



## **GA21 Maize**

For tolerance to herbicide products containing  
glyphosate

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### Disclaimer

From Jan 1, 2021, all activities performed by EuropaBio mentioned  
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# GA21 Maize for tolerance to herbicides containing glyphosate

## Maize: an important crop

Maize, also known as corn, is one of the most important grain crops in the world. Globally, 144 million hectares are harvested annually. In 2006, the area of maize harvested in the EU was approximately 8.6 million hectares with a grain production of 55 million tonnes<sup>1</sup>. Over two-thirds of the world maize production is used directly as animal feed.

## GA21 maize

GA21 maize is a genetically modified (GM) maize expressing a protein which confers tolerance to herbicide products containing glyphosate. This protein, a modified 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) is produced from the *mepsps* gene which is nearly identical to the *epsps* gene from maize but is modified in a way that the gene product tolerates glyphosate. Modern biotechnology techniques were used in the production of the GA21 maize which offers growers a safe and effective way to control weeds.

## Herbicide tolerant maize - delivering alternative solutions

GA21 maize hybrids contain a genetically modified (GM) trait conferring the ability to withstand post-emergence applications of non-selective herbicide products containing glyphosate. Such herbicides provide excellent post-emergence broad-spectrum weed control. As a global leader in agriculture, we are committed to developing solutions, including those that utilize green biotechnology, which address the problems of today's growers.

Besides non-selective herbicides, selective herbicides continue to be a very important method of weed control in maize. Although the adoption of herbicide-tolerant cropping systems has grown in recent years, new selective herbicide products with improved profiles and greater effectiveness are providing grower benefits beyond just glyphosate. With the introduction of its own glyphosate-tolerant corn hybrids, Syngenta is able to expand agronomically sound weed control solutions based on products such as the TOUCHDOWN<sup>®</sup> family of products and a complete line of selective corn herbicides that deliver more complete solutions for our customers.

Syngenta fully supports integrated farming, in which the sustainable use of crop protection products, high quality seeds and GM traits play a significant part. Integrated farming encourages farmers to work in tandem with nature, enabling them to combine a range of farming practices with modern crop protection techniques without compromising yields. By paying closer attention to natural systems, farmers can merge a variety of old and new farming techniques in order to achieve what both consumers and policy makers increasingly demand: the production of sufficient, safe food with optimal respect for natural ecosystems. In this respect, GA21 maize provides an excellent tool to the farmer for weed control.

## GA21 maize: built-in protection

The EPSPS protein is found naturally in all plants, fungi, and bacteria but absent in animals. It has a very specific activity and it is involved in the production of certain amino acids (phenylalanine, tyrosine, tryptophan) which are essential components of proteins. The EPSPS protein is highly sensitive to herbicide products containing glyphosate, which inhibit the activity of the protein, leading to the death of the plants by rendering them unable to synthesize proteins. GA21 maize contains an additional version of the *epsps* gene which encodes for the introduced EPSPS protein. The gene was slightly modified (*mepsps*) to produce a protein which is no longer sensitive to glyphosate. Plants

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<sup>1</sup> <http://faostat.fao.org>: downloaded April, 2007

expressing this protein are therefore capable of being sprayed in the fields with herbicide products containing glyphosate.

The mEPSPS protein is over 99.3% identical to the protein produced in maize. This means that there are no additional factors that might cause concern in respect of health, safety or environmental impact.

## **Benefits of GA21 maize**

The outstanding glyphosate tolerance of GA21 maize provides growers with a valuable weed control tool. Glyphosate controls more than 100 annual and perennial species, including both small and large weeds. Glyphosate can be used alone (or as a mix) in a post-emergent program, or as a post-emergent application following a selective pre-emergence herbicide.

## **Sustainable agriculture**

Syngenta fully supports the principles of sustainable agriculture and believe them to be an essential part of our business strategy. This not only meets the needs of our customers and provides competitive advantage, it also ensures that productive profitable farming can continue whilst at the same time protecting and enhancing the environment. To achieve this, Syngenta is creating a Sustainable Agriculture friendly portfolio of technological solutions supported by appropriate knowledge and services and is building partnerships with our customers to support them in the practical implementation of sustainable agriculture.

