

**MON 15985 cotton**  
**Genuity<sup>®</sup> Bollgard<sup>®</sup> II Cotton**  
Second Generation Insect protection

## **Key facts**



Monsanto EMEA  
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# MON 15985 - Genuity® Bollgard II® cotton

## Cotton

Worldwide, four *Gossypium* species are collectively known as cotton and are grown commercially. These include two diploid species ( $2n=2x=26$ ) *G. arboreum* L. and *G. herbaceum* L., which evolved in Africa and the Middle East, and two allotetraploid species ( $2n=4x=52$ ) *G. barbadense* and *G. hirsutum*, which evolved in the Americas. The major type of cotton being grown commercially around the world is the upland cotton *G. hirsutum*. *G. herbaceum* and *G. arboreum*, are of regional agronomic importance, mostly in areas not suited for *G. hirsutum* or *G. barbadense* (Southeast Asia and the dry, unproductive areas of India and Pakistan) and they comprise less than 4% of the total cotton produced globally. There are no close wild relatives of cotton in the EU.

The fiber, or lint, is used to make cloth—for towels, clothes, sheets, etc. The cottonseeds from the plant are crushed into cottonseed oil, which can be used in everyday items such as cooking oil and salad dressing, and into hulls and meal, which are used for livestock feed.

In the 2013/2014 season, the major cottonseed oil, meal and oilseed producing countries in the world were China, India, Pakistan, Brazil and the USA<sup>1</sup>. In the EU, cotton is commercially grown in Italy, Spain and Greece.

## What is MON 15985 cotton?

Monsanto Company has developed, via re-transformation of MON 531, Bollgard II® cotton (hereafter referred to as MON 15985 cotton) which produces two insect control proteins (Cry1Ac and Cry2Ab2) derived from the naturally occurring soil bacterium, *Bacillus thuringiensis* (*B.t.*). Therefore, MON 15985 cotton provides additional protection to the major lepidopteran insect pests of cotton.

MON 15985 cotton expresses the Cry1Ac and Cry2Ab2 proteins, which provide enhanced protection against key lepidopteran insect pests, including tobacco budworm, pink bollworm, cotton bollworm, beet and fall armyworm. MON 15985 cotton also expresses the neomycin *phosphotransferase II* (*nptII*) gene which provides a plant selectable marker; and the *B-D-glucuronidase* (*GUS*) marker gene, which was used as a visual marker during selection of the transformant. MON 15985 cotton also contains the *3'(9)-O-aminoglycoside adenylyltransferase* (*aad*) gene, a bacterial selectable marker, which is not expressed in the plants.

## MON 15985 cotton: mode of action

Insecticidal activity of the Cry proteins requires that the protein be ingested. In the insect gut, the protein is proteolytically cleaved to the active core of the protein. The core protein binds to specific receptors on the mid-gut of Lepidopteran insects, inserts into the membrane and forms ion-specific

pores. These events disrupt the digestive processes and cause the death of the insect. The digestive tract tissues of non-target insects, mammals, birds and fish do not contain receptors that bind the Cry proteins. Therefore the Cry proteins cannot disrupt digestion and is non-toxic to species other than lepidopteran insects. Combining the Cry2Ab2 protein with the Cry1Ac protein in MON 15985 cotton will provide an additional tool to delay the development of resistance since these two protein classes have different specific molecular modes of action.

## Worldwide plantings and regulatory status of MON 15985 cotton

In 2014, biotech cotton was planted to 25.1 million hectares, which is 68% of the 37 million hectares of global cotton (James, 2014). MON 15985 cotton has received regulatory approvals for cultivation in Australia, Brazil, Burkina Faso, India, Republic of South Africa and the USA. Additional import approvals are received in Canada, China, Colombia, EU, Japan, Korea, New Zealand, the Philippines and Singapore<sup>2</sup>. The first commercial plantings of MON 15985 cotton were in the USA in 1996.

## 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 (repealing Directive 90/220/EEC) and Regulation (EC) No. 1829/2003 on genetically modified 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 authorization 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 15985 cotton in the EU

### Feed materials, feed additives and food additives

Foods produced from MON 15985 cotton (food additives) were authorised under Directive 89/107/EEC, while feed produced from cotton MON 15985 (feed materials and feed additives) were subject to Directive 70/524/EEC.

<sup>1</sup>Source: Foreign Agricultural Service, Official USDA Estimates. <http://apps.fas.usda.gov/psdonline/psdQuery.aspx>

<sup>2</sup> Bollgard II is a registered trademark of Monsanto Technology, LLC.

<sup>2</sup> <http://www.biotradestatus.com/> - accessed 13 April 2015

After the date of entry into force of the Regulation (EC) 1829/2003, the products mentioned above were notified to the European Commission according to Articles 8(1)(a), 8(1)(b) or 20(1)(b) of this Regulation and subsequently included in the Community Register of GM food and feed.

#### ***Renewal application for use of food additives, feed material and feed additives***

On 17 April 2007, Monsanto submitted a renewal application for use of food additives, feed material and feed additives produced from MON 15985 cotton as any other cotton under Regulation (EC) No 1829/2003 to European Food Safety Authority (EFSA) via the European Commission. The application received the reference number EFSA-GMO-RX-15985 and was declared valid on 31 March 2008.

