



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 Insect-Resistant Maize MON810





FOREWORD

This introduction serves as an explanation of the purpose and method of preparation of the following food/feed safety assessment document for insect-resistant maize variety MON810. 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 MON810. 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 maize variety MON810 is 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*¹⁰. *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 crops¹⁻⁷. *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 dies⁸⁻¹⁰. Several lepidopteran insects, while in their caterpillar stage of development, are serious pests of maize, including the European Corn Borer, *Ostrinia nubilalis* (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 in many countries worldwide, and it has been available to international grain markets for many years and has been traded extensively¹¹. MON810 received its first regulatory authorisation for use in food and feed in 1996, and to date, a total of 19 countries have authorised its food/feed use. Appendix 1 provides a list of all countries that have approved the use of MON810 in food.

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, the Government of Saint Lucia acknowledges the possibility that MON810 or varieties derived from MON810 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 MON810 maize, and the results of that assessment are presented herein.



SCOPE OF ASSESSMENT

According to Codex Alimentarius^{12, 13}, 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^{14, 15}. 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^{16–22}. 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.

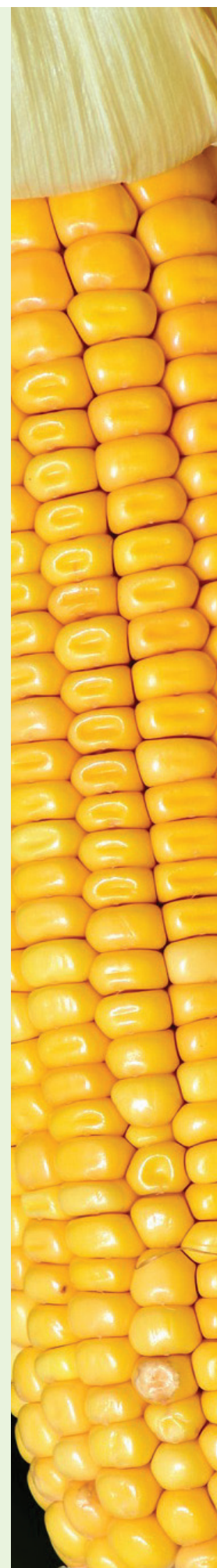
Maize is not known to have naturally occurring toxins at biologically significant levels, although it does contain known anti-nutritive compounds²³. The *Cry1Ab* protein produced by insect-protected maize line MON 810 is identical to the protein produced by the *B. thuringiensis* formulations that have been used commercially for many years to control insect pests. *Cry1Ab* has been well studied and thoroughly characterised^{1, 3, 9, 10, 24, 25}, 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)^{26–33}. 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 found²⁵.

From these data, the Government of Saint Lucia concludes that MON810 has no new or increased levels of toxins, when compared to non-GM varieties of maize.

Potential Allergenicity

Maize is not known to have naturally occurring allergenic proteins²³. 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^{19, 34, 35}. In addition, bioinformatic studies, which compared the amino acid sequence of *Cry1Ab* to the amino acid sequences of known





allergenic proteins¹⁹, 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^{22, 28, 29, 32, 33, 36–45}.

From these data, the Government of Saint Lucia concludes that MON810 has no new 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 (See Appendix 2). 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, but none of these variations are nutritionally significant^{46–49}. The levels of nutritional components of MON810 are within normal ranges for maize, regardless of the growing conditions^{27–29, 32, 33}. 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 MON810 was fed to chickens, cows, and salmon, have indicated that MON810 is nutritionally equivalent to non-GM maize^{50–68}.

From these data, the Government of Saint Lucia concludes that MON810 is 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 *B. 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 time²⁴.

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 unintended effects of the genetic modification have been found^{26, 29, 32}.

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 Saint Lucia concludes that MON810 is as safe in the food supply as its non-GM counterparts.

