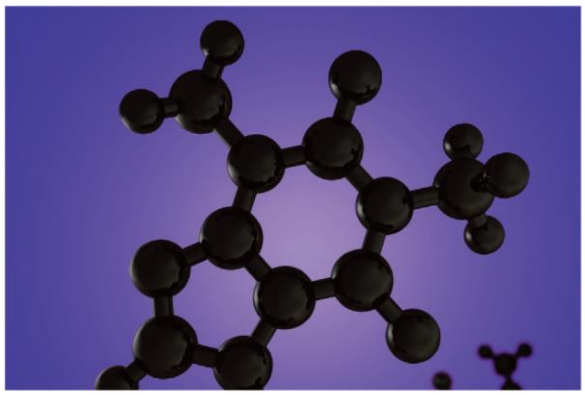
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



Ochratoxin A and Deoxynivalenol in Selected Foods

Canada

Table of Contents

1. Introduction 4
1.1. Food Safety Action Plan 4
1.2. Targeted Surveys 4
1.3. Acts and Regulations 5
2. Survey Details 5
2.1. OTA and DON 5
2.2. Rationale 6
2.3. Sample Overview 6
2.4. Detailed Analytical Methods 7
2.5. Limitations 7
3. Results and Discussion 7
3.1. Ochratoxin A 7
3.2 Deoxynivalenol 13
3.3 Comparison of the results obtained in 2009/10 and 2010/11 18
4 Conclusions 20
5 References 22

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 focussed on two natural toxins, ochratoxin A (OTA) and deoxynivalenol (DON). Contamination of foods (such as grains and fruit) with these toxins may occur in the field (DON) or during storage of the raw commodities (OTA). As OTA and DON are resistant to heat, processing the affected grains/fruit may not completely remove these toxins, which could result in detectable levels in finished or manufactured food products. OTA has been classified as a possible human carcinogen by the International Agency for Research on Cancer. DON is not carcinogenic but exposure to very high levels may cause immunosuppressive and gastrointestinal effects.

The main objectives of this survey were to:

- Establish baseline surveillance data for OTA and DON levels in infant formula, beverages (wine, beer), dried fruit, and grain products (wheat products, corn products, oat products, infant cereals, breakfast cereals)
- Obtain a snapshot of the OTA levels in these specific commodities relative to Health Canada's proposed maximum levels for OTA
- Compare the prevalence of OTA and DON in infant foods, beverages, and wheat, corn, and oat products found in 2009-2010 with that in 2010-2011

A total of 943 samples were analyzed for the presence of OTA and DON. These samples included 197 breakfast cereals, 139 wines, 130 beer, 98 infant formulae, 97 dried fruits, 96 wheat products (flour, bran, germ, cream of wheat), 93 infant cereals, 76 corn products (corn/tortilla chips, cornmeal, semolina), and 17 oat products (whole oats, oatmeal).

Sixty-seven percent of the samples (628/943) did not contain detectable levels of OTA. The 315 remaining samples that were found to have detectable levels of OTA were from all classes of products included in this survey. OTA levels ranged from 0.040 ppb (parts per billion) to 6.773 ppb. Overall, 99.2% of the samples tested for OTA were below the Canadian maximum levels proposed for OTA by Health Canada. Five samples of infant cereal, one sample of breakfast cereal, one sample of wheat flour, and one sample of wheat germ exceeded the proposed maximum levels for OTA. The OTA levels in these eight samples were assessed and appropriate follow-up actions were initiated that reflected the magnitude of the human health concern.

Less than half of the samples (388/943 or 41%) did not contain detectable levels of DON. DON was not detected in any of the wine or dried fruit samples. DON levels ranged from 1 ppb to 2060 ppb. There are no Canadian maximum levels established for DON in finished products so compliance could not be evaluated. However, the levels of DON considered elevated were reviewed, and appropriate follow-up actions were initiated that reflected the magnitude of the human 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.

Within the 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 analysis of foods in 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*, 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 contaminants (hazards) in defined food commodities. The surveys are designed to answer specific questions. Therefore, unlike monitoring activities, testing for a particular hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of hazard/food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all 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. In the most recent FSSC meeting, mycotoxins (including OTA and DON) were ranked as a high priority due to their detrimental health effects. In the past, both Health Canada and the Canadian Grain Commission (CGC) have monitored domestic raw grains and grain commodities for OTA and DON. CGC continues to monitor domestic raw grains for a variety of mycotoxins, however monitoring of finished grain products, particularly imported products, at the retail level is limited. 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 formula, beverages, dried fruit, and milled grain products.

1.3. Acts and Regulations

The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing Canadian laws and regulations on the production, sale, composition and content of foods and food products as outlined in the *Food and Drugs Act & Regulations.*

Health Canada establishes the maximum levels (standards and tolerances) for contaminants in food and maximum residue limits for pesticide residues in food. There are Canadian standards for DON in uncleaned soft wheat. However, there are no established Canadian maximum levels for DON in finished grain products, such as flour and bran. In 2009, Health Canada published proposed maximum levels for OTA in a variety of foods. The proposed Canadian and established international maximum levels for OTA and for DON in foods are presented in the relevant sections below.

Elevated levels of mycotoxins in specific foods may be assessed by Health Canada on a case-by-case basis using the most current scientific data available. When the mycotoxin level in a food product is deemed to pose a human health concern, corrective actions (such as public recalls or product detention) may be taken by the CFIA.

2. Survey Details

2.1. OTA and DON

Mycotoxins have been present as food-borne contaminants for centuries, and are a global health concern. These toxins are released by fungi (mould), which can grow on agricultural commodities. The more favourable the climatic, storage or processing conditions are to fungal proliferation, the more likely mycotoxin levels are to be elevated.

