Implementing National Biosafety Frameworks in the Caribbean Sub-Region

Saint Lucia Document Concerning the Safety Assessment for Foods and Animal Feeds Derived from Genetically Modified Glyphosate-Tolerant Soya bean GTS 40-3-2

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FOREWORD

This introduction serves as an explanation of the purpose and method of preparation of the following food/feed safety assessment document for glyphosate-tolerant soybean variety GTS 40-3-2. The document represents a food/feed safety assessment prepared for a GM crop variety that has been extensively traded internationally, and for which there is both a long history of safe use in food and feed and a breadth of regulatory decisions analysing its safety.

The document uses an approach for food/feed safety assessment that is consistent with CODEX and is based on scientific data that is publicly available and has been thoroughly evaluated by several countries, including Australia/New Zealand, Canada, the European Union, and the United States. The focus of the assessment is whether there are any significant differences between the GM crop variety and conventional varieties of the same crop that would raise significant food safety concerns. The data that has been reviewed in the preparation of this document pertain to the three primary concerns outlined in CODEX guidelines: (a) presence of new toxins or elevated levels of endogenous toxins; (b) presence of new allergens; and (c) nutritional equivalence. Data addressing these three issues has been included in the assessment document or summarized as appropriate.

As provided here, this food/feed safety assessment document may be used in support of regulatory decision making as to GTS 40-3-2. In addition, it may serve as a model in the preparation of other safety assessment documents concerning GM varieties with a similarly long history of safe, international use.

SUMMARY OF FINDINGS

The Government of Saint Lucia has determined that soya bean variety GTS 40-3-2 is 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 soya bean varieties.

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INTRODUCTION

Most plants, including soya bean, produce a protein called 5-enolpyruvylshikimate-3-phosphate synthase (*EPSPS*), which is essential for the biosynthesis of certain amino acids[1, 2]. 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 soya bean, 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[3]. The *CP4 EPSPS* protein is very similar to the *EPSPS* produced by soya bean 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 soya bean fields to control weed plants without harming the soya bean crop[4].

GTS 40-3-2 received its first regulatory authorisation for use in food and feed in 1995, and to date, a total of 22 countries have authorised food/feed use. 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[5]. Appendix 1 provides a list of all countries that have approved the use of GTS 40-3-2 in food.

In addition, many hybrid soya bean 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 soya bean from the international market, the Government of Saint Lucia acknowledges the possibility that GTS 40-3-2 or varieties derived from GTS 40-3-2 may be imported inadvertently.

The Government of Saint Lucia is committed to the protection of human and environmental health through the establishment of transparent and ethical systems, in keeping with international obligations. In the context of 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 soya bean, and the results of that assessment are presented herein.

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SCOPE OF ASSESSMENT

According to Codex Alimentarius[6, 7] 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[8–10]. 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[11–17]. 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

Unprocessed soya beans are known to contain high levels of trypsin inhibitor which has anti-nutritional properties. However, a significant proportion of the trypsin inhibitor is destroyed by heat treatment[18]. The *CP4 EPSPS* protein has been well studied and thoroughly characterised, 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[3]. As 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[19]. 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[20–23]. Additionally, *CP4 EPSPS* has been assessed for acute toxicity using several species of animals, and no indications of oral toxicity have been found[3, 20–26].

From these data, the Government of Saint Lucia concludes that GTS 40-3-2 has no new or increased levels of toxins, when compared to non-GM varieties of soya bean.

Potential Allergenicity

Soya bean is known to have several naturally occurring allergenic proteins. The presence and the relative levels of the endogenous allergenic proteins in all tested control and GTS 40-3-2 soya bean preparations were found to be comparable, indicating that the endogenous allergenic proteins were not altered during production of glyphosate–tolerant soya bean line 40–3–2[23]. 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[14, 21, 23, 25, 27–29]. In addition, bioinformatic studies, which compared the amino acid

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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[21, 23, 30–32]. Laboratory experiments have also confirmed that *CP4 EPSPS* is not allergenic[21, 23, 30–32] and that GTS 40-3-2 soy does not have altered endogenous allergens[33].

From these data, the Government of Saint Lucia concludes that GTS 40-3-2 has no new allergens, compared with non-GM varieties of soya bean.

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 soya bean varieties that have been similarly evaluated, varies depending on climate conditions and geographic location, but none of these variations are nutritionally significant. The levels of nutritional components of GTS 40-3-2, including proximates (See Appendix 2), amino acids, fatty acids, anti-nutrients, and isoflavones, are within normal ranges for soya bean, regardless of the growing conditions[3, 20–23, 34–37]. In assessing the safety of a genetically modified food, a key factor is the need to establish that the food is nutritionally adequate and will support typical growth and well-being of the consumer. Carefully designed feeding studies in animals may provide further reassurance that the food is nutritionally adequate. 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 soya bean[24, 25, 31, 38–48].

From these data, the Government of Saint Lucia concludes that GTS 40-3-2 is nutritionally equivalent to non-GM soya bean.

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[3, 19, 49].

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 unintended effects of the genetic modification have been found[2, 22, 23].

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 soya bean varieties. Therefore, the Government of Saint Lucia concludes that GTS 40-3-2 is as safe in the food supply as its non-GM counterparts.

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Appendix 1: Approvals* for use of GTS 40-3-2 in food by country[50]

Country	Year of Approval
Argentina	1996
Australia[23]	2000
Bolivia	2005
Brazil	1998
Canada[20]	1996
China	2002
Colombia	2005
European Union[2]	2005
Indonesia	2011
Japan	2001
Malaysia	2010
New Zealand[23]	2000
Paraguay	2004
Philippines	2003
Russian Federation	2007
Singapore	2014
South Korea	2002
Switzerland	1996
Taiwan	2002
United States of America[35]	1995
Uruguay	1996
Viet Nam	2015

*Many countries either do not publish their food safety assessment documents, or they are published in languages other than English or Spanish.

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Appendix 2: Nutritional components (proximate analysis for major constituents) of GTS 40-3-2 and control varieties[51]

Component[1]	GTS 40-3-2	Control	Literature Range
Protein (%)	41.4	41.6	36.9 — 46.4
Fat (%)	16.3	15.5	13 — 26
Crude Fibre (%)	6.87	7.13	4.7 — 6.48
Ash (%)	5.24	5.04	3.3 — 6.4
Carbohydrates (%)	37.1	38.1	31.1 — 43.9
Calories (Kcal/100g)	431	429	
Moisture (%)	8.12	8.12	

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