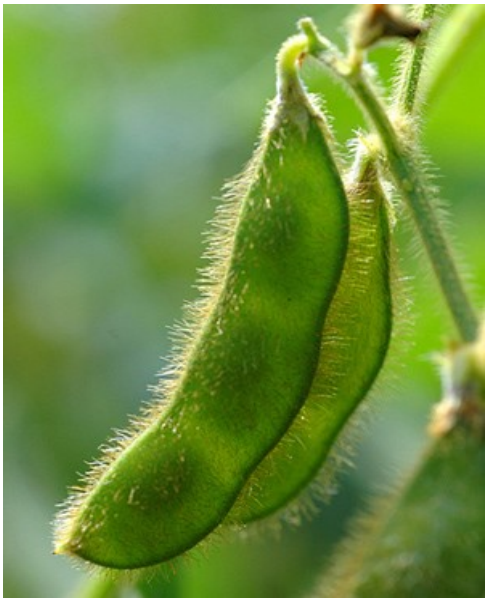
MON 87708 × MON 89788

Roundup Ready 2 Xtend™ soybean

Dicamba and glyphosate tolerant soybean

Key facts



Monsanto EME

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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 the highest natural source of dietary fiber. Eight essential amino acids are found in soybeans, which are necessary for human nutrition and are not produced naturally in the body[1]. 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 2014-2015, approximately 319 million metric tons of soybean were produced in the world, which represents approximately 119 million hectares of soybean harvested globally. Significant areas of production included the United States (US), Brazil, Argentina and China representing 34%, 30%, 19% and 4% of the global soybean hectares, respectively[2].

The European Union (EU) is not a significant soybean producer. In 2014-2015, the soybean area harvested in the EU-28 accounted for approximately 573 thousand hectares. Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal and the second largest importer of whole soybeans, after China. In the period 2014-2015, the EU-28 imported 19.2 million metric tons of soybean meal and 13.4 million metric tons of whole soybeans[2]. Germany, Spain, The Netherlands, Italy and the United Kingdom (UK) are among the largest importer EU Member States[3].

Countries in North America and South America export large quantities of soybeans to the EU. In 2014-2015, about 42% of the EU imports came from Brazil, 28% from the US, 10% from Paraguay, and 8% from Canada[3].

What is MON 87708 × MON 89788?

MON 87708 × MON 89788 was obtained by traditional breeding of two independent genetically modified soybean events, MON 87708 and MON 89788. MON 87708 × MON 89788 combines the traits of agronomic interest from the two parental lines, *i.e.* tolerance to the broadleaf herbicide dicamba and tolerance to the broad-spectrum herbicide glyphosate. MON 87708 × MON 89788, as well as the genetically modified parental soybean lines containing either the MON 87708 or MON 89788 insert, have been developed by Monsanto Company. More information on the parental lines can be found on the EuropaBio website[4].

Worldwide plantings and regulatory status of MON 87708 × MON 89788

Genetically modified crops protected against insect pests and/or tolerant to a specific herbicide have been commercialized in the US by Monsanto since 1996. In 2015, approximately 180 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 2015, occupying 92.1 million hectares[6].

MON 87708 × MON 89788 has received regulatory approval for production in Canada and the US[7]. MON 87708 × MON 89788 also received regulatory approvals in Australia/New Zealand, China, Colombia, Indonesia, Japan, Korea, Mexico, Taiwan and Vietnam for import[8].

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 and Regulation (EC) No 1829/2003 concerning GM Food and Feed.

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.

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.

Regulatory status of MON 87708 × MON 89788 in the EU

On 23 March 2012, Monsanto submitted an application for import, food and feed use of 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-2012-108 and was declared valid on 20 July 2012. The EFSA evaluated the application as well as additional information provided by Monsanto, scientific comments submitted by the EU Member States and relevant scientific publications.

