

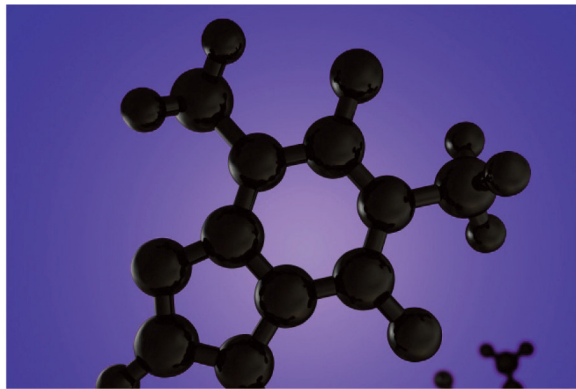


Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



Fumonisin in Corn Products

TS-CHEM-10/11

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Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. As part of the FSAP enhanced surveillance initiative, targeted surveys are used to test various foods for specific hazards.

The main objective of the fumonisin (FMN) survey was to provide baseline surveillance data regarding FMN levels in corn products available on the Canadian retail market.

Fumonisin (FMN) are a family of naturally-occurring toxins released by *Fusarium* moulds. These moulds proliferate and release FMN both on corn growing in the field (pre-harvest) and on raw corn/finished corn products in storage (post-harvest). The growth of the mould is favoured by hot, dry conditions followed by very humid conditions during growth, and subsequent storage under wet conditions.

Although different forms of FMN exist, FMN forms B1 and B2 are the most prevalent, the most toxic forms occurring in plant-based foods, and the most commonly analysed. Fumonisin interfere with human cell metabolism and are considered possible carcinogens. They have been associated with the incidence of oesophageal cancer and neural tube defects in particular geographical areas.

A total of 276 samples (corn-based breakfast cereals (56), corn/tortilla chips (45), cornmeal (34), popcorn (30), canned corn (27), corn starch (23), corn tacos (21), corn flour (21), corn tortillas (10), corn grits (7), and cornbread mix(2)) were collected and analysed in this targeted survey. All samples were analysed for FMN using a multi-residue method that detects the FMN forms B1 and B2. Most of the samples (157/276 or 57%) had detectable levels of FMN. The total FMN levels ranged from 20 parts per billion (ppb) in corn chips and corn grits to 6650 parts per billion (ppb) in cornmeal.

There are no Canadian maximum levels, tolerances, or standards for fumonisin in corn products so compliance could not be determined. Eight products (four samples of corn cereals, two samples of corn grits, one sample of corn tortilla, and one sample of cornmeal) had higher concentrations of FMN (> 800 ppb). These results were evaluated and were considered unlikely to pose a concern to human health. Appropriate product follow-up actions were initiated that reflected the magnitude of the health concern.

1. Introduction

1.1 Food Safety Action Plan

In 2007, the Canadian government launched a five-year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP), aims to modernize and strengthen the food safety regulatory system. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The CFIA's Food Safety Action Plan (FSAP) is one element of the government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food controls, and identify food importers and manufacturers. FSAP also looks to verify that the food industry is actively applying preventive measures and that there is a rapid response when/if these measures fail.

Within FSAP, there are twelve main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess, and prioritize potential food safety hazards through risk mapping, information gathering, and testing foods from the Canadian marketplace. Targeted surveys are one tool used to test for the presence and level of a particular hazard in specific foods. Targeted surveys are largely directed towards the 70% of domestic and imported foods that are regulated solely under the *Food and Drugs Act* and *Regulations* (FDAR), and are generally referred to as non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are pilot surveys used to gather information regarding the potential occurrence of chemical residues in defined commodities. The surveys are designed to answer specific questions; therefore, unlike monitoring activities, testing of a particular chemical hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of chemical hazards and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all chemical hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, media reports, and/or a risk-based model developed by the Food Safety Science Committee (FSSC). The FSSC ranked fumonisin (FMN) as a priority hazard because of its deleterious human health effects, its occurrence in corn products which are widely consumed by many population groups in Canada, and to help provide more recent occurrence data that will be used by Health Canada in order to update the estimated exposure of the Canadian population to the FMNs.

1.3 Acts and Regulations

The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing restrictions on the production, sale, composition, and content of foods and other food products as outlined in the FDAR.

Health Canada establishes the maximum levels (standards and tolerances) for chemical residues and contaminants in food sold in Canada, where necessary. There are no Canadian maximum levels for FMN in any foods, including corn products. See Appendix 1 for a summary of the international maximum levels for FMN in foods.

