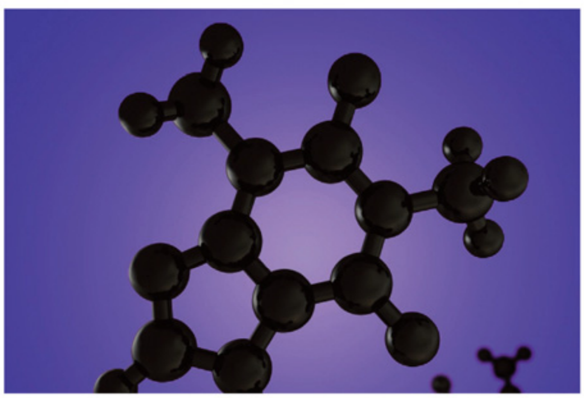
Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2009-2010 Targeted Surveys

Chemistry



Ochratoxin A and Deoxynivalenol in Selected Foods

TS-CHEM-09/10-04

Canada

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1. 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.

This targeted survey focuses on ochratoxin A (OTA) and deoxynivalenol (DON), which are a class of mycotoxins produced by fungal contamination of foods such as grains and fruit. Fungal contamination may occur in the field or during storage of the raw commodities. Processing of the affected grains/fruit may result in detectable levels of these mycotoxins in finished food products.

The main objectives of this survey were to:

- Provide baseline surveillance data for OTA levels in foods that are known to have the potential for OTA and DON contamination. These foods include infant foods (formula, cereal), beverages (grape juice, wine, beer), and grain (wheat, oat and corn) products.
- Obtain a snapshot of the available infant food, beverage and cereal-based commodities and their compliance with Health Canada's proposed guidelines for OTA.
- Provide baseline surveillance data for DON levels in wheat, corn and oat products.

The compliance rate for OTA in infant foods, which included infant formula and infant cereals, was 96%. Out of 150 infant food samples (75 formula and 75 cereal), 20 samples contained detectable levels of OTA. Of the 20 positive samples, six infant cereal samples exceeded the OTA regulations proposed by Health Canada.

The compliance rate for OTA in beverages (grape juice, wine, and beer - 50 samples each) was 100%. There was one wine sample in which OTA was detected at a level that was compliant with Health Canada's proposed regulatory limits for OTA.

In cereal products, the compliance rate for OTA was 98%. Out of 150 cereal products (75 wheat, 50 corn, 25 oat) sampled, 31 contained detectable levels of OTA. Of the 31 positive samples, three oat samples exceeded Health Canada's proposed regulations for OTA.

The compliance rate for DON in cereal products could not be determined as there are no established or proposed regulatory limits for DON in the commodities tested in this survey. No detectable levels of DON were found in 39% of the wheat products, 32% of the corn products, and 72% of the oat products sampled. The measured DON levels ranged from 0.01 ppm to 6.01 ppm in wheat products; 0.01 ppm to 1.38 ppm in corn products; and 0.02 ppm to 0.13 ppm in oat products.

In summary, 450 total samples were tested for OTA resulting in an overall compliance rate of 98%. One hundred and fifty of these samples were also tested for DON, in which

it was detected in 42% of the samples. All samples that exceeded the proposed regulations for OTA and all positive results for DON were referred to the designated CFIA program for appropriate follow-up actions. These actions may range from notification of the producer or importer, follow-up inspections, additional directed sampling, and product recalls.

2. Introduction

2.1. *Food Safety Action Plan*

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. The FSAP unites multiple partners in ensuring safe foods for Canadians.

Within FSAP, the Canadian Food Inspection Agency (CFIA) gained increased authority to monitor potential food risks and to prevent unsafe food products from entering the Canadian marketplace. The CFIA fulfills this mandate through an enhanced surveillance initiative which includes targeted surveys. The CFIA works on these initiatives with input from Federal partners (Agriculture and Agri-Food Canada, Health Canada, the Canadian Grain Commission) and from Provincial and Territorial (P/T) representatives.

2.2. *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. Unlike monitoring activities, targeted surveys often focus on gathering data related to a particular chemical hazard, commodity type and/or geographical area. 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 all foods.

