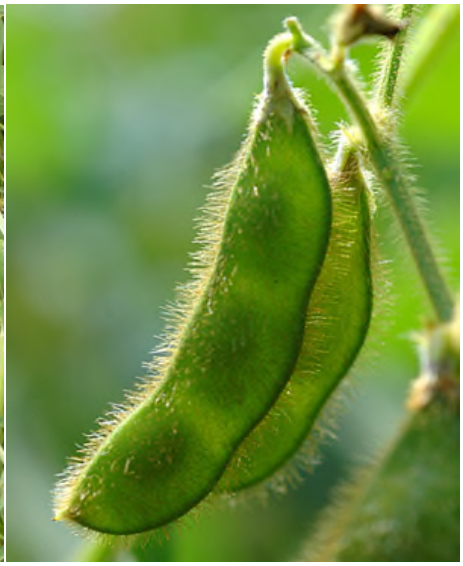
MON 87751 × MON 87701 × MON 87708 × MON 89788 soybean

Intacta 2 Xtend™

Lepidopteran-protected and herbicide-tolerant

Key facts



Bayer Agriculture BV
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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 2020, approximately 362,6 million metric tons of soybean were produced in the world, which represents approximately 126.9 million hectares of soybean harvested globally. Significant areas of production included the Brazil, United States (US), Argentina, India and China representing 30.4%, 26.2%, 13.3%, 9.6% and 7.3% of the global soybean hectares, respectively[1].

The European Union (EU) is not a significant soybean producer. In 2020, the soybean area harvested in the EU-27 accounted for approximately 920 thousand hectares[2]. Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal[2]. In 2020, the EU-27 imported 18.75 million metric tons of soybean meal. Brazil, Argentina, and the US are among the largest exporters to the EU[3].

What is MON 87751 × MON 87701 × MON 87708 × MON 89788 ?

MON 87751 × MON 87701 × MON 87708 × MON 89788 was obtained by traditional breeding of four independent genetically modified soybean events, MON 87751, MON 87701, MON 87708 and MON 89788. MON 87751 × MON 87701 × MON 87708 × MON 89788 combines the traits of agronomic interest from the four parental events, *i.e.* tolerance to dicamba- and glyphosate-based herbicides, and protection against lepidopteran insects.

MON 87751 × MON 87701 × MON 87708 × MON 89788 as well as the genetically modified parental soybean events MON 87751, MON 87701, MON 87708 and MON 89788 have been developed by Monsanto Company, now Bayer CropScience LP.

More information on the parental events can be found on the Crop Life Europe (CLE) website[4].

Worldwide plantings and regulatory status of MON 87751 × MON 87701 × MON 87708 × MON 89788

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide[5]. In the case of biotech soybean, it continued to be the principal biotech crop in 2019, occupying 91.9 million hectares.

MON 87751 × MON 87701 × MON 87708 × MON 89788 has received regulatory approval for production in Brazil and Paraguay. MON 87751 × MON 87701 × MON 87708 × MON 89788 also received regulatory approvals for food and/or feed imports in Canada, Colombia, Japan, Mexico, South Africa, South Korea, Taiwan and the US.

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 87751 × MON 87701 × MON 87708 × MON 89788 in the EU

On 17 December 2015, Monsanto Company submitted an application for import, for food and feed use of MON 87751 × MON 87701 × MON 87708 × MON 89788 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-2016-128 and was declared valid on 22 August 2016. The EFSA evaluated the application as well as additional information provided by Monsanto Company,

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1 USDA, 2020 - https://apps.fas.usda.gov/psdonline/app/index.html#/app/downloads (Accessed on 25 November 2020)

2 Index mundi, 2020 - https://www.indexmundi.com/agriculture/?commodity=soybean-meal&graph=imports (Accessed on 25 November 2020)

3 European Commission, 2020 - https://ec.europa.eu/agriculture/market-observatory/crops/oilseeds-protein-crops/soy-trade_en (Accessed on 25 November 2020)

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

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

scientific comments submitted by the EU Member States and relevant scientific publications.