Foods for which standards have not been established may still contain low levels of FMN. Health Canada assesses any findings of elevated levels of FMN in food on a case-by-case basis using the most current scientific data available. When levels of FMN in food are deemed to pose a health concern, corrective actions (such as product recalls, product detention) may be taken by the CFIA and Health Canada.

2. Survey Details

2.1 Fumonisin in Food

Fusarium moniliforme and *Fusarium proliferatum* are plant pathogens common in grain-growing regions throughout the world. These pathogens can infect crops either in the field (pre-harvest) or during storage (post-harvest). The moulds proliferate if grains are grown in hot, dry weather followed by very humid conditions. Mould growth is also favoured by storage under wet conditions. The plant pathogens produce mycotoxins known as fumonisins (FMN). Corn is the grain most vulnerable to FMN contamination¹. The levels of FMNs can be quite high, even in the absence of visible signs of mould proliferation.² There are several forms of FMN: FMN B1 and FMN B2 are the most prevalent and the most toxic forms; FMN B1 is more toxic than FMN B2^{3,4,5,6}. Fumonisin are heat-stable up to 150°C, are unaffected by mechanical forces such as grinding, but can be reduced by alkaline treatment (traditional means of preparing corn masa and other corn products such as tacos).⁷

The CFIA has published a fact sheet for industry to prevent and reduce mycotoxin contamination of foods and feeds⁸. The Codex Alimentarius Commission has published a Code of Practice for the prevention and reduction of fumonisin contamination in cereals⁹. The U.S. Food and Drug Administration has also published a guidance document for industry¹⁰ aimed at preventing mould proliferation in corn and reducing FMN levels in raw corn and in corn products. These recommendations are based on Good Agricultural Practices for minimising damage by insects and by farm machinery, as well as maintaining appropriate storage and transportation conditions. These guidance documents recommend that the corn be stored at low humidity to prevent mould growth^{9,10}.

The ingestion of corn products containing FMN can be harmful to human health. The precise biological effects of FMN are complex and relate to their interference with cell metabolism². The International Agency for Research on Cancer (IARC) has classified FMN as “possibly carcinogenic to humans”¹. Epidemiological studies have demonstrated an association between FMN occurrence in corn and oesophageal cancer in regions of Africa. An association between FMN occurrence and neural tube defects in Central America and the south-western US have also been observed. For both of these latter studies, the climate favours the proliferation of FMN-producing moulds and corn is a staple food in the diet in these geographical areas^{3,4}.

2.2 Rationale

Dietary exposure of Canadians to FMN has not been assessed recently. The major source of FMN in the Canadian diet is through the ingestion of corn products contaminated with FMN. Canadians of all age groups consume 5.7 kg of corn and corn products per person per year¹¹. The National Chemical Residue Monitoring Program does not monitor for the presence of FMN in any commodity. For these reasons, a survey to provide baseline surveillance data regarding FMN levels in corn products available on the Canadian retail market was considered appropriate.

2.3 Sample Distribution

The 2010-2011 Fumonisin in Corn Products targeted survey sampled domestic and imported corn products. The intent of the survey was to obtain a snapshot of the FMN levels in different corn products available in the Canadian retail market. For this reason, a broad assortment of corn products was selected and tested. Both the product types and the number of samples per product type depended on the availability of these products on store shelves at the time of sampling.

A total of 276 corn product samples were tested for FMN. All foods were sampled at grocery and specialty stores in 11 Canadian cities. The corn products analyzed included 138 domestic samples, 103 imported products and 35 samples of unverifiable origin. It is important to note that products often contained the statement “processed in Country X”, “imported for Company A in Country Y” or “manufactured for Company B in Country Z”. Although the labelling is accurate, it does not clearly identify the true origin of the product ingredients. Only those products labelled with a clear statement of “Product of Country A” were considered as being from a specific country of origin.

2.4 Method Details

Samples from the 2010-2011 FMN targeted survey were analysed by a laboratory under contract with the Government of Canada. A multi-residue method allowed for the simultaneous determination of the FMN B1 and B2 forms in corn products. The method is based on the CFIA reference method “Fumonisin Analysis in Cereal Grains, Cereal Products and Soy Products Using LC-MS/MS”, which consists of immunoaffinity column separation followed by mass spectrometric detection. The limit of detection

(LOD) for each FMN form is 20 ppb and the limit of quantitation (LOQ) is 25 ppb. Both the levels of the individual FMN forms and the total level of FMN were reported. The evaluation of the results was based on the total FMN level.

