MIR162 Maize
Syngenta Agrisure VIPTERA™

EU authorization for food, feed, import and processing

Information for Operators

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Syngenta MIR162 maize: Information for Operators

Introduction

This document summarizes the main characteristics of MIR162 maize and the requirements for post-market environmental monitoring of all operators handling viable grain from this product. It also includes references to the relevant detection methods and contact points for operators to report on general surveillance activities and on any unanticipated adverse effects.

Characteristics and benefits of MIR162 Maize

Maize is susceptible to attack by a variety of insects from the time it is planted until it is consumed as food or feed. Genetically modified event MIR162 maize has been developed by Syngenta to provide growers with maize hybrids that are resistant to feeding damage caused by a number of lepidopteran insect pests.

MIR162 maize contains a Vip3Aa protein from *Bacillus thuringiensis* that confers protection against infestations of *H. zea, S. frugiperda, A. ipsilon,* and *S. albicosta* larvae. MIR162 maize represents an environmentally sustainable and highly effective way to control these pests. This helps farmers improve productivity, secures and increases yields and improves the environmental footprint of modern agriculture.
MIR162 contains as a marker gene, the *pmi (manA)* gene from *Escherichia coli* which encodes phosphomannose isomerase (PMI) as a selectable marker protein. PMI allows transformed maize cells to utilize mannose as a sole carbon source, while maize cells lacking the *pmi* gene fail to grow with mannose as single carbon source.

The genes have been inserted into maize plants using modern biotechnology techniques and their effect is safe, targeted and reliable.

Safety of MIR162 Maize

The safety of Syngenta's products for humans, animals and the environment is of paramount importance. Even before any regulatory submissions were made, many years of research were conducted with MIR162 maize event.

MIR162 maize has been comprehensively and exhaustively analyzed for human health effects, digestibility, allergenicity and toxicity, environmental impact, and effects on mammals and non-target organisms.

MIR162 maize has been assessed and endorsed by numerous independent scientific committees around the world. These conclusions have been based on a full range of scientific studies, including tests which examined the potential for human and animal health effects of the products, nutritional equivalency, the effects of the introduced proteins and marker genes, and the potential impacts of the maize on the environment.

EFSA evaluation of MIR162 maize food, feed, import and processing application

The Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to deliver a scientific opinion on the authorization of MIR162 maize for

food and feed uses, import and processing. In June 2012, EFSA issued a positive scientific safety opinion, stating that:

"In conclusion, the EFSA GMO Panel considers that the information available for maize MIR162 addresses scientific issues indicated by the guidance documents of the EFSA GMO Panel and the scientific comments raised by the Member States, and that the maize MIR162, as described in this application, is as safe as its conventional counterpart and non-GM commercial varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses[1]."

Authorization in the EU of MIR162 maize

On 2 July 2010, Syngenta Seeds SAS submitted to the competent authority of Germany an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MIR162 maize. The application also covered the placing on the market of MIR162 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, with the exception of cultivation

The Commission decision of 18 October 2012 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is published at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:290:0014:0017:EN:PDF[2]

The following products are authorized for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from SYN-IR162-4 maize;
(b) feed containing, consisting of, or produced from SYN- IR162-4 maize;
(c) SYN-IR162-4 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

The Commission Decision does not include the need for specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

However, the Commission Decision mandates the monitoring for environmental effects in accordance with the environmental monitoring plan for maize MIR162 conforming with Annex VII of Directive 2001/18/EC. For more information, please visit the Community Register of GM Food and Feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

[1] EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on application (EFSAGMO-DE-2010-82) for the placing on the market of insect resistant genetically modified maize MIR162 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta. EFSA Journal 2012;10(6): [27 pp.].doi:10.2903/j.efsa.2012.2756. Available online: www.efsa.europa.eu/efsajournal.htm

[2] Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

Conditions for traceability and labelling of MIR162 maize in the EU.

No specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MIR162 maize. However, in order to ensure the use of the products within the limits of the authorisation provided, the labelling of feed containing or consisting of the GMO and products other than food and feed containing or consisting of the GMO for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

The Unique identifier assigned to MIR162 maize is: **SYN-IR162-4**

For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be '*maize*'.
The words '*not for cultivation*' shall appear on the label of and in documents accompanying products containing or consisting of SYN-IR162-4 maize with the exception of products referred to in point (a) of Article 2 of the authorization (foods and food ingredients containing, consisting of, or produced from SYN-IR162-4 maize).

Post Market Environmental Monitoring of MIR162 maize in the EU

The Decision does not require post market monitoring for the use of the food for human consumption. However as required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 a Post Market Environmental Monitoring Plan for Bt11xMIR604 maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

Since traders importing MIR162 maize into the EU may commingle it with other commercial maize, including the other authorised GM maize events, Syngenta is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology. In the framework of this cooperation, the selected networks of operators (COCERAL, UNISTOCK and FEDIOL) (European trade associations) will:

- Inform and remind their member organisations and companies on an annual basis:
  - to monitor for potential unanticipated adverse effects
  - that, in the framework of their management or safety standards (ISO, HACCP, …), procedures must be in place and implemented to limit losses and spillage of viable maize and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects

  - to inform and remind their own member companies of this requirement
  - to report back any adverse effect reported to them to the European trade associations
- Report to the authorisation holders directly or via EuropaBio
  - at least annually, regardless whether an adverse effect was observed or not
  - immediately any adverse effects reported to them.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL will notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio will forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission.

The Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC is publicly accessible on the internet at the Community Register of GM Food and Feed.
http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

Global Regulatory status of MIR162 maize

MIR162 maize is registered in the Biosafety Clearing House information exchange mechanism established by the Cartagena Protocol on Biosafety with the OECD unique identifier **SYN-IR162-4**.

MIR162 maize can be cultivated in Argentina, Brazil, Canada and the United States. Import of MIR162 maize is granted in the main importing countries of maize grain, including Australia/ New Zealand, Colombia, EU, Indonesia, Japan, Korea, Mexico, Philippines, Russia, Taiwan and Uruguay. An updated list of the global authorizations is maintained at the BIO trade website www.BIOTradeStatus.com.

Methods for detection

Event specific real-time quantitative PCR based methods for genetically modified MIR162 maize are validated by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

Reference Material AOCS 1208-A and AOCS 0407-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

Contact points for Operators

As there are other technology providers for genetically modified maize it is essential to develop an industry wide approach because the shipments entering the European ports may be comingled. EuropaBio, the European Association for Bioindustries, plays an important role in this area and is the central communication point for all GM plant technology providers.

EuropaBio is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio will transfer the messages to the relevant GMO industry partner if further action is required. Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to EuropaBio at: www.europabio.org/InfoOperators

If required, additional comments or questions relative to MIR162 maize can also be addressed to:

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