To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of media reports, scientific literature, and/or a risk-based model developed by the Food Safety Science Committee (FSSC). In the most recent FSSC meeting, mycotoxins were ranked as a high priority due to their negative health effects. Both Health Canada (HC) and the Canadian Grain Commission (CGC) have monitored for OTA in raw grains and grain commodities in the past. CGC continues to monitor raw grains for a variety of mycotoxins, however monitoring of finished grain products at the retail level is lacking. The present targeted survey was designed by the CFIA in consultation with federal and provincial partners to gain an appreciation of the OTA and DON levels in infant foods, beverages and cereal products.

2.3. *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 food products as outlined in the *Food and Drugs Act & Regulations*.

Health Canada determines the legal limits for contaminant residues in food, including natural toxins such as DON and OTA. The proposed and established Canadian and International standards for OTA and for DON in foods are presented in Table 2.1.

Table 2.1 – Canadian and International Standards for OTA and DON in Food

Hazard	Commodity	Canada	US	EU	Codex
DON (ppm)	wheat, soft, raw	1-2 *			regulations on hold waiting for info on processing all foods + precursors regulations
	wheat, durum, raw			1.75	
	wheat, other, raw			1.25	
	oats, corn, raw			1.75	
	flour, bran, germ		1	0.75	
	flour, for infant food			-	
	pasta, dry			0.75	
	cereal derived retail food			0.50	
	foods: babies, young children			0.20	
OTA+ (ppb)	wheat+other grains	3-7**		5	5
	flour, food products			3	
	raisins, currants, sultanas	10		10	
	coffee: ground roast			5	5
	coffee: soluble			10	
	wine, grape juice etc	2		2	
	infant foods	0.5		0.5	
	cacao			-	5

\+ Proposed regulation
* 2 ppm for use in non-staple foods, 1 ppm for use in baby foods
** 3 ppb for directly consumer grains, derived cereal products (flour), breakfast cereals
** 5 ppb for raw cereal grains
** 7 ppb derived cereal products (wheat bran)

3. Ochratoxin and Deoxynivalenol Survey

3.1. Natural Toxins

Natural toxins have contaminated foods for centuries and are a global concern. These chemical compounds are released by micro-organisms such as algae, fungi and moulds. Natural toxins, such as mycotoxins, are distinct from other chemical hazards (e.g pesticides or veterinary drugs), in that they are neither deliberately added nor absorbed from the environment. Mycotoxins are released by fungi, which can grow on agricultural commodities. The more favourable the climatic, storage or processing conditions are to fungal contamination, the higher the levels of the mycotoxins will likely be.

The mycotoxins released by fungal growth can have harmful human health effects. Canada and the International Community are dedicated to reducing the levels of these toxins to the lowest possible achievable levels due to the seriousness of some of the health effects associated with their exposure (i.e., possible carcinogens). Two mycotoxins of interest in this targeted survey are deoxynivalenol (DON) and ochratoxin A (OTA). DON is a toxin generally produced in crops prior to harvest, while OTA is a toxin that generally forms during storage of crops. These toxins can be found individually or at the same time in some agricultural commodities and are of concern because of their deleterious health effects and the high consumption of the commodities in which they are normally found.

3.1.1. OTA

OTA is a naturally occurring metabolite of fungal species belonging to the strains of the *Aspergillus* and *Penicillium* moulds. Under favourable moisture and temperature conditions, the fungi can grow on stored material and produce OTA[1]. It has been widely detected in cereal grains (wheat, corn, oat, and barley), green coffee, grape juice, beer, wines, cocoa, dried fruits and nuts[2]. Cheese and meat products of animals consuming OTA-contaminated grains have also been found to contain OTA[3]. Health Canada determined that OTA is consumed at very low levels on a daily basis by most Canadians; and due to their low body weight, young children are the age group with the highest exposure to OTA[4].

The International Agency for Research on Cancer classified OTA as a possible human carcinogen[5]. OTA is also suspected to have negative health effects on the kidneys, developing fetus, and immune system. As a result of Health Canada's Bureau of Chemical Safety recently completed risk assessment for OTA, maximum limits for OTA in various food commodities have been proposed (refer to Table 2.1)[4,6].