2.5 Limitations

The FMN survey was designed to provide a snapshot of the prevalence and levels of FMN in corn products available to Canadian consumers. In comparison to the total number of these products existing on the Canadian retail market, a sample size of 276 is small. Therefore, care should be taken in the interpretation or extrapolation of the results. Given that the label may not clearly identify the actual origin of the products or their ingredients, no distinct comparison could be made regarding the country of origin and the FMN levels in products. This survey does not examine the impact of product shelf-life or the cost of the commodity on the open market.

3. Results

Of the 276 samples of corn products tested, 119 (43%) did not have detectable levels of FMN (limit of detection of 20 ppb). The levels of total FMN in the remaining 157 samples ranged from 20 ppb to 6650 ppb. The average FMN level (average of all positive results) in corn products available to Canadian consumers was 286 ppb. Figure 1 below shows the distribution of corn samples and the proportion of products sampled with detectable vs. non-detectable levels of FMN by product type.

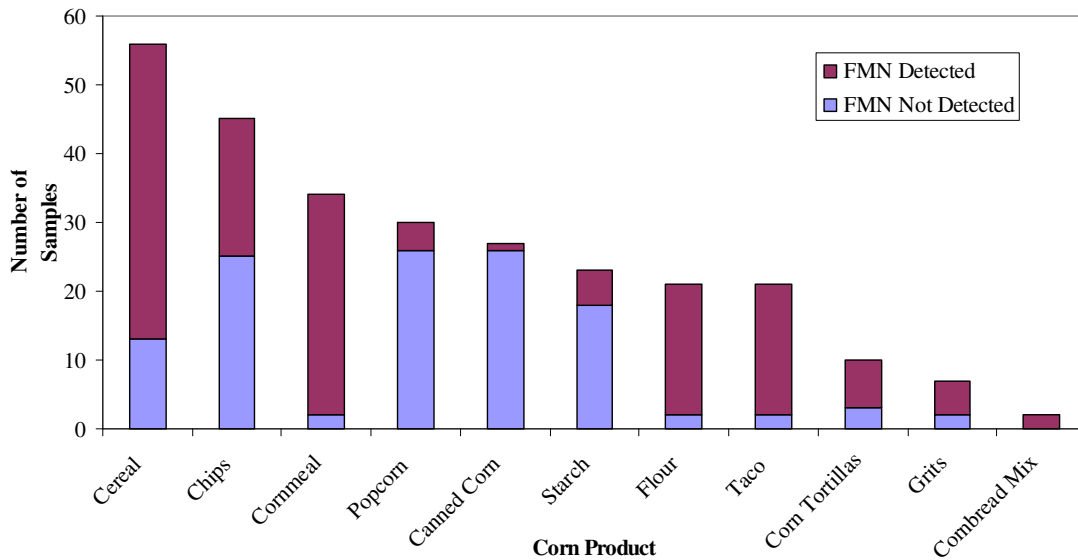


Figure 1 - Distribution of corn product samples by product type

All eleven types of corn products analyzed in this targeted survey were associated with detectable FMN levels. However, the percentage of positive samples and the average

concentration of FMN varied from product type to product type. See Table 1 below for the maximum and average total FMN levels by product type.

**Table 1 - Summary of FMN data by corn product type
(arranged in order of increasing average total FMN level)**

Corn Product Type	Number of Samples	Number of Positives	% Positive	Min (ppb)	Max (ppb)	Mean (ppb)
Popcorn	30	4	13	21	90	41
Canned corn	27	1	4	94	94	94
Starch	23	5	22	33	290	118
Cornbread mix	2	2	100	131	210	171
Taco	21	19	90	30	592	194
Flour	21	19	90	22	480	196
Corn tortillas	10	7	70	22	742	236
Chips	45	20	44	20	822	253
Cereal	56	43	77	21	1910	260
Cornmeal	34	32	94	20	6650	375
Grits	7	5	71	20	1627	723

The percentage of positive samples ranged from 4% in canned corn (1/27) to 100% in cornbread mix (2/2). The percentage of positive samples can be divided into three groups: low, medium, and high positive rates. A low positive rate (less than 25% positive) was associated with popcorn, canned corn, and corn starch. A medium positive rate (between 25% and 89%) was associated with corn chips, corn grits, corn tortillas, and corn cereals. A high positive rate (90% and over) was associated with corn tacos, corn flour, cornmeal and cornbread mix. As depicted in Table 1 above, the average concentration of FMN per product type (average of all positive results) varied from 41 ppb in popcorn to 723 ppb in corn grits.

