

# MON 87419 maize

Glufosinate and dicamba herbicide tolerant maize

## Key facts



Bayer Agriculture BV<sup>1</sup>  
October 2023

---

<sup>1</sup> Hereafter referred to as 'Bayer'.

## Maize, a key crop

Maize (*Zea mays*) is one of the most frequently cultivated crops in the world, together with rice and wheat<sup>2</sup>. Following European discovery of the Americas where this crop is indigenous, maize was rapidly adopted in Europe, Africa and Asia. In 2023 over 1.2 billion metric tons of maize were produced in the world, which represents approximately 203 million hectares of maize harvested globally<sup>3</sup>. Significant areas of production included the US, China, Brazil, the European Union (EU), Argentina, India, Mexico, and Ukraine representing in total over 80 % of the global maize productions<sup>4</sup>. Today, maize is one of the few intensively cultivated crops in European agriculture<sup>5</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 2023, the maize area harvested in the EU accounted for approximately 8.6 million hectares, with a production of around 64 million metric tons<sup>4</sup>. The EU imported about 20 million tons of maize grain in 2021<sup>4</sup>. The major exporters of maize to the EU are Ukraine and Brazil, followed by Serbia<sup>6</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 87419?

MON 87419, developed by Bayer CropScience LP through *Agrobacterium*-mediated transformation of maize tissues, contains *pat* gene from *Streptomyces viridochromogenes* that expresses the PAT protein to confer tolerance to glufosinate herbicide, and *dmo* gene from *Stenotrophomonas maltophilia* that expresses a DMO protein to confer tolerance to dicamba herbicide.

### Worldwide plantings and regulatory status of MON 87419

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide<sup>7</sup>. Of the 190.4 million hectares of global

biotech crops planted in 2019, 32% or 60.9 million hectares were biotech maize.

MON 87419 maize received regulatory approval for cultivation in Argentina, Brazil, Canada, and the United States. MON 87419 has also received regulatory approvals for food and/or feed uses in Australia/New Zealand, Colombia, Indonesia, Japan, Mexico, the Philippines, South Korea, Singapore, Vietnam and Taiwan.

It is likely that this product will not be commercialised as a single event.

### 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, 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 enforcement on 18 April 2004.

Furthermore, a regulation laying down the methods of sampling and analysis for the official control of feeding as regards to the presence of GM 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 87419 in the EU

On 31 March 2017, Bayer CropScience LP (then Monsanto Company) submitted an application for the authorisation for food and feed containing, consisting of, or produced from MON 87419 maize and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (Commission Decision 2009/813/EC). This application received the reference number EFSA-GMO-NL-2017-140 and was declared valid on 17 July 2017. 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.

<sup>2</sup> FAOSTAT, 2023 - <http://www.fao.org/faostat/en/#data/QC> (Accessed on 25 May 2023).

<sup>3</sup> USDA, 2023 - <https://apps.fas.usda.gov/psdonline/app/index.html#/app/home> (Accessed on 25 May 2023).

<sup>4</sup> Index mundi, 2022 - <https://www.indexmundi.com/agriculture/?commodity=corn&graph=production> (Accessed on 25 May 2023).

<sup>5</sup> Eurostat, 2022 - [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Agricultural\\_production\\_-\\_crops](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Agricultural_production_-_crops) (Accessed on 6 June 2023).

<sup>6</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 25 May 2023).

<sup>7</sup> ISAAA, 2019 - <http://www.isaaa.org/resources/publications/> (Accessed on 25 May 2023).

On 20 January 2023, the EFSA published a positive Scientific Opinion on the safety of MON 87419 maize<sup>8</sup>. The EFSA GMO panel concluded that “*the maize MON 87419 is as safe as its conventional counterpart and the tested non-GM maize varieties with respect to potential effects on human and animal health and the environment*”.

On 01 June 2023, 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 maize MON 87419 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 06 July 2023, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 13 October 2023<sup>9</sup>.

### Traceability, labelling, unique identifier

Operators handling or using MON 87419 maize and derived food 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-87419-8.

In March 2017, MON 87419 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF). The validated method, as well as the validation report for MON 87419, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), are available at the EURL website<sup>10</sup>.

### Food, feed and environmental safety of MON 87419

#### Food and feed safety

The food and feed safety assessment of MON 87419 was established based on:

- A detailed molecular characterisation of the inserted DNA confirming that a single copy of the PAT and DMO expression cassettes was integrated at a single locus within the maize genome;
- The long history of safe use of the PAT and DMO proteins in general;
- The compositional and nutritional equivalence of the seed and forage derived from MON 87419 with those of conventional maize;

- The rapid digestibility of PAT and DMO proteins by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of PAT and DMO proteins 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 PAT and DMO proteins in MON 87419.

MON 87419 was found to be as safe and nutritious as conventional maize by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals<sup>8</sup>. In its Scientific Opinion, the EFSA GMO Panel concluded that forage and grains of maize MON 87419 are compositionally, phenotypically and agronomically equivalent to those of the non-GM counterpart and conventional maize varieties, except for the presence of PAT and DMO proteins in maize MON 87419.

Further details on the safety of MON 87419 are available in the EFSA scientific opinion adopted on 30 November 2022<sup>8</sup>.

#### Environmental safety

The environmental safety of MON 87419 was established through extensive laboratory and field testing of plant tissue or purified PAT and DMO proteins, and with a wide range of non-target species demonstrating that MON 87419 poses negligible risk to human and animal health or the environment.

The agronomic and phenotypic analyses confirmed that MON 87419 does not possess characteristics that would confer a plant pest risk compared to conventional maize.

The environmental interaction analyses confirmed that MON 87419 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 87419 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 as any other maize, but excludes cultivation from MON 87419 maize 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.

#### Contact point for further information

Since traders may commingle MON 87419 with other commercial maize, including authorised GM maize, Bayer is working together with other members of the plant biotechnology industry within the CroLife Europe 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

<sup>8</sup> EFSA - <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.7730> (Accessed on 18 Oct 2023)

<sup>9</sup> European Commission – [https://eur-lex.europa.eu/eli/dec\\_impl/2023/2134](https://eur-lex.europa.eu/eli/dec_impl/2023/2134) – (Accessed on 18 Oct 2023)

<sup>10</sup> EURL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> (Accessed on 25 May 2023)

maize products, can refer to the CroLife Europe website at:

<https://croplifeeurope.eu/product-information/>

If required, additional comments or questions relative to MON 87419 can also be addressed to Bayer at:

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