

MON 87751

Insect-protected soybean

Key facts



Bayer Agriculture BVBA

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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 fiber (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 2017-2018, approximately 341.6 million metric tons of soybean were produced in the world, which represents approximately 124.6 million hectares of soybean harvested globally. Significant areas of production included the Brazil, United States (US), Argentina and China representing 36%, 35%, 11% and 4% of the global soybean hectares, respectively¹.

The European Union (EU) is not a significant soybean producer. In 2017-2018, the soybean area harvested in the EU-27 accounted for approximately 930 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 meal². In 2018, the EU-27 imported 18.5 million metric tons of soybean meal. The US, Brazil, Ukraine, and Canada are among the largest exporter to the EU³.

What is MON 87751?

MON 87751 is a genetically modified (GM) soybean developed through *Agrobacterium*-mediated transformation. It contains genes derived from *Bacillus thuringiensis* (*Bt*) that express Cry1A.105 (a modified Cry1A protein) and Cry2Ab2 proteins conferring protection against certain lepidopteran insect pests.

Insect protection

Susceptible insects contain receptors in their midgut that bind to the specific Cry protein. This leads to the creation of pores which interfere with ion transport systems across the midgut wall causing lysis of the midgut epithelium and, depending on the dose, subsequent paralysis of the gut or death of the insect (Nester *et al.*, 2002).

Worldwide plantings and regulatory status of MON 87751

In 2017, approximately 189.8 million hectares of genetically modified (GM) crops were grown worldwide⁴. In the case of biotech soybean, it continued to be the principal biotech crop in 2017, occupying 94.1 million hectares⁵.

MON 87751 has received regulatory approval for production in Brazil, Canada and the US. It also received regulatory approvals for food and/or feed imports in Australia; Colombia, Indonesia, Japan, Korea, Mexico, Philippines, Singapore and Taiwan.

MON 87751 single product is not and will not be commercialised on its own, instead stacked products, made via traditional breeding, are the aimed commercial products.

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 in the EU

On 26 September 2014, Monsanto submitted an application for import for food and feed use of MON 87751 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-2014-121 and was declared valid on 22 January 2015. 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.

¹ USDA, 2019 - <https://apps.fas.usda.gov/psdonline/app/index.html#/app/downloads> (Accessed on 29 July 2019)

² Index mundi, 2018 - <https://www.indexmundi.com/agriculture/?commodity=soybean-meal&graph=imports> (Accessed on 29 July 2019)

³ European Commission, 2019 - <https://ec.europa.eu/agriculture/market-observatory/crops/oilseeds-protein-crops/soy-trade-en> (Accessed on 29 July 2019)

⁴ ISAAA - <http://isaaa.org/resources/publications/briefs/53/download/isaaa-brief-53-2017.pdf> (Accessed on 29 July 2019)

On 2 August 2018, the EFSA published a positive scientific opinion on the safety of MON 87751 (EFSA, 2018). The EFSA GMO Panel concluded that “*soybean MON 87751, as described in this application, is as safe as its conventional counterpart and the tested non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment*”.

On 7 March 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 87751, 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 11 April 2019, again without reaching a qualified majority. Therefore, the Appeal Committee forwarded the draft decision to the EC who granted the authorisation on 26 July 2019 (European Commission, 2019).

Traceability, labelling, unique identifier

Operators handling or using GM products 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. MON 87751 single product is not and will not be commercialised on its own. The unique identifier for this product is MON-87751-7.

On 06 August 2014, a MON 87751-specific PCR-based detection method allowing the identification and quantification of MON 87751 was provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL). The validated method, as well as the validation report for MON 87751, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), were published on 2 August 2016 at the CRL website⁵. A report on the validation of the DNA extraction method for soybean seeds was published on 21 March 2018.

Food, feed and environmental safety of MON 87751

Food and feed safety

The food and feed safety assessment of MON 87751 was established based on:

- A detailed molecular analysis of the inserted DNA confirmed that a single copy of the *cry1A.105* and *cry2Ab2* expression cassettes was integrated at a single locus within the soybean genome;
- The long history of safe use of *Bt* Cry proteins (including the Cry1A.105 and Cry2Ab2 proteins);
- The compositional and nutritional equivalence of the seed and forage derived from MON 87751 with those of conventional soybean;

- The rapid digestibility of Cry1A.105 and Cry2Ab2 proteins by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of the introduced proteins as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies of the Cry1A.105 and Cry2Ab2 proteins;
- A large margin of safety resulting from the low dietary exposure to the introduced Cry1A.105 and Cry2Ab2 proteins in MON 87751.

MON 87751 was found to be as safe and nutritious as conventional soybean by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals (EFSA, 2018). In its Scientific Opinion, the EFSA GMO Panel concluded that “*soybean MON 87751 is nutritionally equivalent to and as safe as the conventional counterpart and the non-GM reference varieties tested*”.

Further details on the safety of MON 87751 are available in the EFSA scientific opinion adopted on 20 June 2018 (EFSA, 2018).

Environmental safety

The environmental safety of MON 87751 was established through extensive laboratory and field testing of plant tissue or purified Cry1A.105 and Cry2Ab2 proteins demonstrating that MON 87751 poses negligible risk to human and animal health or the environment.

Results from the agronomic and phenotypic assessments confirm that MON 87751 does not possess characteristics that would confer a plant pest risk compared to conventional soybean. Data on the environmental interaction also confirm that MON 87751 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors. This, together with the history of safe use of the Cry1A.105 and Cry2Ab2 proteins, demonstrate that the ecological interactions of MON 87751 with non-target organisms or soil processes are not different from conventional soybean.

Soybean does not have wild relatives in Europe to which the introduced traits could outcross. The likelihood of MON 87751 soybean 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 excluding cultivation in the EU, and no deliberate release of the viable plant material in the EU environment is expected. Also, MON 87751 single product is not and will not be commercialised on its own. Therefore, no deliberate release of the viable plant material in the EU environment is expected.

In conclusion, the environmental impact of growing MON 87751 is not different from that of growing conventional soybean, as stated in the June 2018 EFSA scientific opinion (EFSA, 2018).

⁵ CRL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
(Accessed on 29 July 2019)

Contact point for further information

MON 87751 single product is not and will not be commercialised on its own.

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>

If required, additional comments or questions relative to MON 87751 can also be addressed at:

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

References

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