3.1.2. DON

DON is a mycotoxin produced by various species of *Fusarium* mould. It is most commonly found in grain products (most notably wheat, barley and corn), and is typically the result of grains suffering from Fusarium head blight (FHB). Wet, warm weather conditions will particularly favour the development of FHB, and subsequently DON.

DON is not known to be carcinogenic. Short term effects of consuming foods heavily contaminated with DON include vomiting, abdominal pain and dizziness. Long term exposure to low levels of DON may cause dangerous reduction in appetite, weight loss, damage to the intestinal tract and impairment of the immune system[7].

3.2. Rationale

Raw cereal grains are tested by the CGC for mycotoxins, pesticides, and metals. Mycotoxins, such as DON and OTA, in grains and grain products have been periodically examined by Health Canada and other CFIA activities[6,11,12]. The CGC does not have jurisdiction over finished grain products and CFIA has no regular monitoring program for natural toxins in finished foods.

Since mycotoxins in finished products have not been regularly monitored, there was a need to collect baseline surveillance data for both OTA and DON levels in finished retail products. The present targeted survey was designed to gain an appreciation of the OTA and DON levels in infant foods, beverages and grain products.

3.3. OTA and DON in the Selected Commodities

3.3.1. OTA in Infant Foods

Infant foods are of interest because of the vulnerable target population that consumes them. Infant formula may be the only food source for infants in the first months of life and infant cereals are typically the first solid foods consumed.

Studies have shown that there is the possibility of transfer of OTA from the consumption of OTA affected grain by cattle to their milk[8], which could then potentially be detected in milk-based formula. Soy-based samples were also tested to explore the potential for OTA contamination of the raw soy commodity and subsequent transfer to the finished soy based formula. A health risk assessment performed by Health Canada stated that OTA exposure in infants (<1 year) was generally lower than for 1-year-olds, except for infants consuming soy based infant formula. As infants have been cited as one of the most vulnerable age categories due to the large proportion of formula in their diet, the levels of OTA that may be present in milk-based and soy-based infant formula was investigated.

Infant cereals are typically the first solid foods consumed by infants. They may be a major dietary component of their diet for a short period of time. Infant cereals are generally made up of either single grains (most commonly rice, wheat, barley or oats), or multigrain (which can contain any combination of rice, wheat, barley, oats or corn). OTA contamination may result from using contaminated grains in the production of these cereals.

3.3.2. OTA in Beverages

Grape juice, wine and beer were selected for this survey as levels of OTA have been observed in the past[9,11]. In addition, grape juice is the third most-consumed juice in Canada while wine and beer are commonly consumed by Canadian adults. In 2008, the per capita consumption of grape juice, wine and beer were 3.99 L, 15.0 L and 77.2 L, respectively.

There have been a number of scientific studies that have detected OTA in grapes, and processed grape products[9,11]. Grape juice and wine are of particular interest because large volumes of grapes are used to produce these products and climatic conditions during the grape-growing season can greatly influence the growth of organisms that can produce OTA. A limited study of OTA in wines and grape juices sold in Canada showed that Canadian red and white wines had lower levels and incidences of OTA contamination than imported wines particularly of Mediterranean origins. Also, the presence and levels of OTA detected in Canadian and US grape juices were lower than those reported in Europe. This survey will add to the data from the Health Canada study by examining domestic and imported red wines, from both Europe and other wine growing regions of the world. Additionally this data will provide an indication of year to year variability.

Beer is a beverage that is made primarily from cereal grains, mainly barley. The main source of ochratoxin in beer is from the proliferation of ochratoxin producing fungi on the raw ingredients themselves. Levels present in the finished beer product will depend on the conditions in which the raw ingredients were grown and subsequently stored, as well as processing/brewing steps. A review of recent literature indicated that OTA is a usual contaminant in beer and that OTA occurs in beers from all over the world. This survey looked to examine the levels of OTA in beer products readily available to the Canadian public.

3.3.3. OTA and DON in Wheat, Corn and Oat Products

Deoxnivalenol is the mycotoxin most commonly encountered in cereals produced in Canada[10]. It arises mainly in the field when cereal grains become contaminated with *Fusarium* fungi. Ochratoxin A is less commonly observed in Canadian grains, but is a potent renal carcinogen and therefore warrants investigation. It is usually associated with wet, temperate storage or transportation conditions.