On 08 November 2019, the EFSA published a positive scientific opinion on the safety of MON 87751 × MON 87701 × MON 87708 × MON 89788 (EFSA, 2019). The EFSA concluded that "*soybean* MON 87751 × MON 87701 × MON 87708 × MON 89788*, as described in this application, is 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 7 October 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 soybean MON 87751 × MON 87701 × MON 87708 × MON 89788, 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 3 December 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 MON 87751, MON 87701, MON 87708 and MON 89788 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 26 July 2019 (Commission Implementing Decision (EU) 2019/1309), 10 February 2012 (Commission Implementing Decision 2012/83/EU[6]), 24 April 2015 (Commission Implementing Decision (EU) 2015/700[6]) and 28 November 2019 (Commission Implementing Decision (EU) 2019/2083), respectively.

Traceability, labelling, unique identifier

Operators handling or using MON 87751 × MON 87701 × MON 87708 × MON 89788 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-87751-7 × MON 877Ø1-2 × MON-877Ø8-9 × MON-89788-1.

In November 2015, MON 87751 × MON 87701 × MON 87708 × MON 89788 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 87751, MON 87701, MON 87708 and MON 89788, show a comparable performance when applied to MON 87751 × MON 87701 × MON 87708 × MON 89788. The detection methods for MON 87751, MON 87701, MON 87708 and MON 89788 had been previously validated by the EURL and are available on the EURL website[7]. The validation report for MON 87751 × MON 87701 × MON 87708 × MON 89788, prepared by the EURL is also available on the same website.

Food, feed and environmental safety of MON 87751 × MON 87701 × MON 87708 × MON 89788

Food and feed safety

MON 87751 × MON 87701 × MON 87708 × MON 89788 was obtained by traditional breeding of four independent genetically modified soybean events, MON 87751, MON 87701, MON 87708 and MON 89788. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 87751 × MON 87701 × MON 87708 × MON 89788.
- 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 87751 × MON 87701 × MON 87708 × MON 89788 confirmed that the insert structures of the parental soybean lines were retained. Also, Cry1A.105, Cry2Ab2, Cry1Ac, DMO and CP4 EPSPS protein levels in grain and forage of MON 87751 × MON 87701 × MON 87708 × MON 89788 were comparable to the levels in the corresponding parental soybean lines.

The conclusions of safety for Cry1A.105, Cry2Ab2, Cry1Ac, DMO and CP4 EPSPS, as already demonstrated in the context of MON 87751, MON 87701, MON 87708 and MON 89788, remain applicable when these proteins are produced in combination in MON 87751 × MON 87701 × MON 87708 × MON 89788. It is unlikely that when interactions between Cry1A.105, Cry2Ab2, Cry1Ac, DMO and CP4 EPSPS would occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended Cry1A.105, Cry2Ab2, Cry1Ac, DMO and CP4 EPSPS protein expressions, there are no biologically relevant differences in the characteristics of MON 87751 × MON 87701 × MON 87708 × MON 89788 as compared with its conventional counterpart and that the composition fell within the range of non-GM soybean varieties.

Also, in their scientific opinion, the EFSA concluded that "that four-event stack soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 as described in this application, is nutritionally equivalent to and as safe as the comparator and the non-GM reference varieties tested" (EFSA, 2019)

In conclusion, combining MON 87751, MON 87701, MON 87708 and MON 89788 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 87751, MON 87701, MON 87708 and MON 89788 was shown to be as safe and as nutritious as the conventional soybean counterpart.

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

[7] EURL - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 28 January 2021)

Further details on the safety of MON 87751 × MON 87701 × MON 87708 × MON 89788 are available in the EFSA scientific opinion adopted on 25 September 2019 (EFSA, 2019).

Environmental safety

The environmental safety of MON 87751 × MON 87701 × MON 87708 × MON 89788 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 87751 × MON 87701 × MON 87708 × MON 89788 does not possess characteristics that would confer a plant pest risk compared to conventional soybean.
- The environmental interaction analyses confirmed that MON 87751 × MON 87701 × MON 87708 × MON 89788 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 87751 × MON 87701 × MON 87708 × MON 89788 would spread 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 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 "*soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 would not raise safety concerns in the event of accidental release of viable GM soybean seeds into the environment*" (EFSA, 2019).

