NK603 × T25 maize

Glyphosate and glufosinate tolerance maize

Key facts

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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 NK603 × T25?

NK603 × T25 was obtained by traditional breeding of two independent genetically modified maize events, NK603 and T25. NK603 × T25 combines the traits of agronomic interest from the two parental lines, *i.e.* tolerance to the broad-spectrum herbicide glyphosate and tolerance to the broad-spectrum herbicide glufosinate ammonium. NK603 × T25, as well as the genetically modified parental maize event NK603 have been developed by Monsanto Company, whereas the genetically modified parental maize event T25 has been developed by Bayer CropScience. More information on the parental lines can be found on the EuropaBio website[3].

NK603 was developed through *Agrobacterium*-mediated transformation and is tolerant to glyphosate herbicide. It contains a gene (*epsps*) derived from *Agrobacterium* sp. strain CP4 that expresses EPSPS, an enzyme that is not rendered inactive by glyphosate and thereby confers tolerance to glyphosate herbicide.

T25 was developed through *Agrobacterium*-mediated transformation and is tolerant to glufosinate herbicide. It contains a gene (*pat*) derived from *Steptomyces viridochromogenes* that expresses PAT, an enzyme that rapidly acetylates glufosinate-ammonium rendering it inactive thereby conferring tolerance to glufosinate-based herbicides.

More information on this product can be obtained from the Center for Environmental Risk Assessment (CERA) GM Crop Database[4] and the EuropaBio website[5].

Worldwide plantings and regulatory status of NK603 × T25

In 2014, 181.5 million hectares of genetically modified (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 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).

NK603 × T25 has received regulatory approval for production in Canada, Brazil and the US. NK603 × T25 also received regulatory approvals for import in Colombia, Japan, Korea, Mexico, the Philippines and Taiwan[6].

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 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 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 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.

1 FAOSTAT - http://faostat.fao.org/site/339/default.aspx (Accessed on 04 December 2015)

2 Index mundi - http://www.indexmundi.com/ (Accessed on 04 December 2015)

3 EuropaBio - http://www.europabio.org/information-operators-product-information (Accessed on 04 December 2015)

4 CERA - http://www.cera-gmc.org/GMCropDatabase (Accessed on 04 December 2015)

5 EuropaBio - http://www.europabio.org/information-operators-product-information (Accessed on 04 December 2015)

6 ISAAA - http://www.isaaa.org/gmapprovaldatabase/ (Accessed on 04 December 2015)

Regulatory status of NK603 × T25 in the EU

On 17 May 2010, Monsanto submitted an application for import, food and feed use of NK603 × T25 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. The application received the reference number EFSA-GMO-NL-2010-80 and was declared valid on 12 October 2010. The EFSA evaluated the application as well as additional information provided by Monsanto during the scientific review, scientific comments submitted by the EU Member States and relevant scientific publications.

On 15 July 2015, the EFSA published a positive Scientific Opinion adopted on 24 June 2015 on the safety of NK603 × T25 (EFSA, 2015). The EFSA concluded that "*maize NK603 × T25, as described in this application, is as safe as its non-GM comparator and non-GM conventional maize varieties with respect to potential effects on human and animal health and the environment in the context of its scope*".

On 19 October 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 NK603 × T25, 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).

Regulatory status of the parental lines

NK603 and T25 are authorized in the EU for import, food and feed use as any other maize (excluding cultivation)[7].

Traceability, labelling, unique identifier

Operators importing, handling or using NK603 × T25 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. The unique identifier for this product is MON-ØØ603-6 × ACS-ZMØØ3-2.

In April 2010, NK603 × T25 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The EURL considers that the detection methods validated on the parental maize events, NK603 and T25, show a comparable performance when applied to NK603 × T25. The detection methods for NK603 and T25 had been previously validated by the EURL and were published at the EURL website on 10 January 2005 and 30 November 2011, respectively[8]. The validation report for NK603 × T25 was published on 30 April 2015 on the same website.

Food, feed and environmental safety of NK603 × T25

Food and feed safety

NK603 × T25 was obtained by traditional breeding of two independent genetically modified maize events, NK603 and T25. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental products are maintained in NK603 × T25.
- Safety assessment of the combined product, taking into consideration the safety of the parental products.

