GM Food/Feed Safety Assessment: ANTIGUA AND BARBUDA

Safety Assessment for Foods and Animal Feeds Derived from Genetically Modified, Glyphosate-Tolerant Soybean GTS 40-3-2

Summary of findings

Based on an assessment of available information from developed and developing countries, Soybean variety GTS 40-3-2 appears to be as safe as its non-genetically modified counterparts. The allergenicity and toxicity of GTS 40-3-2 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 soybean varieties.

Introduction

Most plants, including soybean, produce a protein called EPSPS, which is essential for the biosynthesis of certain amino acids. When the herbicide glyphosate is sprayed on plants, it specifically inhibits the activity of EPSPS, thereby killing those plants. GTS 40-3-2 is a genetically modified (GM) variety of soybean, developed by the Monsanto Company. The genetic modification enables GTS 40-3-2 plants to produce a new protein called CP4 EPSPS. The gene responsible for the production of CP4 EPSPS is found in a common soil bacterium, *Agrobacterium tumefaciens* strain CP4[1]. The CP4 EPSPS protein is very similar to the EPSPS produced by soybean plants, but it is not affected by glyphosate, and therefore GTS 40-3-2 is not affected by glyphosate. This property allows farmers to spray glyphosate on their soybean fields to control weed plants without harming the soybean crop[2].

GTS 40-3-2 is grown is many countries worldwide, and it has been available to international grain markets for many years and has been traded extensively[3]. Table 1 provides a list of all countries that have approved the use of GTS 40-3-2 in food.

Table 1: Approvals for use of GTS 40-3-2 in food by country[4]

Country	Year of Approval
Argentina	1996
Australia	2000
Bolivia	2005
Brazil	1998
Canada	1996
China	2002
Colombia	2005
European Union	2005
Indonesia	2011
Japan	2001
Malaysia	2010
New Zealand	2000
Paraguay	2004
Philippines	2003
Russian Federation	2007
Singapore	2014
South Korea	2002
Switzerland	1996
Taiwan	2002
United States	1995
Uruguay	1996
Vietnam	2015

In addition, many hybrid soybean varieties have GTS 40-3-2 in their pedigree, to take advantage of the glyphosate-tolerance trait, and these varieties are also widely traded. As an importer of soybean from the international market, Antigua and Barbuda acknowledges the possibility that GTS 40-3-2 or varieties derived from GTS 40-3-2 may be imported inadvertently.

Our Biosafety Policy states that the government of Antigua and Barbuda 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 GTS 40-3-2 soybean 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[5,6] 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[7,8] This comparison includes an evaluation of intended and unintended effects, new and altered hazards, specifically toxicity and allergenicity, and nutritionally significant changes in composition[9–13]. 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 CP4 EPSPS protein has been well studied and thoroughly characterized, and the consensus view of scientists and regulatory authorities is that the biological activity of CP4 EPSPS is limited to the biosynthesis of the three amino acids: phenylalanine, tryptophan, and tyrosine[1]. Because the non-GM EPSPS protein is ubiquitous in plants and microorganisms, humans and livestock are routinely exposed to this protein in the food and feed supply, and there is thus a long history of safe exposure to this protein[14]. Furthermore, bioinformatic studies, which compared the amino acid sequence of CP4 EPSPS to the amino acid sequences of known toxic proteins, indicate that CP4 EPSPS has no relevant sequence similarity to proteins known to be toxic to humans[15–18]. Additionally, CP4 EPSPS has been assessed for acute toxicity using several species of animals, and no indications of oral toxicity have been found[1,15,17–22].

From these data, the government of Antigua and Barbuda concludes that GTS 40-3-2 has no apparent new or increased levels of toxins, when compared to non-GM varieties of soybean.

Potential Allergenicity

Allergenic proteins tend to resist digestion by gastric fluids in the stomach, but laboratory studies have indicated that CP4 EPSPS is quickly degraded in simulated gastric fluids[12,17,21,23–25]. In addition, bioinformatic studies, which compared the amino acid sequence of CP4 EPSPS to the amino acid sequences to known allergenic proteins, indicate that CP4 EPSPS has no relevant sequence similarity to proteins known to cause allergic reactions in humans[17,20,26–28]. Laboratory experiments have also confirmed that CP4 EPSPS is not allergenic[17,20,26–28] and that GTS 40-3-2 soy does not have altered endogenous allergens[29].

From these data, the government of Antigua and Barbuda concludes that GTS 40-3-2 has no new apparent allergens, compared with non-GM varieties of soybean.

Potential Changes in Nutritional Composition

The nutritional composition of GTS 40-3-2, grown under a variety of environmental conditions and geographic locations, has been thoroughly evaluated. These studies have determined that the nutritional composition of GTS 40-3-2, like the composition of all conventional soybean varieties that have been similarly evaluated, varies depending on climate conditions and geographic location. However, the levels of nutritional components of GTS 40-3-2 are within normal ranges for soybean, regardless of the growing conditions[1,15,17,18,20,30,31]. In addition, numerous feeding studies, in which GTS 40-3-2 was fed to chickens, cows, swine, goats, catfish, and salmon, have indicated that GTS 40-3-2 is nutritionally equivalent to non-GM soybean[19,21,27,32–42].

From these data, the government of Antigua and Barbuda concludes that GTS 40-3-2 is apparently nutritionally equivalent to non-GM soybean.

General Safety Issues

There is a long history of safe exposure to both the EPSPS protein in non-GM plants and to the CP4 EPSPS from *Agrobacterium tumefaciens.* In addition, GM crops expressing CP4 EPSPS 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[1,14,43].

In addition, there is no evidence that any changes, other than the insertion of DNA necessary for the expression of the CP4 EPSPS protein, have occurred. This insertion has been demonstrated to be stable, and no apparent unintended effects of the genetic modification have been found[18,20,44].

Conclusions

The consensus of scientific studies and regulatory decisions in other countries indicate that GTS 40-3-2 has no detectable new toxins or allergens, no increased levels of endogenous toxins, and no nutritionally significant differences when compared to non-GM soybean 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 GTS 40-3-2 is as safe in the food supply of Antigua and Barbuda as its non-GM counterparts.

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