MON 87427 maize

Roundup® Hybridization System (RHS)
Glyphosate tolerance maize

Key facts

Monsanto Europe
December 2015

Maize, a key crop

After sugar cane, maize (*Zea mays*) is the second most frequently cultivated crop worldwide, followed by rice and wheat[1]. 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. In 2014-2015, approximately 1000 million metric tons of maize were produced in the world. Significant areas of production included the US, China and Brazil, representing approximately 36%, 22% and 8% of the global maize production, respectively (USDA, 2015).

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 2014, the area of maize harvested in the European Union (EU) was approximately 10 million hectares, with a production of around 74.2 million tons. The EU imports about 8 million tons of maize grain per year[2]. The major exporters of maize to the EU are Ukraine and Brazil, followed by Russia (European Commission, 2014)

What is MON 87427?

MON 87427 is a genetically modified (GM) maize with tissue-selective glyphosate tolerance to facilitate the production of viable hybrid maize seed. MON 87427 produces the same 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein that is produced in commercial Roundup Ready® crop products, via the incorporation of a *cp4 epsps* coding sequence. CP4 EPSPS confers tolerance to the herbicide glyphosate (see Figure 1). Tissue-selective expression of CP4 EPSPS protein in MON 87427 enables an extension of the use of glyphosate tolerant maize as a tool in hybrid maize seed production.

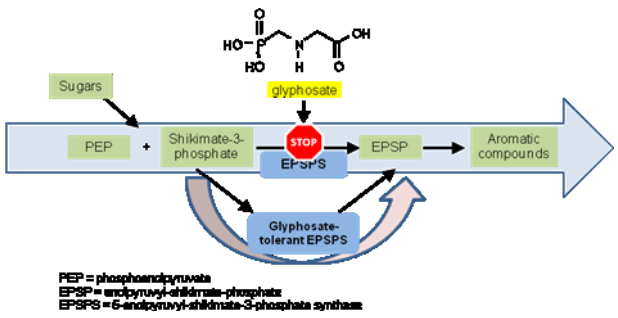

Figure 1: Schematic of the mode of action of the genetic modification in MON 87427

MON 87427 utilizes a specific promoter and intron combination to drive CP4 EPSPS protein expression in vegetative and female reproductive tissues, conferring tolerance to glyphosate in the leaves, stalk and root tissues and tissues that develop into grain or grain and silks. Consequently, limited or no production of CP4 EPSPS occurs in two key male reproductive tissues: pollen microspores and tapetum cells. Specifically timed glyphosate applications are made during the maize vegetative growth stages (V8-V13), treated MON 87427 will produce a male sterile phenotype through tissue-selective glyphosate tolerance, resulting in a plant that can be pollinated by pollen donor (male) plants.

As a result of this genetic modification, the need for detasseling, which is currently used in the production of hybrid maize seed, is greatly reduced. Further, MON 87427 is tolerant to glyphosate at vegetative stages.

More information on this product can be obtained from the Center for Environmental Risk Assessment (CERA) GM Crop Database[3] and the EuropaBio website[4].

Worldwide plantings and regulatory status of MON 87427

In 2014, 181.5 million hectares of GM crops were grown worldwide. Of the 184 million hectares of global maize planted in 2014, 30% or 55.2 million hectares were biotech maize (James, 2014). The first commercial planting of herbicide tolerant (HT) maize plants was in the US in 1997. Planted surfaces increased rapidly, equalling approximately 99 million hectares worldwide in 2013 (as a single trait or stacked with insect tolerance trait) or approximately 57% of the total GM plant acreage (James, 2014).

MON 87427 was first planted under regulated conditions for testing in North America in 2005. Today, MON 87427 has received regulatory approval for production in Canada and the US. MON 87427 also received regulatory approvals for import in Australia, Colombia, Japan, Korea, Mexico, the Philippines and Taiwan[5].

A stringent regulatory system for genetically modified crops in the EU

In the EU, the regulatory system for GM crops comprises several directives and regulations, including Directive 2001/18/EC for deliberate release of GMOs in the environment and Regulation (EC) No 1829/2003 on GM Food and Feed.

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.

[1] FAOSTAT - http://faostat.fao.org/site/339/default.aspx (Accessed on 24 November 2015)

[2] Index mundi - http://www.indexmundi.com/ (Accessed on 24 November 2015)

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology, LLC

[3] CERA - http://www.cera-gmc.org/GMCropDatabase (Accessed on 24 November 2015))

[4] EuropaBio - http://www.europabio.org/information-operators-product-information (Accessed on 24 November 2015)

[5] ISAAA - http://www.isaaa.org/gmapprovaldatabase/ (Accessed on 24 November 2015)

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 authorization procedure is pending or the authorization of which has expired (Commission regulation (EU) No 619/2011) entered into force on 24 June 2011.

