MS8 × RF3 × GT73

Herbicide-tolerant oilseed rape hybrid

Key facts

BASF Agricultural Solutions Seed US LLC[1] and Bayer Agriculture BV[2]

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[1] Hereafter referred to as 'BASF'.

[2] Hereafter referred to as 'Bayer'.

Oilseed rape, a little known but economically important crop

Oilseed rape[3] *(Brassica napus)* is the third most important source of vegetable oil in the world, after palm and soybean[4]. It 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 feed.

In 2019-2020, 70.51 million metric tons of oilseed rape were produced in the world, which represents approximately 34.03 million hectares of oilseed rape harvested globally. Significant areas of production included Canada, EU, China, and India representing 26.48%, 21.93%, 19.65% and 13.19% of the global oilseed rape production, respectively[5]. For the same period, the oilseed rape area harvested in the EU-27 accounted for approximately 5.33 million hectares, with a production of around 20.5 million metric tons[7]. Furthermore, the EU-27 imported 6.2 million metric tons of oilseed rape during the same time span; about 97% of the EU imports came from Ukraine, Canada and Australia[6]. The Netherlands, France, Germany and Belgium are among the largest importer EU Member States.

As in other world areas, oilseed rape use in Europe is dominated by the demand for oil for human consumption (salad oil, cooking oil, raw materials for the production of margarine and mayonnaise, etc.), industrial purposes (lubricants for engines, slipping agents, plasticisers, cosmetics, pharmaceuticals, surfactants, soaps, detergents, etc.) and biodiesel. Oilseed rape meal is also fed to animals (OECD, 2012).

What is MS8 × RF3 × GT73?

MS8 × RF3 × GT73 was obtained by traditional breeding of three independent genetically modified oilseed rape events, MS8, RF3 and GT73. MS8 × RF3 × GT73 combines the traits of agronomic interest from the three parental lines, *i.e.* herbicide-tolerance and hybrid system. Oilseed rape is a segregating crop and therefore MS8 × RF3 × GT73 grain includes the combined event product and any combination of these events (sub-combinations).

MS8 × RF3 × GT73, as well as the genetically modified parental oilseed rape lines MS8 and RF3 are currently owned by BASF, whereas the genetically modified parental oilseed rape event GT73 is currently owned by Bayer.

More information on the parental lines can be found on the CropLife Europe (CLE) website [7].

Worldwide plantings and regulatory status of MS8 × RF3 × GT73

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide[8]. GM oilseed rape, continued to be a significant biotech crop in 2019, occupying 10.1 million hectares[9].

MS8 × RF3 × GT73 has received regulatory authorisation for production in Australia, Canada and USA. It also received regulatory authorisation for import and food and feed use in the EU, Japan, Korea, Mexico, New Zealand and Taiwan.

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.

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[3] Also known as canola, rapeseed or colza

[4] SoyStats® 2021 - http://soystats.com/international-world-vegetable-oil-consumption/ (Accessed on 30 August 2021)

[5] FAOSTAT, 2020 - http://www.fao.org/faostat/en/ (Accessed on 30 August 2021)

[6] Eurostat, 2020 - http://ec.europa.eu/eurostat (Accessed on 30 August 2021)

[7] CropLife Europe - https://croplifeeurope.eu/product-information/ (Accessed on 30 August 2021)

[8] ISAAA - https://www.isaaa.org/resources/publications/briefs/55/#:~:text=In%20total%2C%20190.4%20million%20hectares,farmers%20and%20their%20families%20worldwide. (Accessed on 30 August 2021)

[9] ISAAA - https://www.isaaa.org/resources/infographics/top5biotechcrops/pdf/Top_5_Biotech_Crops_2018.pdf (Accessed on 30 August 2021)

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, and processing), in addition to 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 force on 18 April 2004.

Furthermore, a regulation laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified 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 MS8 × RF3 × GT73 in the EU

On 14 October 2009, the co-applicants (Bayer Crop Science AG and Monsanto Company, now BASF and Bayer, respectively) submitted an application for import for food and feed use of MS8 × RF3 × GT73 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. The application received the reference number EFSA-GMO-NL-2009-75 and was declared valid on 11 March 2012. The EFSA evaluated the application as well as additional information provided by BASF and Bayer, scientific comments submitted by the EU Member States and relevant scientific publications.

