

**MON 87427 × MON 87460 ×  
MON 89034 × 1507 × MON 87411  
× 59122 maize**

**DroughtGard® Hybrids with SmartStax® Pro**  
**Insect-protected, drought-tolerant and**  
**herbicide-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<sup>1</sup>. 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<sup>2</sup>. 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<sup>3</sup>. Today, maize is one of the few intensively cultivated crops in European agriculture<sup>4</sup>. 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<sup>3</sup>. The EU imported about 23 million tons of maize grain in 2020<sup>3</sup>. The major exporters of maize to the EU are Ukraine and Brazil, followed by Serbia<sup>5</sup>. 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 × 1507 × MON 87411 × 59122?

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was obtained by traditional breeding of six independent genetically modified maize events, MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122. MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 combines the traits of agronomic interest from the six parental events, *i.e.* tolerance to glufosinate-ammonium and glyphosate-based herbicides, drought tolerance and protection against coleopteran and lepidopteran insects. As maize is a segregating crop, MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 grain includes the combined event product and any combination of these events (sub-combinations).

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 as well as the genetically modified parental maize events MON 87427, MON 87460, MON 89034 and MON 87411 have been developed by Monsanto Company<sup>6</sup>, whereas the

genetically modified parental maize events 1507 and 59122 have been developed by Corteva<sup>7</sup>.

More information on the parental events can be found on the CropLife Europe (CLE) website<sup>8</sup>.

### Worldwide plantings and regulatory status of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide<sup>9</sup>. 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 × 1507 × MON 87411 × 59122 has received regulatory approval for production in the US and Canada. MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 also received regulatory approvals for food and/or feed imports in Columbia, Japan, Mexico, South Africa, South Korea and Taiwan.

### 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 × 1507 × MON 87411 × 59122 in the EU

On 15 February 2017, Monsanto Company submitted an application for import, for food and feed use of

<sup>1</sup> FAOSTAT, 2020 - <http://www.fao.org/faostat/en/#data/QC> (Accessed on 26 August 2021).

<sup>2</sup> USDA, 2020 - <https://apps.fas.usda.gov/psdonline/app/index.html#/app/home> (Accessed on 26 August 2021).

<sup>3</sup> Index mundi, 2018 - <https://www.indexmundi.com/agriculture/?commodity=corn&graph=production> (Accessed on 26 August 2021).

<sup>4</sup> Eurostat, 2020 - <http://ec.europa.eu/eurostat> (Accessed on 26 August 2021).

<sup>5</sup> European Commission - [https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics\\_en](https://ec.europa.eu/agriculture/market-observatory/crops/cereals/statistics_en) (Accessed on 26 August 2021).

<sup>6</sup> Now Bayer CropScience LP

<sup>7</sup> Formerly Dow AgroSciences LLC and DuPont (Pioneer Hi-Bred International Inc.)

<sup>8</sup> CropLife Europe, 2021- <https://croplifeeurope.eu/product-information/> (Accessed on 26 August 2021)

<sup>9</sup> ISAAA, 2019 - <http://www.isaaa.org/resources/publications/> (Accessed on 26 August 2021).

MON 87427 x MON 87460 x MON 89034 x 1507 x  
MON 87411 x 59122 maize 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-2017-139 and was declared valid on 31 May  
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 19 January 2021, the EFSA published a positive scientific opinion on the safety of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 (EFSA, 2021). The EFSA concluded that “*maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 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.*”

On 8 June 2021, 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 × 1507 × MON 87411 × 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 (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 authorised MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 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)<sup>10</sup>, 24 April 2015 (Commission Implementing Decision (EU) 2015/683)<sup>11</sup>, on 30 October 2009 (Commission Decision 2009/813/EC)<sup>12</sup>, on 21 December 2017 (Commission Implementing Decision (EU) 2017/2452 of)<sup>13</sup>, on 26 July 2019 (Commission Implementing Decision (EU) 2019/1308)<sup>14</sup>, and on 1 August 2018

(Commission Implementing Decision (EU) 2018/1109)<sup>15</sup> respectively.

## Traceability, labelling, unique identifier

Operators handling or using MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 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) 2021/1394 of 17 August 2021 are:

On 26 January and 7 February 2017, MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 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 87460, MON 89034, 1507, MON 87411 and 59122, show a comparable performance when applied to MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122. The detection methods for MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 had been previously validated by the EURL and are

<sup>10</sup> Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

<sup>11</sup> Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

<sup>12</sup> Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

The application for the renewal of this authorisation is pending EC decision.

<sup>13</sup> Amended by Commission Implementing Decision (EU) 2019/241 of 6 February 2019.

<sup>14</sup> Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

<sup>15</sup> Amended by Commission Implementing Decision (EU) 2019/241 of 6 February 2019.

available on the EURL website<sup>16</sup>. The validation report for MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, prepared by the EURL was published on the same website<sup>16</sup> on 11 May 2020.

