# MON 87427 × MON 89034 × 1507 × MON 88017 × 59122

## Roundup® Hybridization System × Genuity®[1] SmartStax®[2]

Herbicide-tolerant and insect-protected maize

# Key facts

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[1] Roundup and Genuity are registered trademarks of Monsanto Technology LLC.

[2] SmartStax is a registered trademark of Monsanto Technology LLC and Dow AgroSciences.

## Maize, a key crop

Maize (*Zea mays)* is one of the most frequently cultivated crops in the world, together with rice and wheat[3]. Following European discovery of the Americas where this crop is indigenous, maize was rapidly adopted in Europe, Africa and Asia. In 2018, over 1 billion metric tons of maize were produced in the world, which represents approximately 184 million hectares of maize harvested globally[4]. 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[5].Today, maize is one of the few intensively cultivated crops in European agriculture[6]. 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 2018, the maize area harvested in the EU accounted for approximately 8.3 million hectares, with a production of around 59.8 million metric tons[5]. The EU imported about 18 million tons of maize grain in 2018[5]. The major exporters of maize to the EU are Ukraine and Brazil, followed by Canada[6]. 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 89034 × 1507 × MON 88017 × 59122?

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was obtained by traditional breeding of five independent genetically modified maize events, MON 87427, MON 89034, 1507, MON 88017 and 59122. MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 combines the traits of agronomic interest from the five parental lines, *i.e.* tolerance to glyphosate- and glufosinate-based herbicides, and protection against lepidopteran and coleopteran insect pests. Like MON 87427, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 provides maize lines with tissue-selective glyphosate tolerance to facilitate a production of viable hybrid maize seed. Besides, as maize is a segregating crop, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 grain includes the combined event product and any combination of these events (sub-combinations).

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, as well as the genetically modified parental maize lines containing either the MON 87427, MON 89034 or MON 88017 insert, have been developed by Monsanto Company, whereas the genetically modified parental maize events 1507 and 59122 have been developed by Dow AgroSciences.

More information on the parental lines can be found on the European Association for Bioindustries (EuropaBio) website[7].

## Worldwide plantings and regulatory status of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122

In 2017, approximately 189.8 million hectares of GM crops were grown worldwide[8]. Of the 189.8 million hectares of global maize planted in 2017, 31.5% or 59.7 million hectares were biotech maize.

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 has received regulatory authorisations for cultivation in Canada and the US[9]. MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 has also received regulatory authorisations for food and feed imports in Australia/New Zealand, Canada, Colombia, Japan, Malaysia, Mexico, South Korea, Singapore, South Africa, Taiwan and US.

## 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, 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 authorization procedure is pending or the authorisation of which has expired (Commission regulation (EU) No 619/2011) entered into force on 24 June 2011.

3 FAOSTAT, 2018 - http://faostat.fao.org/site/339/default.aspx (Accessed on 11 December 2018).

4 USDA, 2018 - https://apps.fas.usda.gov/psdonline/app/index.html#/app/home (Accessed on 11 December 2018).

5 Index mundi, 2018 - https://www.indexmundi.com/agriculture/?commodity=corn&graph=production (Accessed on 11 December 2018).

6 Eurostat, 2018 - http://ec.europa.eu/eurostat (Accessed on 11 December 2018).

7 EuropaBio, 2017 - http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information (Accessed on 11 December 2018)

8 ISAAA, 2018 - http://www.isaaa.org/resources/publications (Accessed on 11 December 2018).

9 This product is a combined event. The authorization(s) by the appropriate regulatory agency (or agencies) of the country indicated may be found in the Crop Life International database under the individual event(s) listed with this product. Crop Life International - http://www.biotradestatus.com/ (Accessed on 11 December 2018)

