MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 maize

Drought-tolerance × Trecepta®

Lepidopteran-protected, drought tolerant and glyphosate-tolerant

Key facts

Bayer Agriculture BV
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Maize, a key crop

Maize (*Zea mays)* is one of the most frequently cultivated crops in the world, together with rice and wheat[1]. 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 globally[2]. 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[3]. Today, maize is one of the few intensively cultivated crops in European agriculture[4]. 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 tons[3]. The EU imported about 23 million tons of maize grain in 2020[3]. The major exporters of maize to the EU are Ukraine and Brazil, followed by Serbia[5]. 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 87427 × MON 87460 × MON 89034 × MIR162 × NK603?

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 was obtained by traditional breeding of five independent genetically modified maize events, MON 87427, MON 87460, MON 89034, MIR162 and NK603. MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 combines the traits of agronomic interest from the five parental events, *i.e.* tolerance to glyphosate-based herbicides, drought tolerance and protection against lepidopteran insect pests. As maize is a segregating crop, MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 grain includes the combined event product and any combination of these events (sub-combinations).

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 as well as the genetically modified parental maize events MON 87427, MON 87460, MON 89034 and NK603 have been developed by Monsanto Company[6], whereas the genetically modified parental maize event MIR162 has been developed by Syngenta.

[1] FAOSTAT, 2020 - http://www.fao.org/faostat/en/#data/QC (Accessed on 25 November 2020).

[2] USDA, 2020 - https://apps.fas.usda.gov/psdonline/app/index.html#/app/home (Accessed on 25 November 2020).

[3] Index mundi, 2018 - https://www.indexmundi.com/agriculture/?commodity=corn&graph=production (Accessed on 25 November 2020).

[4] Eurostat, 2020 - http://ec.europa.eu/eurostat (Accessed on 25 November 2020).

[5] European Commission - https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en (Accessed on 25 November 2020).

[6] Now Bayer CropScience LP.

More information on the parental events can be found on the Crop Life Europe (CLE) website[7].

Worldwide plantings and regulatory status of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide[8]. Of the 190.4 million hectares of global biotech crops planted in 2019, 32% or 60.9 million hectares were biotech maize.

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 has received regulatory approval for production in Canada and the US. MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 also received regulatory approvals for food and/or feed imports in Mexico and South Africa.

A stringent regulatory system for genetically modified 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 87427 × MON 87460 × MON 89034 × MIR162 × NK603 in the EU

On 28 October 2016, Monsanto Company submitted an application for import, food and feed use of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 maize and its sub-combinations as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Dutch Competent Authority. The application received the reference number EFSA-GMO-NL-2016-134 and was declared valid on

[7] Crop Life Europe, 2021 - https://croplifeeurope.eu/product-information/ (Accessed on 28 January 2021).

[8] ISAAA, 2019 - http://www.isaaa.org/resources/publications/ (Accessed on 1 December 2020).

19 January 2017. The EFSA 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 8 August 2019, the EFSA published a positive scientific opinion on the safety of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and sub-combinations (EFSA, 2019). The EFSA concluded that "*maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 and its subcombinations, as described in this application, are as safe as the non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment*" (EFSA, 2019).

On 15 September 2020, 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 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87424, MON 87460, MON 89034, MIR162 and NK603, 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 12 November 2020, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 22 January 2021 (European Commission, 2021).

Regulatory status of the parental lines

The EC authorised/renewed MON 87427, MON 87460, MON 89034, MIR162 and NK603 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 4 December 2015 (Commission Implementing Decision (EU) 2015/2281)[9], 25 April 2015 (Commission Implementing Decision (EU) 2015/683)9, 21 January 2021 (Commission Implementing Decision (EU) 2021/63), on 18 October 2012 (Commission Implementing Decision 2012/651/EU)[10], and on 24 April 2015 (Commission Implementing Decision (EU) 2015/684)[9], respectively.

Traceability, labelling, unique identifier

Operators handling or using MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations 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. The unique identifier for the products covered by Commission Implementing Decision (EU) 2021/61 of 22 January 2021 are:

MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6; MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4; MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6; MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6; MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6; MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3; MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4; MON-87427-7 × MON-8746Ø-4 × MON-ØØ6Ø3-6; MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6; MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4; MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6; MON-87427-7 × MON-8746Ø-4; MON-8746Ø-4 × MON-89Ø34-3. MON-8746Ø-4 × SYN-IR162-4; MON-8746Ø-4 × MON-ØØ6Ø3-6.