On 20 May 2016, the EFSA published a scientific opinion on the safety of MS8 × RF3 × GT73 and sub-combinations, which have not been authorised previously, independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food (EFSA, 2016). The EFSA GMO Panel concluded that " *In line with previous assessments and considering the scope of this application, the GMO Panel did not find indications of safety concern for food and feed with trace levels of glyphosate oxidoreductase (GOX)v247 protein derived from the three-event stack OSR; whereas, the GMO Panel cannot assess the safety of three-event stack OSR products rich in protein, such as rapeseed protein isolates in feed*" (EFSA, 2016). Following the 2016 EFSA Opinion, the co-applicants provided complementary information to the European Commission (EC) on 23 October 2018. On 30 July 2020, the EFSA published a Statement complementing the EFSA Scientific Opinion on application EFSA-GMO-NL-2009-75 for placing on the market of genetically modified oilseed rape MS8 × RF3 × GT73 and sub-combinations, which have not been authorised previously (*i.e.* MS8 × GT73 and RF3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003), taking into consideration additional information. The EFSA GMO Panel concluded that "*food and feed containing, consisting and produced from genetically modified oilseed rape MS8 × RF3 × GT73 and its sub combinations MS8 × GT73 and RF3 × GT73, are as safe as its conventional counterpart, according to the scope as defined in the application EFSA-GMO-NL-2009-75"* (EFSA, 2020).

On 19 April 2021, the EC presented the Draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MS8 × RF3 × GT73 and its sub-combinations which have not been authorised previously, independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, 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 9 June 2021, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 17 August 2021 (European Commission, 2021).

Regulatory status of the parental lines

The EC authorised/renewed MS8, RF3 for import, food and feed use as any other oilseed rape (excluding cultivation) under Regulation (EC) No 1829/2003 on 25 June 2013 and amendment on 26 July 2019 with respective Commission Implementing Decisions 2013/327[10] and (EU) 2019/1301. GT73 was authorised/renewed for import, food and feed use as any other oilseed rape (excluding isolated seed protein for food and cultivation) under Regulation (EC) No 1829/2003 on 24 April 2015/17 August 2021 with respective Commission Implementing Decisions (EU) 2015/701[11] and 2021/1385).

Traceability, labelling, unique identifier

Operators handling or using MS8 × RF3 × GT73 and derived foods 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. The unique identifiers for the products covered by Commission Implementing Decision (EU) 2021/1391 are ACS-BNØØ5-8 x ACS-BNØØ3-6 x MON-ØØØ73-7; ACS-BNØØ5-8 x MON-ØØØ73-7 and ACS-BNØØ3-6 x MON-ØØØ73-7.

On 7 September 2009, MS8 × RF3 × GT73 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The EURL considers that the detection methods validated on the parental oilseed rape events, MS8, RF3, and GT73 show a comparable performance when applied to MS8 × RF3 × GT73. The detection methods for MS8, RF3 and GT73 had been previously validated by the EURL and were published at the EURL website on 29 January 2007, 29 January 2007 and 8 February 2007, respectively[12]. The validation report for MS8 × RF3 × GT73, prepared by the EURL was published on 18 December 2014 on the same website[12].

Food, feed and environmental safety of MS8 × RF3 × GT73

Food and feed safety

MS8 × RF3 × GT73 was obtained by traditional breeding of three independent genetically modified oilseed rape lines, MS8, RF3 and GT73. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MS8 × RF3 × GT73.
- Safety assessment of the combined product, taking into consideration the safety of the parental lines.

The molecular analysis of the DNA inserts present in MS8 × RF3 × GT73 confirmed that the insert structures of the parental oilseed rape lines were retained. Also, PAT and GOX protein levels in seed of MS8 × RF3 × GT73 were comparable to the levels in the corresponding parental oilseed rape lines.

The conclusions of safety for the PAT and GOX proteins, as already demonstrated in the context of MS8, RF3, and GT73, remain applicable when these proteins are produced in combination in MS8 × RF3× GT73. It is unlikely that when interactions between PAT and GOX would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended PAT and GOX proteins expression, there are no biologically relevant differences in the characteristics of MS8 × RF3 × GT73 as compared with its conventional counterpart and that the composition fell within the range of conventional oilseed rape varieties (EFSA, 2016).

