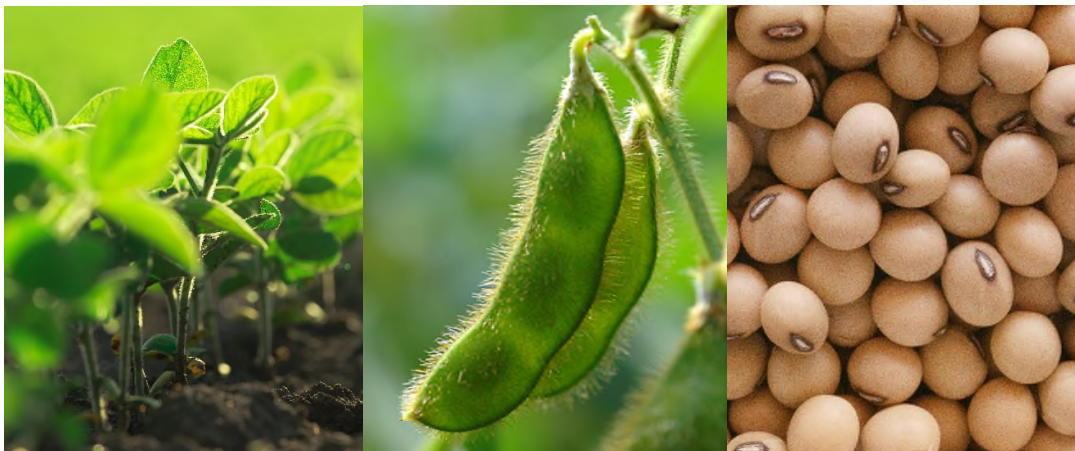


MON 87708 × MON 89788 × A5547-127 soybean

XtendFlex® soybeans

Herbicide-tolerant

Key facts



Bayer Agriculture BV
October 2020

Soybean, a key crop

Soybean (*Glycine max*) is a high-protein legume grown mainly as food for humans and livestock. It is one of the highest natural source of dietary fibre (Dhingra *et al.*, 2012). Nine essential amino acids are found in soybeans, which are necessary for human nutrition and are not produced naturally in the body (Tessari *et al.*, 2016). This crop is also used in industrial products including oils, soaps, cosmetics, resins, plastics, inks, solvents, and biodiesel.

The first record of domesticated soybean dates back to the 11th century BC in the eastern half of China where it was grown as food. Soybean was cultivated for the first time in Europe in the early 1700's and in North America in the early 1800's.

In 2019-2020, approximately 337.1 million metric tons of soybean were produced in the world, which represents approximately 122.7 million hectares of soybean harvested globally. Significant areas of production include Brazil, United States (US), Argentina, India and China, representing 30.1%, 24.7%, 13.9%, 9.8% and 7.6% of the global soybean hectares, respectively¹.

The European Union (EU) is not a significant soybean producer. In 2019, the soybean area harvested in the EU-27 accounted for approximately 916 thousand hectares². Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal³. In 2019, the EU-27 imported almost 18.5 million metric tons of soybean meal⁴. Brazil and Argentina are among the largest exporters to the EU⁵.

What is MON 87708 × MON 89788 × A5547-127?

MON 87708 × MON 89788 × A5547-127 was obtained by traditional breeding of three independent genetically modified soybean events, MON 87708, MON 89788 and A5547-127. MON 87708 × MON 89788 × A5547-127 combines the traits of agronomic interest from the three parental events, *i.e.* tolerance to dicamba-, glyphosate- and glufosinate-ammonium-based herbicides.

MON 87708 × MON 89788 × A5547-127 as well as the genetically modified parental soybean events MON 87708 and MON 89788 have been developed by Monsanto Company, now Bayer CropScience LP, whereas the genetically modified parental soybean event A5547-127 is owned by BASF Agriculture Solutions Seed US LLC.

More information on the parental events can be found on the European Association for Bioindustries (EuropaBio) website⁶.

