Bt-11 Sweet Corn Update

March, 2004

Sweet Corn in Europe

While both fresh and processed sweet corn is very popular in the US and Asia, it is a relatively new vegetable in Europe. Over the last 25 years both consumption and production have constantly and consistently expanded. In Europe, sweet corn consumption is primarily canned or frozen sweet corn, although it is also eaten on the cob. In 2000, the annual per capita consumption of sweet corn by Western Europeans was 2,3 kilograms of sweet corn (fresh and processed). It is estimated that less than 80,000 hectares of sweet corn are grown in Western and Eastern Europe, combined.

Sweet corn and field maize are the same species, *Zea mays*. They are nearly identical genetically, except for slight changes in sweet corn that prevent the conversion of sugar to starch. The result is that sweet corn produces and retains large amounts of sugars in the kernels. Standard sweet corn contains about 10% sugar, and super-sweet varieties may contain up to 12% sugar. For comparison regular field maize varieties contain about 4% sugar.

Insect-Protected Bt Sweet Corn

Just as humans enjoy sweet corn, there are several insect pests that are highly attracted to sweet corn and of course the last thing a consumer wants to find when preparing fresh or canned vegetables is a worm. To help address this issue, Syngenta Seeds has developed insect resistance sweet corn varieties, which have been commercially available in the United States since 1998.

The mechanism that provides the insect protection is based on naturally occurring soil bacterium, *Bacillus thuringiensis*, known as Bt. This naturally occurring bacterium is found in soils around the world and has been used by farmers and organic gardeners alike.

The Bt sweet corn varieties were developed using conventional breeding methods and crossing to Syngenta Bt-11 maize.

Specific strains of *Bacillus thuringiensis* produce a protein, referred to as Bt protein, or Cry1Ab. When eaten by the European corn borer or corn earworm, two important sweet corn pests, the Bt protein is broken down by digestive enzymes in the larva's alkaline intestine, generating a shorter protein that binds to the wall of the intestine. This damages the cell membrane, making it leaky, and stops the larva in its tracks.

This is an important step forward for pest control because it allows the corn plant to protect itself from corn borers and earworms where they eat – inside the plant.

Figure 1: Bt and Non-Bt sweet corn in an unsprayed field. Left: Bt-protected sweet corn; Right: Unprotected non-Bt sweet corn with corn earworm

Why do we need Bt-protected sweet corn?

Bt is the active ingredient in sprays that have been used by farmers and gardeners for over 40 years. The mode of action is so specific that, while these sprays are very effective against the corn borer and earworm, in general they have no effect on non-target insects and are safe for humans and animals. Bt breaks down rapidly in the environment and, as it is naturally occurring, the sprays are accepted for use in organic farming systems.

However, the spray has one main limitation. The corn borer and corn earworm moths lays eggs on the outside of the plant but, once they hatch, the larvae eat into the plant, destroying it as they go. Once inside the stem or ear of the plant, the larvae cannot be touched by insecticide sprays or other control methods. Therefore, farmers have to carefully monitor their crops and hope the weather won't prevent spraying during the time period when larvae are outside the plant.

Compared to traditional insect control methods, Bt-protected sweet corn provides farmers with more targeted control of insect pests and potentially reduce the number of measures required to control insects.

Bt-11 sweet corn: mode of action

Bt sweet corn's built-in protection against corn borers and corn earworms has been achieved through modern biotechnology, where two additional genes have been added:

- A synthetic Bt gene (*Cry1Ab*), which was derived from the common soil bacterium *Bacillus thuringiensis*, widely used as a biological control agent against various insect pests. The presence of the Bt protein (Cry1Ab) protects the plant from insect damage.
- A marker gene, (called *pat*), which gives the plant a tolerance to phosphinothricine, the active ingredient of glufosinate ammonium herbicides. This gene is derived from the soil bacterium *Streptomyces viridochromogenes*. The herbicide tolerance gene allowed selection of transformed plants in the development stage and although it is present in plants, glufosinate ammonium herbicides are not registered for use with Bt sweet corn.

Bt-11 insect-protected sweet corn produces the Bt protein in its leaves, silks, stalks and ears throughout its life, enabling it to provide season-long protection against these devastating insect pests. Details on these inserted genes can be found at: http://www.essentialbiosafety.info/main.php.

Regulatory status of Bt-11 sweet corn in the European Union

Food use

Syngenta submitted a regulatory dossier, for the marketing of Bt sweet corn as food, under the Novel Food Regulation in November 1998, through the Netherlands as the Rapporteur Member State.

