AUSTRALIAN PILOT SURVEY OF GM FOOD LABELLING OF CORN AND SOY FOOD PRODUCTS

by

The TAG Working Group on GM Food Labelling

June 2003

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1. SUMMARY

Following commencement of the genetically modified (GM) food labelling requirements of Standard 1.5.2, of the *Australia New Zealand Food Standards Code*, (in December 2001) a small preliminary examination in the form of an Australian pilot survey of corn and soy derived food products was undertaken to ascertain:

- how food businesses are adapting to the need to comply with the GM food labelling provisions of Standard 1.5.2, which require food products which are GM or contain GM ingredients to be labelled, and the consequential need to determine the GM status of ingredients used in their products; and
- the usefulness of document surveys to regulatory authorities in determining compliance or non-compliance with the mandatory GM food labelling requirements, as an alternative to undertaking expensive testing.

The survey tested a representative range of soy and corn derived food products (soy milk, bread, cornflakes, corn chips and tacos) for the presence of novel DNA. Because of international trade and the commercial cultivation of GM crops overseas these products have the potential for the inclusion of GM ingredients. The manufacturers, importers or retailers (supermarkets with generic products) of selected products were also asked to present evidence on how they determined the GM status of their food products.

All 51 samples tested complied with the GM food labelling requirements of Standard 1.5.2. GM material within the 1% limit of the labelling exemption for unintentional presence of an approved GM food in a non-GM food was detected in 10 samples (5 soymilk, 3 taco and 2 corn chip samples. Starlink corn was not detected in any of the corn products tested.

Four of the five soy milk samples in which GM material was detected had voluntary negative label claims about the GM status of ingredients. The manufacturers of these samples had implemented management systems to determine the GM status of the ingredients used in their food products. The remaining 6 samples in which GM material was detected did not have voluntary negative label claims. The samples were produced by 4 manufacturers, 3 of which were document surveyed. Two (which produced 4 of the samples) had implemented management systems to determine the GM status of the ingredients used in their food products.

In general the large food businesses document surveyed had management systems (documentation or testing) in place to demonstrate the GM status of ingredients used in their products. In contrast, the smaller food businesses document surveyed were unable to provide evidence that their products did not contain GM ingredients because they had not implemented management systems. However, this did not result in non-compliance with the mandatory GM food labelling requirements.

2. INTRODUCTION

2.1 Regulation of Food Produced Using Gene Technology

Food produced using gene technology is regulated by Standard 1.5.2 - *Food Produced Using Gene Technology*, of the *Australia New Zealand Food Standards Code* and is defined by the Standard as:

Food which has been derived or developed from an organism which has been modified by gene technology [1].

2.1.1 Safety Assessment of Food Produced Using Gene Technology

Standard 1.5.2 prohibits the sale and use of a food produced using gene technology unless it is included in the Table to clause 2 of the Standard and complies with any special conditions specified by that Table. The Standard requires Food Standards Australia New Zealand (FSANZ) to assess the safety for human consumption of each food or class of food prior to its inclusion in the Table. The safety assessment must be performed according to the Authority' s approved safety assessment criteria [2].

Currently 20 GM foods are approved for human consumption under the Standard [1].

2.1.2 Labelling of GM Food

All foods produced using gene technology must be safety assessed by FSANZ prior to release onto the market for human consumption. Hence, the labelling of GM food is not a safety issue but rather is one of consumer information and enables consumers to make a choice regarding selecting the food they wish or do not wish to consume [3].

In December 2001 the labelling provisions of Standard 1.5.2 came into force which require GM food to be labelled with the statement 'genetically modified' [1].

GM food is defined as:

Food that is, or contains as an ingredient, including a processing aid, a food produced using gene technology which:

- *contains novel DNA and/or novel protein; or*
- *has altered characteristics [1].*

GM food does not include:

- highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein;
- a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added;
- flavours present in the food in a concentration no more than 1g/kg; or

- a food, ingredient, or processing aid in which genetically modified food is unintentionally present in a quantity of no more than 10g/kg per ingredient[1] [1] [18].

Standard 1.5.2 is silent with regard to negative label claims regarding the GM status of a food or ingredient such as 'GM free', 'GMO free' or 'non-GM'. The Standard does not prescribe statements to be used for negative label claims nor does it prohibit the use of negative claims. Negative claims are made by food businesses on a voluntary basis. However such claims are subject to the fair trading requirements of the Australian *Trade Practices Act 1974.* Food businesses must ensure any claims made are not false, misleading or deceptive.

2.2 Australian Pilot Survey for GM Food Labelling

Following commencement of the GM food labelling requirements of Standard 1.5.2 of the *Australia New Zealand Food Standards Code* (in December 2001), a small preliminary examination in the form of an Australian pilot survey of corn and soy derived food products was undertaken to ascertain:

- how food businesses are adapting to the need to comply with the GM food labelling provisions of Standard 1.5.2 and the need to determine the GM status of ingredients used in their products; and
- the usefulness of document surveys to regulatory authorities in determining compliance or non-compliance with the mandatory GM food labelling requirements, as an alternative to undertaking Polymerase Chain Reaction (PCR) testing.

