

# MON 88302 × MS8 × RF3

Herbicide-tolerant oilseed rape hybrid

## Key facts



Monsanto EME and Bayer CropScience  
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## Oilseed rape, a little known but economically important crop

Oilseed rape<sup>1</sup> (*Brassica napus*) is the third most important source of vegetable oils in the world, after palm and soybean<sup>2</sup>. 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 13<sup>th</sup> century, initially as a source of fuel, then more recently as food and animal feed.

In 2016-2017, 71.26 million metric tons of oilseed rape were produced in the world, which represents approximately 34.30 million hectares of oilseed rape harvested globally. Significant areas of production included EU, Canada, China, and India representing 28.8%, 27.5%, 20.3% and 9.9% of the global oilseed rape production, respectively<sup>3</sup>.

In 2016, the oilseed rape area harvested in the EU-28 accounted for approximately 6.5 million hectares, with a production of around 19.7 million metric tons<sup>4</sup>.

In the period 2016, the EU-28 imported 3.9 million metric tons of oilseed rape. Germany, Belgium, France, Portugal and Poland are among the largest importer EU Member States. In 2016, about 60% of the EU imports came from Australia, 20% from Ukraine, and 19% from Canada<sup>5</sup>.

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, raw materials to produce margarine and mayonnaise, etc.) and industrial purposes (lubricants for engines, slipping agents, plasticisers, cosmetics, pharmaceuticals, surfactants, soaps, detergents, etc.). Oilseed rape meal is also fed to animals (OECD, 2012).

### What is MON 88302 × MS8 × RF3?

MON 88302 × MS8 × RF3 was obtained by traditional breeding of three independent genetically modified oilseed rape events, MON 88302, MS8 and RF3. MON 88302 × MS8 × RF3 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 MON 88302 × MS8 × RF3 grain includes the combined event product and any combination of these events (sub-combinations).

MON 88302 × MS8 × RF3, as well as the genetically modified parental oilseed rape lines containing events MS8 and RF3 have been developed by Bayer CropScience (hereafter referred to as Bayer), whereas the genetically modified parental oilseed rape line containing the MON 88302 event has been developed by Monsanto Company (hereafter referred to as Monsanto).

More information on the parental lines can be found on the European Association for Bioindustries (EuropaBio) website<sup>6</sup>.

### Worldwide plantings and regulatory status of MON 88302 × MS8 × RF3

In 2016, approximately 185 million hectares of GM crops were grown worldwide<sup>7</sup>. Biotech oilseed rape, continued to be a significant biotech crop in 2016, occupying 8.6 million hectares<sup>8</sup>.

MON 88302 × MS8 × RF3 has received regulatory authorisation for production in Canada and USA. MON 88302 × MS8 × RF3 also received regulatory authorisation for import in Australia, New Zealand, EU, Japan, Korea, Mexico 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.

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 MON 88302 × MS8 × RF3 in the EU

On 3 December 2013, Monsanto and Bayer submitted an application for import for food and feed use of MON 88302 × MS8 × RF3 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

<sup>1</sup> Also known as canola, rapeseed or colza

<sup>2</sup> SoyStats® 2017 - <http://soystats.com/international-world-vegetable-oil-consumption/> (Accessed on 21 March 2018)

<sup>3</sup> USDA, 2018 - <http://apps.fas.usda.gov/psdonline/psdQuery.aspx> (Accessed on 21 March 2018)

<sup>4</sup> FAOSTAT, 2018 - <http://faostat.fao.org/site/339/default.aspx> (Accessed on 21 March 2018)

<sup>5</sup> Eurostat, 2018 - <http://ec.europa.eu/eurostat> (Accessed on 21 March 2018)

<sup>6</sup> EuropaBio - <http://www.europabio.org/information-operators-product-information> (Accessed on 21 March 2018)

<sup>7</sup> ISAAA - <http://isaaa.org/resources/publications/briefs/52/download/isaaa-brief-52-2016.pdf> (Accessed on 21 March 2018)

<sup>8</sup> ISAAA - <http://isaaa.org/resources/publications/pocketk/16/default.aspx> (Accessed on 21 March 2018)

EFSA-GMO-NL-2013-119 and was declared valid on 24 April 2014. The EFSA evaluated the application as well as additional information provided by Monsanto and Bayer, scientific comments submitted by the EU Member States and relevant scientific publications.