[10] Amended as regards the representative of the authorisation holder by Commission Implementing Decisions (EU) 2019/1195

[11] Amended as regards the representative of the authorisation holder by Commission Implementing Decisions (EU) 2019/1579 and 2021/184

[12] EURL - https://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 30 August 2021)

In conclusion, combining MS8, RF3 and GT73 via traditional breeding does not lead to safety concerns, and like the parental lines, MS8 × RF3 × GT73 and its sub-combinations independently of their origin were shown to be as safe and nutritious as the conventional oilseed rape counterpart.

Environmental safety

The environmental safety of MS8 × RF3 × GT73 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MS8 × RF3 × GT73 does not possess characteristics that would confer a plant pest risk compared to conventional oilseed rape.
- The environmental interaction analyses confirmed that MS8 × RF3 × GT73 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

Also, in its scientific opinion, the EFSA GMO Panel concluded that "*oilseed rape MS8 × RF3* × GT73 *would not raise environmental safety concerns in the event of accidental release of viable GM oilseed rape seeds into the environment*."(EFSA, 2016).

The likelihood of MS8 × RF3 × GT73 spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional oilseed rape. Moreover, the scope of the authorisation covers the import, processing and all uses as any other oilseed rape, with the exception of isolated seed protein for food and 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.

MS8 × RF3 × GT73, the potential benefits

MS8 × RF3 × GT73 has the potential to provide the following benefits to both farmers and the environment:

- Superior weed control compared to other oilseed rape varieties that have tolerance to either glyphosate or glufosinate-ammonium;
- The ability to use a group 9 herbicide (aromatic amino acid inhibitors, *e.g.* glyphosate) in crop to control prevalent group 1 (ACCase inhibiting herbicides) and group 2 (acetolactase synthase inhibiting herbicides) resistant weeds;
- A combination of glyphosate and glufosinate-ammonium tolerance will provide oilseed rape growers more choice in their selection of herbicides, potentially reducing weed resistance;
- Glufosinate-ammonium (Group 10) is an excellent alternative to glyphosate, helping manage the risk of glyphosate (Group 9) resistance. Glufosinate-ammonium is highly biodegradable, has no residual activity, and very low toxicity for humans and wild fauna;
- The opportunity to replace several selective herbicides by a single broad-spectrum herbicide. Glyphosate can provide an environmentally sustainable, flexible, and profitable option in weed control programs. It 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 species including fish, birds, mammals and invertebrates (Giesy *et al.*, 2000; Williams *et al.*, 2000);
- 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 CO_2 emissions (Brookes and Barfoot, 2020; Carpenter et al., 2002; Fawcett and Towery, 2002; Phipps and Park, 2002). According to Brookes and Barfoot (2020), a reduction of over 34 billion kg of CO_2 emissions was accomplished from the reduced use of fuel associated with herbicide tolerant crops between 1996 and 2018. Additionally, carbon sequestration in the soil resulting from the use of "no-tillage" or "reduced tillage" practices eliminated the equivalent of over 302 billion kilograms of CO_2 emissions during the same period;

- Reduced pesticide use and/or number of pesticide spray applications. In Canada where genetically modified herbicide-tolerant (GMHT) canola has been planted since 1996, a report estimated a reduction of 6 000 metric tons (2.02 kg/ha) of herbicide used as a result (Gianessi *et al.*, 2003);
- Hybrids of MS8 x RF3 x GT73 are estimated to yield 20-25% more than the best open-pollinated oilseed rape varieties. The uniformity of the hybrid plants is an advantage in commercial fields facilitating harvesting and marketing;
- Product will contribute to sustainability by increasing productivity per unit area of land. Hybrids based on MS8 x RF3 revolutionised the North American industry with their ability to consistently outperform other hybrids and oilseed rape varieties, even under stressful growing conditions. These hybrids continue to dominate yield rankings in a multitude of trials and represented 58% market share in Canada (2020) and >80% market share in the US (2020) due to their high productivity.

Contact point for further information

Since traders may commingle MS8 × RF3 × GT73 with other commercial oilseed rape, including authorised GM oilseed rape, BASF and Bayer are working together with other members of the plant biotechnology industry within CLE 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 BASF and Bayer GM oilseed rape products, can refer to the CLE website at:

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

If required, additional comments or questions relative to MS8 × RF3 × GT73 and its sub-combinations can also be addressed to BASF and Bayer at:

gent.info.operators@basf.com

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

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