## Regulatory status of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 in the EU

On 15 November 2013, Monsanto submitted an application for import for food and feed use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Belgian Competent Authority. The application received the reference number EFSA-GMO-BE-2013-118 and was declared valid on 10 March 2014. 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 September 2017, the EFSA published a positive scientific opinion on the safety of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 (EFSA, 2017). The EFSA concluded that "*the five-event stack maize is as safe and as nutritious as the non-genetically modified (GM) comparator and the tested non-GM reference varieties in the context of its scope. For the 14 maize subcombinations for which no experimental data were provided, the GMO Panel assessed the likelihood of interactions among the single events, and concluded that their combinations would not raise safety concerns. These maize subcombinations are therefore expected to be as safe as the single events, the previously assessed subcombinations and maize MON 87427 ×MON 89034 × 1507 × MON 88017 × 59122*"

On 11 September 2018, the European Commission (EC) presented the Draft Commission Implementing Decision authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, 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 who met for a vote on 23 October 2018, again without reaching a qualified majority. Therefore, the Appeal Committee forwarded the draft decision to the EC who granted the authorization on 19 December 2018 (Commission Implementing Decision (EU) 2018/2046).

### *Regulatory status of the parental lines*

The EC authorised MON 87427, MON 89034, 1507, MON 88017 and 59122 for import, food and feed use as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 on 4 December 2015 (Commission Implementing Decision (EU) 2015/2281), 30 October 2009 (Commission Decision 2009/813/EC), 21 December 2017 (Commission Implementing Decision (EU) 2017/2452), 30 October 2009 (Commission Decision 2009/814/EC) and 1 August 2018 (Commission Implementing Decision (EU) 2018/1109), respectively.

## Traceability, labelling, unique identifier

Operators handling or using MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 identifiers for the products covered by Commission Implementing Decision (EU) 2018/2046 of 19 December 2018 are:

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 ; MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3; MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7; MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7; MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7; MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1; MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3; MON-87427-7 × MON-89Ø34-3 × DAS-59122-7; MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3; MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7; MON-87427-7 × MON-88Ø17-3 × DAS-59122-7; MON-87427-7 × DAS-Ø15Ø7-1; MON-87427-7 × MON-88Ø17-3; MON-87427-7 × DAS-59122-7; MON-89Ø34-3 × MON-88Ø17-3.

On 21 August 2013, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 89034, 1507, MON 88017 and 59122, show a comparable performance when applied to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. The detection methods for MON 87427, MON 89034, 1507, MON 88017 and 59122 had been previously validated by the EURL and were published at the EURL website on 12 June 2015, 5 November 2008, 9 March 2005, 30 March 2010 and 8 June 2007, respectively[10]. The validation report for MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), was published on the same website[10] on 24 August 2017.

## Food, feed and environmental safety of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122

### *Food and feed safety*

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was obtained by traditional breeding of five independent genetically modified maize lines, MON 87427, MON 89034, 1507, MON 88017 and 59122. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.
- 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 89034 × 1507 × MON 88017 × 59122 confirmed that the insert structures of the

[10] EURL - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 11 December 2018)

parental maize lines were retained. Also, CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1 and PAT protein levels in grain and forage of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 were comparable to the levels in the corresponding parental maize lines.

The conclusions of safety for CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1 and PAT proteins, as already demonstrated in the context of MON 87427, MON 89034, 1507, MON 88017 and 59122, remain applicable when these proteins are produced in combination in MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. It is unlikely that when interactions between CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1 and PAT would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1 and PAT protein expressions, there are no biologically relevant differences in the characteristics of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 is as safe and as nutritious as the non-genetically modified (GM) comparator and the tested non-GM reference varieties*" (EFSA, 2017).

In conclusion, combining MON 87427, MON 89034, 1507, MON 88017 and 59122 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was shown to be as safe and as nutritious as the conventional maize counterpart.

As maize is a segregating crop and MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is produced using traditional breeding methods; the conclusions derived in this section are equally applicable to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 as to any of its sub-combinations.

### *Environmental safety*

The environmental safety of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 does not possess characteristics that would confer a plant pest risk compared to conventional maize.
- The environmental interaction analyses confirmed that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

Also, in their scientific opinion, the EFSA concluded that "maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 would not raise safety concerns in the event of accidental release of viable GM maize grains into the environment".