The mycotoxins released by fungi can have harmful human health effects. Given the seriousness of these effects, Canada and the international community have taken actions (e.g. producer education regarding the environmental factors that promote toxin production in cereal crops at the farm level, and pre-harvest/post-harvest strategies) to reduce levels of mycotoxins to the lowest possible achievable levels. Codex Alimentarius has generated a code of practice, available to all interested parties (including industry stakeholders), for the prevention and reduction of mycotoxins in grain products[1]. The mycotoxins of interest in this targeted survey are OTA and DON. DON is a toxin produced in crops prior to harvest, while OTA is a toxin produced during the storage of crops. These toxins can be found individually or together in some agricultural commodities.

OTA is a naturally occurring metabolite of fungal species belonging to strains of *Aspergillus* and *Penicillium* moulds. Under favourable moisture and temperature

conditions, the fungi can grow on stored material and produce OTA[2]. OTA has been widely detected in cereal grains (wheat, corn, oat, and barley), green coffee, grape juice, beer, wines, cocoa, dried fruits and nuts[3]. The International Agency for Research on Cancer (IARC) has classified OTA as a possible human carcinogen[4]. OTA is suspected to have negative health effects on the kidneys, the developing fetus, and the immune system. Health Canada's Bureau of Chemical Safety has completed a risk assessment for OTA, and as a result, has proposed maximum levels for OTA in various food commodities[5].

DON is a mycotoxin produced by various species of *Fusarium* mould. It is most commonly found in grain products (notably wheat, barley and corn), and is typically the result of grains suffering from Fusarium head blight (FHB) in the field. Wet, warm weather conditions in the field will particularly favour the development of FHB, and subsequently DON[6]. DON is mainly associated with cereal grains and their derived products (flours, meals, bran, grits, infant cereals, breakfast cereals, and beer). 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].

2.2. Rationale

The CFIA does not have regular monitoring activities that target these natural toxins in finished foods. The CGC tests raw, domestic cereal grains for mycotoxins, pesticides, and metals, but does not have jurisdiction over finished or imported grain products. Mycotoxins, specifically DON and OTA, in grains and grain products have been periodically examined by Health Canada and through other CFIA activities. Health Canada has also conducted periodic surveys of OTA and DON in some ingredients and finished foods. Therefore, the documented incidence of mycotoxins in finished food products available in Canada is limited. There was a need for surveillance for the presence of both OTA and DON in infant formula, beverages, dried fruit, and grain products (domestic and imported). The possible presence of OTA in infant formula is of particular interest as it may be the sole food source for infants in the first months of life. There is little data in the scientific literature on the levels of DON in infant formula, dried fruits, or wine.

As the production and occurrence of these mycotoxins are strongly affected by climate and storage conditions, it was important to expand on the 2009-2010 FSAP OTA/DON survey to provide a more thorough appreciation of Canadian exposure to these natural toxins.

2.3. Sample Overview

The current FSAP OTA/DON targeted survey sampled domestic and imported infant formula, beverages, dried fruit, and grain products. The intent of this survey was to obtain a snapshot of the OTA and DON levels in food products that may contribute most to

OTA and DON exposure. A wide variety of foods available on the Canadian retail market were 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.

A total of 943 product samples were tested for OTA and DON. The 943 samples were separated into nine product types. The survey included 197 samples of breakfast cereals, 139 samples of wine, 130 samples of beer, 98 samples of infant formula, 97 samples of dried fruit, 96 samples of wheat products (flour, bran, germ, cream of wheat), 93 samples of infant cereals, 76 samples of corn products (corn/tortilla chips, cornmeal, semolina), and 17 samples of oat products (whole oats, oatmeal).

All foods were sampled at grocery and specialty stores in 11 Canadian cities. The products analyzed included 452 domestic samples, 424 imported products and 67 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 unambiguously 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. Detailed Analytical Methods

Samples were analyzed by a laboratory under contract with the Government of Canada. The two analytical methods used, one for OTA and one for DON, were based on CFIA laboratory methods. Both the OTA and DON methods were single-residue liquid chromatography-tandem mass spectrometry (LC-MS-MS) methods. For the OTA method, the limit of detection (LOD) was 0.04 ppb and the limit of quantitation (LOQ) was 0.1 ppb for all matrices tested. For the DON method, both the LOD and LOQ were 1 ppb.

2.5. Limitations

The present survey was designed to provide a snapshot of the prevalence and levels of OTA and DON in food products available to Canadian consumers. In comparison to the total number of these products existing on the Canadian retail market, a sample size of 943 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 levels of OTA or DON in products.

3. Results and Discussion

3.1. Ochratoxin A

3.1.1 Overview of OTA Results

Of the 943 samples, 628 (67%) did not have detectable levels of OTA. The levels of OTA in the remaining 315 samples ranged from 0.040 ppb to 6.773 ppb. Of these 315 positive results, 307 contained OTA at levels below the Canadian proposed maximum levels[*]. Please refer to Table 1 below for a summary of proposed Canadian and established international OTA maximum levels in foods. One sample of wheat germ and one sample of wheat flour exceeded the 3 ppb proposed maximum level for grain-derived products, which is applicable to wheat products. Five samples of infant cereals exceeded the 0.5 ppb proposed maximum level for OTA in infant foods. One sample of breakfast cereal exceeded the 3 ppb proposed maximum level for OTA in breakfast cereals. Overall, 99.2% of the samples were negative for OTA or contained OTA levels below the Canadian proposed maximum levels.