The grains selected for testing included wheat, corn and oats, as they are high consumption items. These commodities are also of interest due to their susceptibility to fungal contamination that can lead to OTA and DON formation. Although mycotoxin testing of raw grains is undertaken by the CGC, a survey of finished grain commodities would be of interest to gain an appreciation of what effects the milling and processing of grains had on the levels of OTA and DON in cereal products available at the retail level.

3.4. Targeted Survey Sample Overview

This survey encompassed a number of commodities. These commodities were collected as pre-packed retail packages from grocery stores, ethnic markets and specialty shops in the Vancouver area.

A total of 450 products were analysed for OTA and/or DON. These samples were divided equally (150 samples each) between infant food, beverages and cereal products. See Table 3.1 for a detailed description of survey samples.

Table 3.1. – Distribution of OTA and DON samples

Commodity	Sample Type	Description	No. of Samples	Tested for OTA	Tested for DON
Infant food	Infant formula	—	**75**	X	—
	Infant Cereal	—	**75**	X	—
Beverage	Beer	—	**50**	X	—
	Wine	—	**50**	X	—
	Grape juice	—	**50**	X	—
Grain Products	Wheat	Bran Bulgur Couscous Flour **TOTAL**	24 4 1 46 **75**	X	X
	Corn	Flour Grits Masa Meal **TOTAL**	9 10 2 29 **50**	X	X
	Oats	Bran Meal Whole grains **TOTAL**	3 6 16 **25**	X	X

3.5. Detailed Analytical Methods

The OTA and DON targeted survey samples were analyzed by CFIA's Burnaby laboratory.

Analytical method BFCL-040 was used to quantitate the levels of OTA in infant foods, beverages and cereal products. The limit of detection (LOD) for this single residue HPLC-MS-MS method was 0.1 ppb, and the limit of quantitation (LOQ) was 0.3 ppb for all matrices tested.

Analytical method BFCL-038 was used to determine the levels of DON in cereal products. The LOD for this single residue LC MS-MS method was 0.0005 ppm and the LOQ was 0.001 ppm for all of the matrices tested. The reporting limit for the analytical method was 0.01 ppm for all matrices tested.

3.6. Limitations

The OTA and DON survey in food was designed to provide a snapshot of the infant food, beverage and grain commodities available to consumers. In comparison to the total number of such products available to Canadian consumers, a sample size of 450 is considered small. Therefore, care should be taken in the interpretation of the results as data cannot be considered as being representative of OTA or DON levels in all food categories or from specific countries of origin. This survey does not examine seasonality, year-to-year trends, impact of product shelf-life, or cost of the commodity on the open market.

4. Results and Discussion

4.1. Ochratoxin A

4.1.1. OTA in Infant Foods

Infant food products included 75 samples of powdered infant formulae targeted for infants 0 to 24 months of age and 75 samples of infant cereals targeted at infants 6 to 12 months of age and labelled as “wheat”, “multigrain”, “mixed” or “muesli”. Figure 4.1 shows the distribution of samples by country of origin as stated on the product label.

