

Canadian Food

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys Chemistry



Fumonisins in Corn-based and Soy-based Products



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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. As part of the FSAP enhanced surveillance initiative, targeted surveys are used to provide data in order to evaluate various foods for specific hazards.

The main objectives of the fumonisins survey were to provide baseline surveillance data regarding fumonisin levels in corn-based and soy-based products available on the Canadian retail market, and to compare these levels to the fumonisin levels observed in the previous FSAP survey, where feasible.

Fumonisins are a family of naturally-occurring toxins released by *Fusarium* moulds. These moulds proliferate and release fumonisins on crops growing in the field (preharvest) and on crops in storage (post-harvest). The growth of these moulds is favoured by hot, dry conditions followed by very humid conditions, and subsequent storage under wet conditions.

Although 15 different fumonisins have been identified, fumonisin B1 is the most abundant and most commonly detected. Frequently, lesser amounts of fumonisin B2 and fumonisin B3 are also detected. Fumonisin B1 has been shown to be toxic to the liver and kidney in animal studies and is classified as possibly carcinogenic to humans. Epidemiological studies have found an association between high dietary concentrations of fumonisin B1 and the incidence of oesophageal cancer (China, Iran, Africa) and neural tube defects (Central America and the southwestern US).

A total of 454 samples (274 corn-based and 180 soy-based) were collected and analysed in this targeted survey. All samples were analysed for fumonisins forms B1 and B2. Thirty-six percent of samples tested (162/454) had detectable levels of fumonisins.

Of the 274 corn-based samples tested (e.g. corn flour, corn tacos, corn/tortilla chips), one hundred sixty-one (59%) had detectable levels of fumonisins, ranging from 20.8 parts per billion (ppb) to 4442.5 ppb. Of the 180 soy-based samples (e.g. soybeans, soy beverages, soy flour), one sample (soy flour; 22.4 ppb) had a detectable level of fumonisins. The positive rates and the fumonisin levels were comparable between the two survey years for corn-based products (soy-based products were not analysed in the previous FSAP survey).

There are no Canadian maximum levels, tolerances, or standards for fumonisins in cornbased or soy-based products so compliance to a numerical standard could not be assessed. One cornmeal result (4442.5 ppb) had an elevated level of fumonisins relative to other corn-based products. Health Canada's Bureau of Chemical Safety evaluated all fumonisin results, including the elevated result for cornmeal, and determined that they did not pose a concern to human health. Due to the lack of a human health concern, no product recalls were required.

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 Canada's safety system for food, health, and consumer products. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The Canadian Food Inspection Agency's (CFIA) 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.

Within the current regulatory framework, some commodities (such as meat products) traded internationally and interprovincially are legislated under specific Acts. These are referred to as federally registered commodities. Under the current regulatory framework, the non-federally registered commodities encompass 70% of domestic and imported foods and are regulated solely under the *Food and Drugs Act* and *Regulations*. Targeted surveys are primarily directed towards non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the potential occurrence of chemical residues, contaminants, and/or natural toxins 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), a group of federal, provincial, and territorial subject matter experts in the area of food safety.

The FSSC ranked fumonisins as a priority hazard because of their deleterious human health effects and their occurrence in products which are widely consumed by many population groups in Canada. This survey provided more recent occurrence data that could be used by Health Canada's Bureau of Chemical Safety in order to update the estimated exposure of the Canadian population to fumonisins.

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 *Food and Drugs Act* and its associated *Regulations*.