MON 87751 × MON 87701 × MON 87708 × MON 89788, the benefits

MON 87751 × MON 87701 × MON 87708 × MON 89788 provides the following benefits to both farmers and the environment:

- *Weed management:* It provides tolerance to dicamba and glyphosate and offers growers additional weed control options prior to planting, at planting and after crop emergence. Dicamba and glyphosate use rates, timings and recommendations for weed management will not be different than those recommended for the previously authorised parent events allowing flexible broad-spectrum weed control options that allows over-the-top applications of dicamba or glyphosate in soybean on an "as needed" basis.
- *Consistency in weed control:* Contribution to achieve more consistency in the weed control results combined with the full and superior selectivity of dicamba or glyphosate on MON 87751 × MON 87701 × MON 87708 × MON 89788 varieties to protect the yield potential of those varieties; and tolerance to dicamba or glyphosate in vegetative stages allowing for over-the-top use of the herbicide.
- Effective and sustainable management of herbicide-resistant weeds due to the different modes of action of dicamba and glyphosate.
- 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; Carpenter *et al.*, 2002; Fawcett and Towery, 2002). According to Brookes and Barfoot (2008) the carbon sequestration resulting from more plant residue being stored in the soil because of reduced tillage, saved the equivalent of almost 14 billion kilograms of carbon dioxide emissions in 2006.
- Consistent and reliable control of lepidopteran pests: The Cry1A.105, Cry2Ab2 and Cry1Ac proteins are expressed at consistently high levels in MON 87751 × MON 87701 × MON 87708 × MON 89788 throughout the entire growing season providing nearly complete control of the targeted lepidopteran pests for the entire season (MacRae *et al.*, 2005). Given the difficulty in controlling certain soybean lepidopteran pests, MON 87751 × MON 87701 × MON 87708 × MON 89788 should provide protection that is superior to existing chemical and cultural control practices.
- Control of target insects while maintaining beneficial species: The major lepidopteran pests causing significant soybean defoliation and yield loss across tropical and subtropical regions are the velvetbean caterpillar (*Anticarsia gemmatalis*), soybean looper (*Chysodeixis includens*), soybean borer (*Crocidosema aporema*), and sunflower looper (*Rachiplusia nu*), Tobacco budworm *Chloridea virescens,* Old World bollworm *Helicoverpa armigera,* black armyworm *Spodoptera cosmioides,* fall armyworm, *Spodoptera frugiperda* (Aragon *et al.*, 1997). MON 87751 × MON 87701 × MON 87708 × MON 89788 will provide efficacious control of these insect pests with reduced reliance on the insecticides currently used to control these lepidopteran pests. At the same time, MON 87751 × MON 87701 × MON 87708 × MON 89788 does not impose any adverse impact on beneficial species compared to conventional insecticide-based programs. On the contrary, there is a general consensus among specialists that less use of insecticides in *Bt* containing soybean crops will reduce the impact on the initial population of desirable insects such as predators that control insect pests (like sap sucking stink bugs), which are prevalent at the end of the season (Correa-Ferreira and Panizzi, 1999). This would improve natural control of stink bugs (and other sap sucking pests) and reduce insecticide applications even further, bringing improved general insect population equilibrium to the crop.

- Reduced production costs and improved farming efficiency: Growers must work diligently to control lepidopteran pests at an early stage to prevent severe crop damage. MON 87751 × MON 87701 × MON 87708 × MON 89788 provides better control of key lepidopteran insect pests with less scouting and reduces risk of losses due to suboptimal timing of an insecticide application under traditional farm pest management, resulting in the prevention of potential damage to the crop later in the season. In addition, it will be safer and more convenient for growers to grow MON 87751 × MON 87701 × MON 87708 × MON 89788 because no special equipment is required, and it reduces or eliminates the labour and time for growers to spray insecticides under traditional insect control practices, as well as reduces applicator exposure to chemical pesticides.

Contact point for further information

Since traders may commingle MON 87751 × MON 87701 × MON 87708 × MON 89788 with other commercial soybean, including authorised GM soybean, 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 soybean 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 87751 × MON 87701 × MON 87708 × MON 89788 can also be addressed at:

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

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