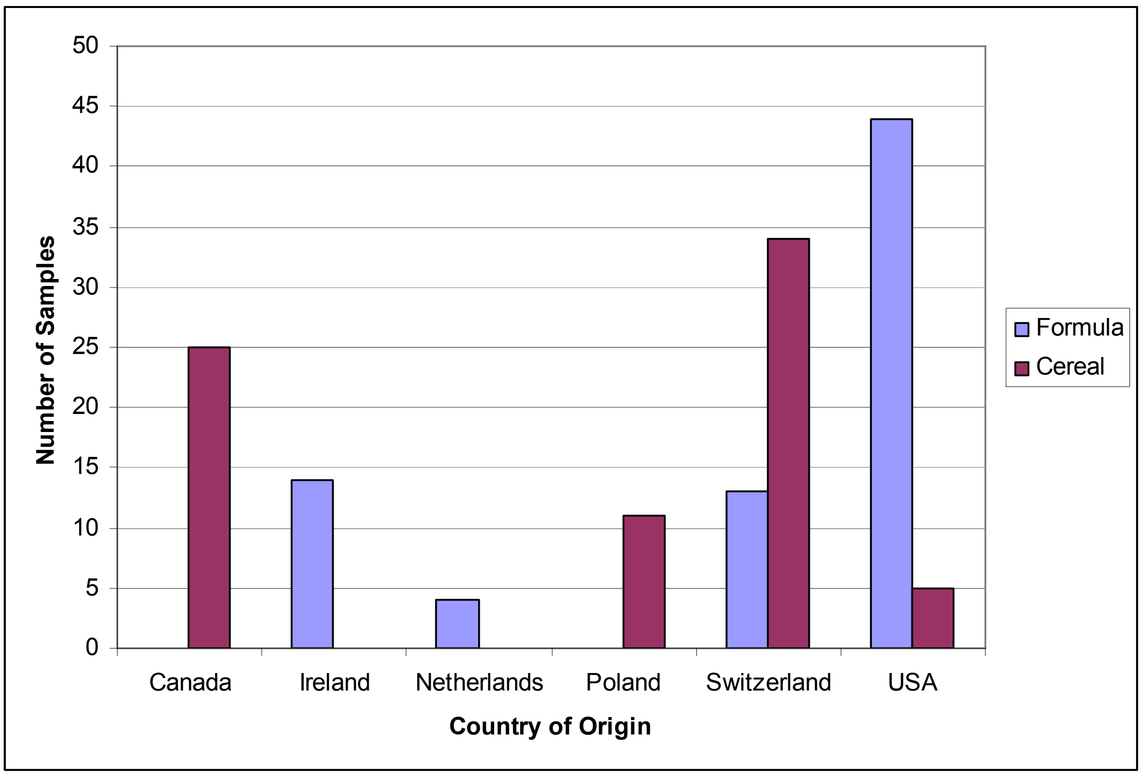

Figure 4.1. Distribution of powdered infant formula and infant cereals by country of origin

Seventy-five samples of infant formula were tested for OTA, nine of which were soy-based and the remainder of which were milk-based. These samples included iron fortified, low iron, nutritional supplement, omega-3/omega-6 and calcium-enriched formulae. There were 4 products labelled as organic (3 milk-based, 1 soy-based).

Out of the 75 samples, only one sample of soy infant formula had detectable levels (0.4 ppb) of OTA. All 75 samples of infant formula tested for OTA were compliant with the proposed Canadian standard of 0.5 ppb for baby foods. The compliance rate was 100% for all types of infant formula and for all countries of origin encompassed by this survey.

Seventy-five samples of infant cereals were tested for OTA. None of the products tested were labelled as organic. Of these, 69 samples (92%) were compliant with the proposed Canadian OTA standard of 0.5 ppb in infant foods. Fifty-six samples had no detected OTA, while thirteen samples had levels of OTA below 0.5 ppb. Six samples had OTA levels above the proposed Canadian standard that ranged from 0.6 ppb to 4.1 ppb. The non-compliant results were referred to the appropriate CFIA program for follow-up. The results from this survey were forwarded to Health Canada for a health risk assessment. A voluntary recall of the two products with the highest levels of OTA detected was initiated as a result. The overall compliance rate for OTA was 92% for infant cereals. None of these products were tested for DON.

4.1.2. OTA in Beverages

Of the 150 beverage samples collected, there were 50 samples of domestic or imported grape juice (concentrate and ready-to-serve), 50 samples of domestic or imported red wine, and 50 samples of domestic or imported beer. Table 4.1 shows the distribution of beer, grape juice, and wine samples, respectively, by country of origin as stated on the product label.

Table 4.1 Distribution of beverage samples by country of origin

Country Of Import	Beer	Grape Juice	Wine	Grand Total
Argentina			4	4
Australia			4	4
Belgium	3			3
Canada	25	5	25	55
Chile			4	4
China	1			1
Germany	5			5
France		1	5	6
United Kingdom	8	1		9
Italy			4	4
Netherlands	2			2
Singapore	1			1
United States	5	42	4	51
South Africa		1		1
Grand Total	50	50	50	150

Ochratoxin A was not detected in any of the 50 grape juice products tested. A survey performed by Health Canada in 2004, yielded similar results where only 4 of 71 grape juice samples were positive for OTA. The average level of OTA in the Health Canada survey was 0.013 ppb[11]. It should be noted that the average level of 0.013 ppb was below the LOQ for the method used in this targeted survey, and therefore results cannot be directly compared at these levels. The compliance rate was 100% when compared to the proposed regulations for the grape juice types tested in this targeted survey.

