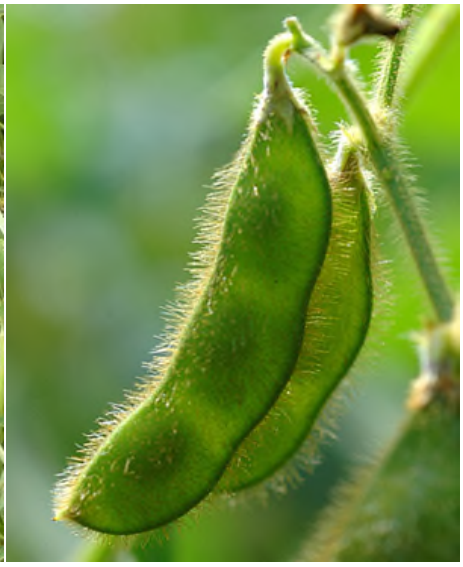
MON 89788 soybean

Genuity® Roundup Ready 2 Yield® Soybeans

Glyphosate-tolerant

Key facts



Bayer Agriculture BVBA
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Soybean, a key crop

Soybean (*Glycine max*) is a high-protein legume grown mainly as food for humans and livestock. It is one of the highest natural source of dietary fibre (Dhingra *et al.*, 2012). Nine essential amino acids are found in soybeans, which are necessary for human nutrition and are not produced naturally in the body (Tessari *et al.*, 2016). This crop is also used in industrial products including oils, soaps, cosmetics, resins, plastics, inks, solvents, and biodiesel.

The first record of domesticated soybean dates back to the 11th century BC in the eastern half of China where it was grown as food. Soybean was cultivated for the first time in Europe in the early 1700's and in North America in the early 1800's.

In 2018-2019, approximately 358,8 million metric tons of soybean were produced in the world, which represents approximately 125.1 million hectares of soybean harvested globally. Significant areas of production included Brazil, United States (US), Argentina, India and China representing 28.7%, 28.4%, 13;3%, 9% and 7% of the global soybean hectares, respectively[1].

The European Union (EU) is not a significant soybean producer. In 2019, the soybean area harvested in the EU-27 accounted for approximately 910 thousand hectares[2]. Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal[2]. In 2018, the EU-27 imported 18 million metric tons of soybean meal. Brazil, Argentina, and the US are among the largest exporters to the EU[3].

What is MON 89788?

MON 89788 is a second-generation genetically modified (GM) soybean developed through *Agrobacterium*-mediated transformation and is tolerant to glyphosate.

Herbicide tolerance

MON 89788 expresses CP4 EPSPS which confers tolerance to glyphosate, the active ingredient in the Roundup®[4] family of agricultural herbicides, allowing use of this herbicide for weed control in the crop not just in pre-emergence, but also throughout the growth season.

Glyphosate is a broad-spectrum herbicide that acts via inhibition of the protein "5-enolpyruvyl-shikimate-3-phosphate synthase" (EPSPS) in the green parts of plants. This protein, found naturally in all plants, fungi and bacteria 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 leading ultimately to plant death (Alibhai and Stallings, 2001).

MON 89788 plants produce glyphosate-tolerant EPSPS. This ensures the continued function of the aromatic amino acid pathway, even in the presence of the herbicide (Heck *et al.*, 2005).

Worldwide plantings and regulatory status of MON 89788

In 2018, approximately 191.7 million hectares of genetically modified (GM) crops were grown worldwide[5]. Soybean continued to be the principal biotech crop in 2018, occupying 95.9 million hectares.

MON 89788 has received regulatory approval for production in Argentina, Canada, Paraguay and the US. It also received regulatory approvals for food and/or feed imports in Australia; China, Colombia, EU, India, Indonesia, Japan, Korea, Malaysia, Mexico, Philippines, Russia, Singapore, South Africa, Taiwan, Thailand and Vietnam.

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 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 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.

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1 USDA, 2019 - https://apps.fas.usda.gov/psdonline/app/index.html#/app/downloads (Accessed on 16 November 2019)

2 Index mundi, 2018 - https://www.indexmundi.com/agriculture/?commodity=soybean-meal&graph=imports (Accessed on 16 November 2019)

3 European Commission, 2019 - https://ec.europa.eu/agriculture/market-observatory/crops/oilseeds-protein-crops/soy-trade_en (Accessed on 16 November 2019)

4 Roundup® is a registered trademark of Monsanto Technology LLC

5 ISAAA, 2018 - http://www.isaaa.org/resources/publications/ (Accessed on 16 November 2019).

Regulatory status of MON 89788 in the EU

On 17 November 2017, Monsanto Company submitted an application for renewal of the authorisation of foods, food ingredients, and feed containing, consisting of, or produced from MON89788 soybean and other products containing or consisting of MON89788 soybean for the same uses as any other soybean with the exception of cultivation under the Regulation (EC) No 1829/2003 (Commission Decision, 2008)[6]. This renewal application received the reference number EFSA-GMO-RX-011 and was declared valid on 9 April 2018. 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 16 November 2018, the EFSA published a positive Scientific Opinion on the safety of MON 89788 (EFSA, 2018). The EFSA GMO panel concluded that "*there is no evidence in renewal application EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788*".