2.3 Product Selection for the Survey

2.3.1 GM Varieties of Crops Grown Worldwide

Currently only 13 different crops have GM varieties commercially grown and used in the production of food and animal feeds worldwide (see Table 1) [5,6].

Table 1 Crops which have commercially grown GM varieties worldwide

Canola	Corn	Papaya	Soybean	Tomato
Chicory	Flax/Linseed	Potato	Squash	
Cotton	Melon (Cantaloupe)	Rice	Sugarbeet	

Currently 6 (canola, cotton, corn, potato, soybean and sugar beet) of the above 13 crops have GM varieties approved for use in food for human consumption in Australia and New Zealand under Standard 1.5.2 [1].

2.3.2 Presence of Novel DNA and/or Protein in Food Products

DNA or protein can be removed or damaged by various processing steps in the production of processed foods such as solvent extraction, refining or cooking, so that it is no longer recognised or detected by analysis [7]. For highly processed products, such as sugar and oils, the production process removes the proteins and DNA

[1] The 1% threshold level for unintentional presence of a GM food in a non GM food only applies when the manufacturer has intended to source non-GM ingredients.

[8,9,10,11] and so it is not possible to determine whether they are derived from a GM source [7].

Proteins are generally denatured by heat and so usually cannot be recognised in cooked food [12]. Also exposure to strong acids and alkalis denatures proteins [7].

In general, no DNA is detectable in highly heat-treated food products, hydrolysed plant proteins, purified starch derivatives and refined oils derived from a genetically modified organism (GMO) [13]. Failures in extracting detectable amounts of DNA have also been reported for soybean sauce, refined sugar and distilled ethanol produced from GM potatoes [14].

2.3.3 Categories of Foods

The potential for a food product to contain GM ingredients is based on:

- the crop from which a food product is derived;
- the size of commercial plantings worldwide of GM varieties of the crop;
- the extent to which products from a crop are used as food or as ingredients in food products; and
- the level of processing to which the ingredient and food product are subjected.

Table 2 categorises food products based on the above four criteria with category I having the greatest potential and category IV having the smallest potential for containing GM ingredients.

Table 2 Category of food products

Category	Food products which are derived from or contain ingredients derived from:
I	Soy, Corn
II	Cotton, Canola, Potato, Sugarbeet
III	Chicory, Flax, Papaya, Rice, Rockmelon, Squash, Tomato
IV	All other crops

Based on the above criteria, food products derived from soy or corn have the greatest potential to contain GM ingredients. Consequently, the national survey targeted soy and corn derived food products by sampling soy milk, bread, cornflakes, corn chips and tacos, as these are widely consumed soy and corn derived food products.

3. METHODS

3.1 Sampling Programme

The soy milk, bread, cornflake, corn chip and taco products sampled represented domestically produced and imported brands widely available nationally.

Table 3 provides numbers of samples collected, tested and subject to document survey, and numbers of food businesses whose samples were collected, tested and subject to document survey.

Table 3 Numbers of samples and food businesses covered by survey

	No. samples			No. food businesses*		
Product	**Collected**	**Tested**	**Document surveyed**	**Samples collected from**	**Samples tested from**	**Document surveyed**
Soy milk	12	12	7	9	9	5
Bread	33	15	30	21	9	20
Cornflakes	7	7	3	7	7	3
Corn chips	13	13	9	9	9	5
Tacos	4	4	4	3	3	3
Totals	**69**	**51**	**53**	**49**	**37**	**36**

*food business = manufacturer, importer or supermarket with generic products.

3.2 Testing Programme

3.2.1 Testing Methodology

Currently available testing methods detect either a novel DNA sequence or a novel protein present in a food product from a GM crop. However, the range of detection methods available generally decreases with an increase in the level of processing to which the product has been subjected [7].

Polymerase Chain Reaction (PCR), a DNA detection method, was determined to be the most suitable detection method for the survey because it met the following needs (whereas a protein detection method did not). PCR:

- detects DNA in processed foods which have undergone cooking or other processes known to denature proteins [7,12];
- allows for the extremely varied compositions and degrees of processing of the foods to be tested [15];
- is extremely sensitive, enabling detection of low levels of DNA which may be present in processed foods [3,7];
- is available for a wide range of GM crops [7,12];
- is suited to an initial general broad screen for a wide variety of GM crops [7]; and
- is quantitative [7,16] and enables a relative quantitation rather than an absolute quantitation to be obtained [7,17].

