MON 89034 maize

YieldGard VT® PRO

Corn borer protection

Key Facts

Monsanto Europe-Africa
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Maize, a key crop

After wheat and rice, maize is the third most frequently cultivated crop worldwide. Following European discovery of the Americas where this crop is indigenous, maize was rapidly adopted in Europe, Africa and Asia. Today, it is one of the few intensively cultivated crops in European agriculture. Significant areas of production include the Danube basin from southwest Germany to the Black Sea and southern France through to the Po Valley of northern Italy.

As in other world areas, maize use in Europe is dominated by the demand for animal feed. Maize is also processed into valuable industrial and food products such as ethyl alcohol, maize meal, starch and sweeteners.

In 2008, the area of maize harvested in the European Union (EU) was approximately 10 million hectares, with a production of around 59.1 million tons[1]. The EU is a large importer of maize, importing about 10 million tonnes of maize grain per year[2] (the majority from Brazil and Argentina).

What is MON 89034?

MON 89034 is a second generation genetically modified (GM) insect-protected maize, following the widely planted MON 810[3]. It was developed through *Agrobacterium*-mediated transformation of maize and expresses two proteins, Cry1A.105 and Cry2Ab2. These Cry proteins protect the plants from feeding damage caused by the European corn borer (*Ostrinia nubilalis*) and other lepidopteran (moths and butterflies) insect pests.

Cry proteins naturally occur in the *Bacillus thuringiensis* (*Bt*) bacterium. Several Cry proteins exist and are classified by structure and by insects they control. 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). 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.

Cry1A.105 is a modified version of the *Bt* Cry1A protein (with amino acid sequence identity to Cry1Ab, Cry1Ac and Cry1F proteins of 90.0%, 93.6% and 76.7%, respectively) which provides increased activity against fall armyworm (*Spodoptera* sp.) compared to the Cry1Ab expressed in MON 810 maize.

Cry2Ab2 is a protein originating from *Bacillus thuringiensis* subsp. *kurstaki*. It provides improved control over Cry1Ab from damage caused by corn earworm (*Helicoverpa zea*).

The combination of the Cry1A.105 and Cry2Ab2 insecticidal proteins in a single plant provides improved insect control and offers an additional insect resistance management (IRM) tool.

More information on this product can be obtained from the Agbios website[4].

Worldwide planting of MON 89034

Genetically modified crops protected against insect pests were first commercialized in the US in 1997. In 2007, over 114 million hectares of GM crops were grown worldwide; from which 37.3 million hectares was maize (James, 2008).

Products containing MON 89034 were planted commercially for the first time in 2009 in the US.

A strict regulatory system for genetically modified crops in the EU

In the EU, the regulatory system for genetically modified (GM) crops comprises several directives and regulations, including Directive 2001/18/EC for deliberate release of GMOs in the environment (repealing Directive 90/220/EEC) and Regulation (EC) No. 1829/2003 concerning GM food and feed (replacing Regulation (EC) No. 258/97 on novel foods and novel food ingredients for GM products).

Furthermore, a regulation on traceability and labeling of genetically modified organisms (GMOs) and products produced from GMOs (Regulation (EC) No. 1830/2003) entered into application on 18 April 2004.

Regulatory status of MON 89034 in the EU

On December 14, 2006, Monsanto submitted an application for food and feed uses, import and processing under the Regulation (EC) No. 1829/2003 on GM Food and Feed to the European Food Safety Authority (EFSA) via the Netherlands.

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 adopted a

[1] Eurostat: http://www.eds-destatis.de/de/downloads/sif/qa_08_041.pdf (Accessed on November 13,09)

[2] Eurostat: http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/search_database - Search for *food_in_imp5*, open the highlighted file,in the *Select Data* tab under the *PROD_CN* subtab, select only *maize or corn* and click on *update.* (Accessed on November 13, 09)

[3] MON 810 maize, commercialised since 1997, expresses the *Bacillus thuringiensis* Cry1Ab protein which confers protection against certain lepidopteran pests, including the European corn borer (*Ostrinia nubilalis*) and the Mediterranean corn stalk borer (*Sesamia* spp.).

[4] Agbios: http://www.agbios.com/ (Accessed on November 13, 09)

scientific opinion on December 03, 2008, concluding that "*MON 89034 is as safe as its non genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore the GMO Panel concludes that maize MON 89034 is unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses*."[5]

The EFSA overall opinion, which fulfils the requirements of Articles 6 and 18 of Regulation (EC) No. 1829/2003, was published on December 18, 2008[6].

