March 2024).

⁴ <https://apps.fas.usda.gov/psdonline/app/index.html#/app/download> (Accessed on 15 March 2024).

⁵ European Commission - https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en (15 March 2024).

⁶ Eurostat, 2022 - [Statistics | Eurostat \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&plugin=1) (Accessed on 15 March 2024).

⁷ European Commission - [oilseeds-trade-2017-18-marketing-year-July-December.pdf \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&plugin=1) (Accessed on 15 March 2024).

⁸ ISAAA, 2019 - <http://www.isaaa.org/resources/publications/> (Accessed on 15 March 2024).

⁹ CropLife International - [Biotradestatus.com - Results Page](https://www.crop-life.com/~/media/2023/09/Biotradestatus.com-Results-Page.pdf) (Accessed on 15 March 2024).

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 GT73 in the EU

GT73 has been subject to many scientific reviews in the EU since 1995 and is authorised¹⁰ for

- 1) Foods and food ingredients containing, consisting of or produced from genetically modified oilseed rape MON-00073-7;
- 2) Feed containing, consisting of or produced from genetically modified oilseed rape MON-00073-7;
- 3) Products containing or consisting of genetically modified oilseed rape MON-00073-7 for uses other than food and feed, with the exception of cultivation.

Traceability, labelling, unique identifier

Operators handling or using GT73 oilseed rape 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) and 1830/2003. The unique identifier for this product is MON-00073-7.

GT73 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL)¹¹. The validated method, as well as the validation report for GT73, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), are available at the EURL website¹².

Food, feed and environmental safety of GT73

Food and feed safety

The food and feed safety assessment of GT73 was established based on:

- The long history of safe use of the CP4 EPSPS and GOX proteins in general;
- An assessment of the toxic and allergenic potential of CP4 EPSPS and GOX proteins based on a history of safe use, extensive information collected and safety evaluations performed, demonstrates that CP4 EPSPS and GOX proteins are unlikely to be a toxin or allergen;
- Compositional and nutritional analyses confirmed that GT73 were compositionally and nutritionally equivalent to conventional oilseed rape;
- From an agronomic and phenotypic (morphological) point of view, GT73 is equivalent to conventional oilseed rape, except for the introduction of genes

and the production of the proteins from the introduced genes

- A large margin of safety resulting from the low dietary exposure to the CP4 EPSPS and GOX proteins.

GT73 oilseed rape was found to be as safe and nutritious as conventional oilseed rape by analysis of key nutrients, as well as by a feed performance study using grain fed to broiler. Furthermore, in over two decades of commercial plantings of GT73 oilseed rape in Australia, Canada and the United States, there have been no verified incidents of adverse health effects linked to GT73 oilseed rape.

Environmental safety

The environmental safety of GT73 was established through extensive field trials conducted in Canada and the EU between 1992 to 2000. All these field trials demonstrated that GT73 poses negligible risk to human health or to the environment. Results showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of GT73 compared to the conventional oilseed rape control. On the basis of these studies, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in GT73 and that GT73 is not different in its phenotypic and agronomic behaviour relative to conventional oilseed rape.

The scope of the EU authorisations excludes cultivation in the EU, and no deliberate release of the viable plant material in the EU environment is expected thereby limiting the environmental exposure to accidental spillage only.

The likelihood of GT73 spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional oilseed rape. During the general surveillance activities covering the previous authorisations period of GT73, no adverse effects were reported.

GT73, the benefits

In the countries where GT73 oilseed rape is grown, this crop benefits both farmers and the environment by providing:

- A broad-spectrum weed control option in oilseed rape and increased flexibility to treat weeds on an “as needed” basis;
- The opportunity to replace several selective herbicides by a single broad-spectrum herbicide. The active ingredient glyphosate is non-persistent and has limited mobility as it binds tightly to soil. The compound presents very low toxicity to humans. Furthermore, it does not bioaccumulate and presents minimal risk to terrestrial and aquatic

¹⁰ EC - Community register of GM food and feed - <https://webgate.ec.europa.eu/dyna2/gm-register/> (Accessed on 15 March 2024).

¹¹ Now called European Union Reference Laboratory (EURL).

¹² EURL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> (Accessed on 15 March 2024)

species including fish, birds, mammals and invertebrates;

- An excellent fit with reduced tillage systems, which are linked to many environmental advantages including improved soil and water quality, reduced soil erosion and runoff, improved wildlife habitat and reduced fuel use and CO₂ emissions (Fawcett and Towery, 2002);
- Reduced pesticide use and/or number of pesticide spray applications. In Canada where GMHT canola has been planted since 1996, a report estimated a reduction of 6,000 tonnes (2.02 kg/ha) of herbicide used as a result (Gianessi *et al.*, 2003). Several projections made for Europe suggest potential savings in herbicide use of 12-60% (Brookes, 2003; Phipps and Park, 2002) and reductions in herbicide costs of up to 30% (CETIOM, 2000). A reduction in the total number of chemical applications over a 3-year period, resulting in a decrease of nearly 1.3 million kg annually herbicide active ingredient being applied. Fewer tillage passes over the survey period, improving moisture conservation, decreasing soil erosion and contributing to carbon sequestration in annual cropland (Smyth *et al.*, 2011).

Contact point for further information

Since traders may commingle GT73 with other commercial oilseed rape, including authorised GM oilseed rape, Bayer is working together with other members of the plant biotechnology industry within the CropLife Europe and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

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 oilseed rape products, can refer to the CropLife Europe website at:

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

If required, additional comments or questions relative to GT73 can also be addressed to Bayer at:

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

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