On 30 April 2019, the European Commission (EC) presented the Draft Commission Implementing Decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 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 5 June 2019, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 28 November 2019 (European Commission, 2019).

Traceability, labelling, unique identifier

Operators handling or using MON 89788 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 identifier for this product is MON-89788-1.

In October 2006, a MON 89788-specific PCR-based detection method allowing the identification and quantification of MON 89788 as well as samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL)[7]. The validated method, as well as the validation report for MON 89788, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), are available at the EURL website[8].

Food, feed and environmental safety of MON 89788

Food and feed safety

The food and feed safety assessment of MON 89788 was established based on:

- A detailed molecular characterisation of the inserted DNA confirming that a single copy of *cp4 epsps* expression cassette was integrated at a single locus within the soybean genome;
- The long history of safe use of CP4 EPSPS-producing crops, such as Roundup Ready soybean 40-3-2, Roundup Ready maize NK603 and Roundup Ready oilseed rape GT-73, which were commercialised starting from 1996;
- The compositional and nutritional equivalence of the seed and forage derived from MON 89788 with those of conventional soybean;
- The rapid digestibility of CP4 EPSPS protein by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of EPSPS proteins generally and 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 introduced CP4 EPSPS protein in MON 89788.

MON 89788 was found to be as safe and nutritious as conventional soybean by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals (EFSA, 2008). In its Scientific Opinion, the EFSA GMO Panel concluded that "*soybean MON 89788 is compositionally equivalent to the non-GM counterparts soybean A3244 and other conventional soybean varieties, except for the introduced trait*".

Further details on the safety of MON 89788 are available in the EFSA scientific opinion adopted on 17 October 2018 (EFSA, 2018).

Environmental safety

The environmental safety of MON 89788 was established through extensive laboratory and field testing of plant tissue or CP4 EPSPS protein demonstrating that MON 89788 poses negligible risk to human and animal health or the environment.

Results from the agronomic and phenotypic assessments confirm that MON 89788 does not possess characteristics that would confer a plant pest risk compared to conventional soybean. Data on the environmental interaction also confirm that MON 89788 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors. This, together with the history of safe use of the CP4 EPSPS protein, demonstrate that the ecological interactions of MON 89788 with other organisms or soil processes are not different from conventional soybean.

[6] Amended by Commission Implementing Decision (EU) 2019/1579 of 16 November 2019

[7] Now called European Union Reference Laboratory (EURL)

[8] EURL - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 16 November 2019)

Soybean does not have wild relatives in Europe to which the introduced trait could outcross. The likelihood of MON 89788 soybean spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional soybean. Moreover, the scope of the renewed authorisation covers the import, processing and all uses as any other soybean, but excludes cultivation in the EU, and no deliberate release of the viable plant material in the EU environment is expected.

In conclusion, the environmental impact of growing MON 89788 is not different from that of growing conventional soybean.

MON 89788, the benefits

MON 89788 provides similar benefits to both farmers and the environment as Roundup Ready soybean 40-3-2, while offering further yield advantages:

- A 7 to 11% yield increase compared to Roundup Ready 40-3-2 soybean;
- A simple and flexible broad-spectrum weed control option in soybean (Carpenter *et al.*, 2002); glyphosate tolerance can be combined with other herbicide tolerance traits, providing growers with multiple tools for managing weed pressure in a variety of conditions.
- Tolerance to an herbicide with a favorable human health and environmental profile. 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 (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, 2018a; Fawcett and Towery, 2002). According to data from Brookes and Barfoot on herbicide tolerant soybean (Brookes and Barfoot, 2018a), the carbon sequestration resulting from more plant residue being stored in the soil because of reduced tillage saved the equivalent of almost 17.2 billion kilograms of carbon dioxide emissions in 2016. This is in addition to the 1.9 billion kilograms of CO_2 emissions saved from reduction in fuel consumption in 2016.
- In the USA, an estimated soybean production-cost saving of between $54 and $78/ha (based on a comparison of conventional herbicide regimes from 2001 onward required to deliver a comparable level of weed control to 40-3-2 soybean system) (Brookes and Barfoot, 2018b).

Contact point for further information

Since traders may commingle MON 89788 with other commercial soybean, including authorised GM soybean, Bayer is working together with other members of the plant biotechnology industry within the 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 Bayer soybean 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 89788 can also be addressed at:

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

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