The National Association of Testing Authorities Australia (NATA), is the Commonwealth Government recognised national authority for accreditation of

laboratories. It has not at this time accredited laboratories for the quantification of GMO residues in food products.

3.2.2 PCR Testing Programme

Three rounds of PCR testing were undertaken. Initially 51 samples were subject to broad screen PCR to test for the presence of the Cauliflower Mosaic Virus (*CaMV*) *35S* promoter DNA sequence and the *nos* terminator DNA sequence, because 86% of all GM crop varieties currently approved around the world contain either or both of these DNA sequences [3,7,13].

In round two, 5 soy milk samples were tested by quantitative PCR for Roundup Ready® soy and 1 bread sample was subject to qualitative PCR for Roundup Ready® soy. Also, 3 samples of tacos and 2 samples of corn chips were subject to 3 PCR tests simultaneously: quantitative for *CaMV 35S*, qualitative for Roundup Ready® corn and qualitative for Starlink corn.

In round three, 2 samples of tacos and 2 samples of corn chips were subject to quantitative PCR for Roundup Ready® corn. Also, 1 bread sample was subject to PCR testing to detect the *CaMV* reverse transcriptase gene and the corn high mobility group gene.

Duplicates of the 12 samples collected by Queensland Health and tested in the survey were also tested by Queensland Health's Scientific Services (QHSS). QHSS undertook 2 rounds of PCR testing.

In round one, 3 soy milk and 3 bread samples were tested by qualitative PCR for Roundup Ready® soy. Also, 2 cornflake and 3 corn chip samples as well as 1 taco sample were subject to qualitative PCR for MON 810 corn and Starlink corn.

In round two, 2 soy milk samples were tested by quantitative PCR for Roundup Ready® soy. Also, 1 sample of tacos and 1 sample of corn chips were subject to quantitative PCR for MON 810 corn.

3.3 Document Survey Methodology

Thirty six manufacturers, importers or retailers (supermarkets with generic products) supplying 53 of the samples were asked to present evidence demonstrating the GM status of potential GM ingredients used in their products to ascertain whether they had implemented management systems (i.e. documentation or testing) to determine the GM status of ingredients.

A mixture of small, medium and large food businesses were document surveyed. Small businesses were non-franchised local businesses with only one or two outlets. Medium businesses were local or national, possibly franchised, with a small number of outlets or a small number of manufacturing sites. Large businesses were national or multinational with multiple outlets or multiple manufacturing sites.

A Documentation Survey Protocol was developed to facilitate consistency in the document surveys undertaken by 4 jurisdictions. Observations about the efficacy of management systems were recorded to identify:

- whether they covered all ingredients that may be GM;
- how far back through the supply chain documentation extended; and

- whether steps were included to verify, by auditing or testing, information from suppliers.

If a food business had no system in place enquiries were made regarding whether it was proposed to introduce a system, what form it would take and regarding the nature of any impediments to introducing a system. Food businesses were offered information on documentation from the *User Guide – Labelling Genetically Modified Food* [18].

4. RESULTS

4.1 Test Results

The results of the initial broad screen PCR testing are presented in Table 4.

Table 4 Detection of CaMV 35S and nos DNA sequences

Product	No. samples	Detection of *CaMV 35S* and *nos* DNA sequences
Soy milk	12	5 samples positive for both *CaMV 35S* and *nos* DNA sequences
		7 samples negative for both *CaMV 35S* and *nos* DNA sequences
Bread	15	1 sample positive for *CaMV 35S* DNA sequence and negative for *nos* DNA sequence
		14 samples negative for both *CaMV 35S* and *nos* DNA sequences
Cornflakes	7	7 samples negative for both *CaMV 35S* and *nos* DNA sequences
Corn chips	13	2 samples positive for both *CaMV 35S* and *nos* DNA sequences
		11 samples negative for both *CaMV 35S* and *nos* DNA sequences
Tacos	4	3 samples positive for both *CaMV 35S* and *nos* DNA sequences
		1 sample negative for both *CaMV 35S* and *nos* DNA sequences

The results of round two testing are presented in Table 5.

Table 5 Results of round 2 PCR testing

SAMPLE	PCR TEST UNDERTAKEN	RESULT
soy milk 1	quantitative Roundup Ready® soy	Roundup Ready® soy DNA content in relation to total soy DNA is less than 0.2%
soy milk 2	quantitative Roundup Ready® soy	Roundup Ready® soy DNA content in relation to total soy DNA is 0.2% (+/-0.04%)
soy milk 3	quantitative Roundup Ready® soy	Roundup Ready® soy DNA content in relation to total soy DNA is 0.4% (+/- 0.1%)
soy milk 4	quantitative Roundup Ready® soy	Roundup Ready® soy DNA content in relation to total soy DNA is 0.1% (+/-0.05%)
soy milk 5	quantitative Roundup Ready® soy	Roundup Ready® soy DNA content in relation to total soy DNA is less than 0.5%
bread 1	qualitative Roundup Ready® soy	Negative
corn chips 1	35S corn quantitation	35S DNA content in relation to total corn DNA is less than 0.1%
	qualitative Roundup Ready® corn	Positive
	qualitative Starlink corn	Negative
corn chips 2	35S corn quantitation	35S DNA content in relation to total corn DNA is less than 0.1%
	qualitative Roundup Ready® corn	Positive
	qualitative Starlink corn	Negative