Forty-nine of 50 wine samples tested had no detectable levels of OTA. One sample of red wine from France contained 0.5 ppb of OTA. The results are compliant with the proposed Canadian limit of 2 ppb for OTA in wine and grape juice. These results are similar to a previous HC survey published in 2004, where 47 of 180 wine samples contained OTA, where the average level of OTA was 0.163 ppb[24]. As in the case of grape juice, the average OTA level in wine from the Health Canada study was below the LOQ for the method used in this targeted survey. The compliance rate was 98% when compared to the proposed regulations for the wine types tested in this targeted survey.

Ochratoxin A was not detected above the LOQ of 0.3 ppb in any of the beer samples tested in this targeted survey. These results are similar to a Health Canada survey carried out in 1995. The HC survey detected OTA in 26 of 41 beer samples where the maximum OTA level detected was 0.2 ppb and the average OTA level was 0.061 ppb[12]. Presently there are no proposed standards for OTA in beer; however the levels of OTA in the current targeted survey and the previous HC surveys were below the EU maximum of 0.3 ppb in malt barley.

4.1.3. OTA and DON in Grain Products

The grain products sampled for this survey (75 wheat, 50 corn and 25 oat products) were analysed for OTA and DON in this targeted survey. Figure 4.2 shows the distribution of wheat, corn and oat products by country of origin as stated on the product label.

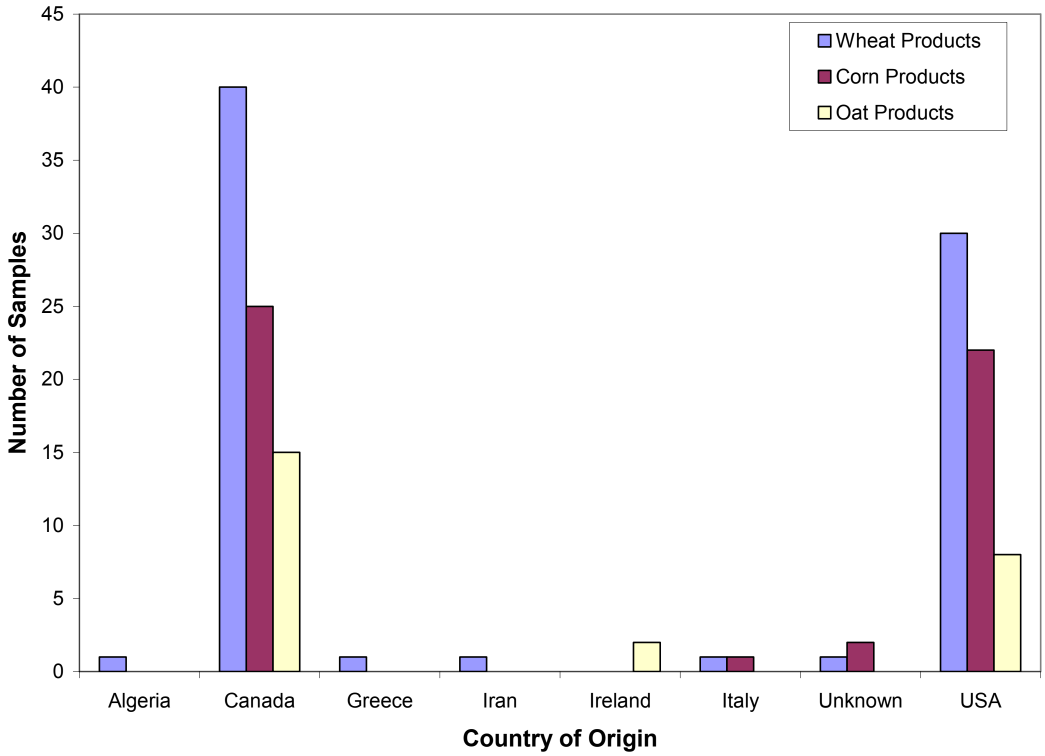

Figure 4.2. Distribution of grain products by country of origin

Seventy-five samples of wheat products were further divided into 46 samples of flour, 24 samples of bran, one sample of couscous and four samples of bulgur wheat. Of the 75 samples, 53 (70.6%) had no detectable levels of OTA. The remaining 22 samples had OTA levels that ranged from 0.3 to 3.5 ppb.