Molecular analysis of the DNA inserts present in NK603 × T25 confirmed that the insert structures of the parental maize events were retained. Also, the CP4 EPSPS and PAT protein levels in seed and forage of NK603 × T25 were comparable to the levels in the corresponding parental maize events.

The conclusions of safety of the CP4 EPSPS and PAT proteins, as already demonstrated in the context of the NK603 and T25, remain applicable when these proteins are expressed in combination in NK603 × T25. It is unlikely that when interactions between these proteins would occur, these raise any safety concerns. The EFSA concluded that "*The safety assessment identified no concerns regarding the potential toxicity of the newly expressed proteins CP4 EPSPS and PAT in maize NK603 × T25*" (EFSA, 2015).

Compositional analyses showed that the composition fell within the range of non-GM maize varieties, with exception of the intended CP4 EPSPS and PAT protein expression. The EFSA concluded that: "*compositional data of maize NK603 × T25, did not give rise to food/feed and environmental safety concerns*" (EFSA, 2015).

In conclusion, combining NK603 and T25 via traditional breeding does not lead to safety concerns, and like the parental lines, NK603 × T25 was shown to be as safe and nutritious as the conventional maize control.

Environmental safety

The environmental safety of NK603 × T25 was established through extensive laboratory and field testing of plant tissues conducted in the US in 2008 with materials that are representative of commercial maize production. These field trials demonstrated that NK603 × T25 poses negligible risk to human health or to the environment.

[7] **EU Register of authorised GMOs** http://ec.europa.eu/food/dyna/gm_register/index_en.cfm **(Accessed on** 04 December 2015**)**

[8] EU-RL GMFF - http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx (Accessed on 04 December 2015)

Results from the phenotypic and agronomic assessments demonstrate that NK603 × T25 does not possess characteristics that would confer a plant pest risk compared to conventional maize. Data on environmental interactions also indicate that NK603 × T25 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.

The herbicide tolerance traits in NK603 × T25 maize can be regarded as providing only a potential agronomic and selective advantage for this GM maize plant where and when glyphosate- and/or glufosinate-based 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 its scientific opinion on NK603 × T25, the EFSA concluded that: "*Potential interactions of maize NK603 × T25 with the biotic and abiotic environment were not considered a relevant issue*" (EFSA, 2015).

NK603 × T25, the benefits

NK603 × T25 provides the following benefits:

- It enables use of structured refuge and refuge-in-the-Bag (RIB) for products containing events tolerant to both glyphosate and glufosinate herbicides, ensuring effectiveness and durability of insect-protected products.
- It enables the use of seed blend, or Refuge-in-the-Bag technology, for Genuity® SmartStax® RIB Complete®[9] Corn Blend, the industry's first reduced refuge system for both above and below ground insect protection. Refuge percentage is reduced from 20% to 5%, the lowest in the US Corn Belt.
- It provides growers flexibility in choice of herbicide application by offering an additional weed control option prior to planting, at planting and after crop emergence.
- It helps maize growers maintain yields and quality necessary to meet the growing demands of the food, feed and industrial markets by providing an effective and sustainable management of economically-important herbicide-resistant weed species.
- It helps to preserve the environmental benefits of conservation tillage practices (reduced tillage/no-till). The combined glyphosate and glufosinate-tolerant technology will enable pre-plant and pre-emergence applications of glyphosate and glufosinate without a planting interval for effective control of glyphosate-resistant or glufosinate-resistant weeds in conservation tillage cropping systems. Conservation tillage systems 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, 2000)

[9] Genuity® SmartStax® RIB Complete® is a collaboration between Monsanto and Dow AgroSciences LLC.

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) 2015/2279 of 4 December 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (MON-ØØ6Ø3-6 × ACS-ZMØØ3-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. European Commission, L 322/58, 1-6.

EFSA, 2015. Scientific opinion on an application (EFSA-GMO-NL-2010-80) for the placing on the market of herbicide-tolerant genetically modified maize NK603 × T25 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal, 13 (7), 1-23.

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, 2000. 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), http://www.ctic.purdue.edu/CTIC/BiotechPaper.pdf,

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

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