MON 87701

Insect Protected Soybean

Key facts


Monsanto EMEA
January 2012

MON 87701 Soybean

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 (http://www.soystats.com/2008/Default-frames.htm). It 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 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 2010, 261.5 million metric tons (MMT) of soybean were produced in the world, which represents approximately 100 million hectares of soybean harvested globally (FAO, http://faostat.fao.org/site/567/DesktopDefault.aspx?PageID=567#ancor). Significant areas of production included the US, Brazil, Argentina, India, China, representing 30.3%, 22.8%, 17.7%, 9% and 8.3% of the global soybean hectares, respectively.

The EU is not a significant soybean producer. In 2010, the soybean area harvested in the EU-27 accounted for approximately 374 thousand hectares (FAO, http://faostat.fao.org/site/567/DesktopDefault.aspx?PageID=567#ancor) distributed principally between Italy, Romania and France, Hungary and Austria (42.6%, 16.9%, 13.6%, 10.1% and 9.2% of the harvested area, respectively). Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal (22 million metric tons of soybean meal were imported in the EU-27 during the period 2010-2011) and the second largest importer of whole soybeans, after China. 13 million metric tons of soybeans were imported in the EU-27 during the period 2010-2011 (USDA,FAS, http://www.fas.usda.gov/psdonline/psdHome.aspx).

Particularly for Brazil, soybean is the main product of the agribusiness. In the harvest 2010/2011, Brazil produced 73 million tons of soybean and it generated $51 billions (~22.3 billions Euro) for the producers (http://www.abiove.com.br/). In 10 years the export of Brazilian soy has almost doubled, from 18 to 32 million tons

(www.taskforcesustainablesoy.org/index.php?option=com_content&task=view&id=27&Itemid). Brazil alone accounted for approximately 66% of the total extra-EU soybean imports into the EU in 2010. Brazilian farmers spend every year thousands of Euros in weeds and pests control.

What is MON 87701?

MON 87701 was developed by Monsanto Company through *Agrobacterium*-mediated transformation of soybean meristem tissues, to express relatively high levels of the Cry1Ac protein in leave tissue throughout the entire growing season. Cry1Ac protein in MON 87701 provides protection from feeding damage caused by targeted pests including velvetbean caterpillar (*Anticarcia gemmatalis*), soybean looper (*Pseudoplusia includens*), soybean anxil borer (*Epinotia aporema*) and sunflower looper (*Rachiplusia nu*). The distribution of these primary target pests varies in different soybean production countries within the South American region.

Soybean production can be affected substantially and can suffer considerable economic damage due to the infestation of soybean pests. Lepidopteran pests in soybean production regions located in tropical and sub-tropical areas can consistently cause significant plant damage and yield loss. Chemical insecticides are commonly used for controlling lepidopteran infestations in soybean but are not always effective. Therefore, biotechnology-derived plants producing the Cry1Ac protein providing insect control within plant cells is an alternative to reach a more consistent and reliable control of lepidopteran pests in soybean production.

Insect protected soybean: mode of action

Cry proteins naturally occur in the *Bacillus thuringiensis* (*Bt*) bacterium. Several Cry proteins exist and are classified by structure and by insects they control. The general mode of action of the Cry proteins is well understood. The bacterially-produced crystal proteins are first solubilized in the insect midgut, followed by activation of the protoxins by midgut proteases. The activated proteins then bind to midgut membrane receptors in susceptible insects and form pores. Formation of the pores causes loss of osmotic regulation, and eventually leads to cell lysis, which is thought to be responsible for insect death (Gill *et al.*, 1992; Schnepf *et al.*, 1998; Zhuang and Gill, 2003).

No receptors for these proteins have been identified on intestinal cells of mammals to date. A large number of insecticidal products based on this bacterium and/or its proteins have been developed and sold commercially since the late 1930's. Historically, *Bt* has been considered a safe option for pest control. Using biotechnology, the genes coding for specific *Bt* proteins were isolated and introduced into various crop plants.