Worldwide plantings and regulatory status of MON 87708 × MON 89788 × A5547-127

In 2018, approximately 191.7 million hectares of genetically modified (GM) crops were grown worldwide⁷. In the case of biotech soybean, it continued to be the principal biotech crop in 2018, occupying 95.9 million hectares.

MON 87708 × MON 89788 × A5547-127 is intended for production in the US and Canada. MON 87708 × MON 89788 × A5547-127 has received regulatory approvals for food and/or feed imports in Colombia, Japan, Mexico, Philippines, South Africa, South Korea and Taiwan. The most current information on regulatory status, can be accessed on the CropLife International website⁸.

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 (cultivation and/or import, and processing) 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, 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.

¹ USDA, 2019-2020
<https://apps.fas.usda.gov/psdonline/app/index.html#/app/downloads/> Perform a custom query (Accessed on 30 September 2020).

² Index mundi, 2020
<https://www.indexmundi.com/agriculture/?commodity=soybean-oilseed&graph=area-harvested> (Accessed on 30 September 2020).

³ Index mundi, 2020
<https://www.indexmundi.com/agriculture/?commodity=soybean-meal&graph=imports> (Accessed on 30 September 2020).

⁴ Index mundi, 2020
<https://www.indexmundi.com/agriculture/?commodity=soybean-meal&graph=imports> (Accessed on 30 September 2020).

⁵ European Commission, 2020
https://ec.europa.eu/info/food-farming-fisheries/farming/facts-and-figures/markets/overviews/market-observatories/crops/oilseeds-and-protein-crops_en#trade (Accessed on 30 September 2020).

⁶ EuropaBio, 2020
<http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information> (Accessed on 30 September 2020).

⁷ ISAAA, 2018
<http://www.isaaa.org/resources/publications/> (Accessed on 30 September 2020).

⁸ CropLife International
<http://www.biotradestatus.com/> (Accessed on 30 September 2020).

Furthermore, a regulation laying down the methods of sampling and analysis for the official control of feed as regards to 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 87708 × MON 89788 × A5547-127 in the EU

On 28 October 2016, Monsanto Company submitted an application for import, for food and feed use of MON 87708 × MON 89788 × A5547-127 soybean as any other soybean (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-2016-135 and was declared valid on 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 5 July 2019, the EFSA published a positive scientific opinion on the safety of MON 87708 × MON 89788 × A5547-127 (EFSA, 2019). The EFSA concluded that “soybean MON 87708 × MON 89788 × A5547-127, as described in this application, is as safe as its conventional counterpart and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment”.

On 09 December 2019, 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 soybean MON 87708 × MON 89788 × A5547-127, 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 23 January 2020, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 28 September 2020 (European Commission, 2020).

Regulatory status of the parental lines

The EC authorised/renewed MON 87708, MON 89788 and A5547-127 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 soybean with the exception of cultivation under Regulation (EC) No 1829/2003 on 24 April 2015 (Commission Implementing Decision (EU) 2015/700⁹), 28 November 2019 (Commission Implementing Decision (EU) 2019/2083), and 10 February 2012 (Commission Implementing Decision 2012/81/EU¹⁰), respectively.

Traceability, labelling, unique identifier

Operators handling or using MON 87708 × MON 89788 × A5547-127 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 this product is MON-87708-9 × MON-89788-1 × ACS-GM006-4.

In October 2016, MON 87708 × MON 89788 × A5547-127 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 soybean events, MON 87708, MON 89788 and A5547-127, show a comparable performance when applied to MON 87708 × MON 89788 × A5547-127. The detection methods for MON 87708, MON 89788 and A5547-127 had been previously validated by the EURL and are available on the EURL website¹¹. The validation report for MON 87708 × MON 89788 × A5547-127, prepared by the EURL is also available on the same website.

Food, feed and environmental safety of MON 87708 × MON 89788 × A5547-127

Food and feed safety

MON 87708 × MON 89788 × A5547-127 was obtained by traditional breeding of three independent genetically modified soybean events, MON 87708, MON 89788 and A5547-127. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 87708 × MON 89788 × A5547-127.
- 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 87708 × MON 89788 × A5547-127 confirmed that the insert structures of the parental soybean lines were retained. Also, DMO, CP4 EPSPS and PAT protein levels in grain and forage of MON 87708 × MON 89788 × A5547-127 were comparable to the levels in the corresponding parental soybean lines.

