MON 88302

Herbicide Tolerance

Key facts

Monsanto EMEA
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MON 88302 - oilseed rape

Oilseed rape, a little known but economically important crop

Oilseed rape[1] *(Brassica napus)* is the third most important source of vegetable oils in the world, after palm and soybean oil[2]. 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 2013-2014 reached approximately 70 million metric tons. The main oilseed rape producing regions globally are EU (30% of global production), Canada (25.7%), China (16.7%), India (10.5%) and Australia (5.6%)(Oil World Annual, 2014). Today, oilseed rape is one of the few intensively cultivated crops in European agriculture, with a total volume of 6760 thousand hectares. The most significant areas of production in Europe for the 2013-2014 season include Germany (21.7% of total EU production), France (21.3%), Poland (13.8%), the United Kingdom (10.6%) and the Czech Republic (6.2%). For the 2013-2014 season, the main suppliers of oilseed rape to the EU are Australia (45% of imports) and Ukraine (48% of imports)(Oil World Annual, 2014).

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.

Rationale for the development of herbicide tolerant oilseed rape

Oilseed rape is a slow-growing crop and, consequently very sensitive to weed competition, especially during the early stages of development. Weed control in agriculture is usually carried out early in the growing season (pre- to early post-emergence of the crop) to remove small weeds which compete with the crop. Weed management is a critical step in maximizing oilseed rape yields, while retaining a high-quality grain harvest that is free of weed seeds.

Herbicide-tolerant crops were developed in the 1980's to provide farmers with options for more efficient weed control.

Today, one of the most frequently planted genetically modified herbicide tolerant (GMHT) oilseed rape varieties is, tolerant to the herbicides glyphosate. Oilseed rape varieties tolerant to the herbicide imidazolinone or bromoxynil, obtained via other methods than genetic modification have also been commercialized. MON 88302 oilseed rape is a second generation Roundup Ready tolerant oilseed rape developed to given farmers superior weed control and an extended herbicide application window.

What is MON 88302 oilseed rape?

MON 88302 oilseed rape has been developed to enable farmers to effectively control weeds during the growing season by using Roundup® agricultural herbicides.

MON 88302 expresses the 5 enolpyruvylshikimate-3 phosphate synthase (EPSPS) protein from *Agrobacterium tumefaciens* sp. strain CP4 (CP4 EPSPS), which confers tolerance to glyphosate, which is the active ingredient in Roundup® agricultural herbicides. MON 88302 is the second-generation glyphosate-tolerant oilseed rape product from Monsanto Company, designed to provide growers with improved weed control through tolerance to higher rates of glyphosate and greater flexibility for glyphosate herbicide application. MON 88302 utilizes a chimeric promoter sequence to drive CP4 EPSPS expression in different plant tissues including pollen. By virtue of CP4 EPSPS expression in pollen, MON 88302 provides tolerance to glyphosate during the sensitive reproductive stages of growth, and enables the application of glyphosate at higher rates up to first flower with no detectable impact to male fertility.

MON 88302: mode of action

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.

MON 88302 oilseed rape plants contain a glyphosate tolerant EPSPS, isolated from the CP4 strain of the common soil bacterium *Agrobacterium tumefaciens*. 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.

A stringent regulatory system for genetically modified 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 (repealing Directive 90/220/EEC) and Regulation (EC) N° 1829/2003 on genetically modified food and feed (replacing Regulation (EC) N° 258/97 on novel foods and novel food ingredients for GM products).

A regulation on traceability and labeling of GMOs and products produced from GMOs (Regulation (EC) N° 1830/2003) entered into force on 18 April 2004. 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 authorization procedure is pending or the authorisation of which has expired (Commission regulation (EU) No 619/2011) entered into force on 24 June 2011.

[1]Also known as canola, rapeseed or colza.
[2]http://soystats.com/international-world-vegetable-oil-consumption/ l - accessed July 18, 2014)

Regulatory status of MON 88302 oilseed rape in the EU

On 31 August 2011, Monsanto submitted an application for import for food and feed use of MON 88302 oilseed rape as any other oilseed rape (excluding cultivation) under Regulation (EC) No 1829/2003 to European Food Safety Authority (EFSA) via the Belgian Competent Authority.