Table 5 (cont.) Results of round 2 PCR testing

SAMPLE	PCR TEST UNDERTAKEN	RESULT
tacos 1	35S quantitation	35S DNA content in relation to total corn DNA is 0.2% (+/-0.05%)
	qualitative Roundup Ready® corn	Negative
	qualitative Starlink corn	Negative
tacos 2	35S quantitation	35S DNA content in relation to total corn DNA is less than 0.1%
	qualitative Roundup Ready® corn	Positive
	qualitative Starlink corn	Negative
tacos 3	35S quantitation	35S DNA content in relation to total corn DNA is less than 0.1%
	qualitative Roundup Ready® corn	Positive
	qualitative Starlink corn	Negative

The results of round 3 testing are presented in Table 6.

Table 6 Results of round 3 PCR testing

Sample	PCR TEST UNDERTAKEN	Results
1 bread	Cauliflower Mosaic Virus reverse transcriptase gene	Positive
	Corn high mobility group gene (HMG)	Negative
corn chips 1	quantitative Roundup Ready® corn	Roundup Ready® corn DNA content in relation to total corn DNA is less than 0.1%
corn chips 2	quantitative Roundup Ready® corn	Roundup Ready® corn DNA content in relation to total corn DNA is less than 0.1%
tacos 2	quantitative Roundup Ready® corn	Roundup Ready® corn DNA content in relation to total corn DNA is less than 0.1%
tacos 3	quantitative Roundup Ready® corn	Roundup Ready® corn DNA content in relation to total corn DNA is less than 0.1%

A comparison of the results of PCR testing undertaken by QHSS and GeneScan for the survey are presented in Table7.

Table 7 Comparison of results of testing performed by GeneScan and QHSS

Sample	Testing performed by GeneScan	Testing performed by QHSS
soymilk 1	GM material not detected	GM material not detected
soymilk 2	Roundup Ready® soy DNA content in relation to total soy DNA is 0.4% (+/- 0.1%)	Roundup Ready® soy DNA content is <0.03%
soymilk 3	Roundup Ready® soy DNA content in relation to total soy DNA is 0.1% (+/0.05%)	Roundup Ready® soy DNA content is <0.03%
bread 1	GM material not detected	GM material not detected
bread 2	GM material not detected	GM material not detected
bread 3	GM material not detected	GM material not detected

Table 7 (cont.) Comparison of results of testing performed by GeneScan and QHSS

Sample	Testing performed by GeneScan	Testing performed by QHSS
cornflakes 1	GM material not detected	GM material not detected
cornflakes 2	GM material not detected	GM material not detected
corn chips 1	GM material not detected	GM material not detected
corn chips 2	Roundup Ready® corn DNA content in relation to total corn DNA is less than 0.1%	MON 810 DNA content is <0.01% of total corn DNA
	CaMV 35S promoter DNA content in relationto total corn DNA is less than 0.1%	
corn chips 3	GM material not detected	GM material not detected
tacos 1	Roundup Ready® corn DNA content in relation to total corn DNA is less than 0.1%	MON 810 DNA content is <0.01% of total corn DNA
	CaMV 35S promoter DNA content in relation to total corn DNA is less than 0.1%	

4.2 Documentation Survey Results

The results of the document surveys regarding the number of food businesses that have or have not implemented a management system to determine the GM status of ingredients used in their products are provided in Table 8.

Table 8 Results of document surveys

Size of food business	No. of businesses document surveyed	Management system in place to determine the GM status of ingredients	
		Yes	No
Large	14	12	2
Medium	5	2	3
Small	17	0	17
	36	**14**	**22**

4.2.1 Food Businesses that Have Implemented a Management System

Twelve out of 14 (86%) large food businesses and 2 out of 5 (40%) of medium businesses surveyed had implemented management systems and were able to demonstrate the GM status of ingredients of their products sampled by the survey.

Most of these food businesses had implemented a documentation based management system. Examples of such systems used by food businesses are:

- Using supplier's product specification sheets.
- Guarantees from suppliers that ingredients are derived from Australian grown crops (where no GM varieties are commercially grown *e.g.* corn and soybeans).
- Requiring questionnaires/templates to be completed, supplier certification or supplier declaration statements. Assurances may be validated by audits or testing.