After consideration by the Standing Committee on the Food Chain and Animal Health (SCFCAH) on July 22, 2009, and the Council of Agriculture Ministers on October 19, 2009, MON 89034 was approved by the European Commission on October 30, 2009 for food, feed, import and processing in accordance with Regulation (EC) No. 1829/2003 on GM food and feed (Commission Decision, 2009)[7], which adopted the proposals for 10 years authorisation. MON 89034 is listed in the Community Register[8].

Detection method

An event-specific method for the quantification of MON 89034 using real-time PCR has been validated by the European Commission Joint Research Centre (JRC). It was published on the Community Reference Laboratory (CRL) website on November 05, 2008[9].

Traceability, labelling, unique identifier

Once authorised for commercialisation, operators importing, handling or using MON 89034 grain and derived foods and feeds in the EU will be informed of the legal obligations regarding traceability and labelling, laid down in Regulation (EC) No. 1830/2003 and in the conditions of placing on the market of the consent.

The unique identifier of YieldGard VT PRO (MON 89034) is MON-89Ø34-3.

Food, feed and environmental safety of MON 89034

Food and feed safety

The food and feed safety of MON 89034 was established through:

- The long history of safe use of *Bt* Cry proteins in general;
- A large margin of safety resulting from the low dietary exposure to Cry1A.105 and Cry2Ab2 proteins.
- The rapid digestibility of Cry1A.105 and Cry2Ab2 proteins in simulated mammalian gastric and intestinal fluids (SGF and SIF);
- The lack of toxicity or allergenicity of Cry1A.105 and Cry2Ab2 proteins, as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies of these proteins;

Also, studies using the sensitive target insect species of European corn borer and corn earworm demonstrated that Cry1A.105 and Cry2Ab2 proteins have no synergistic or antagonistic effects to each other.

MON 89034 was shown to be as safe and nutritious as conventional maize by analysis of key nutrients, including protein, fat, carbohydrates, amino acids, fatty acids and minerals, as well as by a feed performance study using grain fed to broiler chickens (Taylor *et al.*, 2007).

Environmental safety

The environmental safety of MON 89034 was established through extensive laboratory and field testing of plant tissue or purified Cry1A.105 and Cry2Ab2 proteins, and with a wide range of non-target species. No adverse effects have been observed in non-target species exposed to maximum expected concentrations of Cry1A.105 and Cry2Ab2 proteins. Furthermore, environmental fate studies demonstrate that Cry1A.105 and Cry2Ab2 proteins rapidly degrade in a variety of soil types. Agronomic, morphological and pest susceptibility observations have been recorded in multiple field trials conducted across major maize growing regions of the US as well as in the EU. Results of these trials confirm that MON 89034 is phenotypically equivalent to conventional maize except for its protection against European corn borer and other lepidopteran pests.

MON 89034, the expected benefits

MON 89034 benefits both farmers and the environment:

- A method to control corn borers and other lepidopteran pests of maize, compatible with integrated pest management (IPM) approaches, that offers improved pest control and higher yields, while at the same time being safe for humans and the environment (Marra *et al.*, 2002);
- Better control of fall armyworm (*Spodoptera* sp.) and corn earworm (*Helicoverpa zea*) compared to the first generation insect protected maize, MON 810 (MON 89034 has a wider spectrum of activity);
- Increased benefits for farmers linked to the reduced exposure to insecticides, ease of use and handling, time and labor savings, as well as better pest control (Alston *et al.*, 2002; Brookes and Barfoot, 2008; Marra *et al.*, 2002);

[5] EFSA Scientific Opinion on application ESFA-GMO-NL-2007-37: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902216540.htm (Accessed on November 13, 09)

[6] EFSA website: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-042 - the overall opinion can be found under "Question Documents" tab(Accessed on November 13, 09)

[7] Europa EUR-Lex: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:289:0021:0024:EN:PDF (Accessed on November 13, 09)

[8] European Commission : http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=34 (Accessed on November 13, 09)

[9] CRL: http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm (Accessed on November 13, 09)

- Negligible to no risks for adverse effects on beneficial, non-target organisms when compared to fields treated with conventional pesticides;
- Decreased occurrence of fungal mycotoxins associated with adverse health effects, as a result of lower damage to maize plants by lepidopteran pests (Bakan *et al.*, 2002; Brookes, 2008; de la Campa *et al.*, 2005; Munkvold, 2003; Wu, 2006);
- Resource conservation linked to reduced insecticide and herbicide use, *e.g.* less diesel fuel consumed in the manufacture and delivery of insecticides, less water used for insecticide application, conservation of aviation fuel and reduced use of insecticide containers (Carpenter *et al.*, 2002; NCGA and USGC, 2007; Phipps and Park, 2002);
- Improvement in economic profitability of between 12 and 21% were imputed to the use of insect protected biotech crops in the European Union (Brookes and Barfoot, 2008).

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