As part of the review of Syngenta Bt-11 sweet corn for food use under the Novel Food Regula-

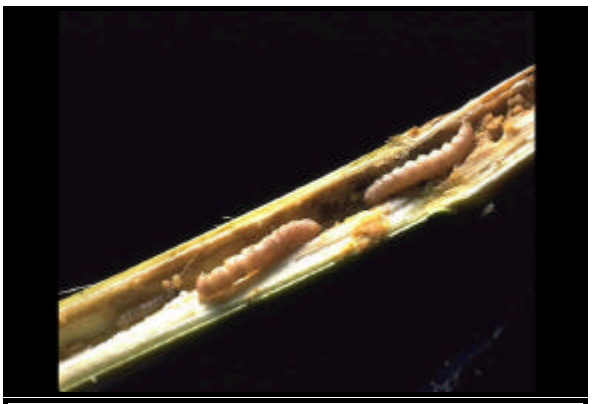

Figure 2: European Corn Borer (ECB) feeding on a maize stem

tion, the European Union (EU) Scientific Committee on Food (SCF) adopted an opinion on the safety of Bt-11 sweet corn on April 17, 2002. The opinion concluded:

"*Bt-11 sweet maize is as safe for human food use as its conventional counterparts*." (http://europa.eu.int/comm/food/fs/sc/scf/out129_en.pdf)

This decision marked the end of the scientific review of the file and acknowledges the safety of genetically enhanced Bt-11 sweet corn. It also reflects the opinion of several other regulatory authorities worldwide, and the experiences in countries in which Bt sweet corn is already approved.

The European Commission then drafted a proposal for a decision, which was considered by the EU Standing Committee on the Food Chain and Animal Health (also referred to as the Regulatory Committee), on which each Member State has a representative. The Regulatory Committee voted on December 8, 2003, but did not reach a qualified majority in favor of the approval of Bt-11 sweet corn for food use in the EU. As the next step in the regulatory process, the European Commission sent the file to the Council of Ministers for their consideration in January 2004.

If the European Union authorities approve Syngenta Bt-11 sweet corn, it would be possible to sell Bt sweet corn as food in the European Union. Sale and purchase of food products containing Bt-11 sweet corn would be subject to consumer demand. Any such Bt-11 sweet corn would have to be clearly labeled.

This approval would also allow the adventitious, or unintended, presence of trace amounts of Bt-11 sweet corn in conventional sweet corn products, up to 0.9 percent without the requirement for labeling, subject to Regulation No 1830/2003 on Traceability and Labelling.

The food clearance permit will not allow any cultivation of Bt-11 sweet corn in EU.

Cultivation

Syngenta has submitted an additional regulatory dossier to the European Union, which covers cultivation of both Bt-11 field maize and sweet corn. This file was submitted in May 1996, with France as the Rapporteur Member State under Directive 90/220/EEC (Deliberate Release of Genetically Modified Organisms into the Environment). This was replaced by Directive 2001/18/EC. Syngenta updated the Bt-11 maize cultivation file to meet the new requirements of Directive 2001/18/EC in January 2003. As the next step in the process, the file will be forwarded to the European Food Safety Authority.

Global regulatory status of Bt-11 sweet corn

Bt-11 sweet corn was first approved in the US and Canada in 1998. Since then, it has been approved for cultivation in Argentina, Japan, and South Africa.

Table 1: Global regulatory status of Bt-11 sweet corn

Country	Approval
USA	Cultivation
Canada	Cultivation
Argentina	Cultivation
South Africa	Cultivation
Japan	Cultivation
Switzerland	Import
Australia	Import
New Zealand	Import
The Philippines	Import
Korea	Import

Additionally, it has been approved for food use in Argentina, Switzerland, Australia, New Zealand, Japan, the Philippines, Korea, and South Africa.

Global regulatory status of Bt-11 field maize

Bt-11 field maize is approved for food use and for cultivation in the United States, Canada, Argentina, Japan and South Africa. It is approved for import for food use in the European Union, Switzerland, Australia, Korea, New Zealand, Taiwan, the Philippines and China.

European Union

As noted above, Syngenta has submitted another regulatory file to the European Union for the cultivation of Bt-11 maize, including Bt-11 filed maize and Bt-11 sweet corn. This file was

submitted to France as the Rapporteur Member State in 1996 and was forwarded to the other Member States in 1999.

On 30 November 2000, the European Union (EU) Scientific Committee on Plants (SCP) adopted an opinion on the safety of Syngenta (then Novartis) genetically enhanced Bt-11 maize. The opinion concluded:

"*The Committee is of the opinion that there is no evidence to indicate that the placing on the market for cultivation purposes of maize line Bt-11 and varieties derived from this line by conventional crossing with maize lines other than genetically modified ones, is likely to cause adverse effects on human health and the environment.*" (http://europa.eu.int/comm/food/fs/sc/scp/out86_gmo_en.html)

The file was updated to the new directive in January 2003. Review of the updated file by Member States was completed in September 2003. Syngenta has submitted responses to questions from the Member States regarding the scientific review. As the next step in the process, the file will be reviewed by the European Food Safety Authority. At the completion of the scientific review, the European Commission may draft a Decision, which will be presented to the Regulatory Committee for an opinion. The Regulatory Committee is composed of representatives of Member States. If the Regulatory Committee votes to accept the decision by a qualified majority, then the European Commission would allow the product to be placed on the market.