- Independent third party certification.
- An 'Approved Supplier Program' requiring suppliers to meet certain requirements.
- The most complete system identified included a database classifying the GM status of all raw materials and ingredients used in products *e.g.* of classes: GM; GM derived/contains novel DNA or protein; GM derived/DNA negative; Non GM sourced (IP system in place;) and, GM free (no known GM types).

Thirteen of the fourteen businesses that had implemented management systems relied on documentation. The other business had implemented a testing based management system in which every batch of a raw material was tested.

Observations about the efficacy of management systems were recorded to identify:

- whether they covered all ingredients that may be GM;
- how far back through the supply chain documentation extended; and
- whether steps were included to verify, by auditing or testing, information from suppliers.

All 14 systems covered all ingredients that had the potential to be GM in products sampled by the survey. The extent to which documentation extended back through the supply chain varied between the 14 systems. It also varied within many of the systems for different ingredients.

As a minimum all 13 documentation based management systems required documentation from suppliers. Examples included supplier documentation for canola oil stating that the oil is highly refined and does not contain novel DNA and/or protein and therefore would not require labelling under Standard 1.5.2 and declarations from suppliers of soy or corn ingredients that they are derived from soy or corn grown in Australia and that currently no GM varieties of soy or corn are commercially grown in Australia.

However, documentation provided by suppliers frequently extended further back through the supply chain for corn and soy ingredients. These included a declaration that soybeans imported are not GM, a letter from the Office of the Gene Technology Regulator stating that no GM corn is commercially grown in Australia and declarations from corn and soybean seed producers and marketers that seed sold in Australia is not GM.

Another example was a declaration from a supplier that corn milled for its products were solely bred and grown in Australia and were currently free of GM material and that an identity preservation system was used to ensure the product delivered was non-GM. The identity preservation system included seeking statements from seed companies, use of specially selected contracted growers, inspection of crops during the season and prior to harvest, use of dedicated corn storage sites and not using other ingredients or blending in manufacture of products.

A number of the documentation based management systems required a supplier to provide independent third party certification of the identity preservation system used to deliver a non-GM soy ingredient.

Seven of the 13 (54%) documentation based management systems include steps to verify the information provided by suppliers by either auditing or testing. In addition 1 food business will have its products analysed for GM on request by customers.

A number of the businesses whose documentation based management systems do not currently include a verification step reported they were considering introducing one.

The food business with the testing based management system itself commissions the testing of the raw materials, therefore verification of information provided by a supplier is not required.

4.2.2 Food Businesses That Have Not Implemented A System

All small food businesses (17 out of 17) and 60% (3 out of 5) of medium businesses surveyed had not implemented a management system to determine the GM status of ingredients and could not demonstrate the GM status of ingredients of products sampled by the survey. As the sample size is relatively small, this may not be indicative of all small to medium size businesses in relation to implementing management systems to determine the GM status of ingredients they source. In addition, suppliers servicing large companies demanding non-GM ingredients would be providing the same stock to small and medium enterprises.

Reasons recorded by the survey as to why these food businesses had not implemented a management system were:

- ingredients sourced from a large ingredient supply company with documentation systems in place to demonstrate the GM status of ingredients.
- suppliers verbally advised ingredients not GM because derived from Australian grown crops (with no GM varieties commercially cultivated *e.g*. corn).
- assumptions were made that ingredients non-GM because sourced from local producers or locally grown crops.
- assumptions were made that all the information required for labelling would be found on the invoice accompanying ingredients.
- products were sold from the manufacturing premises or supplied unpackaged which did not need to be labelled.
- hadn't got around to it because it was not necessary or was a low priority.
- lack of awareness of the GM food labelling requirements of Standard 1.5.2.

5. CONCLUSIONS

5.1 PCR Results

5.1.1 Potential Detection of An Unapproved GM Crop Variety

The survey had the potential to detect a GM crop variety in a food product not approved for food use in Australia and New Zealand but produced overseas *e.g.*Corn MON 802 or MON805. This did not occur.

5.1.2 Presences of CaMV 35S and nos DNA sequences in GM crops

Either or both of the *CaMV 35S* promoter DNA sequence and the *nos* terminator DNA sequence are present in:

- 86% of all GM crop varieties currently approved around the world [3,7,13];
- 19 out of 21 of the GM crop varieties approved for human food use in Australia and New Zealand under Standard 1.5.2; and
- the 7 GM corn varieties and the 2 GM soy bean varieties approved under Standard 1.5.2 (see Table 9).

Neither DNA sequence is present in 6 GM canola varieties, 1 cotton variety and 1 tomato variety currently approved worldwide. However, the only products for human consumption from canola and cotton are highly refined canola oil and highly refined cotton oil and linters respectively which undergo extensive processing which destroys or removes DNA. Therefore, even if the CaMV 35S or nos DNA sequences were present in these GM crops they would not be detectable in food products by broad screen PCR.

