

MON 88017 × MON 810 maize

YieldGard VT Triple®

Insect-protected and glyphosate-tolerant

Key facts



Bayer Agriculture BV
September 2021

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 2020, over 1.1 billion metric tons of maize were produced in the world, which represents approximately 197 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 2020, the maize area harvested in the EU accounted for approximately 9 million hectares, with a production of around 68.3 million metric tons³. The EU imported about 23 million tons of maize grain in 2020³. The major exporters of maize to the EU are Ukraine and Brazil, followed by Serbia⁵. 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 88017 × MON 810?

MON 88017 × MON 810 was obtained by traditional breeding of two independent genetically modified maize events, MON 88017 and MON 810. MON 88017 × MON 810 combines the traits of agronomic interest from the two parental events, *i.e.* tolerance to glyphosate-based herbicides and protection against coleopteran and lepidopteran insects.

MON 88017 × MON 810 as well as the genetically modified parental maize events MON 88017 and MON 810 have been developed by Monsanto Company⁶.

More information on the parental events can be found on the CropLife Europe website⁷.

Worldwide plantings and regulatory status of MON 88017

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide⁸. Of the 190.4 million hectares of global biotech crops planted in 2019, 32% or 60.9 million hectares were biotech maize.

MON 88017 × MON 810 maize received regulatory approval for production in Canada and the United States. MON 88017 × MON 810 has also received regulatory approvals for food and feed uses in Colombia, Japan, Mexico, the Philippines, South Africa, Korea and Taiwan.

MON 88017 × MON 810 is no longer commercialised⁹.

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.

¹ FAOSTAT, 2020 - <http://www.fao.org/faostat/en/#data/QC> (Accessed on 19 August 2021).

² USDA, 2020 - <https://apps.fas.usda.gov/psdonline/app/index.html#/app/home> (Accessed on 19 August 2021).

³ Index mundi, 2018 - <https://www.indexmundi.com/agriculture/?commodity=corn&graph=production> (Accessed on 19 August 2021).

⁴ Eurostat, 2020 - <http://ec.europa.eu/eurostat> (Accessed on 19 August 2021).

⁵ European Commission - https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en (Accessed on 19 August 2021).

⁶ Now Bayer CropScience LP.

⁷ CropLife Europe, 2021 - <https://croplifeeurope.eu/product-information/> (Accessed on 19 August 2021).

⁸ ISAAA, 2019 - <http://www.isaaa.org/resources/publications/> (Accessed on 19 August 2021).

⁹ CropLife International - <http://www.biotradestatus.com/> (Accessed on 02 September 2021).

Regulatory status of MON 88017 × MON 810 in the EU

On 27 June 2019, Monsanto Company submitted an application for renewal of the authorisation for products containing, consisting of, or produced from MON 88017 × MON 810 maize authorised under Regulation 1829/2003 (Commission Decision 2010/429/EU). This renewal application received the reference number EFSA-GMO-RX-017 and was declared valid on 24 October 2019. 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 29 January 2021, the EFSA published a positive Scientific Opinion on the safety of MON 88017 × MON 810 maize (EFSA, 2021). The EFSA GMO panel concluded that *“there is no evidence in the renewal application EFSA-GMO-RX-017 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810”*.

On 8 June 2021, 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 88017 × MON 810 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 22 July 2021, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 17 August 2021 (European Commission, 2021).

Regulatory status of the parental lines

The EC renewed MON 88017 and MON 810 foods, food ingredients, and feed containing, consisting of, or produced from these events, or products other than food and feed containing or consisting of these events for the same uses as any other maize with the exception of cultivation under Regulation (EC) No 1829/2003 on 22 January 2021 (Commission Implementing Decision (EU) 2021/67) and on 6 November 2013 - 4 July 2017 (Commission Implementing Decisions 2013/649/EU - 2017/1207)¹⁰, respectively.

