MON 87460

Drought tolerant Maize

Key Facts

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MON 87460 – Drought tolerant maize

Maize, a key crop

After sugar cane, maize (*Zea mays*) is the second most frequently cultivated crop worldwide, followed by 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 2013-2014, approximately 988 million metric tons of maize were produced in the world. Significant areas of production included the US, China and Brazil, representing 35.6%, 22.12% and 8.03% 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 is a large importer of maize, importing 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 87460?

MON 87460 is the first genetically modified (GM) maize with drought-tolerant characteristics that reduces yield loss under water-limited conditions, developed by Monsanto in collaboration with BASF.

Under well-watered conditions, grain yield for MON 87460 is equivalent to conventional maize.

MON 87460 is a GM maize developed through *Agrobacterium*-mediated transformation of conventional maize variety embryos and encodes a cold shock protein B (CspB), derived from *Bacillus subtilis*, and NptII from Tn*5* of *Escherichia coli*. CspB is an extensively studied protein known to facilitate adaptation to environmental stresses in bacteria. CspB is an RNA chaperone, which are proteins that bind transiently and non-specifically with RNA to resolve kinetically trapped, misfolded conformers (Horn *et al.*, 2007; Rajkowitsch *et al.*, 2007). RNA chaperones are required for RNA unfolding to occur but not for the RNA to maintain its structure (Cristofari and Darlix, 2002). Under environmental stress, the CspB protein unfolds RNA structures that compromise the ability of the cell to translate those molecules, thereby helping to preserve the normal cellular functions (Graumann *et al.*, 1997; Schindler *et al.*, 1999). The NptII protein confers resistance to kanamycin, which was used to facilitate the selection process of transformed plant cells.

More information on MON 87460 can be obtained from the Center of Environmental Risk Assessment (CERA)[3] and the EuropaBio website[4].

Worldwide plantings and regulatory status of MON 87460

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).

MON 87460 has received regulatory approval for production in the US and Canada. MON 87460 also received regulatory approvals in Korea, Mexico, Japan, Colombia, Philippines, China, Australia, New Zealand and Taiwan for import[5].

A stringent regulatory system for genetically modified crops

In the EU, the regulatory system for GM crops comprises several directives and regulations, including Directive 2001/18/EC for deliberate release of genetically modified organisms (GMOs) in the environment and Regulation (EC) No 1829/2003 concerning GM food and feed.

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 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 authorisation of which has expired (Commission regulation (EU) No 619/2011) entered into force on 24 June 2011.

Regulatory status of MON 87460 in the EU

On 25 May 2009, Monsanto submitted an application for food and feed use of MON 87460 maize as any other maize (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA), via the Dutch Competent Authority. This application received the reference number EFSA-GMO-NL-2009-70 and was declared valid on 28 January 2010.

EFSA evaluated the application as well as additional information provided by Monsanto during the scientific review, scientific comments

[1] FAOSTAT - http://faostat.fao.org/site/339/default.aspx (Accessed on 6 May 2015)

[2] Index mundi - http://www.indexmundi.com/ (Accessed on 6 May 2015)

[3] CERA - http://cera-gmc.org/index.php?action=gm_crop_database&mode=ShowProd&data=MON87460&frmat=LONG (Accessed on 6 May 2015)

[4] EuropaBio - http://www.europabio.org/information-operators-product-information (Accessed on 6 May 2015)

[5] Crop Life International - http://www.biotradestatus.com/ (Accessed on 6 May 2015)

submitted by the EU Member States and relevant scientific publications.

On 15 November 2012, the EFSA published its Scientific Opinion (adopted 18 October 2012) (EFSA, 2012) for the placing on the market of genetically modified maize MON 87460. In its scientific opinion EFSA concludes that "*the maize MON 87460 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 its intended uses*"

The EFSA overall opinion, which fulfils the requirements of Articles 6 and 18 for the placing on the market of MON 87460, was published on 15 November 2012.

On 13 September 2013, the European Commission (EC) presented the Draft Commission Implementing Decision authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460, 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 21 October 2013. The Appeal Committee forwarded the draft decision to the EC with a recommendation for an approval. The authorization was finally granted by the EC on 24 April 2015 (Commission Decision, 2015).

Traceability, labelling, unique identifier

Operators importing, handling or using MON 87460 grain and derived foods and feeds in the EU should be informed of the legal obligations regarding traceability and labelling, laid down in Regulations (EC) No 1829/2003 and 1830/2003 and in the conditions of placing on the market of the consent (Commission Decision 2004/643/EC). The unique identifier of MON 87460 is MON-8746Ø-4.

In March 2009, a MON 87460-specific PCR-based detection method allowing the identification and quantification of MON 87460 was provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The validated methods, as well as the validation report for MON 87460, prepared by the CRL in collaboration with the European Network of GMO Laboratories (ENGL) were published on 2 February 2012 on the EURL website[6].

Food, feed and environmental safety of MON 87460

Food and feed safety

The food and feed safety assessment of MON 87460 was established based on:

- A detailed molecular characterization of the inserted DNA, where the results confirm the insertion of a single functional *cspB* and *nptII* expression cassette at a single locus within the maize genome;
- The history of safe use of the CspB and NptII proteins (EFSA, 2004);
- The CspB and NptII proteins have no structural similarity to known toxins, allergens or other biologically active proteins that could cause adverse effects in humans or animals;
- The lack of toxicity or allergenicity of the CspB and NptII proteins generally and as demonstrated with *in vitro* and *in vivo* safety studies, such as digestibility studies and acute toxicity studies in mammals;
- A large margin of safety resulting from the low dietary exposure to the introduced CspB and NptII proteins in MON 87460.

Compositional analyses showed that there are no biologically relevant differences in the characteristics of MON 87460 as compared with its conventional counterpart and that the composition fell within the range of non-GM maize varieties, except that MON 87460 expressed the CspB and NptII proteins.

In conclusion, MON 87460 was shown to be as safe and nutritious as conventional maize.

Further details on the safety of MON 87460 are available in EFSA's scientific opinion published on 15 November 2012 (EFSA, 2012).

Environmental safety

The environmental safety of MON 87460 was established through extensive laboratory and field testing of plant tissue or purified CspB and NptII 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 CspB and NptII proteins. Agronomic, morphological and pest susceptibility observations have been recorded in multiple field trials conducted across major maize growing regions of North and South America. Results of these trials confirm that MON 87460 is phenotypically equivalent to conventional maize except for its introduced drought tolerance trait. This demonstrates that MON 87460 poses negligible risk to human health or to the environment. Data on environmental interactions also indicate that MON 87460 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect, or abiotic stressors, or changes in agronomic and phenotypic characteristics.

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.

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

MON 87460, the benefits

MON 87460 provides the following benefits:

- Increasing maize yield stability under drought stress. This would have far reaching benefits, as limited water availability is the single most important factor that reduces global crop yields. In North America alone, it is estimated that 40% of annual crop losses are caused by sub-optimal water availability.
- This is the first biotech drought solution for agriculture focused on improving yield and consistency in water deficit environmental conditions.
- It is designed to help farmers mitigate the risk of yield loss when experiencing drought stress.
- It is the first product in a pipeline of yield and stress traits. The trait helps the maize plants to use less water when drought stress occurs. The plants acclimate to the stress more quickly and utilize water more efficiently, leaving them with more water to help through critical periods of growth.
- This hydro-efficiency can help the maize plants better endure challenging drought conditions and can help reduce yield loss caused by drought stress while at the same time being safe for humans and the environment.

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