Health Canada establishes the health-based maximum levels for chemical residues and contaminants in food sold in Canada. Certain maximum levels for chemical contaminants in food appear in the Canadian *Food and Drug Regulations*, where they are referred to as tolerances. Tolerances are established as a risk management tool, and generally only for foods that significantly contribute to the total dietary exposure of the food contaminant in question. There are also a number of maximum levels that do not appear in the regulations that are referred to as standards. Currently, no maximum level, tolerance, or standard has been established by Health Canada for fumonisins in food and therefore, comparison with a Canadian numerical standard was not possible. However, all foods sold in Canada must comply with the provisions in section 4(a) of the *Food and Drug Act* (i.e. which prohibits the sale of a food that contains a harmful substance). Refer to the Appendix for a summary of the international maximum levels for fumonisins in cornbased products. There are no tolerances, standards, or maximum levels for fumonisins in soy-based products anywhere in the world.

In the absence of tolerances or standards, fumonisin levels may be assessed by Health Canada's Bureau of Chemical Safety (BCS) on a case-by-case basis using the most current scientific data available. If BCS identifies a potential safety concern, the CFIA can exercise follow-up actions. Follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification of the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

2. Survey Details

2.1 Fumonisins

Fusarium moniliforme (F. verticillioides) Fusarium proliferatum and other Fusarium species are plant pathogens common in grain-growing regions throughout the world. These pathogens can infect grain 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. Corn is the grain most vulnerable to fumonisin contamination¹. The levels of fumonisins can be quite high, even in the absence of visible signs of mould proliferation². There are several forms of fumonisin: Fumonisins B1, B2 and B3 are the most abundant. While toxicological studies have focussed on fumonisin B1, the available data suggests that fumonisins B2 and B3 have a similar toxicological profile^{3,4,5}. Fumonisins are heat-stable up to 150°C and are

unaffected by mechanical forces (such as grinding), but can be reduced by alkaline treatment, which is a traditional means of preparing corn masa and other corn-based products such as tacos⁶.

The CFIA has published a fact sheet for industry to prevent and reduce mycotoxin contamination, including fumonisins, of foods and feeds⁷. The Codex Alimentarius Commission has published a Code of Practice for the prevention and reduction of fumonisin contamination in cereals⁸. The U.S. Food and Drug Administration has also published a guidance document for industry⁹ aimed at preventing mould proliferation in corn and reducing fumonisin levels in raw corn and in corn-based 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 corn be stored in low humidity conditions to prevent mould growth^{8,9}.

Although fumonisin contamination is mainly observed in corn, some scientific studies have shown the presence of fumonisins in red wine¹⁰, sorghum¹¹, white beans¹¹, wheat, barley¹¹, soybeans¹¹, figs¹¹, rice¹², black tea¹¹, and medicinal herbs¹¹. As fumonisins are heat-stable and are unaffected by most processing steps⁶, fumonisins in the derived products may be observed.

The ingestion of foods containing fumonisins may be harmful to human health. Studies in laboratory animals have shown fumonisin B1 to be hepatotoxic, nephrotoxic⁶ and carcinogenic¹³. The biological effects of fumonisins are complex¹⁴ and relate to their interference with cell metabolism^{3,4,5}. Epidemiological studies of populations where corn is a major component of the diet and where the climate and agronomic practices can favor fumonisin proliferation, suggest an association between fumonisin exposure and esophageal cancer (China, Iran, Africa^{3,6,1}) and neural tube defects (Central America and the southwestern US⁴).

2.2 Rationale

The occurrence of fumonisins in the Canadiandiet has not been assessed recently. The major source of fumonisins in the diet is through the ingestion of corn-based products contaminated with fumonisins^{15,16}. Fumonisins are more likely to be a problem in corn grown in the southern US than in Canada. Consequently, Canadians' exposure is more likely to result from the consumption of imported corn products or products made from imported corn. Averaged over all age groups, Canadians consume approximately 5.7 kg of corn and corn-based products per person per year¹⁷. Canada is generally the tenth biggest producer of corn in the world¹⁸. The corn is used both for human food and for animal feed.