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1 SoyStats® 2015 - http://soystats.com/composition-of-a-soybean (Accessed on 5 August 2016)

2 USDA, 2015 - http://apps.fas.usda.gov/psdonline/psdQuery.aspx (Accessed on 5 August 2016)

3 Eurostat - http://ec.europa.eu/eurostat (Accessed on 5 August 2016)

4 EuropaBio - http://www.europabio.org/information-operators-product-information (Accessed on 5 August 2016)

5 ISAAA - http://isaaa.org/resources/publications/briefs/51/executivesummary/default.asp (Accessed on 5 August 2016)

6 ISAAA - http://isaaa.org/resources/publications/pocketk/16/default.asp (Accessed on 5 August 2016)

7 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.

8 Crop Life International - http://www.biotradestatus.com/ (Accessed on 5 August 2016)

On 18 June 2015, the EFSA published a positive Scientific Opinion on the safety of MON 87708 × MON 89788 (EFSA, 2015).The EFSA concluded that MON 87708 × MON 89788 "*is as safe as its non-GM comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its scope*".

On 18 November 2015, 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 soybean MON 87708 × MON 89788, to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote. After this vote, the draft decision was passed to the Appeal Committee who met for a vote on 11 January 2016. The Appeal Committee forwarded the draft decision to the EC who granted the authorization on 22 July 2016 (Commission Decision, 2016).

Regulatory status of the parental lines

The EC authorized MON 89788 and MON 87708 for import, food and feed use as any other soybean (excluding cultivation) under Regulation (EC) No 1829/2003 on 4 December 2008 and 24 April 2015, respectively (Commission Decision, 2008).

Traceability, labelling, unique identifier

Operators handling or using 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-877Ø8-9 × MON-89788-1.

In December 2011, 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 87708 and MON 89788, show a comparable performance when applied to MON 87708 × MON 89788. The detection methods for MON 87708 and MON 89788 had been previously validated by the EURL and were published at the EURL website on 16 May 2013 and 27 February 2008, respectively[9]. The validation report for MON 87708 × MON 89788, prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), was published on 28 March 2014 on the same website.

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

Food and feed safety

MON 87708 × MON 89788 was obtained by traditional breeding of two independent genetically modified soybean events, 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 87708 × MON 89788.
- Safety assessment of the combined product, taking into consideration the safety of the parental lines.

Molecular analysis of the DNA inserts present in MON 87708 × MON 89788 confirmed that the insert structures of the parental soybean events were retained. Also, DMO and CP4 EPSPS protein levels in seed and forage of MON 87708 × MON 89788 were comparable to the levels in the corresponding parental soybean events.

The conclusions of safety for the DMO and CP4 EPSPS proteins, as already demonstrated in the context of MON 87708 and MON 89788, remain applicable when these proteins are produced in combination in MON 87708 × MON 89788. It is unlikely that interactions between these proteins that would raise any safety concerns would occur. The EFSA concluded that: "*the safety assessment identified no concerns regarding the potential toxicity of the newly expressed proteins DMO and CP4 EPSPS*" (EFSA, 2015).

Comparative assessment showed that, except for the intended DMO and CP4 EPSPS protein expression, there are no biologically relevant differences in the characteristics of MON 87708 × MON 89788 as compared with its conventional counterpart and that the composition fell within the range of non-GM soybean varieties. The EFSA concluded that: "*none of the differences identified in the composition, agronomic and phenotypic characteristics of seed and forage obtained from soybean MON 87708 × MON 89788 is relevant to food and feed safety*" (EFSA, 2015).

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

Environmental safety

The environmental safety of MON 87708 × MON 89788 was established through extensive field trials conducted in the US and Canada which are representative of commercial soybean production regions of North America. These field trials demonstrated that MON 87708 × MON 89788 poses negligible risk to human health or to the environment. Results from the phenotypic and agronomic assessments demonstrate that MON 87708 × MON 89788 does not possess characteristics that would confer a plant pest risk compared to conventional soybean. Data on environmental interactions also indicate that MON 87708 × MON 89788 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect, or abiotic stressors, or changes in agronomic and phenotypic characteristics.

Soybean does not have wild relatives in Europe to which the introduced traits could outcross. The likelihood of MON 87708 × MON 89788 soybean spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional soybean. Moreover, the

[9] EURL GMFF - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 5 August 2016)

scope of the authorization 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.