Regulatory status of MON 87427 in the EU

On 11 June 2012, Monsanto submitted an application for import, food and feed use of MON 87427 maize as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Belgian Competent Authority. The application received the reference number EFSA-GMO-BE-2012-110 and was declared valid on 3 January 2013. The EFSA evaluated the application as well as additional information provided by Monsanto, scientific comments submitted by the EU Member States and relevant scientific publications.

On 19 June 2015, the EFSA published a positive Scientific Opinion adopted 27 May 2015 on the safety of on MON 87427 (EFSA, 2015). The EFSA concluded that *"MON 87427, as described in this application, is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application"*.

On 14 September 2015, the European Commission (EC) presented the Draft Commission Implementing Decision authorizing the placing on the market of products containing, consisting of, or produced from GM maize MON 87427 to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote. After this vote, the draft decision was passed to the Appeal Committee who met for a vote on 10 November 2015. The Appeal Committee forwarded the draft decision to the EC. The authorisation was granted by the EC on 4 December 2015 (Commission Decision, 2015).

Traceability, labelling, unique identifier

Operators importing, handling or using MON 87427 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-87427-7.

In April 2012, a MON 87427-specific PCR-based detection method allowing the identification and quantification of MON 87427 was provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The validated method as well as the validation report for MON 87427 prepared by the EURL in collaboration with the European Network of GMO Laboratories (ENGL), were published on 9 June 2015 at the EURL website[6].

[6] EU-RL GMFF - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 24 November 2015)

Food, feed and environmental safety of MON 87427

Food and feed safety

The food and feed safety of MON 87427 was established based on:

- A detailed molecular characterization of the inserted DNA, where the results confirm that a single copy of the *cp4 epsps* expression cassette was integrated at a single locus within the maize genome;
- The long history of safe use of the CP4 EPSPS protein (EFSA, 2003, 2012);
- The evaluation of CP4 EPSPS activity and its homology to EPSPS proteins present in a diversity of plants, including those used for foods;
- The rapid digestibility of the CP4 EPSPS protein by proteases found in the human gastrointestinal tract (pepsin and pancreatin);
- The lack of toxicity or allergenicity of the CP4 EPSPS protein generally and as demonstrated with bioinformatics as well as *in vitro* and *in vivo* safety studies of the CP4 EPSPS protein;
- A large margin of safety resulting from the low dietary exposure to the introduced CP4 EPSPS protein in MON 87427.

MON 87427 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 (EFSA, 2015). In the EFSA Scientific Opinion on MON 8742, the EFSA concluded that MON 87427 *"is as safe and nutritious as its conventional counterpart and the commercial non-GM maize varieties tested"*.

Further details on the safety of MON 87427 are available in the EFSA scientific opinion published on 19 June 2015 (EFSA, 2015).

Environmental safety

The environmental safety of MON 87427 was established through extensive laboratory and field testing conducted of plant tissue or purified CP4 EPSPS protein demonstrating that MON 87427 poses negligible risk to human and animal health or to the environment.

Results from the phenotypic and agronomic assessments demonstrate that MON 87427 does not possess characteristics that would confer a plant pest risk compared to conventional maize. Data on environmental interactions also indicate that MON 87427 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect, or abiotic stressors, or changes in agronomic and phenotypic characteristics compared to the conventional control (EFSA, 2015).

This, together with the history of safe use of the CP4 EPSPS protein, demonstrates that the ecological interactions of MON 87427 with non-target organisms or soil processes are not different from conventional maize.

Maize has no wild relatives in Europe to which the introduced trait could outcross. The likelihood of this maize spreading into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional maize. Moreover, the scope of the authorization covers the import, processing and all uses as any other maize, but excluding cultivation in the EU, and no deliberate release of the viable plant material in the EU environment is expected thereby limiting the environmental exposure to accidental spillage only.

The HT trait in MON 87247 can be regarded as providing only a potential agronomic and selective advantage for this GM maize plant where and when glyphosate herbicides are applied. Survival of maize plants outside cultivation where glyphosate- and/or glufosinate-based herbicides are applied is mainly limited by a combination of low competitiveness, absence of a dormancy phase and susceptibility to plant pathogens and cold climatic conditions.

In conclusion, the environmental impact of growing MON 87427 is not different from that of growing conventional maize, as stated in the June 2015 EFSA scientific opinion (EFSA, 2009).