Worldwide plantings and regulatory status of MON 87701

Genetically modified crops protected against insect pests and/or tolerant to a specific herbicide are commercialized in the US by Monsanto since 1996. In 2010, 148 million hectares of GM crops were grown worldwide. In the case of soybean, approximately 77% of global production is achieved with GM soybeans. The field area for GM soybean increased globally in 2009 by 4.9% in comparison to 2008 from 65.8 to 69 million hectares (http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/257.global_gm_planting_2009.html). In the EU, the cultivation of GM soybean not yet authorized.

MON 87701 has received regulatory approvals around the world (US, Australia/New Zealand, Canada, Mexico, Japan, Taiwan, Korea).

MON 87701 will be cultivated solely for the production of the combined product MON 87701 × MON 89788 (Bt and glyphosate tolerant traditionally bred soybean event), the targeted article of commerce which will be cultivated in Brazil. After a regulatory review (scrutiny and consideration) by the CTNBio (Comissão Técnica Nacional de Biossegurança), MON 87701 × MON 89788 was approved for cultivation on 19 August 2010 in Brazil.

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 GMOs in the environment (repealing Directive 90/220/EEC) and Regulation (EC) No. 1829/2003 on GM Food and Feed (replacing Regulation (EC) No. 258/97 on novel foods and novel food ingredients for GM products).

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 labeling 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 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 87701 in the EU

On 6 May 2010, Monsanto submitted an application for food and feed use of MON 87701 soybean as any other soybean (excluding cultivation) under Regulation (EC) No. 1829/2003 to EFSA, via the Belgian Competent Authority. This application was given the number EFSA-GMO-NL-2009-79 and was declared valid on 11 June 2010.

The European Food Safety Authority (EFSA) evaluated the application as well as Monsanto's responses to comments and reasoned objections from certain Member States. EFSA finalized the risk assessment and adopted its Scientific Opinion on MON 87701 on 6 July 2011 concluding that "*the soybean MON 87701 is as safe as its conventional counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses*". .

The EFSA overall opinion, which fulfils the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003 was published on 26 July 2011 (http://www.efsa.europa.eu/en/efsajournal/pub/2309.htm).

On 12 December 2011, the European Commission presented the Draft Commission Implementing Decision authorizing the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 to the Standing Committee on the Food Chain and Animal Health (SCFCAH) for a vote. After this vote, the draft decision was passed to the Appeal Committee who met for a vote on 17 January 2012. The Appeal Committee forwarded the draft decision to the European Commission with a recommendation for an approval. The authorization was finally granted by the European Commission on 10 February 2012.

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.

In July 2009, a MON 87701-specific PCR-based detection method allowing the identification and quantification of MON 87701 was provided to the Joint Research Centre (JRC), acting as the Community Reference Laboratory (CRL). The validated methods, as well as the validation report for MON 87701, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), were published on 15 July 2011 at the CRL website (http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm).
A report on the validation of the DNA extraction method for soybean seeds was also published on the same date.
MON 87701 is also listed as one of the products that currently fulfils the requirements of Regulation (EC) No. 619/2011 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 is expired (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

Food, feed and environmental safety of MON 87701

Food and feed safety

The food and feed safety of MON 87701 was confirmed based on the following lines of evidence:

1. A detailed molecular characterization of the inserted DNA, where the results confirm the insertion of a single functional *cry1Ac* expression cassette at a single locus within the soybean genome;

2. An extensive set of biochemical evaluations that demonstrate the equivalence of the full-length Cry1Ac protein produced in MON 87701 to the *E. coli*-produced Cry1Ac protein used for safety evaluation;

3. An assessment of the toxic and allergenic potential of Cry1Ac based on a history of safe use, extensive information collected and safety evaluations performed, demonstrates that Cry1Ac is unlikely to be a toxin or allergen; and,

4. The compositional and nutritional assessment confirmed that the seed and forage from MON 87701 are compositionally and nutritionally equivalent to, and as safe as, those of conventional soybean.