The herbicide tolerance traits in MON 87708 × MON 89788 soybean can be regarded as providing only a potential agronomic and selective advantage for this GM soybean plant where and when dicamba- and/or glyphosate-based herbicides are applied. Survival of soybean plants outside cultivation where dicamba- and/or glyphosate-based herbicides are applied is mainly limited by a combination of low competitiveness, absence of a dormancy phase and susceptibility to plant pathogens and cold climatic conditions.

In their scientific opinion on MON 87708 × MON 89788, the EFSA concluded that: "*Potential interactions of soybean MON 87708 × MON 89788 with the biotic and abiotic environment were not considered a relevant issue*" (EFSA, 2015).

MON 87708 × MON 89788, the benefits

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

- It provides tolerance to both dicamba and glyphosate herbicides and offers growers an additional weed control option prior to planting, at planting and after crop emergence. Dicamba displayed excellent crop tolerance in weed control systems that include sequential pre-emergence and in-crop post-emergence applications of dicamba or in systems with glyphosate including two sequential in-crop post-emergence applications of dicamba (Bauerle *et al.*, 2012; Bernards *et al.*, 2011; Bradley *et al.*, 2012; Edwards *et al.*, 2012; Eubank *et al.*, 2012; Maxwell *et al.*, 2011; Peterson *et al.*, 2011; Spaunhorst *et al.*, 2011; Spaunhorst *et al.*, 2012; Stebbing *et al.*, 2011; Steckel *et al.*, 2012; Steckel and Montgomery, 2008; York *et al.*, 2012).
- It helps soybean growers maintain yields and quality necessary to meet the growing demands of the food, feed and industrial markets by providing effective management of economically-important herbicide-resistant weed species such as Palmer amaranth, marestail, common ragweed, giant ragweed and waterhemp (Bradley *et al.*, 2012; Crespo *et al.*, 2012; Edwards *et al.*, 2012; Eubank *et al.*, 2012; Johnson *et al.*, 2010; Peterson *et al.*, 2011; Spaunhorst *et al.*, 2011; Spaunhorst *et al.*, 2012; Stebbing *et al.*, 2011; Steckel *et al.*, 2012; Steckel and Montgomery, 2008; York *et al.*, 2012). Dicamba also offers a new management tool for improved control of hard-to-control broadleaf weed species. Post-emergence applications of the glyphosate plus dicamba tank mixture will improve the control of these hard-to-control broadleaf weed species, such as lambs quarters and velvetleaf, compared to glyphosate alone. (Bauerle *et al.*, 2012; Cogdill and Chandler, 2012; Johnson *et al.*, 2010; Maxwell *et al.*, 2011; Peterson *et al.*, 2011).
- It provides effective and sustainable management of herbicide-resistant weeds (Bradley *et al.*, 2012; Edwards *et al.*, 2012; Johnson *et al.*, 2010; Maxwell *et al.*, 2011; Peterson *et al.*, 2011; York *et al.*, 2012). Dicamba kills weeds by a different mode of action than glyphosate and other commonly used soybean herbicides. Herbicide resistance has a much lower likelihood when multiple modes of action are used. Dicamba, when used in a diversified weed management program, will offer growers an effective and sustainable method to manage herbicide resistance and help maintain the durability of critically important soybean herbicides (including glyphosate, the acetolactate synthase (ALS) inhibitors, and the protoporphyrinogen oxidase (PPO) inhibitors) and trait technologies.
- It helps to preserve the environmental benefits of conservation tillage practices (reduced tillage/no-till). The combined dicamba- and glyphosate-tolerant technology will enable pre-plant and pre-emergence applications of dicamba and glyphosate without a planting interval for effective control of glyphosate-resistant or tough-to-control broadleaf weeds in conservation tillage cropping systems (Bernards *et al.*, 2011; Bradley *et al.*, 2012; Peterson *et al.*, 2011; Stebbing *et al.*, 2011; Steckel *et al.*, 2012; York *et al.*, 2012). Conservation tillage systems 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 CO2 emissions (Brookes and Barfoot, 2014; Fawcett and Towery, 2000).

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