MON 87427, the benefits

MON 87427 provides the following benefits:

- *Increased Flexibility in Hybrid Seed Production*: Each year approximately 0.5 M acres used for hybrid maize seed production must be detasseled in order to meet commercial growers' hybrid maize seed needs and to meet established seed purity criteria in the maize seed producing countries. The critical time period for detasseling is after the tassel has emerged but prior to pollen shed and silk emergence, and encompasses an average 3 - 4 day window. Current detasseling practices may require up to two passes with mechanical detasseling equipment and up to three passes if hand detasseling is used. Further complicating detasseling activity is the logistical planning required for moving enough labor and resources to the designated hybrid seed production fields at the appropriate time. Glyphosate applications to MON 87427 that will result in the male sterile phenotype through tissue-selective glyphosate tolerance will take place during approximate maize vegetative growth stages ranging from V8 to V13. The two glyphosate applications would take place during an approximate 14 day window within these growth stages, a much longer time period compared to an average 3 – 4 day window between tassel emergence and pollen shed and silk emergence. This timing accounts for significantly improved flexibility in hybrid seed production.
- *Economic Benefits for Hybrid Seed Producers:* Seed manufacturers continually seek ways to improve hybrid seed productivity and reduce the inputs and land area used to produce high quality hybrid seed. Agricultural field labor costs tend to outpace inflation in typical maize seed producing markets. Compounding this increasing cost is population migration towards urban areas that is shrinking the agricultural labor pool, thus reducing a reliable labor pool for this work. Costs associated with labor recruitment and deployments to perform detasseling are one of the single largest cost improvement opportunities in hybrid seed production. MON 87427 will decrease hybrid seed production costs primarily from a reduction in direct and associated labor costs.
- When MON 87427 hybrids are commercialized, they will be offered as traditional breeding stacks with other previously approved traits for insect control and weed control including RoundupReady Corn 2 events, affording the opportunity to replace several selective herbicides by a single broad-spectrum herbicide with a favourable human health and environmental profile. The active ingredient glyphosate is non-persistent and has limited mobility as it binds tightly to soil. The compound presents very low toxicity to humans. Furthermore, it does not bioaccumulate and presents minimal risk to terrestrial and aquatic species including fish, birds, mammals and invertebrates (Giesy et al., 2000; Williams et al., 2000);
- Glyphosate use rates, timings and recommendations for weed management will not be different than those recommended for the previously de-regulated Roundup Ready Corn 2 products (NK603 and MON 88017) allowing flexible broad-spectrum weed control options that allows over-the-top applications of glyphosate in maize on an "as needed" basis (Johnson et al., 2000);
- Contribution to achieve more consistency in the weed control results combined with the full and superior selectivity of Roundup on MON 87427 hybrids to protect the yield potential of those hybrids;
- An excellent fit with reduced tillage systems, which are linked to many environmental advantages including improved soil and water quality, reduced soil erosion and runoff, improved wildlife habitat and reduced fuel use and CO_2 emissions (Brookes and Barfoot, 2014; Fawcett and Towery, 2002; Phipps and Park, 2002);
- Tolerance to glyphosate in vegetative stages allowing for over-the-top use of the herbicide.

References

Brookes G and Barfoot P, 2014. GM crops: the first ten years - global socio-economic and environmental impacts 1996-2012. PG Economics Ltd, 1.

Commission Decision, 2015. Commission implementing decision (EU) 2015/2281 of 4 December 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 (MON-87427-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. European Commission, L 322/67, 1-6.

EFSA, 2003. Opinion of the Scientific Panel on genetically modified organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto (Question No EFSA-Q-2003-002). The EFSA Journal, 9, 1-14.

EFSA, 2009. Scientific opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-NL-2005-22 and EFSA-GMO-RX-NK603) for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses and import and processing, and for renewal of the authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 from Monsanto (Questions No EFSA-Q-2005-249, No EFSA-Q-2008-075). The EFSA Journal, 1137, 1-50.

EFSA, 2012. Scientific opinion on an application (EFSA-GMO-NL-2005-24) for the placing on the market of the herbicide tolerant genetically modified soybean 40-3-2 for cultivation under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal, 10(6), 1-110.

EFSA, 2015. Scientific opinion on application (EFSA-GMO-BE-2012-110) for the placing on the market of tissue-selective herbicide-tolerant genetically modified maize MON 87427 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal, 13 (6), 1-25.

European Commission, 2014. EU cereals trade 2013/14 marketing year. Committee for the Common Organisation of Agricultural Markets, 1-16.

Fawcett R and Towery D, 2002. Conservation tillage and plant biotechnology: how new technologies can improve the environment by reducing the need to plow. Report of the Conservation Technology Information Center (CTIC), 1-24.

Giesy JP, Dobson S and Solomon KR, 2000. Ecotoxicological risk assessment for Roundup® herbicide. Rev. Environ. Contam. Toxicol., 167, 35-120.

James C, 2014. Global status of commercialized biotech/GM crops: 2014. ISAAA, 49, Executive Summary.

Johnson WG, Bradley PR, Hart SE, Buesinger ML and Massey RE, 2000. Efficacy and economics of weed management in glyphosate-resistant corn (Zea-Mays). Weed Technology, 14, 57-65.

Phipps RH and Park JR, 2002. Environmental benefits of genetically modified crops: global and European perspectives on their ability to reduce pesticide use. Journal of Animal and Feed Sciences, 11, 1-18.

USDA, 2015. Grain: World Markets and Trade. USDA, November edition, 1-56.

Williams GM, Kroes R and Munro IC, 2000. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. Regulatory Toxicology and Pharmacology, 31, 117-165.