On 10 April 2017, the EFSA published a positive scientific opinion on the safety of MON 88302 × MS8 × RF3 and sub-combinations independently of their origin (EFSA, 2017). The EFSA GMO Panel concluded that “*the three-event stack OSR is as safe and as nutritious as its conventional counterpart and the tested non-GM reference varieties in the context of the scope of this application*”. Also, MON 88302 × MS8 and MON 88302 × RF3 “*are expected to be as safe as the single events, the previously assessed OSR MS8 × RF3, and OSR MON 88302 × MS8 × RF3*”.

On 17 September 2017, the European Commission (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 MON 88302 × MS8 × RF3 and its sub-combinations independently of their origin, 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 who met for a vote on 19 October 2018, again without reaching a qualified majority. Therefore, the Appeal Committee forwarded the draft decision to the EC who granted the authorisation on 21 December 2017 (European Commission, 2017).

#### **Regulatory status of the parental lines**

The EC authorised MON 88302, MS8 and RF3 for import, food and feed use as any other oilseed rape (excluding cultivation) under Regulation (EC) No 1829/2003 on 24 April 2015 and 26 March 2007/25 June 2013, respectively (European Commission, 2007, 2013, 2015).

#### **Traceability, labelling, unique identifier**

Operators handling or using MON 88302 × MS8 × RF3 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) 2017/2453 of 21 December 2017 (European Commission, 2017) are MON-88302-9 × ACSBN005-8 × ACS-BN003-6; MON-88302-9 × ACSBN005-8 and MON-88302-9 × ACS-BN003-6.

On 25 November 2013, MON 88302 × MS8 × RF3 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EU-RL). The EU-RL considers that the detection methods validated on the parental oilseed rape events, MON 88302, MS8 and RF3, show a comparable performance when applied to MON 88302 × MS8 × RF3. The detection methods for MON 88302, MS8 and RF3 had been previously validated by the EU-RL and were published at the EU-RL website on 26 November 2013, 29 January 2007 and

29 January 2007, respectively<sup>9</sup>. The validation report for MON 88302 × MS8 × RF3, prepared by the EU-RL in collaboration with the European Network of GMO Laboratories (ENGL), was published on 27 November 2015 on the same website<sup>9</sup>.

#### **Food, feed and environmental safety of MON 88302 × MS8 × RF3**

##### **Food and feed safety**

MON 88302 × MS8 × RF3 was obtained by traditional breeding of three independent genetically modified oilseed rape lines, MON 88302, MS8 and RF3. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 88302 × MS8 × RF3.
- Safety assessment of the combined product, taking into consideration the safety of the parental lines.

The molecular analysis of the DNA inserts present in MON 88302 × MS8 × RF3 confirmed that the insert structures of the parental oilseed rape lines were retained. Also, CP4 EPSPS and PAT protein levels in seed of MON 88302 × MS8 × RF3 were comparable to the levels in the corresponding parental oilseed rape lines.

The conclusions of safety for the CP4 EPSPS and PAT proteins, as already demonstrated in the context of MON 88302, MS8 and RF3, remain applicable when these proteins are produced in combination in MON 88302 × MS8 × RF3. It is unlikely that when interactions between CP4 EPSPS and PAT would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended CP4 EPSPS and PAT proteins expression, there are no biologically relevant differences in the characteristics of MON 88302 × MS8 × RF3 as compared with its conventional counterpart and that the composition fell within the range of non-GM oilseed rape varieties.