Table 9 Presence of *CaMV 35S* promoter and *nos* terminator DNA sequences in GM corn and soy varieties approved by FSANZ under Standard 1.5.2

Approved GM variety	*CaMV 35S*	*nos*
soybeans		
Roundup Ready® (glyphosate tolerant)	present	present
High Oleic Acid	present	present
corn		
Bt-11 (insect protected, glufosinate ammonium tolerant)	present	present
MON810 (insect protected)	present	present
NK603 (glyphosate tolerant)	present	present
Bt-176 (insect protected)	present	not present
DBT418 (insect-protected, glufosinate ammonium tolerant)	present	not present
T25 (glufosinate ammonium tolerant)	present	not present
GA21 (glyphosate tolerant – 'Roundup Ready®')	not present	present

The *CaMV 35S* and *nos* DNA sequences occur naturally in plants and soil micro-organisms [13,14] and consequently a positive broad screen PCR result will not necessarily prove the presence in a food of novel DNA from a GM plant, but it will suggest that it is probable [7,13,14]. If both the *CaMV* 35S and *nos* DNA sequences are detected, then the probability of this being due to the presence of novel DNA from a GM plant is far greater than if only one is detected [7].

5.1.3 Conclusions regarding the Testing of Soy Milk Samples

None of the 12 soy milk samples had ingredients labelled as GM. Eight of the samples had voluntary negative label claims regarding the GM status of ingredients. All samples complied with the GM food labelling requirements of Standard 1.5.2.

Broad screen PCR detected both the *CaMV 35S* and *nos* DNA sequences, which are characteristic of GM plants [3,7,13], in 5 of the 12 soy milk samples tested. However, this did not prove that the novel DNA was from a GM plant but suggested that it was probable [7,13,14]. Further analysis was necessary [7].

From the ingredient lists of the samples, the ingredient most likely to be derived from a GM source and with the greatest potential to contain DNA were soy protein or soy protein isolate. Roundup Ready® soy and high oleic acid soy are both approved under Standard 1.5.2 and both contain the *CaMV 35S* and the *nos* DNA sequences. However, the most likely GM source is Roundup Ready® soy as the high oleic acid soy is a more valuable specialty product which is segregated from other soybeans and its use will be associated with positive claims.

To confirm Roundup Ready® soy as the source of the DNA sequences and to determine the amount of DNA present, the 5 soy milk samples were tested further by quantitative PCR for Roundup Ready® soy. Roundup Ready® soy was detected in the 5 soy milk samples (see Table 5), however it was present at levels below the 1% threshold for unintentional presence of an approved GM food in a non-GM food.

Four of these 5 soy milk samples had negative label claims about the GM status of ingredients. All 5 manufacturers had implemented a management system to demonstrate that they have sourced non-GM ingredients to use in their products.

5.1.4 Conclusions regarding the Testing of Bread Sample

Broad screen PCR detected only the *CaMV 35S* DNA sequence, characteristic of GM plants [3,7,13], in 1 of the 15 bread samples tested. However, this did not prove that the novel DNA was from a GM plant and the probability of this being the case was far less than if both the *CaMV 35S* and the *nos* DNA sequences were detected [7, 13,14].

From the ingredient list, the ingredient most likely to be from a GM source and with the greatest potential to contain DNA was soy flour from Roundup Ready® soy. However, Roundup Ready® soy contains both the *CaMV 35S* and *nos* DNA sequences but only the *CaMV 35S* DNA sequence was detected in the sample. Consequently, there were 3 possibilities regarding the presence of the *CaMV 35S* DNA sequence:

1. It was from soy flour from Roundup Ready® soy, but *CaMV 35S* was present at a very low level near the limit of detection which explains why *nos* was not detected.
2. It was due to contamination of an ingredient of the bread (*e.g.* flour) with the CaMV [7] from which the *CaMV 35S* DNA sequence present in many GM crops is derived [13,14].
3. It was due to adventitious contamination from a GM corn variety which contains *CaMV 35S* but not *nos* (*e.g.* Bt-176 see Table 9). Such contamination can occur during transport, storage, handling or manufacturing.

Initially scenario 1 was investigated by the 1 bread sample being tested further by qualitative PCR for Roundup Ready® soy and it was not detected.

The remaining 2 scenarios were investigated by further PCR testing simultaneously for the presence of the:

Corn high mobility group gene (HMG)

The corn HMG is present in all corn varieties both non-GM and GM [19]. HMG was not detected in the sample, which indicates that there is no corn (from either a non-GM or GM variety) present in the bread. Consequently, the CaMV 35S DNA sequence detected in the sample is not from a GM corn variety.

Cauliflower Mosaic Virus reverse transcriptase gene

The CaMV reverse transcriptase gene is present in the Cauliflower Mosaic Virus [20]. It was detected in the bread sample which indicates that there is CaMV contamination of the sample, probably from a flour ingredient [7]. Therefore, the *CaMV 35S* DNA sequence detected in the sample was most likely to be due to CaMV contamination and not due to the presence of novel DNA from a GM crop.