### Food, feed and environmental safety of MON 87460 × MON 87427 × MON 89034 × 1507 × MON 87411 × 59122

#### Food and feed safety

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was obtained by traditional breeding of five independent genetically modified maize events, MON 87427, MON 87460, MON 89034, 1507, MON 87411 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 87460 × MON 89034 × 1507 × MON 87411 × 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 87460 × MON 89034 × 1507 × MON 87411 × 59122 confirmed that the insert structures of the parental maize lines were retained. Also, CP4 EPSPS, CSPB, NPTII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and *DvSnf7* dsRNA levels in grain and forage of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 were comparable to the levels in the corresponding parental maize lines.

The conclusions of safety for CP4 EPSPS, CSPB, NPTII, Cry1A.105, Cry2Ab2, Cry1F PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and *DvSnf7* dsRNA, as already demonstrated in the context of MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122, remain applicable when these proteins are produced in combination in MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122. It is unlikely that when any interactions between CP4 EPSPS, CSPB, NPTII, Cry1A.105, Cry2Ab2, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and *DvSnf7* dsRNA 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, Cry1F, PAT, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins and *DvSnf7* dsRNA expressions, there are no biologically relevant differences in the characteristics of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 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 “*that the six-event stack maize, as described in this application, does not raise any nutritional concern and is as safe as the non-GM comparator and the selected non-GM reference varieties.*” (EFSA, 2021).

In conclusion, combining MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122 were shown to be as safe and as nutritious as the conventional maize counterpart.

As maize is a segregating crop and MON 87427 × MON 87460 × 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 87460 × MON 89034 × 1507 × MON 88017 × 59122 as to any of its sub-combinations.

Further details on the safety of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 are available in the EFSA scientific opinion adopted on 25 November 2020 (EFSA, 2021).

#### Environmental safety

The environmental safety of MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 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 87460 × MON 89034 × 1507 × MON 87411 × 59122 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 × 1507 × MON 87411 × 59122 would spread 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 “*that the six-event stack maize would not raise safety concerns in the event of accidental release of viable GM maize grains into the environment.*” (EFSA, 2021).

### MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122, the benefits

MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 provides the following benefits to both farmers and the environment:

- *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

<sup>16</sup> EURL - <http://gmo-crl.jrc.ec.europa.eu>StatusOfDossiers.aspx>  
(Accessed on 26 August 2021).

- 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 × 1507 × MON 87411 × 59122 will decrease hybrid seed production costs primarily from a reduction in direct costs and from associated labour costs;
- **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);
  - **Consistency in weed control:** Contribution to achieve more consistency in the weed control results combined with the full and superior selectivity of Roundup® and glufosinate-ammonium-based herbicides on MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 hybrids to protect the yield potential of those hybrids;
  - **Insect protection traits with multiple modes-of-action:** Multiple modes-of-action targeting above and below ground insect pests help protect plants: i) Protected roots enable season long nutrient and water uptake ii) Protected shoots maximize photosynthesis and protect grain production. In addition, insect resistance has a much lower likelihood when plants present dual and triple modes of action against target pests. Use of multiple modes-of-action that are each efficacious against a target pest 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.
  - **5% Seed Blend Refuge:** Results from efficacy studies and mathematical modeling of the CRW-active components, Cry3Bb1 and Cry34/35Ab1 proteins, and DvSnf7 dsRNA support maintaining a 5% seed blend refuge for D1× SmartStax PRO for corn rootworm and the use of Cry1A.105, Cry2Ab2, and Cry1F proteins for control of key lepidopteran pests. This product with multiple modes of action and a 5% seed blend refuge presents a lower resistance risk and is more durable compared to SmartStax and has significantly greater durability than a single mode of action product with a 20% refuge.
  - **Compatibility with integrated pest management (IPM):** A method to control coleopteran and 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 and glufosinate-ammonium in maize on an “as needed basis (Johnson *et al.*, 2000; Marra *et al.*, 2002);
  - **An effective insect resistance management tool with improved control of fall armyworm, corn earworm, and corn rootworm:** The presence of six insecticidal proteins, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 and DvSnf7 dsRNA that provide combined control of fall armyworm (*Spodoptera* sp.), corn earworm (*Helicoverpa zea*), and corn rootworm (*Diabrotica* spp.)
  - Potential for 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<sub>2</sub> 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; 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);
  - 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).
  - Increasing 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.
  - It is designed to help farmers mitigate the risk of yield loss when experiencing drought stress.
  - The drought tolerance trait helps the maize plants to use less water when drought stress occurs. The plants acclimate to the stress more quickly and utilize water more efficiently, leaving them with more water to help through critical periods of growth.
  - This hydro-efficiency can help the maize plants better endure challenging drought conditions

and can help reduce yield loss caused by drought stress while at the same time being safe for humans and the environment.

## Contact point for further information

Since traders may commingle MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 with other commercial maize, including authorised GM maize, Bayer is working together with other members of the plant biotechnology industry within the CLE 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 CLE website at:

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

If required, additional comments or questions relative to MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 can also be addressed at:

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

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