4. Discussion

A total of 276 corn product samples were tested for FMN, including corn-based breakfast cereals, corn/tortilla chips, cornmeal, popcorn, canned corn, corn starch, corn tacos, corn flour, corn tortillas, corn grits, and cornbread mix. The majority of the samples (157/276 or 57%) tested in this targeted survey contained detectable levels of FMN.

All of the eleven different types of corn products tested for FMN had detectable levels of FMNs and overall, the total FMN levels ranged from 20 ppb to 6650 ppb. The sample types and the number of samples per product type depended on product availability at the retail level. Canned corn, popcorn, and starch had the lowest positive rates, the lowest average FMN levels, and the lowest maximum FMN levels. The highest positive rates, the highest maximum levels and the highest average levels of FMN were associated with corn-based breakfast cereals, corn grits, and cornmeal.

The FMN levels in the final product may depend upon several factors, including the part of the corn kernel used in the finished product, whether a wet milling or dry milling process is used, the initial FMN levels in the raw corn, whether the corn was dried prior to use, the degree and type of processing, and the storage conditions of the raw corn and/or finished products⁷. As this survey focused on finished corn products available at retail, it is unknown which, if any, of these factors played a role in the FMN levels in the final product.

There are no Canadian maximum levels, tolerances, or standards established for FMN so compliance could not be evaluated. The FMN levels found in this survey were compared to existing maximum levels established by Canadian trading partners. Four samples of corn cereals exceeded the EU maximum level of 800 ppb FMN in breakfast cereals. Two samples of corn grits, one sample of corn tortilla, and one sample of cornmeal exceeded the EU maximum level of 1000 ppb FMN in corn products intended for direct human consumption. Of these eight samples identified as exceeding the EU maximum levels, only the cornmeal sample also exceeded the US maximum level of 4000 ppb FMN in whole or partially degermed corn products intended for human consumption. This sample of cornmeal had almost ten times the concentration of FMN of the other cornmeal samples, including other lots of the same brand, and may represent an isolated incident. Health Canada provided an opinion that the product with the highest FMN level did not pose a human health concern. The remaining seven samples contained much lower levels of FMN, so it was deemed that they would not pose a human health concern. Appropriate product follow-up actions were taken reflecting the magnitude of the health concern.

5. Conclusions

This targeted survey was carried out to examine the levels of FMN in a selection of corn products available on the Canadian retail market. Most of the samples tested (157/276 or 57%) contained detectable levels of FMN. The FMN levels ranged from 20 ppb in corn chips and corn grits to 6650 ppb in cornmeal. The average FMN level in corn products (average of all the positive results) was 286 ppb.

Eight products (four samples of corn cereals, two samples of corn grits, one sample of corn tortilla, and one sample of cornmeal) had higher concentrations of FMN levels (> 800 ppb) in comparison to EU maximum limits. Health Canada provided an opinion that the highest level of FMN observed (6650 ppb) was considered unlikely to pose a concern to human health, in consideration of the other results containing much lower levels, and therefore, that consumers were unlikely to be exposed to this level over the long-term. Appropriate product follow-up actions were initiated reflecting the magnitude of the health concern. In the case of domestic products, follow-up actions may include inspection of facilities or manufacturer notification. For imported products, follow-up actions may entail communication with the importer, manufacturer, and/or appropriate food safety authority (e.g. United States Food and Drug Administration).

6. Appendix 1

Various Tolerances/Standards/Maximum Levels for Fumonisin in Corn Products

Commodity	Canada	United States	European Union	Codex*
Corn and corn-based products (canned corn, corn flour, corn meal, corn bran, corn starch) intended for direct consumption	None	2000 ppb for Degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of < 2.25%, dry weight basis);	1000 ppb in Maize intended for direct human consumption, maize-based foods for direct human consumption, with the exception of certain foodstuffs where more stringent MLs are applied	2000 ppb for corn flour/corn meal
		4000 ppb for whole or partially degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of ≥ 2.25 %, dry weight basis)		
		4000 ppb for dry milled corn bran		
		4000 ppb for cleaned corn intended for masa production		5000 ppb for corn grain, unprocessed
Corn-based breakfast cereals, snacks	None	Not specified	800 ppb	1000 ppb, including chips
Corn-based infant and Children's foods	None	Not specified	200 ppb	500 ppb
Popcorn	None	3000 ppb	None	2000 ppb

ppb = parts per billion

*Draft FMN maximum levels under consideration by the Codex Committee on Contaminants in Food

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