The conclusions of safety for DMO, CP4 EPSPS and PAT, as already demonstrated in the context of MON 87708, MON 89788 and A5547-127, remain applicable when these proteins are produced in combination in MON 87708 × MON 89788 × A5547-127. It is unlikely that when interactions between DMO, CP4 EPSPS and PAT would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended DMO, CP4 EPSPS and PAT protein expressions, there are no biologically relevant differences in the characteristics of MON 87708 × MON 89788 × A5547-127 as compared with its conventional counterpart and that the

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

¹⁰ Amended by Commission Implementing Decision (EU) 2019/1195 of 10 July 2019.

¹¹ EURL
<http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
(Accessed on 30 September 2020).

composition fell within the range of non-GM soybean varieties.

Also, in their scientific opinion, the EFSA concluded that *“that the three-event stack soybean, as described in this application, is as safe as and nutritionally equivalent to its conventional counterpart and the non-GM reference varieties tested”* (EFSA, 2019).

In conclusion, combining MON 87708, MON 89788 and A5547-127 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 87708, MON 89788 and A5547-127 was shown to be as safe and as nutritious as the conventional soybean counterpart.

Further details on the safety of MON 87708 × MON 89788 × A5547-127 are available in the EFSA scientific opinion adopted on 22 May 2019 (EFSA, 2019).

Environmental safety

The environmental safety of MON 87708 × MON 89788 × A5547-127 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 87708 × MON 89788 × A5547-127 does not possess characteristics that would confer a plant pest risk compared to conventional soybean.
- The environmental interaction analyses confirmed that MON 87708 × MON 89788 × A5547-127 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 87708 × MON 89788 × A5547-127 spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional soybean. Moreover, the scope of the authorisation covers the import, processing and all uses as any other soybean, 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 *“the three-event stack soybean would not raise safety concerns in the event of accidental release of viable GM soybean seeds into the environment”* (EFSA, 2019).

MON 87708 × MON 89788 × A5547-127, the benefits

MON 87708 × MON 89788 × A5547-127 provides the following benefits to both farmers and the environment:

- MON 87708 × MON 89788 × A5547-127 soybeans combine the proven performance of Roundup Ready 2 Xtend^{®12} soybeans (MON 87708 × MON 89788) with added tolerance to glufosinate from the LibertyLink^{®13} technology (A5547-127).

- Use rates, timings and recommendations for weed management will not be different than those recommended for the previously authorised parent events.
- Excellent fit with reduced tillage systems, which are linked to many environmental advantages including improved soil and water quality, reduced soil erosion and runoff, and reduced fuel use and CO₂ emissions (Brookes and Barfoot, 2020; Carpenter *et al.*, 2002; Fawcett and Towery, 2002; Phipps and Park, 2002). According to Brookes and Barfoot (2020), a reduction of over 34 billion kg of CO₂ emissions was accomplished from the reduced use of fuel associated with herbicide tolerant crops between 1996 and 2018. Additionally, carbon sequestration in the soil resulting from the use of “no-tillage” or “reduced tillage” practices eliminated the equivalent of over 302 billion kilograms of CO₂ emissions during the same period

Contact point for further information

Since traders may commingle MON 87708 × MON 89788 × A5547-127 with other commercial soybeans, including authorised GM soybeans, Bayer is working together with other members of the plant biotechnology industry within the 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 Bayer soybean products can therefore refer to the EuropaBio website at:

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

(Accessed on 30 September 2020)

If required, additional comments or questions relative to MON 87708 × MON 89788 × A5547-127 can also be addressed at:

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

(Accessed on 30 September 2020)

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¹² Roundup Ready 2 Xtend[®] is a trademark of Bayer Group.

¹³ LibertyLink[®] is a trademark of BASF Group.

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