## **Global regulatory status of GA21 maize**

GA21 is approved for cultivation in the USA, Canada, Argentina and Japan. It is approved for feed use in USA, Canada, Argentina, South Africa, Mexico, Japan, Philippines, Russia, the EU, Switzerland (specific processed products<sup>2</sup>), Taiwan, Korea and China, and for food use in USA, Canada, Argentina, Mexico, Japan, South Africa, Russia, the EU, Australia, New Zealand, Korea, Philippines, Taiwan and China.

## **Regulatory status of GA21 maize in the European Union**

Syngenta submitted a regulatory dossier in the European Union which covers the import of all products, including grain, derived from GA21. This file was submitted to the European Food Safety Authority (EFSA) under Regulation (EC) No 1829/2003 in July 2005, with the UK as the Rapporteur Member State. The European Food Safety Authority (EFSA) has reviewed the dossier and issued a positive recommendation, stating that "*maize GA21 is as safe as its non genetically modified counterparts with respect to potential effects on human health and animal health or the environment. Therefore the GMO panel concludes that maize GA21 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses*"<sup>3</sup>. Leading on from this positive opinion, the import of GA21 maize for all uses was approved under Regulation (EC) No 1829/2003 on 28<sup>th</sup> March 2008. The Commission decision relating to this approval (Decision 2008/280/CE) may be found in the Official Journal of the European Union<sup>4</sup>. GA21 has also previously received positive opinions from both the EU Scientific Committee on Plants on 22 September 2000<sup>5</sup>, and the EU Scientific Committee on Food on 27 February 2002<sup>6</sup>.

## **Tolerances in Switzerland**

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<sup>2</sup> Please see section "Tolerances in Switzerland" for further information

<sup>3</sup> The EFSA Journal (2007) 541, 1-25

<sup>4</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:087:0019:0022:EN:PDF>

<sup>5</sup> [http://europa.eu.int/comm/food/fs/sc/scp/out77\\_gmo\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/scp/out77_gmo_en.pdf)

<sup>6</sup> <http://europa.eu.int/comm/research/biosociety/pdf/opinion.pdf>

As part of the Swiss legislation, the approval of GA21 maize under the Regulation (EC) No 1829/2003 allows processed products to be used as feed in the form of maize gluten, maize gluten feed and cob flour in Switzerland<sup>7</sup>. In addition, a tolerance of 0.5% applies for the presence of GA21 maize in all other feed products (including viable grain) providing the presence is adventitious and below 0.5% (by weight)<sup>8</sup>.

## **Traceability and labelling**

In the European Union, the legal obligations relating to traceability and labelling are specified in the Regulation (EC) No 1839/2003. GM products derived from GA21 maize are required to be labelled according to this legislation. The unique identifier for GA21 maize is MON-ØØØ21-9.

## **Detection method**

An event specific detection method has been developed by Syngenta and validated by the DG-JRC-CRL (Joint Research Council) which can identify the presence of GA21 maize and differentiate it from other GM events. The detection method may be found on the DG-JRC-CRL website<sup>9</sup>

## **Certified Reference material**

Certified reference material prepared from GA21 maize may be found on the webpage of the American Oil Chemists Society webpage<sup>10</sup>.

## **Safety profile**

Many years of safety testing has been conducted with GA21 maize and the mEPSPS protein. These studies have been performed according to very strict safety assessment procedures developed through the cooperation of countries across the world. The assurance of safety and nutritional equivalence to conventional maize of GA21 maize for food and feed is based on a thorough assessment of the data from these studies. GA21 maize was determined to be as safe for food, feed, and the environment as conventional maize.

Syngenta recognizes that there is a great deal of public interest in the safety assessments of crops developed through the use of biotechnology. Therefore, the following sections describe some of the regulatory assessments for GA21 maize in more detail.

## ***Molecular biology and expression studies***

Studies have been undertaken to demonstrate that the inserted *mepsps* gene is expressed as expected, and that the level of mEPSPS protein is appropriate for the desired effect of herbicide tolerance. The data demonstrate that the mEPSPS protein is expressed in all parts of the plant, and that the expression levels are stable across many generations.