There is the potential for a GM plant variety which contains the *CaMV 35S* DNA sequence but does not contain *nos* DNA sequence to contribute to the presence of the *CaMV 35S* DNA sequence. However, as other testing performed on the sample rules out the presence of any corn variety (see above corn HMG) and the presence of Roundup Ready® soy and these are the most likely source of GM ingredients, this scenario was considered highly unlikely. Consequently, no further testing of the sample was undertaken.

None of the 15 bread samples tested had ingredients labelled as GM and none had voluntary negative label claims regarding the GM status of ingredients. All samples complied with the GM food labelling requirements of Standard 1.5.2.

5.1.5 Conclusions regarding the Testing of Samples of Corn Chips and Tacos

Broad screen PCR detected both the *CaMV 35S* and *nos* DNA sequences, which are characteristic of GM plants [3,7,13], in 2 of the 13 corn chip samples and 3 of the 4 taco samples tested. For reasons discussed above this did not prove that the novel DNA was present from a GM plant and further analysis was performed.

From the ingredient lists, the ingredient most likely to be from a GM source and with the greatest potential to contain DNA was corn or corn flour. There are 7 GM corn varieties approved under Standard 1.5.2. (see Table 9) and the corn or corn flour could be derived from any one or a mixture of a number of these. Three of the approved GM corn varieties contain both *CaMV 35S* and *nos*; 3 contain only *CaMV 35S;* and, 1 (Roundup Ready® corn) contains only *nos*.

To identify the source of the GM material, the 2 samples of corn chips and the 3 samples of tacos were tested further using a combination of 3 different tests simultaneously:

Quantitative PCR for the CaMV 35S DNA sequence

The *CaMV 35S* promoter DNA sequence was detected in the 3 samples of tacos and the 2 samples of corn chips (see Table 5). However, the level of GM material in

these 5 samples was below the 1% level for unintentional presence of GM material in a non-GM food.

PCR for Roundup Ready® corn

Roundup Ready® corn was detected by qualitative PCR in 2 of the 3 samples of tacos and in both samples of corn chips. To determine the amount of GM material present, the 2 samples of tacos and the 2 samples of corn chips were further tested by quantitative PCR for Roundup Ready® corn. Roundup Ready corn was found to be present at levels less than the 1% threshold for unintentional presence of GM material in a non-GM food(see Table 5).

Qualitative PCR for Starlink corn

Starlink corn was not detected in any of the 5 samples that tested positive for GM material.

The manufacturers of 4 of the 5 samples that tested positive for the presence of GM corn were document surveyed and 3 of the 4 had implemented a management system to determine the GM status of ingredients used in their products.

None of the 13 samples of corn chips or the 4 samples of tacos had labelled any ingredients as GM and none had voluntary negative label claims regarding the GM status of ingredients. All samples complied with the GM food labelling requirements of Standard 1.5.2.

Table 10 Summary of conclusions of PCR testing

Product and No. samples tested	Conclusions of testing
Soy milk 12 samples	All samples complied with Standard 1.5.2. Five samples contained GM soy, present below the 1% limit of the labelling exemption for unintentional presence of GM food per ingredient. Four of these samples had voluntary negative GM label claims about the GM status of the soy ingredient. The manufacturers of the 5 samples had systems in place to determine the GM status of ingredients used in their products.
Bread 15 samples	All samples complied with Standard 1.5.2. None of the samples contained GM material.
Cornflakes 7 samples	All samples complied with Standard 1.5.2. None of the samples contained GM material
Corn chips 13 samples	All samples complied with Standard 1.5.2. Two samples contained GM corn, present below the 1% limit of the labelling exemption for unintentional presence of GM food per ingredient. None of the samples had voluntary negative GM label claims. The manufacturer of 1 of the samples was document surveyed and had a system in place to determine the GM status of ingredients used in its products.
Tacos 4 samples	All samples complied with Standard 1.5.2. Three samples contained GM material, present below the 1% limit of the labelling exemption for unintentional presence of GM food per ingredient. None of the samples had voluntary negative GM label claims. The manufacturers of the 3 samples were document surveyed and 2 had systems in place to determine the GM status of ingredients used in their products.

Starlink corn was not detected in any of the corn derived food samples tested.

The results of the testing undertaken by QHSS on 12 of the 51 (24%) survey samples (see Table 7) validated the PCR testing undertaken by GeneScan for the survey.

5.2 Documentation Survey Conclusions

Standard 1.5.2 does not require a food business to establish a management system to determine the GM status of ingredients used in its products to demonstrate the basis of decisions to label or not label products as GM. The Standard is silent with regard to documentation. However, documentation has been proposed as a method to determine the GM integrity of products.