Of the 50 corn products that were analysed, there were 29 samples of corn meal, 10 samples of corn grits, nine samples of corn flour, and two samples of corn masa. Forty-eight of the samples (96%) had no detectable levels of OTA. The remaining two samples had OTA levels of 0.5 ppb and 0.9 ppb.

All of the levels of OTA detected in wheat and corn products are compliant with Health Canada's proposed maximum limits of 3 ppb for directly consumed grains and for cereal derived products such as flour and 7 ppb for wheat bran. The compliance rate was 100% for the wheat and corn products tested in this targeted survey.

Of the 25 oat products sampled, 16 were samples of whole oats, six were samples of oatmeal and three were samples of oat bran. Eighteen of the samples (72%) had no detectable levels of OTA. The remaining seven samples had OTA levels between 0.3 and 7.2 ppb. All of the positives were associated with whole oat samples four of which were compliant with the proposed OTA standards. The three samples that were not compliant with the proposed Canadian standards contained residues that ranged from 4.1 to 7.2 ppb. These oat samples were referred to the appropriate CFIA program for follow-up. Follow-up actions included notification of the producer or importer, follow-up inspections, additional directed sampling, and product recalls. The highest OTA levels in oats were associated with three product recalls. The compliance rate was 88% for the oat products tested in this targeted survey.

4.1.3.1. DON in Grain Products

The aforementioned 75 wheat products, 50 corn products and 25 oat products were also analyzed for DON. Twenty-nine wheat samples (38.6%) had no detectable levels of DON. The remaining wheat samples had DON levels ranging from 0.01 to 6.01 ppm. Sixteen of the corn products (34%) had no detectable levels of DON. The remaining corn samples had DON levels which ranged from 0.01 to 1.38 ppm. Eighteen of 25 oat samples (72%) had no detectable levels of DON. While the remaining oat samples had DON levels which ranged from 0.02 to 0.13 ppm.

There are no standards in place for the level of DON in hard wheat (i.e. bulgur wheat or couscous), finished wheat products (i.e. flour and bran), corn (or corn products) and oats (or oats products). Any detectable level of DON in grains was referred to the appropriate CFIA program for follow-up. The follow-up actions included notification of the producer or importer, follow-up inspections, additional directed sampling, and product recalls. None of the DON levels measured in grain products were associated with a human health risk, and no recalls were performed.

5. Conclusions

A total of 450 samples were tested for OTA. Of these samples, 88.4% (398 samples) had no OTA residues detected. For the infant foods tested, the highest levels of OTA detected were 4.1 ppb in infant cereals and 0.4 ppb in infant formula. In beverages, only one wine sample had OTA residues of 0.5 ppb. In the grain products tested, the highest levels of OTA measured were 7.2 ppb in oats, 3.5 ppb in wheat and 0.9 ppb in corn. The overall compliance rate with the newly proposed Canadian regulations was 98%.

In addition, 150 of these samples were also tested for DON. Of the 150 samples tested for DON, 58% (87 samples) had detectable levels. The highest levels of DON detected were 6.01 ppm in wheat, 1.38 ppm in corn and 0.13 ppm in oats. The compliance rate for DON in cereal products could not be determined as there are no regulatory limits for DON in these commodities.

All samples with levels of OTA that exceeded Health Canada's proposed regulatory limits, and all positive results for DON were referred to the designated CFIA program for appropriate follow-up actions. These actions included notification of the producer or importer, follow-up inspections, additional directed sampling, and product recalls. As a result of this targeted survey a number of voluntary recalls were initiated in oat products and infant cereals.

6. Future Considerations

These targeted surveys provided valuable information regarding the prevalence and levels of OTA and DON in foods. These studies indicated that OTA and DON are detected in some products available on the Canadian market. However, the sample size of this survey per commodity was small compared to the relative number of such products available in the marketplace. In addition, as mycotoxin levels are highly dependent on climatic conditions. Future surveys will be needed to gain a complete understanding of the level of exposure to Canadians for OTA and DON from these products.

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