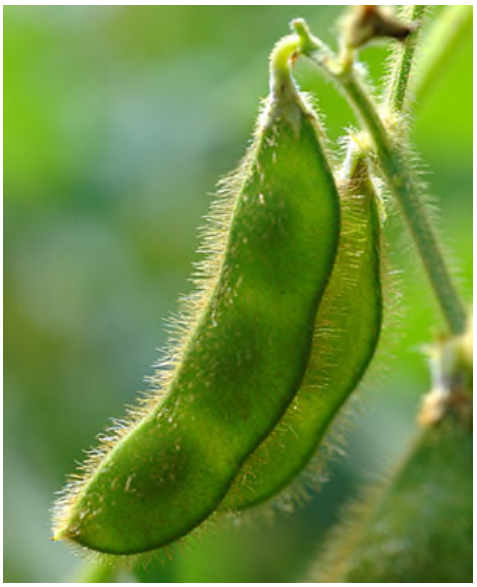
MON 87701

Insect Protected Soybean

Key facts

Bayer Agriculture BV[1]
July 2023

[1] Hereafter referred to as ‘Bayer’.

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 fibre. Eight essential amino acids are found in soybeans, which are necessary for human nutrition and are not produced naturally in the body. It is also used in industrial products including oils, soaps, cosmetics, resins, plastics, inks, solvents, and biodiesel[2].

The first record of domesticated soybean dates back to between the 17th and the 11th centuries 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 2021, 388.1 million metric tons (MMT) of soybean were produced in the world, which represents approximately 138 million hectares of soybean harvested globally.[3]. Significant areas of production included Brazil, the US, Argentina, India, China.

The EU is not a significant soybean producer. In 2022, the soybean area harvested in the EU-27 accounted for approximately one million hectares[4]. Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal (16.0 million metric tons of soybean meal were imported in the EU-27 during the period 2022-2023) and the second largest importer of whole soybeans, after China. 14.0 million metric tons of soybeans were imported in the EU-27 during the period 2022-2023[5].

What is MON 87701?

MON 87701 was developed to express the Cry1Ac protein throughout the entire growing season. Cry1Ac protein in MON 87701 provides protection from feeding damage caused by targeted lepidopteran pests.

Worldwide plantings and regulatory status of MON 87701

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide[6]. Of the 190.4 million hectares of global biotech crops planted in 2019, 48% or 91.9 million hectares were biotech soybean.

MON 87701 soybean received regulatory approvals for cultivation and/or food/feed uses in many countries[7].

MON 87701 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 strict 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, processing and, 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.

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 87701 in the EU

On 18 December 2020, Bayer CropScience LP submitted an application for renewal of the authorisation for products containing, consisting of, or produced from MON 87701 soybean authorised under Regulation 1829/2003 (Commission Implementing Decision 2012/83/EU). This renewal application received the reference number EFSA-GMO-RX-021 and was declared valid on 4 May 2021. The EFSA evaluated the application as well as additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications.

On 19 December 2022, the EFSA published a positive Scientific Opinion reiterating the safety of MON 87701 soybean[8].

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[2] SoyStats 2023, http://soystats.com/composition-of-a-soybean/ (Accessed 22 June 2023).

[3] FAO, https://www.fao.org/faostat/en/#data (Accessed 22 June 2023).

[4] Index mundi, https://www.indexmundi.com/agriculture/?commodity=soybean-oilseed&graph=area-harvested (Accessed 22 June 2023).

[5] USDA,FAS, https://apps.fas.usda.gov/psdonline/app/index.html#/app/home (Accessed 22 June 2023).

[6] ISAAA, 2019 - http://www.isaaa.org/resources/publications/ (Accessed on 22 June 2023).

[7] CropLife international - http://www.biotradestatus.com/ (Accessed on 22 June 2023).

[8] EFSA, 2022. Scientific Opinion on the assessment of genetically modified soybean MON 87701 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-021). EFSA Journal 2022; 20(12):7683, 11p (Accessed on 23 June 2023).

On 31 March 2023, the European Commission (EC) presented the Draft Commission Implementing Decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87701 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 11 May 2023, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who renewed the authorisation on 21 June 2023 (Commission Implementing Decision (EU) 2023/1212[9]).

Traceability, labelling, unique identifier

Operators handling or using MON 87701 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-877Ø1-2.

MON 87701 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL)[10]. The validated method, as well as the validation report for MON 87701, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), are available at the EURL website[11].

Food, feed and environmental safety of MON 87701

In its opinion, the EFSA GMO panel concluded that "*there is no evidence in the renewal application EFSA-GMO-RX-021 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 87701*".

Contact point for further information

MON 87701 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 refer to the CropLife Europe website at:

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

If required, additional comments or questions relative to MON 87701 can also be addressed to Bayer at:

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

[9] European Commission, 2023. Commission Implementing Decision (EU) 2023/1212 of 21 June 2023 renewing the authorisation for placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87701 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Accessed on 5 July 2023).

[10] Now called European Union Reference Laboratory (EURL).

[11] EURL - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 03 July 2023).