Table 1 – Proposed Canadian and established international OTA maximum levels in foods

Hazard	Commodity	Canada[8,9]	United States[†10]	European Union[11]	Codex[12]
OTA (ppb)	Raw cereal grains	5†	-	5	5
	Grains for direct consumption	3†	-	3	-
	Derived cereal products (flour)	3†	-	3	-
	Breakfast cereals	3†	-	3	-
	Derived cereal products (wheat bran)	7†	-		-
	Dried vine fruit (raisins, currants)	10†	-	10	-
	Ground roasted coffee	-	-	5	-
	Instant coffee	-	-	10	-
	Grape juice and related products (and as ingredients in other beverages)	2†	-	2	-
	Wine	-	-	2	-
	Baby foods and processed cereal-based foods for infants and young children	0.5†	-	0.5	-

† Proposed maximum level

[*] The 315 positive samples included beer – there is no existing or proposed ML for OTA in beer, however, the values were compared to the proposed MLs for derived cereal products for comparison and information only

[†] The US FDA guidance document is limited to DON only and no equivalent guidance could be found relating to OTA

Figure 1 below shows the distribution of samples by product type. All product types had samples with detectable levels of OTA. The percentage of samples with detectable levels of OTA (positives) in a given product type ranged from 2% in wine to 94% in wheat products. All average OTA levels were calculated using only the results which exceeded the applicable limits of detection (indicated as the average of the positive results throughout the report).

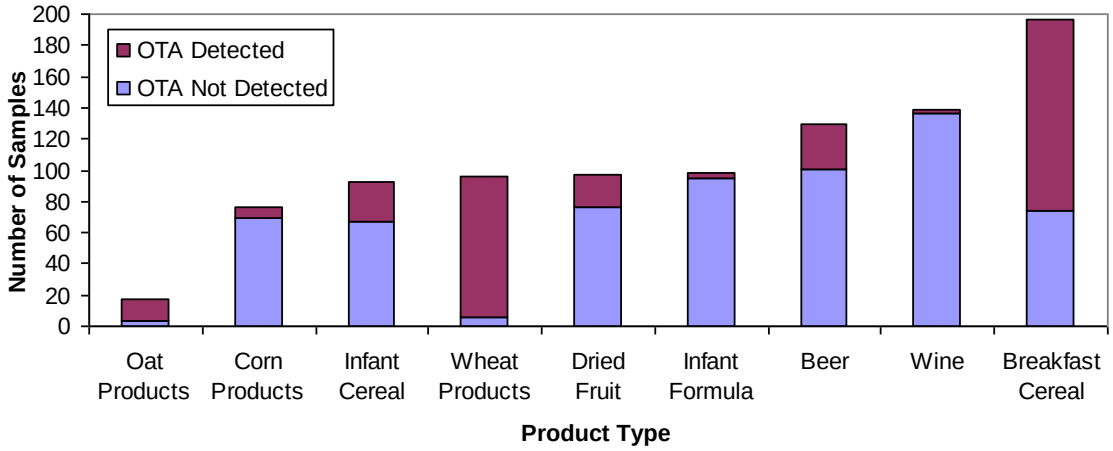


Figure 1 - Number of samples with detectable and non-detectable levels of OTA by product type

Figure 2 below shows the average OTA level as a function of product type. The average level of OTA by product type (in order of decreasing concentration) was: wheat products, dried fruit, breakfast cereals (consumed by adults and children), corn products, infant cereals, oat products, infant formula, wine, and beer.

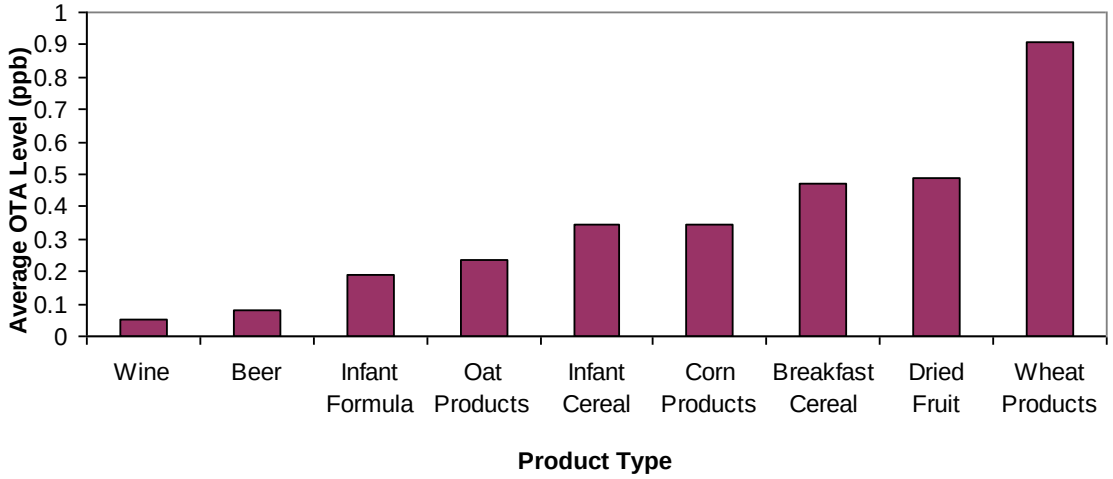


Figure 2 - Average OTA level (calculated as average of positive results only) by product type

A total of eight products (five infant cereals, one breakfast cereal, one sample of wheat bran and one sample of wheat germ) had OTA levels in excess of the Canadian proposed maximum levels. The five infant cereals (up to 1.587 ppb) exceeded Health Canada's proposed maximum level of 0.5 ppb OTA in infant foods. In the 2009-2010 FSAP survey, some infant cereals were found to contain up to 9 ppb of OTA. Based on Health Canada's input, public recall product action was not warranted in that instance. It was assumed that the current infant cereal samples in question would result in a similar assessment and not pose an unacceptable human health concern. The level of OTA in the breakfast cereal (3.077 ppb) was barely above the proposed maximum level of 3 ppb and so was deemed unlikely to be of concern to human health. The elevated levels of OTA in the one wheat bran sample and one wheat germ sample resulted in directed sampling of the commodities in question by the CFIA[‡]. For the eight products found to contain elevated levels of OTA, appropriate product follow-up actions were initiated that reflected the magnitude of the human health concern.