#### ***Food, Feed Import and Processing***

On 22 April 2008, Monsanto submitted an application for authorisation of food produced from or containing ingredients produced from MON 15985 cotton, Feed produced from MON 15985 cotton and MON 15985 cotton for Import and processing. The application received the reference number EFSA-GMO-UK-2008-57 and was declared valid on 20 August 2008. On 18 March 2013, Monsanto requested an extension of scope of this application to include MON 15985 cotton for import, processing and all uses as any other cotton.

Since both EFSA-GMO-RX-15985 and EFSA-GMO-UK-2008-57 cover products derived from MON 15985 cotton, the EFSA GMO Panel evaluated the two applications simultaneously. The EFSA also evaluated Monsanto's additional information, scientific comments submitted by the Member States and relevant scientific publications. The EFSA published a positive scientific opinion, covering both applications simultaneously, on 28 July 2014 (adopted 2 July 2014) (EFSA, 2014), in which the EFSA concluded that MON 15985 cotton "*is as safe as its conventional counterpart and non-GM cotton commercial varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of these applications*".

Finally, on 16 March 2015, 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 MON 15985 cotton, to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote. Since no qualifying majority was reached, the draft decision was passed to the Appeal Committee who met for a vote on 31 March 2015, again without reaching a qualified majority. The Appeal Committee forwarded the draft decision to the European Commission. The authorization was finally granted by the European Commission on 24 April 2015 (Commission Decision, 2015), 9 months after the EFSA opinion.

#### **Traceability, labeling, unique identifier**

Operators importing, handling or using MON 15985 derived food and feed in the EU should be informed of the legal obligations regarding traceability and labeling, laid down in Regulation (EC) No. 1830/2003. The unique identifier of MON 15985 cotton is MON-15985-7.

The validated method, as well as the validation report for MON 15985 cotton, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL), were published on June 19, 2008 at the CRL website<sup>3</sup>. A report on the validation of the DNA extraction method for cotton seeds was also published on the same date.

#### **Food, feed and environmental safety of MON 15985 cotton**

##### ***Food and feed safety***

The food and feed safety of MON 15985 cotton was established through:

- A detailed molecular characterization of the inserted DNA,
- An assessment of the toxic and allergenic potential of Cry1Ac, Cry2Ab2, GUS and NPTII, based upon their long history of safe use, their rapid digestibility and their lack of toxicity or allergenicity, as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies with the protein,
- The compositional and nutritional analyses confirmed that MON 15985 cotton is compositionally and nutritionally equivalent to, and as safe as, those of conventional cotton,
- A large margin of safety resulted from the low dietary exposure to the different proteins,
- A dietary risk assessment showed that the intake of the introduced proteins resulting from consumption of foods derived from cotton do not raise nutritional concerns. Dietary safety of MON 15985 cotton was confirmed in a repeated-dose feeding study in rats and catfish.

Further details on the safety of MON 15985 cotton are available in a product safety summary on Monsanto's website<sup>4</sup>

##### ***Environmental safety***

The environmental safety of MON 15985 cotton was established through extensive field trials conducted in 1998, 1999, 2007 in the USA, 2005-2006 in Brazil and in 2002 and 2003 in India. All these field trials demonstrated that MON 15985 cotton poses negligible risk to human health or to the environment.

Results of the phenotypic and agronomic assessment showed that there are no unexpected changes in the phenotype or ecological interactions indicative of increased pest or weed potential of MON 15985 cotton compared to the conventional cotton control. Data on environmental interactions also indicate that MON 15985 cotton does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect, or abiotic stressors, or changes in agronomic and phenotypic characteristics.

On the basis of these studies, it is possible to conclude that no differences in the mode or rate of reproduction, dissemination, survivability or other agronomic, phenotypic or ecological characteristics are expected in MON 15985 cotton and that

<sup>3</sup><http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> - accessed February 26, 2015

<sup>4</sup>[http://www.monsanto.com/products/documents/safety-summaries/bollgard\\_ii\\_pss.pdf](http://www.monsanto.com/products/documents/safety-summaries/bollgard_ii_pss.pdf). Accessed March 03, 2015.

MON 15985 cotton is not different in its phenotypic and agronomic behaviour relative to conventional cotton.

In their scientific opinion on MON 15985 cotton, the EFSA concluded that *“Following a weight of evidence approach and considering the poor ability of cotton to survive outside cultivated land, despite the agronomic and phenotypic data limitations, the Panel concludes that there is very low likelihood of any adverse environmental impacts”*.

### MON 15985 cotton, the benefits

In countries where MON 15985 cotton is grown, a number of benefits for both farmers and the environment are expected. These include:

- Season-long control of a broad spectrum of worm pests, which allows growers to reduce or even eliminate sprays for worms,
- Growers are able to focus more of their attention on non-worm pests and other farm work such as irrigations, weed control and tending to crops,
- Fewer insecticide sprays which can increase the population of beneficial insects for their crops,
- Reduces vulnerability to fluctuating levels of worm pressure and the damage worms do before and between insecticide applications that can severely damage the crop,
- Two Unique Modes of Action: The advanced dual-gene system of Bollgard II cotton allows you to provide a wider spectrum of worm control with even fewer sprays, resulting in greater yield protection. Lessening the number of sprays can enhance beneficial insect populations and reduce infestations of harmful pests like aphids and mites.

### Further reading

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- Commission Decision, 2015. Commission Implementing Decision (EU) 2015/685 of 24 April 2015 authorising the placing on the market of genetically modified cotton MON 15985 (MON-15985-7) and renewing the authorisation for existing genetically modified cotton MON 15985 (MON-15985-7) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2015) 2755). *Official Journal*, L 111, 1.
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