Further details on the safety of this soybean are available in a product safety summary at: http://www.monsanto.com/products/Pages/product-safety-summaries.aspx

Environmental safety

The environmental safety of MON 87701 was established through extensive laboratory and field testing of plant tissue or purified Cry1Ac protein, and with a wide range of non-target species. No adverse effects have been observed in non-target species exposed to Cry1Ac protein. In addition, this protein is expected to degrade rapidly in the environment. Furthermore, agronomic, morphological and pest susceptibility data have been recorded in multiple field trials conducted in major soybean growing regions. Results from these trials confirm that MON 87701 is phenotypically equivalent to their respective conventional soybean counterpart, except for their protection against lepidopteran pests.

MON 87701, the benefits

MON 87701 deliver benefits to both farmers and the environment:

- Consistent and reliable control of lepidopteran pests: The Cry1Ac protein is expressed at consistently high levels in insect-protected soybean MON 87701 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 87701 should provide protection that is superior to existing chemical and cultural control practices.

- Reduced production costs and improved farming efficiency: Growers must work diligently to control lepidopteran pests at an early stage to prevent severe crop damage. Insect-protected soybean MON 87701 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 87701 because no special equipment is required, and it reduces or eliminates the labor and time for growers to spray insecticides under traditional insect control practices, as well as reduces applicator exposure to chemical pesticides.

- 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 (*Pseudoplusia includen*), soybean borer (*Crocidosema aporema*), and sunflower looper (*Rachiplusia nu*) (Aragon *et al.*, 1997). MON 87701 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 87701 does not impose any adverse impact on beneficial species compared to conventional insecticide-based programs.

- Yield benefits and insecticide use reduction. In multi-year field tests in Argentina, MON 87701 was found to provide a significant yield increase of up to 4.5% relative to conventional soybean treated with insecticide under mild to moderate lepidopteran insect infestations. In addition to the benefits associated with its specificity for target pests, the reduced use of insecticides against lepidopteran pests will result in cost savings on insecticide and labor.

The product has a potential socio-economic impact due to the reduction in use of water (*e.g.* through the reduction of agrochemical applications, especially in those crops protected against insect pests), diesel and release of CO_2 into the environment (*e.g*. through the reduction of times the machinery has to enter the field) and insecticides (*e.g.* through the replacement by the plant's introduced protection against insect pests). Considering the volume of water used in agriculture and the scarcity of the resource facing the future, it is worth highlighting that the adoption of biotechnology in Brazil (which includes insect resistant and herbicide tolerant traits for soybean, maize and cotton) has contributed effectively to the reduction of 16.2 billion liters, equivalent for supplying a population of 368,800 people over the period from 1996-1997 to 2009-2010 (Céleres Ambiental:

http://www.celeres.com.br/1/index.html). Also according to Céleres Ambiental, the reduction in the use of active ingredients in GM crops plantations in Brazil recorded for the period from 1996-1997 to 2009-2010 has been of 9.6 tons. Globally, the accumulative reduction in pesticides for the period 1996 to 2009 was estimated at 393 million kilograms of active ingredient, a saving of 8.8% in pesticides (ISAAA, 2010) (http://www.isaaa.org/). This saving of active ingredients contributes not only to farmers' economy and health (through the reduction of his exposure to chemicals) and overall people's quality of life (*e.g.* through less residues in foods) but also to the environment protection. There is a general consensus among specialists that less use of insecticides in Bt soybean in the beginning will reduce impact on the initial population of desirable insects such as predators that could impact the control of the sap sucking insect pests (like 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. Therefore, reduced pesticide use will be linked to a positive impact on resource conservation inside and outside the farm (*e.g.* reduced fuel use, agrochemicals volumes and manpower) as well as on environmental conservation (*e.g*. reduced CO_2 emissions and increased carbon sequestration).

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