3.1.2 OTA Results by Product Type

The following sections present the analysis results for OTA in each of the nine product types. These product types include infant formula, dried fruits, wine, beer, infant cereals, breakfast cereals, wheat products, oat products and corn products. The source of these mycotoxins is not known.

OTA in Infant Formula

Ninety-eight samples of infant formula (11 domestic, 87 imported) were tested for OTA. These samples included three lactose-free formulae, six soy-based formulae, and 89 milk-based formulae. Samples included iron fortified, low iron, nutritional supplement, omega-3/omega-6 and calcium-enriched formulae.

Of the 98 formula samples, 95 did not have detectable levels of OTA. Three infant formula samples, all soy-based, had detectable levels of OTA ranging from 0.063 ppb to 0.370 ppb. These levels are below the Canadian proposed maximum level of 0.5 ppb OTA in infant foods. These results are comparable with previous studies by Health Canada which found elevated levels of OTA in soy-based infant formula (unpublished data)[13]. Soy-based formula may contain OTA if it is made from soy containing OTA. The OTA in soy-based infant formula may also come from the use of corn as a carbohydrate source[14].

[‡] Directed sampling is biased and directed at targeted sample populations (e.g. commodity types or geographical areas) to investigate and verify any suspected problems of potential health risk suggested in the monitoring program.

Studies have shown that it is possible to detect OTA in cow's milk due to the consumption of OTA-contaminated grain by cattle[15]. As a result, OTA could theoretically be detected in milk-based formula. Surveillance data on the presence of OTA in milk-based or lactose-free formulae is of importance as it may be the sole food source for infants in the first months of life. None of the milk-based or lactose-free formulae samples in this survey were found to have detectable levels of OTA.

OTA in Beverages

One hundred thirty-nine wine and 130 beer samples were taken in this survey. The wine samples included 63 samples of red wine, 12 samples of rosé wine, and 64 samples of white wine. One hundred and nine of the wines were imported and the remaining 30 samples were of domestic origin. The beer samples included domestic and imported major beer brands and beers from Canadian brew pubs and microbreweries. One hundred and ten of the beers were domestically produced and the remaining 20 were imported.

None of the domestic wine samples contained detectable levels of OTA. One red wine sample (0.065 ppb), and two white wine samples (0.044 ppb and 0.049 ppb) from Mediterranean countries tested positive for OTA. Mediterranean wines, particularly red wines, have been associated previously with elevated OTA levels[16]. For comparison, all of the wines tested in this survey were below the Canadian proposed maximum level of 2 ppb for OTA in grape juice. These FSAP survey results are consistent with a previous Health Canada survey published in 2004, in which 47 of 180 domestic or imported wine samples contained OTA, and the average level of OTA was 0.163 ppb[17].

OTA was detected in 29 of the 130 (22%) beer samples. The OTA levels ranged from 0.041 ppb to 0.285 ppb. There are no specific Canadian maximum levels established or proposed for OTA in beer. For comparison, these levels are below the proposed maximum level of 3 ppb OTA in cereal-derived products. The low levels of OTA in beer were evaluated and were considered unlikely to pose a concern to human health. These results are consistent with a previous Health Canada survey published in 1995, in which 26 of 41 domestic or imported beer samples contained detectable levels of OTA, the maximum OTA level detected was 0.2 ppb, and the average OTA level was 0.061 ppb[18].

OTA in Dried Fruits

Ninety-seven samples of dried fruit (four domestic, 93 imported) were tested for OTA. The dried fruit samples included 30 samples of raisins, 29 samples of dried figs, 27 samples of dried dates, 10 samples of dried apricots and one sample of prunes.

Twenty-one of the 97 (22%) dried fruit samples contained detectable levels of OTA. These positive samples included one sample of dried figs (0.284 ppb) and twenty samples of raisins (OTA levels ranged from 0.049 to 3.820 ppb). The average level of OTA in raisins was 0.497 ppb. None of the dried fruit samples contained OTA levels in excess of the Canadian proposed maximum level of 10 ppb in dried fruit. The percentage of raisin samples with detectable levels of OTA observed in this survey (67%) was similar to (and

the average/maximum levels lower than) what was found in a previous Health Canada survey of OTA levels in raisins published in 1998-2000[19]. The Health Canada survey detected OTA in 67 of 85 (79%) samples of raisins, the average OTA level was 1.8 ppb and the maximum level of OTA observed was 26.6 ppb.

OTA in Grain Products

Grain products sampled and tested for OTA included infant cereals, breakfast cereals consumed by children and adults, wheat products (flour, bran, germ, cream of wheat), corn products (corn/tortilla chips, cornmeal, semolina), and oat products (whole oats, oatmeal).

Infant Cereals

Ninety-three infant cereals (34 domestically produced, 59 imported) were sampled. These cereals are intended for infants 6 to 12 months of age and were labelled as "barley", "wheat", "multi-grain", "mixed", "oat" or "rice". Two samples were identified only as "infant cereal".