The application received the reference number EFSA-GMO-BE-2011-101 and was declared valid on 02 April 2012. EFSA evaluated the application as well as Monsanto's additional information, scientific comments submitted by the Member States and relevant scientific publications. On 17 June 2014 the EFSA published a positive scientific opinion on the safety of MON 88302 (adopted 21 May 2014) (EFSA, 2014). EFSA concluded that MON 88302 "*is as safe as its conventional counterpart and non-GM commercial oilseed rape varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this application*".

On 24 October 2014, the European Commission presented the Draft Commission Implementing Decision authorizing the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MON 88302, to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote. Since no qualifying majority was reached, the draft decision was passed to the Appeal Committee who met for a vote on 28 November 2014 again without reaching a qualified majority. The Appeal Committee forwarded the draft decision to the European Commission. The authorization was finally granted by the European Commission on 24 April 2015 (Commission Decision, 2015).

Traceability, labelling, unique identifier

Operators importing, handling or using MON 88302 oilseed rape grain and derived foods and feeds in the EU should be informed of the legal obligations regarding traceability and labelling, laid down in Regulation (EC) No. 1830/2003. The unique identifier of MON 88302 oilseed rape is MON-88302-9.

The validated methods, as well as the validation report for MON 88302, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), were published on November 26, 2013 at the CRL website[3]. A report on the validation of the DNA extraction method for maize seeds was also published on the same date.

Food, feed and environmental safety of MON 88302 oilseed rape

Food and feed safety

The food and feed safety of MON 88302 oilseed rape was established through:

- A detailed molecular characterization of the inserted DNA, where the results confirm that a single copy of the *cp4 epsps* gene expression cassette integrated at a single locus within the oilseed rape genome,
- Compositional and nutritional analyses confirmed that MON 88302 oilseed rape is as safe and nutritious as conventional oilseed rape, by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals,
- From an agronomic and phenotypic (morphological) point of view, MON 88302 is equivalent to conventional oilseed rape, except for the introduction of the *cp4 epsps* gene and the production of the protein from the introduced gene,
- The long history of safe use of the CP4 EPSPS protein, the rapid digestibility of the CP4 EPSPS protein and the lack of toxicity or allergenicity of the CP4 EPSPS protein, as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies with the protein,
- A dietary risk assessment showed that the intake of the introduced CP4 EPSPS protein resulting from consumption of foods derived from MON 88302 oilseed rape do not raise nutritional concerns. A large margin of safety resulted from the low dietary exposure to the CP4 EPSPS protein.

Further details on the safety of MON 88302 are available in EFSA's scientific opinion (EFSA, 2014).

Environmental safety

The environmental safety of MON 88302 was established through extensive field trials conducted in 2009 in the US and Canada and in 2009-2010 in Chile as well as laboratory experiments. All these field trials demonstrated that MON 88302 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 MON 88302 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 MON 88302 and that MON 88302 is not different in its phenotypic and agronomic behaviour relative to conventional oilseed rape.

The herbicide tolerance trait in MON 88302 oilseed rape can be regarded as providing only a potential agronomic and selective advantage for this GM oilseed rape plant where and when glyphosate herbicides are applied.

Regarding the possible environmental effects resulting from spillage of MON 88302, the EFSA concluded "*There are no indications of an increased likelihood of spread and establishment of feral oilseed rape MON 88302 plants in the event of the accidental release into the environment of viable oilseed rape MON 88302 seeds during transport and/or processing, or of hybridising wild relatives that may theoretically have acquired the herbicide tolerance trait through vertical gene flow, unless these plants are exposed to glyphosate-based herbicides.*" (EFSA, 2014).

[3] http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx - accessed December 08, 2014

[8] http://www.efsa.europa.eu/en/efsajournal/pub/3701.htm - accessed May 8, 2015

MON 88302 oilseed rape, the benefits

In countries where MON 88302 oilseed rape is grown, a number of benefits for both farmers and the environment are expected. These include:

- 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 (CCC, 2001, Harker et a 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_2 emissions (Fawcett and Towery, 2000),
- 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).

Further reading

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