Document surveys were performed to ascertain how food businesses are adapting to the need to label food products which are GM or contain GM ingredients and the consequential need to determine the GM status of ingredients used in products. Also to ascertain the usefulness of document surveys to regulatory authorities in ascertaining compliance or non-compliance with the GM food labelling requirements of Standard 1.5.2 as an alternative to undertaking expensive PCR testing.

5.2.1 Adaptation of Food Businesses to Determining the GM Status of Ingredients or Products

In general the findings of the survey indicate that large food businesses have adapted to the need to label food products which are GM or contain GM ingredients and the consequential need to determine the GM status of ingredients used in products and have implemented management systems to do so. On the other hand, smaller food businesses do not appear to have adapted. However, from the samples which were subject to testing and also document survey this did not lead to non-compliance with the GM food labelling requirements of Standard 1.5.2.

Many of the larger food businesses document surveyed have made a conscious decision to avoid the use of ingredients derived from GM sources or have made the decision to place voluntary negative label claims on products. These businesses have implemented management systems to support their decisions.

The majority of the medium businesses but none of the small food businesses document surveyed had made a conscious decision to avoid the use of ingredients derived from GM sources or to place voluntary negative label claims on products.

From the document surveys performed on the 36 food businesses, they could be placed in three categories.

Category 1

These are food businesses which have chosen to:

- make a voluntary public commitment not to supply food products containing GM material. They do not apply negative label claims to products; or
- place voluntary negative label claims on products regarding the GM status of particular ingredients or the whole product.

Food businesses in this category had implemented management systems to determine the GM status of ingredients to provide some level of integrity to the commitment or claim.

This illustrates that food businesses are aware of the need for scrutiny of the GM status of ingredients when making a voluntary public commitment not to supply food products containing GM material or when using voluntary negative label claims.

Within this category fell the manufacturers of the 4 soy milk samples which had negative GM label claims but GM soy was present (albeit within the 1% limit of the labelling exemption for unintentional presence of GM food). The manufacturers of the 4 samples had implemented management systems to demonstrate the non-GM status of their soy ingredient. The low level unintentional presence of GM soy highlights the need for food businesses which have systems in place to support negative claims to be vigilant with ongoing verification of these systems to give assurance to their claim.

Food businesses in this category were mostly large in size but also medium businesses were represented.

Category 2

These are food businesses which had implemented management systems to determine the GM status of ingredients to ensure compliance with mandatory GM food labelling requirements. They have made no public commitment regarding the GM status of the food products they supply and they do not apply negative label claims to products.

Food businesses in this category were mostly large in size but included some medium businesses.

This illustrates that larger food businesses are aware of the need for scrutiny of the GM status of ingredients for compliance with the GM food labelling requirements of Standard 1.5.2.

Within this category fell the food businesses from which were collected the 1 soy milk, 3 taco and 2 corn chip samples which had GM soy or corn present (within the 1% limit of the labelling exemption for the unintentional presence of GM food) but did not have negative GM label claims. The 6 samples were produced by 4 manufacturers, 3 of the manufacturers were subject to document survey and 2 had a management system in place to determine the GM status of ingredients. As with category 1, low level unintentional presence of GM food in products from companies with management systems in place highlights the need for ongoing verification of the management systems.

Category 3

These are food businesses which had not implemented management systems to determine the GM status of ingredients used in their products.

Food businesses in this category were mostly small in size but also included medium-sized businesses.

This illustrates that smaller food businesses do not appear to be ready to tackle GM food labelling issues. Some were totally unaware of the mandatory labelling

requirements for GM food. However, from the testing undertaken this did not result in non-compliance with the GM food labelling requirements.

A number of food businesses in this category reported that they would, as a result of the survey, address the issue of putting in place a management system to determine the GM status of ingredients used in their products to ensure continued compliance with the GM food labelling requirements of Standard 1.5.2.

5.2.2 Usefulness of Document Survey to Regulatory Authorities

The total cost of testing was $33,902, making the average cost per sample $664. A document survey on one food business took between 4 hours and 1 day depending on a number of factors such as: the number of samples document surveyed; travelling time; the size, and complexity of the food business; and, the complexity of the management system implemented.

The survey established that a document survey is a useful tool for regulatory authorities as an alternative to expensive PCR testing in determining compliance or non-compliance with the GM food labelling requirements of Standard 1.5.2 if a food business has implemented a management system (documentation or testing) to demonstrate the GM status of ingredients used in its products.
However, of the 36 food businesses document surveyed only 14 (39%) have implemented a management system (documentation or testing) to demonstrate the GM status of ingredients used in its products.

6. ACKNOWLEDGEMENT

The jurisdictions that participated in the pilot survey would like to thank the Genetically Modified Food Unit, Environmental Health Service, South Australian Department of Human Services for co-ordinating the survey and the preparation of this report.

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