Twenty-six of the 93 (28%) infant cereal samples tested positive for OTA, ranging from 0.043 ppb to 1.587 ppb. The average OTA level for the infant cereals (average of all positive results) was 0.343 ppb. Overall, 94.6% of the infant cereal samples were negative for OTA or contained OTA levels below the Canadian proposed maximum level. Five samples (5.4%) of the infant cereals exceeded the proposed OTA maximum level of 0.5 ppb for OTA in infant cereals. These results are similar to a Health Canada survey of OTA levels in infant cereals carried out in 1997-1999, wherein 41 of 155 samples (27%) contained OTA, the average value was 0.61 ppb, and the maximum OTA level was 6.9 ppb[20].

Breakfast Cereals

One hundred ninety-seven breakfast cereals (127 domestic, 70 imported) were sampled. These cereals are intended for children and adults, and were labelled as "buckwheat", "corn", "flax", "granola", "muesli", "multigrain", "oat", "rice", or "wheat".

One hundred twenty-three of the 197 (62%) breakfast cereal samples contained detectable levels of OTA, ranging from 0.040 ppb to 3.077 ppb. The average OTA level (average of the positive results) in breakfast cereals was 0.470 ppb. Overall, 99.5% of the breakfast cereals were negative for OTA or contained OTA levels below the Canadian proposed maximum level. One sample (0.5%) exceeded the proposed maximum levels for OTA in grain-derived products. The results of this targeted survey were compared to a previous Health Canada survey of OTA levels in breakfast cereals. The percentage of samples with detectable levels and the maximum OTA level were lower in similar samples in the Health Canada survey[21]. The Health Canada survey of 156 breakfast cereals showed that 53/156 (35%) of cereals contained OTA and the maximum level was 1.4 ppb.

Wheat Products

Ninety-six samples of wheat products (80 domestic, 16 imported), consisting of 15 samples of wheat bran, 19 samples of wheat germ, one sample of cream of wheat, and 61 samples of wheat flour, were analyzed.

Ninety of the 96 samples (94%) had detectable levels of OTA, with values ranging from 0.044 ppb to 6.773 ppb. The average OTA level (average of the positive results) in the wheat products was 0.91 ppb. All product sub-types had samples with detectable levels of OTA. Overall, 98% of the wheat products sampled were negative for or had OTA levels below the Canadian proposed maximum levels for OTA. One sample of wheat flour and one sample of wheat germ (2%) exceeded the proposed maximum levels for OTA in grain-derived products.

Corn Products

Seventy-six samples of corn products (46 domestic, 30 imported), consisting of 59 samples of corn/tortilla chips, 16 samples of cornmeal, and one sample of semolina, were analyzed.

Seven of the 76 samples (six samples of corn/tortilla chips and one sample of cornmeal) (9%) had detectable levels of OTA, ranging from 0.047 ppb to 1.328 ppb. The average OTA level (average of the positive results) in corn products was 0.346 ppb. All samples of corn products were negative for OTA or had OTA levels below the Canadian proposed maximum levels for OTA in grain products.

Oat Products

Seventeen samples of oat products (10 domestic, 7 imported), consisting of 16 samples of whole oats and one sample of oatmeal, were analyzed.

Thirteen of the 17 (77%) oat samples, all whole oats, had detectable levels of OTA, ranging from 0.042 ppb to 0.735 ppb. The average level of OTA (average of the positive results) in oat products was 0.233 ppb. All of the oat product samples were negative for or had OTA levels below the Canadian proposed maximum levels for OTA in grain products.

3.2 Deoxynivalenol

3.2.1 Overview of DON Results

Of the 943 samples, 388 (41%) did not have detectable levels of DON. The levels of DON in the remaining 555 samples ranged from 1.0 ppb to 2060 ppb. Figure 3 below shows the distribution of samples by product type. None of the wine or dried fruit sampled contained detectable levels of DON. The percentage of samples with detectable levels of DON per product type ranged from 4% in infant formula to 100% in wheat products.

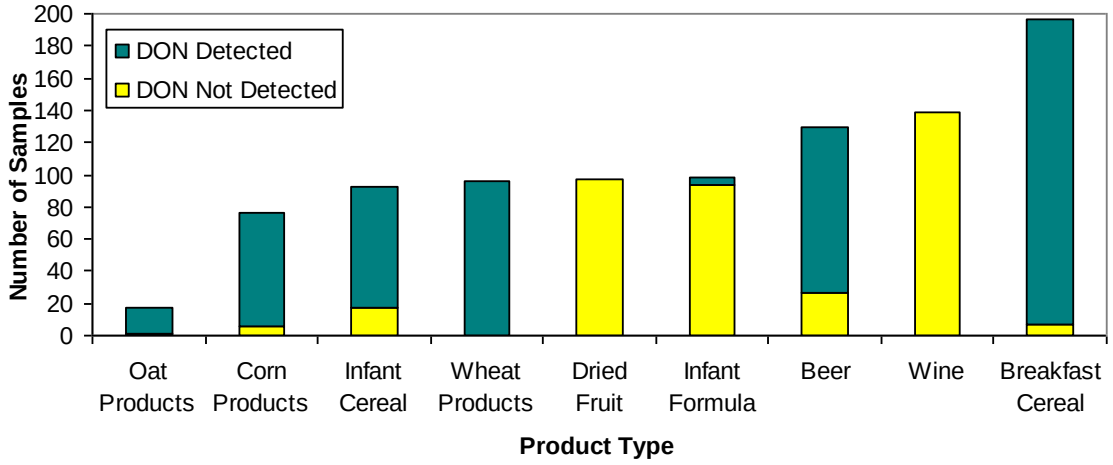


Figure 3 - Number of samples with detectable and non-detectable levels of DON by product type

The average DON level (average of all positive results) was highest in wheat products, breakfast cereals, and corn products, and lowest in infant formula. In the absence of proposed or established maximum levels for DON in finished foods in Canada, Health Canada provided an opinion that the highest DON levels present in the breakfast cereal samples in this survey did not pose a human health concern to Canadians. The remaining elevated DON levels were below the 2000 ppb Canadian maximum level set for raw wheat and were deemed unlikely to be of concern to human health. Appropriate product follow-up actions were initiated that reflected the magnitude of the human health concern. Please refer to Table 2 below for a summary of established Canadian and international DON maximum levels in foods.

