

MON 87411 maize

Corn rootworm protection with
glyphosate tolerance

Key facts



Bayer Agriculture BVBA

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Maize, a key crop

Maize (*Zea mays*) is one of the most frequently cultivated crops in the world, together with rice and wheat¹. Following European discovery of the Americas where this crop is indigenous, maize was rapidly adopted in Europe, Africa and Asia. In 2018, over 1 billion metric tons of maize were produced in the world, which represents approximately 184 million hectares of maize harvested globally². Significant areas of production included the US, China, Brazil, the European Union (EU) and Argentina representing in total over 75 % of the global maize productions³. Today, maize is one of the few intensively cultivated crops in European agriculture⁴. Significant areas of production include the Danube basin from southwest Germany to the Black Sea and southern France through to the Po Valley of northern Italy. In 2018, the maize area harvested in the EU accounted for approximately 8 million hectares, with a production of around 60.8 million metric tons³. The EU imported about 21.5 million tons of maize grain in 2018³. The major exporters of maize to the EU are Ukraine and Brazil, followed by Canada⁵. As in other world areas, maize use in Europe is dominated by the demand for animal feed. Maize is also processed into valuable industrial and food products such as ethyl alcohol, maize meal, starch and sweeteners.

What is MON 87411?

MON 87411 is a genetically modified (GM) maize developed through *Agrobacterium*-mediated transformation. It is protected against corn rootworm (*Diabrotica* spp.) and is tolerant to glyphosate.

Insect protection

MON 87411 carries a gene from the common soil bacteria *Bacillus thuringiensis*, coding for the Cry3Bb1⁶ protein which is selective for coleopterans (Chrysomelidae) of the *Diabrotica* family (Siegfried *et al.*, 2005). Susceptible insects contain receptors in their midgut that bind to the specific Cry protein. This leads to the creation of pores which interfere with ion transport systems across the midgut wall, causing lysis of the midgut epithelium and, depending on the dose, subsequent paralysis of the

gut or death of the insect (Nester *et al.*, 2002; Ostlie, 2001). No receptors for these proteins have been identified on intestinal cells of mammals.

MON 87411 also contains DvSnf7 suppression cassette that expresses an inverted repeat sequence designed to match the sequence in western corn rootworm (WCR) and thereby utilises the RNA interference (RNAi) pathway to control corn rootworm (*Diabrotica* spp.).

Herbicide tolerance

MON 87411 also expresses CP4 EPSPS which confers tolerance to glyphosate, the active ingredient in the Roundup^{®7} 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 87411 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 87411

In 2017, approximately 189.8 million hectares of GM crops were grown worldwide⁸. Of the 189.8 million hectares of global maize planted in 2017, 31.5% or 59.7 million hectares were biotech maize.

MON 87411 has received regulatory authorisation for cultivation in Argentina, Brazil, Canada and the US. It also received regulatory approvals for food and/or feed imports in Australia; Colombia, Indonesia, Japan, Korea, Mexico, Philippines, Singapore and Taiwan.

MON 87411 single product is not and will not be commercialised on its own, instead stacked products, made via traditional breeding, are the aimed commercial products.

¹ FAOSTAT, 2019 - <http://www.fao.org/faostat/en/#data/QC> (Accessed on 24 July 2019).

² USDA, 2018 - <https://apps.fas.usda.gov/psdonline/app/index.html#/app/home> (Accessed on 24 July 2019).

³ Index mundi, 2018 - <https://www.indexmundi.com/agriculture/?commodity=corn&graph=production> (Accessed on 24 July 2019).

⁴ Eurostat, 2018 - <http://ec.europa.eu/eurostat> (Accessed on 24 July 2019).

⁵ European Commission - https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en (Accessed on 24 July 2019).

⁶ The amino acid sequence deduced from the Cry3Bb1 expression cassette present in MON 88017 is identical to that deduced from the Cry3Bb1 expression cassette present in MON 87411. A related Cry3Bb1 protein, which has over 99% amino acid identity to the Cry3Bb1 in MON 87411, is expressed in MON 863. Each of these products were previously reviewed by the EFSA and found to be as safe as its conventional counterpart (EFSA, 2004, 2011).

⁷ Roundup[®] is a registered trademark of Monsanto Technology LLC

⁸ ISAAA, 2018 - <http://www.isaaa.org/resources/publications> (Accessed on 24 July 2019).