If Bt-11 maize were approved for cultivation, it would be possible to grow Bt-11 maize (both field and sweet corn) in the European Union. However, before Bt-11 field maize could be grown in the EU, varieties must be registered.

Variety registration in the EU requires evidence that the variety is distinguishable, stable, and homogenous; as well as agronomic tests that demonstrate it improves yields. This process may take up to several years. There are no variety registration requirements for sweet corn in the EU.

Regulatory framework for genetically modified crops in the EU

The strict regulation of genetically modified crops in the EU is accomplished through a combination of several Regulations and Directives, including Directive 2001/18/EC for deliberate release of GMOs in the environment (repealing Directive 90/220/EEC) and Regulation (EC) No 258/97 on novel foods and novel food ingredients.

Figure 3: On 18 April 2004, the marketing of GMOs in food will be covered by the new Regulation (EC) No 1829/2003.

The main legislation that covers the marketing of GMOs as food in the EU is Regulation (EC) No 258/97 on Novel Foods and Food Ingredients (Novel Food Regulation), adopted on 27 January 1997. The Novel Food Regulation establishes guidelines for authorization and labeling of novel foods including food products that contain, consist of, or are produced from GMOs. On 18 April 2004, the GM portion of the regulation will be replaced with the new Regulation (EC) No 1829/2003. This Regulation will not impose any new safety assessments for GM crops.

Additionally, the new labelling and traceability Regulation (EC) 1830/2003 for GM food and feed extends labeling to feed, sets the threshold for adventitious presence to 0.9% and bases labelling according to the origin of the GM content, rather than the actual presence of detectable GM content in the product.

Food approval of Bt-11 sweet corn

Countries across the world have worked together to develop very strict food safety assessment procedures. The safety of Bt-11 sweet corn for food was established based on a thorough assessment of the data. In addition to the data available on Bt sweet corn, the risk assessment also considered data available on Bt field maize.

The safety of Bt-11 sweet corn for use as food has been demonstrated by:

- Digestibility studies
- Toxicity studies
- Allergenicity studies

Bt-11 sweet corn composition and nutritional

value is comparable, or substantially equivalent, to non-Bt sweet corn, as demonstrated by an analysis of key nutrients.

These included:

- Fat
- Amino acids
- Proteins
- Fatty acids
- Carbohydrates
- Minerals
- Moisture content

The Scientific Committee on Food concluded:

"Bt11 sweet maize kernels are substantially equivalent to non-transformed lines" (http://europa.eu.int/comm/food/fs/sc/scf/out129_en.pdf)

Additionally, the data for Bt-11 field maize was considered in the safety evaluation. The extensive evaluation of Bt-11 sweet corn, and the long history of safe use in many countries, have demonstrated that Bt-11 sweet corn is as safe and nutritious as non Bt-sweet corn.

Consumer acceptance of Bt sweet corn

Should Bt sweet corn be approved for food use in the European Union, products containing more than 0.9% Bt sweet corn would be required to be labelled according to the new Labelling and Traceability legislation. Therefore, the sale and purchase of Bt sweet corn would be subject to consumer demand and acceptance.

A recent publication by researchers at the University of Guelph, Canada, led by Dr. Powell, reported the results of consumer acceptance and purchasing preference for labelled Bt sweet corn compared to conventionally grown sweet corn. According to the authors:

"Bt sweet corn sales were consistently higher than regular sweet corn sales."

While the consumer response varied in follow-up surveys, consumers frequently cited a preference for the Bt sweet corn due to the reduced inputs required by the grower to control insect damage, compared to conventional sweet corn.

Benefits of Bt sweet corn

For growers, Bt sweet corn represents an environmentally sustainable and economical way to control insect pests and, therefore, to ensure yield. For consumers, Bt sweet corn offers another choice, a product that has the potential to reduce the number of insect control measures needed to ensure a high quality product.

Global adoption of GM crops

Since they were first made available almost 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 grew 15% in 2003 over the total area in 2002, to 67.7 million hectares (167 million acres). These crops were grown by seven million farmers in 18 countries.

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

Further reading

European Commission Scientific Committee on Food. 2002. Opinion of the Scientific Committee on Food on a request to place genetically modified sweet maize line Bt11 on the market. Opinion expressed on 17 April 2002. (http://europa.eu.int/comm/food/fs/sc/scf/out129_en.pdf)

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erant (Bt-11) maize for cultivation. Opinion adopted on 30 November 2000. (http://europa.eu.int/comm/food/fs/sc/scp/out86_gmo_en.html)

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James C. 2003. Global review of commercialised transgenic crops: 2002 feature: Bt maize. ISAAA Briefs No. 29. (http://www.isaaa.org)

Wilson DA, Blaine K, Morris S, and Wilson J. 2003. Agronomic and consumer considerations for Bt and conventional sweetcorn. British Food Journal. 105(10): 700-713.

In the United States, Bt-11 sweet corn is marketed under the Rogers® trademark Attribute®. To read more about Attribute sweet corn, please visit the Rogers website: http://www.rogersadvantage.com/products/corn.asp

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