In October 2016, MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 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 87427, MON 87460, MON 89034, MIR162 and NK603, show a comparable performance when applied to MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603. The detection methods for MON 87427, MON 87460, MON 89034, MIR162 and NK603 had been previously validated by the EURL and are available on the EURL website[11]. The validation report for MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603, prepared by the EURL was published on the same website[13].

Food, feed and environmental safety of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603

As maize is a segregating crop and MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 is produced using traditional breeding methods; the conclusions derived in the below sections are equally applicable to MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 as to any of its sub-combinations.

Food and feed safety

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 was obtained by traditional breeding of five independent genetically modified maize events, MON 87427, MON 87460, MON 89034, MIR162 and NK603. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603.
- 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 87427 × MON 87460 × MON 89034 × MIR162 × NK603 confirmed that the insert structures of the parental maize lines were retained. Also,

[9] Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

[10] Amended by Commission Implementing Decision (EU) 2019/60 of 11 January 2019.

[11] EURL - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 24 February 2021).

CP4 EPSPS[12], CSPB, NPTII, Cry1A.105, Cry2Ab2, Vip3Aa20 and PMI protein levels in grain and forage of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 were comparable to the levels in the corresponding parental maize lines.

The conclusions of safety for CP4 EPSPS, CSPB, NPTII, Cry1A.105, Cry2Ab2, Vip3Aa20 and PMI, as already demonstrated in the context of MON 87427, MON 87460, MON 89034, MIR162 and NK603, remain applicable when these proteins are produced in combination in MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603. It is unlikely that when interactions between CP4 EPSPS, CSPB, NPTII, Cry1A.105, Cry2Ab2, Vip3Aa20 and PMI would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended CP4 EPSPS, CSPB, NPTII, Cry1A.105, Cry2Ab2, Vip3Aa20 and PMI protein expressions, there are no biologically relevant differences in the characteristics of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 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 "*the five-event stack maize, as described in this application, is as safe as and nutritionally equivalent to its non-GM comparator and the non-GM reference varieties tested*" (EFSA, 2019).

In conclusion, combining MON 87427, MON 87460, MON 89034, MIR162 and NK603 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 was shown to be as safe and as nutritious as the conventional maize counterpart.

Further details on the safety of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 are available in the EFSA scientific opinion adopted on 3 July 2019 (EFSA, 2019).

Environmental safety

The environmental safety of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 does not possess characteristics that would confer a plant pest risk compared to conventional maize.
- The environmental interaction analyses confirmed that MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 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 excludes 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 "*maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 would not raise safety concerns in the event of accidental release of viable GM maize grains into the environment*" (EFSA, 2019).

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603, the benefits

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 provides the following benefits to both farmers and the environment:

- *Increased flexibility in hybrid seed production*: each year approximately 0.2 M hectares used for hybrid maize seed production must be detasseled in order to meet commercial growers' hybrid maize seed needs and to meet established seed purity criteria in seed producing countries. The critical time period for detasseling is after the tassel has emerged but prior to pollen shed and silk emergence, and encompasses an average of 3-4 days window. Current detasseling practices may require up to two passes with mechanical detasseling equipment and up to three passes if hand detasseling is used. Further complicating detasseling activity is the logistical planning required for transporting the necessary labour force and resources to the designated hybrid seed production fields at the appropriate time. Glyphosate applications to MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 fields, that will result in the male sterile phenotype through tissue-selective glyphosate tolerance, will take place during maize vegetative growth stages ranging from V8 to V13. The two glyphosate applications would take place during an approximate 14 days window within these growth stages, a much longer time period compared to an average 3–4 days window between tassel emergence and pollen shed and silk emergence available for current detasseling practices. This timing accounts for significantly improved flexibility in hybrid seed production.
- *Economic benefits for hybrid seed producers*: seed manufacturers continually seek ways to improve hybrid seed productivity and reduce the inputs and land area used to produce high quality hybrid seed. Agricultural field labour costs tend to outpace inflation in typical maize seed producing markets. Compounding this increase in cost is shrinking of the agricultural labour workforce due to population migration towards urban areas, thus reducing a reliable labour pool for agricultural work. Costs associated with labour recruitment and deployments to perform detasseling work, represent one of the largest opportunities for cost improvements associated to hybrid seed production. MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 will decrease hybrid seed production costs primarily from a reduction in direct costs and from associated labour costs.