Traceability, labelling, unique identifier

Operators handling or using MON 88017 × MON 810 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-88017-3 × MON-00810-6. MON 88017 × MON 810 is no longer commercialised⁹.

In January 2008, MON 88017 × MON 810 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The EURL considers that the detection methods validated on the parental maize events, MON 88017 and MON 810, show a comparable performance when applied to MON 88017 × MON 810. The detection methods for MON 88017 and MON 810 had been previously validated by the EURL and are available at the EURL website¹¹. The validation report for MON 88017 × MON 810, prepared by the EURL, is also available on the same website.

Food, feed and environmental safety of MON 88017 × MON 810

Food and feed safety

MON 88017 × MON 810 was obtained by traditional breeding of two independent genetically modified maize events, MON 88017 and MON 810. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 88017 × MON 810.
- Safety assessment of the combined product, taking into consideration the safety of the parental lines.

The molecular analysis of the DNA inserts present in MON 88017 × MON 810 confirmed that the insert structures of the parental maize lines were retained. Also, Cry3Bb1, CP4 EPSPS and Cry1Ab protein levels in grain and forage of MON 88017 × MON 810 were comparable to the levels in the corresponding parental maize lines.

The conclusions of safety for Cry3Bb1, CP4 EPSPS and Cry1Ab, as already demonstrated in the context of MON 88017 and MON 810, remain applicable when these proteins are produced in combination in MON 88017 × MON 810. It is unlikely that when interactions between Cry3Bb1, CP4 EPSPS and Cry1Ab would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended Cry3Bb1, CP4 EPSPS and Cry1Ab protein expressions, there are no biologically relevant differences in the characteristics of MON 88017 × MON 810 as compared with its conventional counterpart and that the composition fell within the range of non-GM maize varieties.

Also, in their scientific opinion, the EFSA concluded that *“that maize MON 88017 × MON 810 is as safe and as nutritious as its non-GM counterpart and that the overall allergenicity of the whole plant is not changed.”* (EFSA, 2009)

¹⁰ Both amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

¹¹ EURL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> (Accessed on 19 August 2021).

In conclusion, combining MON 88017 and MON 810 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 88017 and MON 810 was shown to be as safe and as nutritious as the conventional maize counterpart.

Further details on the safety of MON 88017 × MON 810 are available in the EFSA scientific opinions (EFSA, 2009, 2021).

Environmental safety

The environmental safety of MON 88017 × MON 810 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 88017 × MON 810 does not possess characteristics that would confer a plant pest risk compared to conventional maize.
- The environmental interaction analyses confirmed that MON 88017 × MON 810 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 88017 × MON 810 would 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 excluding cultivation 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.

Also, in their scientific opinion, the EFSA concluded that *“In case of accidental release into the environment of maize MON 88017 × MON 810 viable grains during transportation and processing, there are no indications of increased likelihood of establishment or survival of feral maize plants.”* (EFSA, 2009).

In their final conclusion EFSA confirms *“that there is no evidence in renewal application EFSA-GMO-RX-017 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810.”* (EFSA, 2021).

MON 88017 × MON 810 is no longer commercialised⁹. Therefore, no deliberate release of the viable plant material in the EU environment is expected.

Contact point for further information

Bayer is working together with other members of the plant biotechnology industry within 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 88017 × MON 810 can also be addressed to Bayer at:

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

References

- EFSA, 2009. Application (Reference EFSA-GMO-CZ-2006-33) for the placing on the market of the insect-resistant and glyphosate-tolerant genetically modified maize MON 88017 × MON 810, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA journal, 7, 1192.
- EFSA, 2021. Assessment of genetically modified maize MON 88017 × MON 810 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-017). EFSA journal, 19, e06375.
- European Commission, 2021. Commission Implementing Decision (EU) 2021/1393 of 17 August 2021 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 88017 × MON 810 (MON-88017-3 × MON-00810-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union, L 300, 54-59.