Also, in their scientific opinion, the EFSA GMO Panel concluded that “*The three-event stack oilseed rape is expected to be as nutritious as its conventional counterpart and the tested non-GM oilseed rape commercial reference varieties.*” (EFSA, 2017).

In conclusion, combining MON 88302, MS8 and RF3 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 88302 × MS8 × RF3 and its sub-combinations independently of their origin were shown to be as safe and nutritious as the conventional oilseed rape counterpart.

<sup>9</sup> EU-RL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> (Accessed on 21 March 2018)

## Environmental safety

The environmental safety of MON 88302 × MS8 × RF3 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 88302 × MS8 × RF3 does not possess characteristics that would confer a plant pest risk compared to conventional oilseed rape.
- The environmental interaction analyses confirmed that MON 88302 × MS8 × RF3 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

Also, in their scientific opinion, the EFSA GMO Panel concluded that “oilseed rape MON 88302 × MS8 × RF3 would not raise environmental safety concerns in the event of accidental release of viable GM oilseed rape seeds into the environment.” (EFSA, 2017).

The likelihood of MON 88302 × MS8 × RF3 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, but excluding 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.

### MON 88302 × MS8 × RF3, the benefits

MON 88302 × MS8 × RF3 provides the following benefits to both farmers and the environment:

- Superior weed control over first generation systems through more effective and consistent control of both annual weeds and tough-to-control perennials, and greater control over a much wider spectrum of weeds. The ability to apply Roundup WeatherMAX in-crop at 1.33 L/ac for single application or 0.67 L/ac for two applications provides significant improvement in weed control and the ability to control 24 additional weed species (Canola Council of Canada, 2005; Harker *et al.*, 2000);
- Being able to control certain hard to control weeds with a single application instead of needing a sequential application will provide an economic advantage to producers by reducing the spraying applications required. Also, selection pressure for glyphosate resistance could be reduced by reducing the number of in-crop applications;
- Increased flexibility for farmers with an application window that extends all the way to first flower (approximately 10-14 days longer than current technology). This much wider window of application provides farmers with significantly increased application flexibility, improving time management and helping them deal better with stressful weather conditions,
- The ability to use a group 9 herbicide in crop to control prevalent group 1 and group 2 resistant weeds;

- 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 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 CO<sub>2</sub> emissions (Fawcett and Towery, 2000);
- Reduced pesticide use and/or number of pesticide spray applications. From 1996 to 2015, the use of GM HT oilseed rape resulted in a 25 million kg reduction in the amount of herbicide active ingredient use (-18.1%), with an improvement in the environmental impact of 29.9%, as measured by the Environmental Impact Quotient (EIQ) indicator (Brookes and Barfoot, 2017). Several projections made for Europe suggest potential savings in herbicide use of 12 - 60% (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);
- Hybrids of MS8 × RF3 hybridisation system 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.
- A combination of glyphosate and glufosinate-ammonium tolerance will allow growers more choice in the oilseed market for herbicide tolerance.
- Glufosinate-ammonium (Group 10) is an excellent alternative to glyphosate, helping manage the risk of glyphosate (Group 9) resistance. Glufosinate-ammonium is a highly biodegradable, has no residual activity, and very low toxicity for humans and wild fauna.
- Product will contribute to sustainability by increasing productivity per unit area of land, even under stressful growing conditions.

### Contact point for further information

Since traders may commingle MON 88302 × MS8 × RF3 with other commercial oilseed rape, including authorised GM oilseed rape, Monsanto and Bayer are working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) 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 Monsanto and Bayer GM oilseed rape products, can therefore refer to the EuropaBio website at:

<http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/product-contact-point>

If required, additional comments or questions relative to MON 88302 × MS8 × RF3 and its sub-combinations can also be addressed to Monsanto (<http://www.monsanto.com>) and/or Bayer (<https://www.cropscience.bayer.com/>).

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