

# **MON 87403 maize**

Increased ear biomass

## **Key facts**



**Bayer Agriculture BVBA**

**August 2019**

## Maize, a key crop

Maize (*Zea mays*) is one of the most frequently cultivated crops in the world, together with rice and wheat<sup>1</sup>. 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 globally<sup>2</sup>. Significant areas of production included the US, China, Brazil, the European Union (EU) and Argentina representing in total over 75 % of the global maize productions<sup>3</sup>. Today, maize is one of the few intensively cultivated crops in European agriculture<sup>4</sup>. 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 tons<sup>3</sup>. The EU imported about 21.5 million tons of maize grain in 2018<sup>3</sup>. The major exporters of maize to the EU are Ukraine and Brazil, followed by Canada<sup>5</sup>. 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 87403?

MON 87403 is a genetically modified (GM) maize developed through *Agrobacterium*-mediated transformation. It has increased ear biomass at an early reproductive growth stage compared to conventional control maize.

#### Increased ear biomass

Insertion of the coding region of the *Arabidopsis ATHB17* gene results in production of a truncated ATHB17 protein (ATHB17Δ113) in MON 87403. ATHB17 is a member of the HD-Zip family of plant transcription factors, which are proteins that bind to specific DNA sequences and regulate gene expression. The HD-Zip family of proteins is found broadly across plant species and specific HD-Zip proteins have been shown to play important roles in the modulation of plant growth and development. Increased ear biomass in MON 87403 is associated with increased partitioning of dry matter (photosynthate) from the source (vegetative) tissue to the sink (ear) tissue.

More information on this product can be obtained from the European Association for Bioindustries (EuropaBio) website<sup>6</sup>.

### Worldwide plantings and regulatory status of MON 87403

In 2017, approximately 189.8 million hectares of GM crops were grown worldwide<sup>7</sup>. Of the 189.8 million hectares of global maize planted in 2017, 31.5% or 59.7 million hectares were biotech maize.

MON 87403 has received regulatory authorisation for cultivation in Canada and the US. It also received regulatory approvals for food and/or feed imports in Australia; Japan, Korea, and Taiwan.

MON 87403 single product is not and will not be commercialised.

### 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 87403 in the EU

On 12 June 2015, Monsanto submitted an application for import for food and feed use of MON 87403 maize as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Belgium Competent Authority. The application received the reference number EFSA-GMO-BE-2015-125 and was declared valid on 2 October 2015. The EFSA

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

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

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

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

<sup>5</sup> European Commission - [https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics\\_en](https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en) (Accessed on 24 July 2019).

<sup>6</sup> EuropaBio - <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information> (Accessed on 24 July 2019)

<sup>7</sup> ISAAA, 2018 - <http://www.isaaa.org/resources/publications> (Accessed on 24 July 2019).

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 March 2018, the EFSA published a positive scientific opinion on the safety of MON 87403 (EFSA, 2018). It was updated on 5 July 2018<sup>8</sup>. The EFSA GMO Panel concluded that “*maize MON 87403, 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 3 December 2018, 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 87403, 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 14 January 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 87403 single product is not and will not be commercialised. The unique identifier for this product is MON-87403-1.

On 26 May 2015, a MON 87403-specific PCR-based detection method allowing the identification and quantification of MON 87403 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 87403, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), were published on the EURL website<sup>9</sup> on 24 April 2018.

#### Food, feed and environmental safety of MON 87403

##### Food and feed safety

The food and feed safety assessment of MON 87403 was established based on:

- A detailed molecular characterisation demonstrated that a single copy of the intended transfer DNA containing the ATHB17 expression

cassette was integrated at a single locus within the maize genome.

- The compositional and nutritional equivalence of the seed and forage derived from MON 87403 with those of conventional maize;
- The rapid digestibility of ATHB17Δ113 protein by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of the introduced protein as demonstrated with bioinformatics as well as *in vitro* safety studies of the ATHB17Δ113 protein;
- A large margin of safety resulting from the low dietary exposure to the introduced ATHB17Δ113 protein in MON 87403.

MON 87403 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 87403, 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*”.

Further details on the safety of MON 87403 are available in the EFSA scientific opinion adopted on 8 March 2018 (EFSA, 2018).

##### Environmental safety

The environmental safety of MON 87403 was established through extensive laboratory and field testing of plant tissue or purified ATHB17Δ113 protein demonstrating that MON 87403 poses negligible risk to human and animal health or the environment.

Results from these assessments comparing MON 87403 and the conventional counterpart demonstrate that MON 87403 does not possess weediness or invasiveness characteristics compared to conventional maize. Data on the environmental interaction also confirm that MON 87403 does not increased susceptibility or tolerance to specific abiotic stress, diseases, or arthropods compared to conventional maize. This, together with the history of safe use of the ATHB17Δ113 protein, demonstrate that the ecological interactions of MON 87403 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 87403 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 87403 as any other maize, with the exception of cultivation in the EU. Also, MON 87403 single product is not and will not be commercialised. Therefore, no deliberate release of the viable plant material in the EU environment is expected.

<sup>8</sup> Erratum/Corrigendum: Reference to the publication Devos *et al.* 2018 was removed from the scientific output. This does not materially affect the content or outcome. The original version was removed from the EFSA Journal, but is available on request.

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

In conclusion, the environmental impact of growing MON 87403 is not different from that of growing conventional maize, as stated in the May 2018 EFSA scientific opinion (EFSA, 2018).

### Contact point for further information

MON 87403 single product is not and will not be commercialised.

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 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 87403 can also be addressed at:

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

### References

EFSA, 2018. Assessment of genetically modified maize MON 87403 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2015-125) - Scientific Opinion. EFSA journal, 16 (3), 1-28.

European Commission, 2019. Commission Implementing Decision (EU) 2019/1307 of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87403 (MON-87403-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council Official Journal of the European Union, L 204/81, 1-4.