Table 2 – Established Canadian and international DON maximum levels in foods

Hazard	Commodity	Canada[8,9]	United States[†]	European Union[11]	Codex[12]
DON (ppb)	Wheat, soft, raw	1000,2000*	-	-	No maximum levels adopted to date
	Wheat, durum, raw	-	-	1750	
	Oats, corn, raw	-	-	1750	
	Other grains, raw	-	-	1250	
	Flour, bran, germ	-	1000	750	
	Pasta, dry	-	-	750	
	Cereal-derived retail food	-	-	500	
	Foods for babies, young children	-	-	200	

*2000 ppb (2 ppm) for use in non-staple foods, 1000 ppb (1 ppm) for use in baby foods

For commodities where Canadian maximum levels are not available, the results of this survey were compared to European Union (EU) maximum levels. None of the infant cereal samples exceeded the EU maximum level for DON in infant foods (200 ppb). Fourteen samples of breakfast cereals, three samples of wheat flour, one sample of wheat bran, three samples of cornmeal and two samples of corn chips had elevated DON levels relative to EU maximum levels (500 or 750 ppb). Figure 4 below shows the average DON level as a function of product type.

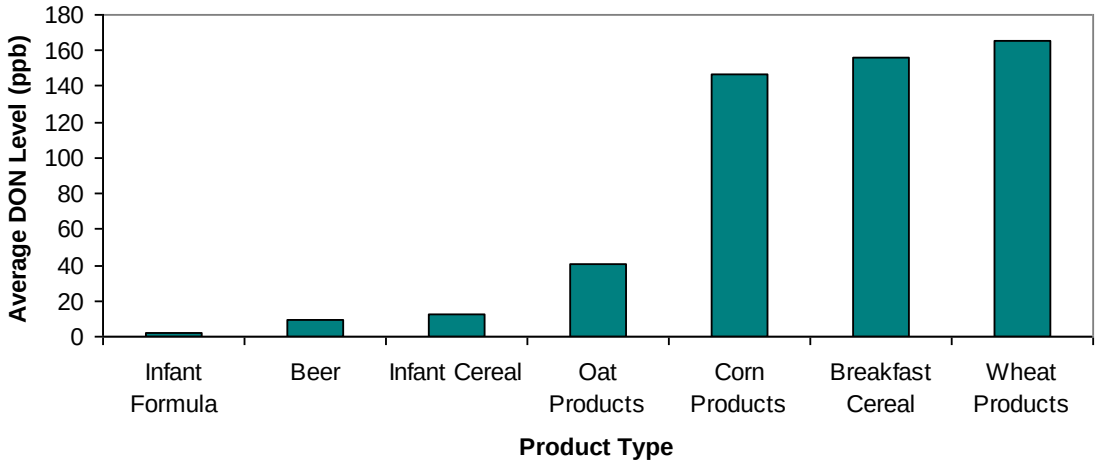


Figure 4 - Average DON level (calculated as average of positive results only) by product type

3.2.2 DON Results by Product Type

The following sections present the analysis results for DON in each of the nine product types. These product types include infant formula, dried fruits, wine, beer, infant cereals, breakfast cereals, wheat products, oat products and corn products. The source of these mycotoxins is not known.

DON in Infant Formula

Ninety-eight samples of infant formula (11 domestic, 87 imported) were tested for DON. These samples included three lactose-free formulae, six soy-based formulae, and 89 milk-based formulae. Samples included iron fortified, low iron, nutritional supplement, omega-3/omega-6 and calcium-enriched formulae.

Four of the 98 samples of infant formula (two milk-based, two soy-based) had detectable levels of DON ranging from 1.1 ppb to 2.5 ppb. There are no Canadian regulations established for DON levels in infant formula so compliance with a numerical standard could not be evaluated. As a comparison, DON levels of up to 1000 ppb are allowed in raw wheat intended for use in infant cereals in Canada. None of the four samples exceeded the EU maximum level of 200 ppb DON in infant foods. The levels were

evaluated and it was determined that the very low levels of DON detected in infant formula in this targeted survey were unlikely to pose a health concern for infants. There are no confirmed sources of DON in infant formula. Potential sources of DON may include transfer of DON from the feed ingested by dairy cattle to their milk, soy products with DON, and the use of DON-containing, grain-based ingredients in infant formula.

DON in Beverages

One hundred thirty-nine wine and 130 beer samples were taken in this survey. The wine samples included 63 samples of red wine, 12 samples of rosé wine, and 64 samples of white wine. One hundred and nine of the wines were imported and the remaining 30 samples were of domestic origin. The beer samples included domestic and imported major beer brands and beers from Canadian brew pubs and microbreweries. One hundred and ten of the beers were domestically produced and the remaining 20 were imported.