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 87411 in the EU

On 5 February 2015, Monsanto submitted an application for import for food and feed use of MON 87411 maize as any other maize (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-2015-124 and was declared valid on 17 August 2015. The EFSA evaluated the application as well as additional information provided by Monsanto Company, scientific comments submitted by the EU Member States and relevant scientific publications.

On 28 June 2018, the EFSA published a positive scientific opinion on the safety of MON 87411 (EFSA, 2018). The EFSA GMO Panel concluded that “*maize MON 87411, as described in this application, is as safe as its conventional counterpart and the tested non-GM maize reference varieties with respect to potential effects on human and animal health and the environment*”.

On 14 January 2019, 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 maize MON 87411, 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 22 February 2019, again without reaching a qualified majority. Therefore, the Appeal Committee forwarded the draft decision to the EC

who granted the authorisation on 26 July 2019 (European Commission, 2019).

Traceability, labelling, unique identifier

Operators handling or using GM products 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. MON 87411 single product is not and will not be commercialised on its own. The unique identifier for this product is MON-87411-9.

On 12 January 2015, a MON 87411 specific PCR-based detection method allowing the identification and quantification of MON 87411 was provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL). The validated method, as well as the validation report for MON 87411, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), were published on the EURL website⁹ on 4 July 2016.

Food, feed and environmental safety of MON 87411

Food and feed safety

The food and feed safety assessment of MON 87411 was established based on:

- A detailed molecular characterisation demonstrated that a single copy of the intended transfer DNA containing the DvSnf7 suppression cassette, the cry3Bb1 and the cp4 epsps expression cassettes were integrated into the maize genome at a single locus within the maize genome;
- The long history of safe use of *Bt* Cry proteins (including members of the Cry3 class), the CP4 EPSPS protein and nucleic acids;
- The compositional and nutritional equivalence of the seed and forage derived from MON 87411 with those of conventional maize;
- The rapid digestibility of Cry3Bb1 and CP4 EPSPS proteins by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of the introduced proteins as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies of the Cry3Bb1 and CP4 EPSPS proteins;
- A large margin of safety resulting from the low dietary exposure to the introduced Cry3Bb1 and CP4 EPSPS proteins in MON 87411.

MON 87411 was shown to be as safe and nutritious as conventional maize by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals (EFSA, 2018). In its Scientific Opinion, the EFSA GMO Panel concluded that “*maize MON 87411, as described in this*

⁹ EURL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> (Accessed on 24 July 2019)

application, is as safe as its conventional counterpart and the tested non-GM maize reference varieties with respect to potential effects on human and animal health and the environment”.

Further details on the safety of MON 87411 are available in the EFSA scientific opinion adopted on 31 May 2018 (EFSA, 2018).

Environmental safety

The environmental safety of MON 87411 was established through extensive laboratory and field testing of plant tissue or purified Cry3Bb1 and CP4 EPSPS proteins demonstrating that MON 87411 poses negligible risk to human and animal health or the environment.

Results from the agronomic and phenotypic assessments confirm that MON 87411 does not possess weediness or invasiveness characteristics compared to conventional maize. Data on the environmental interaction also confirm that, except for the intended coleopteran insect protection and glyphosate tolerance traits, MON 87411 does not confer any biologically meaningful difference in susceptibility or tolerance to specific disease, insect or abiotic stressors compared to conventional maize. This, together with the history of safe use of the Cry3Bb1 and CP4 EPSPS proteins, demonstrate that the ecological interactions of MON 87411 with non-target organisms or soil processes are not different from conventional maize.

Maize has no wild relatives in Europe to which the introduced trait could outcross. The likelihood of MON 87411 spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional maize. Moreover, the scope of the authorisation covers the import, processing and all uses of food and feed products containing, consisting of, or produced from MON 87411 as any other maize, with the exception of cultivation in the EU. Also, MON 87411 single product is not and will not be commercialised on its own. Therefore, no deliberate release of the viable plant material in the EU environment is expected.

In conclusion, the environmental impact of growing MON 87411 is not different from that of growing conventional maize, as stated in the EFSA scientific opinion (EFSA, 2018).

Contact point for further information

MON 87411 single product is not and will not be commercialised on its own.

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 GM maize products, can 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 87411 can also be addressed at:

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

References

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