In North America, the soy-based food industry increased 87 per cent between 2001 and 2006¹⁹, and was forecast to grow a further 45% by 2011. Canada is the seventh biggest producer of soybeans in the world²⁰. Soy-based products encompass foods or food ingredients made from soybeans, including tofu, miso, soy beverages, soy cheese, soy

yoghurt, soy infant formula, soy infant cereals, meat alternatives, and soy sauce. As soy is a good source of protein, it may be heavily consumed by vegetarians, lactose-intolerant individuals, and certain sub-populations in Canada. There is a lack of Canadian and international data regarding the prevalence of fumonisins in soybeans and soy-based foods. However, a Canadian study of mycotoxin levels in infant cereals indicated that 18 of 24 soy infant cereals contained detectable levels of fumonisins².

The CFIA does not routinely monitor for the presence of fumonisins in any commodity under monitoring programs. The current survey will add to baseline data for fumonisins established in the 2010-2011 FSAP survey on fumonisins in corn and corn-based products. For these reasons, a survey to provide additional baseline data regarding fumonisin levels in corn-based and soy-based products available on the Canadian retail market was considered appropriate.

2.3 Sample Distribution

The 2011-2012 Fumonisins in Corn-based and Soy-based Products targeted survey looks at samples of domestic and imported corn-based and soy-based products. The intent of the survey was to obtain a snapshot of the fumonisin levels in different finished food products available in the Canadian retail market. For this reason, a broad assortment of corn-based and soy-based 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 454 samples were tested for fumonisins. The samples were taken at grocery and specialty stores in 11 Canadian cities. The products analyzed included 99 domestic samples, 237 imported products, and 118 samples of unspecified origin, meaning the country of origin could not be confirmed based on the available information recorded during sampling. It is important to note that the products sampled often contained the statement "processed in Country X", "imported for Company A in Country Y" or "manufactured for Company B in Country Z", and though the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labelled with a clear statement of "Product of", "Prepared in", "Made in", "Processed in", and "Manufactured by" were considered as being from a specific country of origin.

2.4 Analytical Method

Samples were analysed by an ISO 17025 accredited laboratory under contract with the Government of Canada.

A multi-analyte, liquid chromatography-mass spectrometry-mass spectrometric method allowed for the simultaneous determination of the B1 and B2 forms in corn-based and soy-based products. The limit of detection (LOD) for each form was 20 parts per billion (ppb) and the limit of quantitation (LOQ) was 25 ppb. The total level reported in this survey refers to the sum of the concentrations of each of the two forms (i.e. level of

fumonisin B1 + level of fumonisin B2). The evaluation of the results was based on the total fumonisin level.

2.5 Limitations

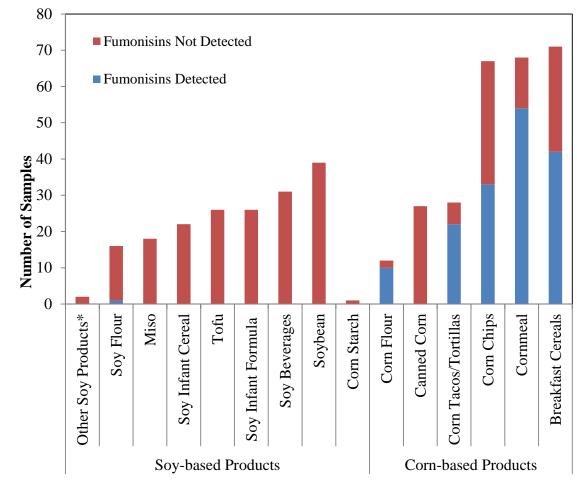
The fumonisins survey was designed to provide a snapshot of the prevalence and levels of fumonisins in corn-based and soy-based products available to Canadian consumers. In comparison to the total number of these products existing on the Canadian retail market, 454 samples represent a small fraction of the products available to Canadian consumers. Therefore, care should be taken in the interpretation or extrapolation of the results. The presence of the fumonisins can be highly dependent on the weather and climates of the region where the corn or soy is grown and stored. As the samples are picked up at retail, there is little information available on neither where and when the corn or soy was harvested nor the conditions under which the crops were stored. Given that the label may not clearly identify the actual origin of the products or their ingredients, inferences or conclusions were not made regarding the data with respect to country of origin and the fumonisins levels in products. This survey does not examine the impact of product shelflife or the cost of the commodity on the open market.

