

MON 95379 maize

Lepidopteran-protected

Key facts



Bayer Agriculture BV¹
July 2023

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 95379?

MON 95379, developed by Bayer CropScience LP, through *Agrobacterium*-mediated transformation of maize tissues, contains *cry1b.868* and *cry1da_7* genes from *Bacillus thuringiensis* that express Cry1B.868 and Cry1Da_7 proteins to confer protection against feeding damage caused by targeted lepidopteran insect pests (Wang *et al.*, 2019).

Cry proteins naturally occur in the *Bacillus thuringiensis* (*Bt*) bacterium. Several Cry proteins exist and are classified by structure and by insects they control. 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). No receptors for these proteins have been identified on intestinal cells of mammals to date.

A large number of insecticidal products based on this bacterium and/or its proteins have been developed and sold commercially since the late 1930's. Historically, *Bt* has been considered a safe option for pest control.

Using biotechnology, the genes coding for specific *Bt* proteins were isolated and introduced into various crop plants.

Worldwide plantings and regulatory status of MON 95379

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 95379 maize received regulatory approval for cultivation in Brazil and Paraguay. MON 95379 has also received regulatory approvals for food and/or feed uses in Argentina, Australia/New Zealand, Canada, Japan, Philippines, Singapore, Taiwan and US.

MON 95379 single product is not and will not be commercialised on its own, instead stacked products, made via traditional breeding, are the aimed commercial products.

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.

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 23 November 2022).

Regulatory status of MON 95379 in the EU

On 30 November 2020, Bayer submitted an application for the authorisation for food and feed containing, consisting of, or produced from MON 95379 maize and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003. This application received the reference number EFSA-GMO-NL-2020-170 and was declared valid on 29 March 2021. 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 15 November 2022, the EFSA published a positive Scientific Opinion on the safety of MON 95379 maize (EFSA, 2022). The EFSA GMO panel concluded that “maize MON 95379 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 31 March 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 95379 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) 2023/1208⁸).

Traceability, labelling, unique identifier

Operators handling or using MON 95379 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-95379-3.

In October 2020, MON 95379 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 95379, 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 95379

Food and feed safety

The food and feed safety assessment of MON 95379 was established based on:

- A detailed molecular characterisation of the inserted DNA confirming that a single copy of the Cry1B.868 and Cry1Da_7 expression cassettes was integrated at a single locus within the maize genome;
- The long history of safe use of Bt Cry proteins in general;
- The compositional and nutritional equivalence of the seed and forage derived from MON 95379 with those of conventional maize;
- The rapid digestibility of Cry1B.868 and Cry1Da_7 proteins by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of Cry1B.868 and Cry1Da_7 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 Cry1B.868 and Cry1Da_7 proteins in MON 95379.

MON 95379 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 95379 does not represent a nutritional concern in humans and animals”.

Further details on the safety of MON 95379 are available in the EFSA scientific opinion adopted on 28 September 2022 (EFSA, 2022).

Environmental safety

The environmental safety of MON 95379 was established through extensive laboratory and field testing of plant tissue or purified Cry1B.868 and Cry1Da_7 proteins, and with a wide range of non-target species demonstrating that MON 95379 poses negligible risk to human and animal health or the environment.

The agronomic and phenotypic analyses confirmed that MON 95379 does not possess characteristics that would confer a plant pest risk compared to conventional maize.

The environmental interaction analyses confirmed that MON 95379 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors, except for its protection against certain lepidopteran pests.

⁸ European Commission, 2023. [Commission Implementing Decision \(EU\) 2023/1208 of 21 June 2023 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 95379 pursuant to Regulation \(EC\) No 1829/2003 of the European Parliament and of the Council](https://eur-lex.europa.eu/eli/dec/2023/1208/20230621/autol) - (Accessed on 26 June 2023)

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

The likelihood of MON 95379 spreading into the non-agricultural environment is negligible, since it is not more invasive in natural habitats than conventional maize. Moreover, the scope of the authorisation covers the hypothetical import, processing and all uses as any other maize, but excludes cultivation from MON 95379 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 95379 with other commercial maize, including authorised GM maize, Bayer is working together with other members of the plant biotechnology industry within the CropLife 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 maize products, can refer to the CropLife Europe website at:

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

If required, additional comments or questions relative to MON 95379 can also be addressed to Bayer at:

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

References

- EFSA, 2022. Assessment of genetically modified maize MON 95379 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-170). EFSA journal, 20, e07588.
- 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.
- Wang Y, Wang J, Fu X, Nageotte JR, Silverman J, Bretsnyder EC, Chen D, Rydel TJ, Bean GJ, Li KS, Kraft E, Gowda A, Nance A, Moore RG, Pleau MJ, Milligan JS, Anderson HM, Asiimwe P, Evans A, Moar WJ, Martinelli S, Head GP, Haas JA, Baum JA, Yang F, Kerns DL and Jerga A, 2019. *Bacillus thuringiensis* Cry1Da₇ and Cry1B.868 protein interactions with novel receptors allow control of resistant fall armyworm, *Spodoptera frugiperda* (J.E. Smith). Appl Environ Microbiol, 85, e00579-00519.