The likelihood of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 authorization 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.

## MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, the benefits

MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 the maize 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 3 - 4 day 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 moving enough labour and resources to the designated hybrid seed production fields at the appropriate time. Glyphosate applications to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 that will result in the male sterile phenotype through tissue-selective glyphosate tolerance will take place during approximate maize vegetative growth stages ranging from V8 to V13. The two glyphosate applications would take place during an approximate 14 day window within these growth stages, a much longer time period compared to an average 3 – 4 day window between tassel emergence and pollen shed and silk emergence. 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 increasing cost is population migration towards urban areas that is shrinking the agricultural labor pool, thus reducing a reliable labor pool for this work. Costs associated with labor recruitment and deployments to perform detasseling are one of the single largest cost improvement opportunities in hybrid seed production. MON 87427 × MON 89034 × 1507 ×

MON 88017 × 59122 will decrease hybrid seed production costs primarily from a reduction in direct and associated labor costs.

- *Weed management*: Glyphosate use rates, timings and recommendations for weed management will not be different than those recommended for the previously de-regulated Roundup Ready Corn 2 products (NK603 and MON 88017) 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) ;
- *Consistency in weed control*: Contribution to achieve more consistency in the weed control results combined with the full and superior selectivity of glyphosate on MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 hybrids to protect the yield potential of those hybrids; and tolerance to glyphosate in vegetative stages allowing for over-the-top use of the herbicide;
- *Insect protection traits with multiple modes-of-action*: Multiple modes-of-action to help protect plants above and below the ground from insect pests: i) Protected roots to enable the best nutrient and water uptake ii) Protected shoots to enhance photosynthesis and grain production. In addition, insect resistance has a much lower likelihood when plants present 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. Overall, the product provides substantial economic benefits to growers by limiting yield losses from corn rootworm and lepidopteran insect pests as well as from weed pressure.
- *Reduced refuge system*: The industry's first reduced refuge system for both above and below ground insect protection. Refuge percentage is reduced from 20% to 5%, the lowest in the US Corn Belt. Efficacy data, analyses, and modeling support the combined use of the Cry3Bb1 and Cry34/35Ab1 proteins for refuge reduction for corn rootworm, and the use of Cry1A.105, Cry2Ab2, and Cry1F proteins for lepidopteran control with multiple modes of insecticidal action. This multiple dose product with a 5% refuge has significantly greater durability than a single dose product with a 20% refuge.
- *Compatibility with integrated pest management (IPM)*: A method to control corn borers and other lepidopteran pests of maize, compatible with 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 fall armyworm and corn earworm*: Better control of fall armyworm (*Spodoptera* sp.) and corn earworm (*Helicoverpa zea*) as compared to the first-generation insect protected maize, e.g. MON 810 (MON 89034 has a wider spectrum of activity);
- An effective insect resistance management (IRM) tool for lepidopteran insect pests due to the presence of three insecticidal proteins, Cry1A.105,Cry2Ab2 and Cry1F;
- 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);
- 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);
- An excellent fit with reduced tillage systems, which are linked to many environmental advantages including improved soil and water quality, reduced soil erosion and runoff, improved wildlife habitat and reduced fuel use and $CO_2$ emissions (Brookes and Barfoot, 2008; Fawcett and Towery, 2002; Phipps and Park, 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, 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);
- Resource conservation linked to reduced insecticide and herbicide use, *e.g.* less fuel consumed in the manufacture and delivery of insecticides, less water used for insecticide application, conservation of aviation fuel and reduced use of insecticide containers (Carpenter *et al.*, 2002; Phipps and Park, 2002).

## Contact point for further information

Since traders may commingle MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 with other commercial maize, including authorised GM maize, Monsanto is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) 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 Monsanto GM maize products, can therefore refer to the EuropaBio website at:

http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/product-contact-point

If required, additional comments or questions relative to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 can also be addressed at:

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

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