The products sampled in this survey include foods for direct consumption, ingredients, and foods that require preparation prior to consumption (e.g. cooking). The CFIA analyzes foods as sold rather than as consumed, and as such the results should only be interpreted as corn-based and soy-based products available as sold and not as they would be consumed. Estimation of the level of fumonisins that may occur in the food as it would be consumed based on the levels detected in the unprepared products available at retail (i.e., the dilution of or destruction of fumonisins during cooking) will not be considered herein.

3. Results and Discussion

3.1 Overview of Survey Results

The analytical method measures fumonisins B1 and B2 individually, however, throughout the remainder of this report, only the total fumonisin level (i.e., the sum of B1 and B2) will be reported and discussed. Of the 454 samples tested, 162 (36%) had detectable levels of fumonisins, ranging from 20.8 ppb to 4442.5 ppb. Figure 1 below shows the distribution of samples and the proportion of products sampled that were positive for fumonisins by product type.



Product Type

*Other Soy Products included meal replacements and protein powders.

Figure 1. Number of samples analyzed for fumonisins by product type (in order of increasing number of samples)

There are no Canadian maximum levels, tolerances, or standards established for fumonisins so compliance to a numerical standard could not be assessed. One cornmeal result (4442.5 ppb) had an elevated level of fumonisins relative to other corn-based products. Health Canada determined that none of the products, including the one cornmeal sample, posed a concern to human health. No product recalls were required.

Overall, corn-based products had a much higher rate of fumonisins detected than soybased products. Only one of the nine types of soy-based products (soy flour) and five of the seven types of corn-based products analyzed in this targeted survey were associated with detectable fumonisin levels. Canned corn, corn starch, and all other types of soy products did not have detectable levels of fumonisins.

Table 1. Minimum, maximum, and average levels of fumonisins in food typesin which fumonisin was detected (arranged in order of decreasing maximum
fumonisin levels)

Product Type	Number	Number	Minimum	Maximum	Average		
	of	(%) of	(ppb)	(ppb)	(ppb)		
	Samples	Positives					
Corn-based Products							
Cornmeal*	68	54 (79)	24.2	4442.5	310.1		
Corn Flour	12	10 (83)	30.8	1462.6	373.4		
Corn Chips	67	33 (49)	20.8	1109.0	222.1		
Corn	28	22 (79)	32.6	819.5	168.7		
Tacos/Tortillas	20						
Breakfast	71	42 (59)	23.1	783.4	220.2		
Cereals	/1	42 (39)	23.1				
Soy-based Products							
Soy Flour	16	1 (6)	<lod< td=""><td>22.4</td><td>-</td></lod<>	22.4	-		

Note: Only the detectable values of fumonisins were included in the calculation of the minimum, maximum, and average levels.

*Cornmeal includes polenta, corn grits, and cornmeal

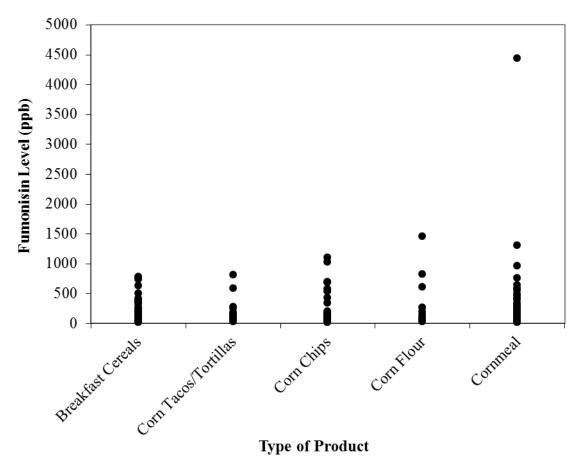
Of the commodity groups listed in Table 1, above, the percentage of samples positive for fumonisins ranged from 6% in soy flour to 83% in corn flour. The maximum concentration of fumonisins by product type varied from 22.4 ppb in soy flour to 4442.5 ppb in cornmeal.