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Appendix 1: Approvals* for use of MON810 in food by country⁶⁹

Country	Year of Approval
Argentina	1998
Australia ^{28, 33}	2000
Brazil	2007
Canada ⁴	1997
China	2002
European Union ³²	1998
Japan	2001
Malaysia	2010
Mexico	2002
New Zealand ^{28, 33}	2000
Paraguay	2012
Philippines	2002
Russian Federation	2009
Singapore	2014
Republic of Korea	2002
Switzerland	2005
Taiwan	2002
United States of America ²⁷	1996
Uruguay	2003
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.



Appendix 2: Nutritional components of MON810 and control varieties

Table 1. Proximate analysis for major constituents of MON810 and control

Component ¹	Control		MON810	
	Mean	Range	Mean	Range
Protein	12.8	11.7 — 13.6	13.1	12.7 — 13.6
Fat	2.9	2.6 — 3.2	3.0	2.6 — 3.3
Ash	1.5	1.5 — 1.6	1.6	1.5 — 1.7
Carbohydrate	82.7	81.7 — 83.8	82.4	81.8 — 82.9
Calories (Kcal/100g)	409	406 — 410	408	407 — 410
Moisture	12.0	10.6 — 14.2	12.4	11.0 — 14.4

¹Data as a percentage of dry weight

Table 2. Amino acid levels in MON810 which are significantly different to control

Amino Acid ²	MON810	Control	Literature Range
Cysteine	2.0	1.9	1.2 — 1.6
Tryptophan	0.6	0.6	0.5 — 1.2
Histidine	3.1	2.9	2.0 — 2.8
Phenylalanine	5.6	5.4	2.9 — 5.7
Alanine	8.2	7.8	6.4 — 9.9
Proline	9.9	9.6	6.6 — 10.3
Serine	5.5	5.2	4.2 — 5.5
Tyrosine	4.4	4.0	2.9 — 4.7

²Data as a percentage of total protein present.

Table 3. Fatty acid composition of maize kernels

Fatty Acid ³	Control		MON810		Literature Range
	Mean	Range	Mean	Range	Range
Linoleic (18:2)	63.0	61.8 — 64.6	62.6	59.5 — 64.7	35 — 70
Oleic (18:1)	22.8	21.6 — 23.9	23.2	21.5 — 25.4	20 — 46
Palmitic (16:0)	10.5	10.2 — 10.7	10.5	10.2 — 11.1	7 — 19
Stearic (18:0)	1.8	1.8 — 1.9	1.9	1.7 — 2.1	1 — 3
Linolenic (18:3)	0.9	0.8 — 0.9	0.8	0.7 — 0.9	0.8 — 2

³Data as a percentage of total lipid content.

Table 4. Analysis of carbohydrates, tocopherols and inorganic components of maize kernels

Component	Control		MON810		Literature Range
	Mean	Range	Mean	Range	Range
Inorganic					
Phosphorus (%)	0.348	0.327 — 0.383	0.358	0.334 — 0.377	0.26 — 0.75
Calcium (%)	0.0033	0.0029 — 0.0037	0.0036	0.0033 — 0.0039	0.01 — 0.1
Carbohydrates					
Starch (%)	66.9	64.6 — 69.0	67.6	65.3 — 69.7	64 — 78.0
Crude Fibre (%)	2.4	2.3 — 2.5	2.6	2.5 — 2.8	2.0 — 5.5
Sugars (g/100g)					
Fructose	0.27	0.22 — 0.40	0.32	0.23 — 0.35	
Glucose	0.41	0.34 — 0.46	0.32	0.23 — 0.35	
Sucrose	0.93	0.68 — 1.11	0.93	0.79 — 1.12	
Phytic Acid	0.84	0.79 — 0.91	0.86	0.81 — 0.91	0.7 — 1.0
Tocopherols					
Alpha	10.9	9.9 — 12.1	10.4	9.7 — 11.3	3.0 — 12.1
Beta	7.5	7.0 — 7.9	8.5	8.1 — 9.2	
Gamma	21.6	18.8 — 27.8	20.2	15.3 — 24.8	



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