

MON 87429 maize

Roundup® Hybridization System (RHS) and
glufosinate, dicamba, quizalofop and 2,4-D herbicide
tolerant maize

Key facts



Bayer Agriculture BV¹
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¹ 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 wheat². 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 globally³. 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 productions⁴. Today, maize is one of the few intensively cultivated crops in European agriculture⁵. 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 tons⁴. The EU imported about 20 million tons of maize grain in 2021⁴. The major exporters of maize to the EU are Brazil and Ukraine, followed by Serbia⁶. 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 87429?

MON 87429, 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, *dmo* gene from *Stenotrophomonas maltophilia* that expresses a DMO protein to confer tolerance to dicamba herbicide, and *ft_t* gene, a modified version of the R-2,4-dichlorophenoxypropionate dioxygenase (Rdpa) gene from *Sphingobium herbicidovorans* that expresses a FOPs and 2,4-D dioxygenase protein (FT_T) that confers tolerance to quizalofop and 2,4-D herbicides. MON 87429 contains also the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 that expresses the CP4 EPSPS protein to provide a glyphosate-based hybridisation system for hybrid seed production. MON 87429 utilizes an endogenous maize RNAi regulatory element to reduce CP4 EPSPS protein expression in pollen. Appropriately timed glyphosate applications produce a non-viable pollen phenotype and allow for desirable cross pollinations to be made in maize without using mechanical or manual detasseling methods to control self-pollination in female inbred parents.

Worldwide plantings and regulatory status of MON 87429

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide⁷. Of the 190.4 million hectares of global biotech crops planted in 2019, 32% or 60.9 million hectares were biotech maize.

MON 87429 maize received regulatory approval for cultivation in Argentina, Brazil, Canada and Japan. MON 87429 has also received regulatory approvals for food and/or feed uses in Argentina, Australia/New Zealand, Brazil, Canada, Japan, Singapore, Taiwan and USA.

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 87429 in the EU

On 27 September 2019, Bayer CropScience LP submitted an application for import and food and feed uses of MON 87429 as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Dutch Competent

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

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

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

⁵ Eurostat, 2022 - https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Agricultural_production_-_crops (Accessed on 6 June 2023).

⁶ European Commission - https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en (Accessed on 25 May 2023).

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

Authority. This application received the reference number EFSA-GMO-NL-2019-161 and was declared valid on 16 January 2020.

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 18 November 2022, the EFSA published a positive Scientific Opinion on the safety of MON 87429 maize (EFSA, 2022). The EFSA GMO panel concluded that “*that maize MON 87429, 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 31 March 2023, the European Commission (EC) presented the Draft Commission Implementing Decision of the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87429 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 11 May 2023, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 21 June 2023 (Commission Implementing Decision (EU) 2023/1211⁸).

Traceability, labelling, unique identifier

Operators handling or using MON 87429 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. It is likely that this product will not be commercialised as a single event.

The unique identifier for this product is MON-87429-9.

In August 2019, MON 87429 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 87429, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), are available at the EURL website⁹.

Food, feed and environmental safety of MON 87429

Food and feed safety

The food and feed safety assessment of MON 87429 was established based on:

- A detailed molecular characterisation of the inserted DNA confirming that a single copy of the PAT, DMO, FT_T and CP4 EPSPS expression

cassettes was integrated at a single locus within the maize genome;

- The long history of safe use of the PAT, CP4 EPSPS, DMO and FT_T proteins in general;
- The compositional and nutritional equivalence of the seed and forage derived from MON 87429 with those of conventional maize;
- The rapid digestibility of PAT, CP4 EPSPS, DMO and FT_T proteins by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of PAT, CP4 EPSPS, DMO and FT_T 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, CP4 EPSPS, DMO and FT_T proteins in MON 87429.

MON 87429 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 (EFSA, 2022). In its Scientific Opinion, the EFSA GMO Panel concluded “*the consumption of food and feed from maize MON 87429 does not represent a nutritional concern in humans and animals*”.

Further details on the safety of MON 87429 are available in the EFSA scientific opinion adopted on 28 September 2022 (EFSA, 2022).

Environmental safety

The environmental safety of MON 87429 was established through extensive laboratory and field testing of plant tissue or purified PAT, CP4 EPSPS, DMO and FT_T proteins, and with a wide range of non-target species demonstrating that MON 87429 poses negligible risk to human and animal health or the environment.

The agronomic and phenotypic analyses confirmed that MON 87429 does not possess characteristics that would confer a plant pest risk compared to conventional maize.

The environmental interaction analyses confirmed that MON 87429 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 87429 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 87429 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.

⁸ European Commission, 2023. [Commission Implementing Decision \(EU\) 2023/1211 of 21 June 2023 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87429 pursuant to Regulation \(EC\) No 1829/2003 of the European Parliament and of the Council](https://eur-lex.europa.eu/eli/reg/2023/1211/20230621) - (Accessed on 26 June 2023)

⁹ EURL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> (Accessed on 25 May 2023)

Contact point for further information

It is likely that MON 87429 will not be commercialised as a single event.

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

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

If required, additional comments or questions relative to MON 87429 can also be addressed to Bayer at:

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

References

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- European Commission, 2021. Commission Implementing Decision (EU) 2021/67 of 22 January 2021 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 88017 (MON-88017-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union, L 26, 50-55.
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