None of the wine samples contained detectable levels of DON. No scientific literature has reported detectable levels of DON in wines. DON was detected in 79% of the beer samples. The levels of DON in the beer samples ranged from 1.1 ppb to a maximum of 102 ppb. There are no Canadian regulations established for DON levels in beer so compliance with a numerical standard could not be evaluated. As a comparison, DON levels of up to 2000 ppb are allowed in raw, soft wheat intended for use in non-staple foods in Canada. The low levels of DON detected in beer were evaluated and considered to be unlikely to pose a concern to human health. These results are similar to a literature survey of 313 Belgian beers wherein 87% of beer samples had detectable levels of DON, the DON levels ranged from 4.0 to 56.7 ppb, and the average DON level was 13.5 ppb. However, different results in both surveys are not likely related to the analytical methods, as the limit of detection (LOD) in the Belgian study was 3.7 ppb[22] and the LOD in the current targeted survey was 1 ppb.

DON in Dried Fruits

Ninety-seven samples of dried fruit (four domestic, 93 imported) were tested for DON. The dried fruit samples included 30 samples of raisins, 29 samples of dried figs, 27 samples of dried dates, 10 samples of dried apricots and one sample of prunes.

None of the dried fruits sampled in this survey contained detectable levels of DON. This is consistent with other studies which indicate that DON forms mainly on grains[7]. Nonetheless, this survey tested for DON in dried fruits in the interest of maximizing the value of each sample taken for this survey.

DON in Grain Products

Grain products sampled and tested for DON included infant cereals, breakfast cereals intended for children and adults, wheat products, corn products and oat products.

Infant Cereals

Ninety-three infant cereals (34 domestically produced, 59 imported) were sampled. These cereals are intended for infants 6 to 12 months of age and labelled as "barley", "wheat", "multi-grain", "mixed", "oat" or "rice". Two samples were identified only as "infant cereal".

Seventy-six of the 93 (82%) samples of infant cereals had detectable levels of DON, ranging from 1.1 to 128 ppb. The average DON level (calculated as average of positive results only) in the infant cereals was 12.1 ppb. There are no Canadian maximum levels established specifically for DON in infant cereals so compliance with a numerical standard could not be evaluated. However, Health Canada has established a standard of 1000 ppb for DON in soft wheat intended for infant foods. None of the infant cereal samples exceeded the EU maximum level of 200 ppb in infant foods. The levels of DON in infant cereals were evaluated and considered to be unlikely to pose a human health concern. The results of this targeted survey were compared to a previous Health Canada survey of DON levels in infant cereals. The percentage of samples with detectable levels in this survey is higher than that of the Health Canada survey but the maximum DON level observed in this targeted survey is lower. The Health Canada survey of DON levels in infant cereals showed that 132/206 samples (64%) contained DON, the range of means (average of positive results only) was 52 - 260 ppb, and the maximum DON level was 980 ppb[20].

Breakfast Cereals

One hundred ninety-seven breakfast cereals (127 domestic, 70 imported) were sampled. These cereals are intended for children and adults, and were labelled as "buckwheat", "corn", "flax", "granola", "muesli", "multigrain", "oat", "rice", or "wheat".

One hundred ninety of the 197 samples (96%) of breakfast cereals were positive for DON, with levels ranging from 1.2 ppb to 2060 ppb. The average DON level (average of the positive results) in breakfast cereals was 156 ppb. There are no Canadian regulations established for DON in breakfast cereals so compliance with a numerical standard could not be evaluated. Fourteen samples of breakfast cereals had DON levels in excess of 500 ppb, the EU maximum level for DON in breakfast cereals. The results of this targeted survey were compared to a previous Health Canada survey of DON levels in breakfast cereals. The percentage of samples with detectable levels and the maximum DON level were lower in the Health Canada survey. The Health Canada survey of 156 breakfast cereals showed that 72/156 (46%) of cereals contained DON, the range of means (average of positive results only) was 30 - 160 ppb, and the maximum level was 940 ppb[21].

Wheat Products

Ninety-six samples of wheat products (80 domestic, 16 imported), consisting of 15 samples of wheat bran, 19 samples of wheat germ, one sample of cream of wheat, and 61 samples of wheat flour, were analyzed.

All 96 wheat product samples had detectable levels of DON, with values ranging from 1.2 to 1500 ppb. The average DON level (average of the positive results) was 165 ppb in wheat products. There are no Canadian regulations established for DON levels in finished wheat products so compliance with a numerical standard could not be evaluated. Three samples of wheat flour and one sample of wheat bran had DON levels in excess of 750 ppb, the EU maximum level for DON in milled wheat products.

Corn Products

Seventy-six samples of corn products (46 domestic, 30 imported), consisting of 59 samples of corn/tortilla chips, 16 samples of cornmeal, and one sample of semolina, were analyzed.

Seventy of the 76 samples had detectable levels of DON (92%), ranging from 1.0 ppb to 1440 ppb. The average DON level (average of the positive results) in corn products was 147.2 ppb. There are no Canadian regulations established for DON in corn products so compliance with a numerical standard could not be evaluated. Three samples of cornmeal and two samples of corn/tortilla chips had DON levels in excess of 500 ppb, the EU maximum level for DON in cereal-based retail foods.

Oat Products

Seventeen samples of oat products (10 domestic, 7 imported), consisting of 16 samples of whole oats and one sample of oatmeal, were analyzed.

All but one sample of whole oats (94%) contained detectable levels of DON, ranging from 1.8 ppb to 192 ppb. The average level of DON in oat products (average of the positive results) was 41 ppb. There are no Canadian regulations established for DON in oat products so compliance with a numerical standard could not be evaluated. None of the products had DON levels in excess of 500 ppb, the EU maximum level for DON in cereal-based retail foods.