[12] NK603 expresses CP4 EPSPS and CP4 EPSPS L214P, further referred to as CP4 EPSPS.

- *Compatibility with integrated pest management (IPM):* A method to control corn borers and other lepidopteran pests of maize, compatible with integrated pest management (IPM) approaches, that offers improved pest control and higher yields, while at the same time being safe for humans and the environment. This is combined with a successful broad-spectrum weed control option that allows over-the-top applications of glyphosate in maize on an "as needed basis" (Johnson *et al.*, 2000; Marra *et al.*, 2002).

- *Improved control of above ground pests, fall armyworm and corn earworm:* Better control of fall armyworm (*Spodoptera* sp.) and corn earworm (*Helicoverpa zea*) compared to the first generation insect protected maize MON 810 (MON 89034 and MIR162 have a wider spectrum of activity); and *improved control of below ground pests* (*Diabrotica sp.*).

- *An effective insect resistance management tool* due to the presence of three insecticidal proteins, Cry1A.105, Cry2Ab2, and Vip3Aa20. Multiple modes-of-action to help protect maize plants above ground injury caused by larval feeding activity of certain insect pests. In addition, insect resistance has a much lower likelihood when plants have dual and triple modes of protection. The use of unique multiple modes-of-action provides enhanced insect protection—while maintaining long-term durability of the technology.

- *Decreased occurrence of fungal mycotoxins* associated with adverse health effects, as a result of lower damage to maize plants by lepidopteran pests (Bakan *et al.*, 2002; Brookes, 2008; de la Campa *et al.*, 2005; Munkvold, 2003; Wu, 2006).

- *Weed management:* Glyphosate use rates, timings and recommendations for weed management will not be different than those previously recommended for MON 87411 allowing flexible broad-spectrum weed control options that allows over-the-top applications of glyphosate in maize on an "as needed" basis (Johnson *et al.*, 2000; Thomas *et al.*, 2014); in addition several other herbicide options are available that are currently used in conventional maize to diversify weed management program and minimize the selection pressure for weed resistance development (USDA, 2015).

- *Consistency in weed control:* Contribution to achieve more consistency in the weed control results combined with the full and superior selectivity of Roundup® on MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 hybrids to protect the yield potential of those hybrids.

- Glyphosate can provide an environmentally sustainable, flexible, and profitable option in weed control programs (Dewar, 2009). It is a broad-spectrum herbicide with a favourable human health and environmental profile. It is non-persistent and has limited mobility as it binds tightly to soil. The compound presents very low toxicity to humans. Furthermore, it does not bioaccumulate and presents minimal risk to terrestrial and aquatic species including fish, birds, mammals and invertebrates (Giesy *et al.*, 2000; Williams *et al.*, 2000).

- *Increased benefits for farmers* linked to the reduced exposure to insecticides, ease of use and handling, time and labour savings, as well as better pest control (Brookes and Barfoot, 2008; Marra *et al.*, 2002).

- *Negligible to no risks for adverse effects on beneficial non-target organisms* when compared to fields treated with conventional pesticides or with untreated controls; this is attributed to the reduction in insecticide use, low toxicity of glyphosate and compatibility with conservation tillage practices (Ammann, 2003; Fawcett and Towery, 2002; Giesy et al., 2000; Lozzia, 1999; Orr and Landis, 1997; Pilcher et al., 1997; Reyes, 2005).

- *Increased maize yield stability under drought stress*. This would have far reaching benefits, as limited water availability is the single most important factor that reduces global crop yields. In North America alone, it is estimated that 40% of annual crop losses are caused by sub-optimal water availability.

- The drought tolerance trait is designed to help farmers *mitigate the risk of yield loss* when experiencing drought stress. It helps the maize plants to use less water when drought stress occurs. The plants acclimate to the stress more quickly and utilise water more efficiently, leaving them with more water to help through critical periods of growth.

Contact point for further information

Since traders may commingle MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 with other commercial maize, including authorised GM maize, Bayer is working together with other members of the plant biotechnology industry within Crop Life 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 therefore refer to the Crop Life Europe website at:

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

If required, additional comments or questions relative to MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 can also be addressed at:

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

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