GM Food/Feed Safety Assessment: ANTIGUA AND BARBUDA

Safety Assessment for Foods and Animal Feeds Derived from Genetically Modified, Insect-Resistant Maize MON810

Summary of findings

Based on an assessment of available information from developed and developing countries, Maize variety MON810 appears to be as safe as its non-genetically modified counterparts. The allergenicity and toxicity of MON810 has not been increased nor has its nutritional content been significantly changed as a result of the genetic modification process, when compared with conventional, non-GM maize varieties.

Introduction

MON810 is a genetically modified (GM) variety of maize, developed by the Monsanto Company. The genetic modification enables MON810 plants to produce a protein called Cry1Ab. The gene responsible for the production of Cry1Ab is found in a common soil bacterium, *Bacillus thuringiensis* [1]. *Bacillus thuringiensis* produces hundreds of proteins that are toxic to different types of insects, and the bacterium has been used in both conventional and organic agriculture for more than fifty years to control insect pests on crops [1–7]. Cry1Ab is one of these proteins, and it is specifically toxic to the larvae (caterpillars) of lepidopteran insects, that is, butterflies and moths. When a caterpillar consumes Cry1Ab, the digestive systems of the caterpillar is disrupted, the insect stops eating, and it eventually dies [8–10]. Several lepidopteran insects, while in their caterpillar stage of development, are serious pests of maize, including the European Corn Borer (ECB) [1], and they cause large losses to farmers if they are not controlled. MON810 produces Cry1Ab in its leaves and other tissues, and when ECB caterpillars eat those

tissues from the MON810 plant, they also consume Cry1Ab, which kills the caterpillars. MON810 is therefore more resistant to attack by, and damage from, ECB caterpillars.

MON810 is grown is many countries worldwide, and it has been available to international grain markets for many years and has been traded extensively [11]. Table 1 provides a list of all countries that have approved the use of MON810 in food.

Table 1: Approvals for use of MON810 in food by country [12]

Country	Year of Approval
Argentina	1998
Australia	2000
Brazil	2007
Canada	1997
China	2002
European Union	1998
Japan	2001
Malaysia	2010
Mexico	2002
New Zealand	2000
Paraguay	2012
Philippines	2002
Russian Federation	2009
Singapore	2014
South Korea	2002
Switzerland	2005
Taiwan	2002
United States	1996
Uruguay	2003
Vietnam	2015

In addition, many hybrid maize varieties have MON810 in their pedigree, to take advantage of the insect-resistance trait, and these varieties are also widely traded. As an importer of maize from the international market, Antigua and Barbuda acknowledges the possibility that MON810 or varieties derived from MON810 may be imported inadvertently.

Our Biosafety Policy states that the government of Antigua and Babuda has a duty to ensure its citizens that the food supply is safe. As for foods derived from GM crops, the government has a duty to ensure its citizens that such foods are as safe and nutritious as foods derived from non-GM crops. The government therefore undertook the assessment of safety of foods derived from MON810 maize based on an academic assessment of information available from developed and developing countries, and the results of that assessment are presented herein.

Scope of assessment

According to CODEX [13,14] food safety assessments are to be done in a comparative way, that is, comparing the food or food ingredient derived from a GM organism to the same food or ingredient derived from a non-GM counterpart [15,16]. The comparison required by the CODEX guidelines includes an evaluation of intended and unintended effects, new and altered hazards, specifically toxicity and allergenicity, and nutritionally significant changes in composition [17–23]. The scope of this comparison comprises four key questions:

1. Does the GM-version of the food contain new toxins or increased levels of existing toxins, compared to the non-GM version of the food
2. Does the GM-version of the food contain new allergens, compared to the non-GM version of the food?

3. Does the GM version of the food differ in nutritional content from the non-GM version of the food to the extent that there will be significant impacts on the human diet?
4. Are there any general safety issues regarding the GM organism?

This assessment will discuss each of these four questions in order.

Potential Toxicity

The Cry1Ab protein has been well studied and thoroughly characterized, and the consensus view of scientists and regulatory authorities is that the biological activity of Cry1Ab is limited to insecticidal effects on a limited number of insects, specifically lepidopteran insects (butterflies and moths) [24–31]. This specificity is due to an interaction between the Cry1Ab protein and a receptor that exists only in the digestive tracts of lepidopteran insects. For humans and animals, which lack this receptor, Cry1Ab acts like any other protein that is consumed—it is broken down and digested harmlessly.

Furthermore, bioinformatic studies, which compared the amino acid sequence of Cry1Ab to the amino acid sequences of known toxic proteins, indicate that Cry1Ab has no relevant sequence similarity to proteins known to be toxic to humans. Additionally, Cry1Ab has been assessed for acute toxicity using several species of animals, and no indications of oral toxicity have been found [32].

From these data, the government of Antigua and Barbuda concludes that MON810 has no apparent new or increased levels of toxins, when compared to non-GM varieties of maize.

Potential Allergenicity

Allergenic proteins tend to resist digestion by gastric fluids in the stomach, but laboratory studies have indicated that Cry1Ab is quickly degraded in simulated gastric fluids [20,33,34]. In addition, bioinformatic studies, which compared the amino acid sequence of Cry1Ab to the amino acid sequences of known allergenic proteins [20], indicate that Cry1Ab has no relevant sequence similarity to proteins known to cause allergic reactions in humans. Laboratory experiments have confirmed that Cry1Ab is not allergenic [23,26,27,30,31,35–44].

From these data, the government of Antigua and Barbuda concludes that MON810 has no new apparent allergens, compared with non-GM varieties of maize.

Potential Changes in Nutritional Composition

The nutritional composition of MON810, grown under a variety of environmental conditions and geographic locations, has been thoroughly evaluated. These studies have determined that the nutritional composition of MON810, like the composition of all conventional maize varieties that have been similarly evaluated, varies depending on climate conditions and geographic location [45–48]. However, the levels of nutritional components of MON810 are within normal ranges for maize, regardless of the growing conditions [25–27,30,31]. In addition, numerous feeding studies, in which MON810 was fed to chickens, cows, and salmon, have indicated that MON810 is nutritionally equivalent to non-GM maize [49–67].

From these data, the government of Antigua and Barbuda concludes that MON810 is apparently nutritionally equivalent to non-GM maize.

General Safety Issues

There is a long history of safe use of *Bacillus thuringiensis*, in conventional and organic agriculture, as well as in dozens of insect-resistant GM crops. GM crops expressing one or more insecticidal proteins from *Bacillus thuringiensis* have been safely grown in many countries for twenty years, and food derived from these crops has been consumed safely by humans and livestock for an equal amount of time [68].

In addition, there is no evidence that any changes, other than the insertion of DNA necessary for the expression of the Cry1Ab protein, have occurred. This insertion has been demonstrated to be stable, and no apparent unintended effects of the genetic modification have been found [24,27,30].

Conclusions

The consensus of scientific studies and regulatory decisions in other countries indicate that MON810 has no new toxins or allergens, no increased levels of endogenous toxins, and no nutritionally significant differences when compared to non-GM maize varieties. Therefore, the government of Antigua and Barbuda (based on an academic assessment of information available from developed and developing countries) concludes , in principle, that MON810 is as safe in the food supply of Antigua and Barbuda as its non-GM counterparts.

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