## ***Toxicology and potential for allergenicity***

The EPSPS protein is expressed in maize and is therefore ubiquitous in the environment. The mEPSPS protein expressed in GA21 maize is nearly identical to the EPSPS protein already expressed in maize - they differ in only 2 amino acids. Studies have been performed to specifically assess the safety of the mEPSPS protein and GA21 maize as food and feed. No adverse effects were observed in test animals, even at very high protein doses. GA21 maize was shown to have nutritional value equivalent to conventional maize and no adverse effects were observed in animals consuming this maize.

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<sup>7</sup> Please see Annex 1 of Ordinance 916.307.11: [http://www.admin.ch/ch/f/rs/916\\_307\\_11/app1.html](http://www.admin.ch/ch/f/rs/916_307_11/app1.html)

<sup>8</sup> Please see Ordinance 916.307, Art 21b: [http://www.admin.ch/ch/f/rs/916\\_307/a21b.html](http://www.admin.ch/ch/f/rs/916_307/a21b.html)

<sup>9</sup> <http://gmo-crl.jrc.it/summaries/GA21-WEB-Protocol%20Validation.pdf>

<sup>10</sup> [http://www.aocs.org/tech/crm/syngenta\\_corn.cfm](http://www.aocs.org/tech/crm/syngenta_corn.cfm)

The allergenicity potential of mEPSPS was also assessed. Data indicate that the mEPSPS protein, as expressed in GA21 maize, will be as readily digested as conventional dietary proteins. The mEPSPS protein is labile to heat, so it will be deactivated in food and feed products by standard processing and cooking methods. The amino acid sequence of the mEPSPS protein was compared to the sequences of known protein toxins and food allergens and it was determined that there were no similarities suggestive of toxic or allergenic potential for mEPSPS. The results of these and other, thorough assessments indicate that GA21 maize is as safe as conventional maize.

### ***Environmental risk assessment***

An environmental risk assessment has been conducted to evaluate the potential environmental impact resulting from the import of GA21 maize or derived products into the EU. The conclusions from this assessment show that the potential impacts on the environment arising from the import and use of GA21 maize can be considered as negligible as those from any other commercial conventional maize.

### **Global adoption of GM crops**

Since they were first made available 10 years ago, GM crops have been adopted at a very rapid rate around the world. A report authored by Dr. C. James of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) reported that the global area of transgenic crops had increased to a total area of 114 million hectares (282 million acres) in 2007. These crops were grown by 12 million farmers in 23 countries.

The rapid adoption rate of GM crops is due to the benefits they offer. Farmers in both developed and developing countries are today using biotechnology to reduce yield loss due to disease and insect damage and to control weeds. In the case of GA21 maize, growers generally improve the quality of their crop, which can directly benefit consumers.

### **Development of herbicide resistant weeds**

The overuse of any single weed control technology, in the absence of sound agronomic practices, opens the door to weed population shifts and/or herbicide resistance. This is why it is important to rotate or use multiple herbicide modes of action in any weed control system. GA21 provides growers with another choice of mode of action for effective weed control in corn, helping them meet weed resistance management guidelines. Syngenta continues to recommend the use of pre-emergence and post-emergence conventional chemistry treatments to avoid the potential for build up of resistant weed populations in corn and soybean rotations. This will help ensure the continued benefits of all weed management technologies.

Syngenta understands the threat of glyphosate resistance and therefore strives to preserve the full utility of this product for the benefit of agriculture. Reflecting this important commitment, Syngenta is the first glyphosate registrant to print glyphosate resistance management guidelines, or "Best Weed Management Practices" on our glyphosate herbicide labels<sup>11</sup>. In addition Syngenta has sponsored several conferences with University Extension personnel in the USA, to agree on how to raise awareness, provide guidance and encourage growers to act to sustain glyphosate usefulness for years to come. More information on recommended weed management practices can be found on the farm assist website<sup>12</sup>.

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<sup>11</sup> Syngenta Crop Protection Inc., "Preserving Land Value, No-Till and RR Crops: The growing importance of managing against herbicide resistance," 2004

<sup>12</sup> [http://www.farmassist.com/resistance\\_fighter/content.html](http://www.farmassist.com/resistance_fighter/content.html)

## Contact point 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: <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/introduction>.

If required, additional comments or questions relative to 5307 maize can also be addressed at:

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## Further reading

**James C. 2007.** Global status of commercialised biotech/GM crops: 2007. ISAAA Briefs No. 37 (<http://www.isaaa.org>).