The following sections present the analysis results for fumonisins in corn-based and soybased products by product type. Where feasible, the results of this survey are compared with the fumonisin levels reported in the previous CFIA FSAP survey²¹ or to levels reported in the scientific literature.

3.2 Results by Product Type

3.2.1. Corn-based Products

Corn-based products included 71 corn-based breakfast cereals, 68 cornmeal samples (including polenta and grits), 67 corn/tortilla chips, 28 corn tacos/tortillas, 27 canned corn, 12 corn flours, and one cornstarch. Fumonisins were not detected in the cornstarch or canned corn samples. Figure 2 shows the range of fumonisin levels observed by cornbased product type (only non-zero values are displayed). Fumonisin levels ranged from 20.8 ppb in corn chips to 4442.5 ppb in cornmeal. One cornmeal result (4442.5 ppb) had an elevated level of fumonisins relative to other corn-based products. All fumonisin results were assessed by Health Canada's Bureau of Chemical Safety and were determined not to pose a concern to human health.



Note: Cornmeal includes polenta, corn grits, and cornmeal

Figure 2. Fumonisin levels in corn-based products by product type

Table 2 presents a comparison of the fumonisin levels observed in corn-based products in the current and previous FSAP surveys. When examining the positive rates of both surveys (i.e., the number of samples with detectable levels of fumonisins relative to the total number of samples), the positive rates are similar from year to year for canned corn, corn starch, tacos/tortillas, and corn chips (i.e., less than 10% difference in positive rate between sample years). In the current survey, breakfast cereals and cornmeal have a lower positive rate. No comparison can be made for cornstarch due to the difference in sample size between the survey years.

Study	Year	Number	Number	Minimum	Maximum	Average			
Author		of	(%) of	(ppb)*	(ppb)*	(ppb)*			
		Samples	Positive						
			Samples						
Canned Corn									
CFIA	2011-2012	27	0 (0)	_	< LOD	-			
Survey	2010-2011 ²¹	27	1 (4)	<lod< td=""><td>94</td><td>-</td></lod<>	94	-			
			Cornstarch						
CFIA	2011-2012	1	0 (0)	-	< LOD	-			
Survey	2010-2011 ²¹	23	5 (22)	33	290	118			
		Bre	akfast Cerea	ls					
CFIA	2011-2012	71	42 (59)	23	783	220			
Survey	2010-2011 ²¹	56	43 (77)	21	1910	260			
		Corn	Tacos/Tortil	las					
CFIA	2011-2012	28	22 (79)	33	820	169			
Survey	2010-2011 ²¹	31	26 (84)	22	742	205			
	· · · · ·		Corn Chips						
CFIA	2011-2012	67	33 (49)	21	1109	222			
Survey	2010-2011 ²¹	45	20 (44)	20	822	253			
	Corn Flour								
CFIA	2011-2012	12	10 (83)	31	1463	373			
Survey	2010-2011 ²¹	21	19 (90)	22	480	196			
Cornmeal									
CFIA	2011-2012	68	54 (79)	24	4442	310			
Survey	2010-2011 ²¹	41	37 (90)	20	6650	422			

 Table 2. Summary of CFIA fumonisin survey results for corn-based products

*Minimum, maximum and average of positive results only

Note: Cornmeal includes polenta, corn grits, and cornmeal

The maximum fumonisin level for canned corn, breakfast cereals, and cornmeal was lower in the current FSAP survey than in the previous 2010-2011 FSAP survey. The maximum fumonisin level for corn tacos/tortillas, corn chips, and corn flour was higher in the current FSAP survey than in the previous 2010-2011 FSAP survey. The average fumonisin level decreased for breakfast cereals, corn tacos/tortillas, corn chips and cornmeal between the current FSAP survey and the previous 2010-2011 FSAP survey. The average level increased slightly in the case of corn flour. The cause of the differences noted between survey years is not known.

3.2.2. Soy-based Products

The 180 soy-based samples included 39 soybean, 31 soy beverage, 26 soy infant formula, 26 tofu, 22 soy infant cereals, 18 miso, 16 soy flours, and 2 "other" soy-based products (one meal replacement and one protein powder). Only one sample, a soy flour, contained a very low level of fumonisins (22.4 ppb).

Soy-based products were not analysed as part of the previous 2010-2011 FSAP Fumonisins targeted survey²¹, and there is little scientific literature on the levels of fumonisins in soy products, so comparison was not possible. A Canadian study of mycotoxin levels in infant cereals indicated that 18 of 24 soy infant cereals contained a detectable level of fumonisins (maximum level observed was 130 ppb)². In contrast, soy-based infant cereals in this survey did not contain detectable levels of fumonisins. The limit of quantitation was lower in the Canadian study than in the current survey, which may explain the difference in the positive rates.

4. Conclusions

This targeted survey examined the levels of fumonisins in a range of corn-based and soybased products available on the Canadian retail market. Thirty-six percent of the samples tested (162/454) had a detectable level of fumonisins. The fumonisin levels ranged from 20.8 ppb in corn chips to 4442.5 ppb in cornmeal.

The positive rates and the fumonisin levels were comparable between the two survey years for corn-based products (soy-based products were not analysed in the previous FSAP survey).

Overall, the occurrence of fumonisins in soy-based products was low (<1%). Corn-based products had a higher occurrence of fumonisins, with 59% of corn-based products tested having a detectable level of fumonisins. One cornneal sample (4442.5 ppb) had an elevated level of fumonisins relative to other corn-based products. The entire dataset, including the elevated result, was forwarded to Health Canada's Bureau of Chemical Safety, which determined that none of the products posed a concern to human health. No product recalls were required.

5. Appendix

Various Tolerances/Standards/Maximum Levels for Fumonisins in Cornbased Products

Commodity	Canada	United States ²²	European Union ²³	Codex*
Corn and corn-based	None	2000 nmh for		2000 mmh fan aam
	None	2000 ppb for	1000 ppb in maize intended	2000 ppb for corn flour/corn meal
products (canned corn,		degermed dry		flour/corn meal
corn flour, corn meal,		milled corn-based	for direct	
corn bran, cornstarch)		products (e.g.,	human	
intended for direct		flaking grits, corn	consumption,	
consumption		grits, corn meal,	maize-based	
		corn flour with	foods for direct	
		fat content of <	human	
		2.25%, dry	consumption,	
		weight basis)	with the	
		4000 ppb for	exception of	
		whole or partially	certain	
		degermed dry	foodstuffs	
		milled corn-based	where more	
		products (e.g.,	stringent MLs	
		flaking grits, corn	are applied	
		grits, corn meal,		
		corn flour with		
		fat content of \geq		
		2.25 %, dry		
		weight basis)		
		4000 ppb for dry		5000 ppb for corn
		milled corn bran		grain, unprocessed
		4000 ppb for		
		cleaned corn		
		intended for masa		
		production		
Corn-based breakfast	None	Not specified	800 ppb	None
cereals, snacks	Tione	rot specifica	000 PPD	TOLL
Corn-based infant and	None	Not specified	200 ppb	None
Children's foods				
Popcorn	None	3000 ppb	None	None

Note: ppb = parts per billion

^{*}Draft fumonisin maximum levels under consideration by the Codex Committee on Contaminants in Food (CX/CF 12/6/18; Feb. 2012; Discussion paper on proposed draft maximum levels for fumonisins in maize and maize products and associated sampling plans)

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