3.3 Comparison of the results obtained in 2009/10 and 2010/11

The results of this targeted survey were compared to the results of the previous OTA/DON survey (2009-2010 FSAP OTA/DON targeted survey: http://www.inspection.gc.ca/english/fssa/microchem/resid/2009-2010/otadone.shtml), where feasible (see Tables 3 and 4 below). Breakfast cereals and dried fruits were not among the commodities analyzed for OTA in 2009-2010, so comparison to the current survey results was not possible. Infant formula, infant cereals, breakfast cereals, wine, and beer were not among the commodities analyzed for DON in 2009-2010, so comparison to the current survey results was not possible.

Table 3 - Comparison of OTA data from present survey with 2009-2010 FSAP survey

Commodity	Survey Year	Number of samples	# of Samples Below Proposed Maximum Levels (%)	Average OTA Level in Positive Results (ppb)	Maximum OTA Level (ppb)
Infant Formula	2009-2010	75	75 (100%)	-	0.4 **
	2010-2011	98	98 (100%)	0.192	0.370
Wine	2009-2010	50	50 (100%)	-	0.5 **
	2010-2011	139	139 (100%)	0.053	0.065
Beer	2009-2010	50	50 (100%)*	< 0.1	< 0.1
	2010-2011	130	130 (100%)*	0.080	0.285
Infant Cereals	2009-2010	75	69 (92%)	0.82	4.1
	2010-2011	93	88 (93%)	0.343	1.587
Wheat Products	2009-2010	75	75 (100%)	1.1	3.5
	2010-2011	96	94 (98%)	0.907	6.773
Corn Products	2009-2010	50	50 (100%)	0.7	0.9
	2010-2011	76	76 (100%)	0.346	1.328
Oat Products	2009-2010	25	22 (88%)	2.6	7.2
	2010-2011	17	17 (100%)	0.233	0.735

* No Canadian proposed maximum levels for OTA in beer, however, comparison was made to the proposed MLs for derived cereal products for information only.
** Only one positive OTA result for infant formula and wine samples analysed in 2009-2010.

As seen in Table 3 above, most of the samples (98.5%) tested for OTA in both the current survey and in the previous year's survey were below the Canadian proposed maximum levels for OTA, and were not expected to pose a concern to human health, as confirmed by Health Canada. When comparing the percentage of samples above/below the Canadian proposed maximum levels in this current survey with the previous year's survey, there is little difference, except in the case of oats. In comparing the average and maximum OTA levels, there is no apparent overall trend in the year-to-year values. The most notable difference was the ten-fold reduction in the average and maximum OTA levels in oat products noted in the current survey relative to the previous survey. OTA is a toxin that predominately forms under specific conditions during grain storage and the samples in this survey were picked up at retail. As such, the history of the product with respect to storage, as well as the storage of the product's ingredients, cannot be determined.

Other similarities between the current and the previous surveys include: all samples with detectable levels of OTA in infant formula were associated with soy infant formula; oat and wheat products were associated with a high proportion of OTA positives; some infant cereals were associated with elevated levels of OTA (five samples in the current survey

and all six samples in the previous survey); most of the wine and beer samples did not have detectable levels of OTA.

Table 4 - Comparison of DON data from present survey with the FSAP 2009-2010 survey

Commodity	Survey Year	Number of samples	# of Positive Samples (%)	Average DON Level (ppb)	Maximum DON Level (ppb)
Wheat Products	2009-2010	75	46 (61%)	300	6010
	2010-2011	96	94 (98%)	165.0	1500
Corn Products	2009-2010	50	34 (68%)	230	1440
	2010-2011	76	76 (100%)	147.2	1380
Oat Products	2009-2010	25	7 (28%)	50	130
	2010-2011	17	16 (94%)	41.0	192

As seen in Table 4 above, most of the samples in both the 2009-2010 survey and the current survey contained detectable levels of DON. None of the samples with detectable levels of DON were expected to pose a concern to human health. For all three grain types (wheat, oat, and corn), the percentage of samples with detectable levels of DON is significantly higher in the current survey than in the previous survey. These differences in positive rates are partially attributed to a ten-fold reduction in the reporting limit (10 ppb in 2009-2010 and 1 ppb in 2010-2011). The average DON levels in wheat and corn products observed in the current survey are almost two times lower than those noted in the previous survey, which may be related to the lower reporting limit in the current survey compared to the 2009-2010 survey. The average level of DON in oat products is quite low and similar for both survey years. The maximum level of DON in corn products and in oat products was very similar for both survey years. The maximum level of DON in the current survey is almost four times lower than that observed in the 2009-2010 survey. DON is a toxin that is primarily produced in the field and the samples in this survey were picked up at retail. As such, the history of the product with respect to prevailing climatic conditions at the time of harvest could not be determined.

4. Conclusions

A total of 943 samples were tested for OTA. Of these samples, 67% (628 samples) had no OTA detected. Overall, 99.2% of the 943 samples were negative for or were below the Canadian proposed maximum levels for OTA. Eight of the 943 samples (five infant cereals, one breakfast cereal, one wheat flour, and one wheat germ) had elevated levels of OTA. The OTA levels in these eight samples were evaluated and appropriate follow-up actions were initiated that reflected the magnitude of the human health concern.

A total of 943 samples were tested for DON. Of these samples, 59% (555 samples) had detectable levels. DON was not detected in dried fruit or wine samples. Twenty-three of the 943 samples (fourteen breakfast cereals, three wheat flour, one wheat bran, three cornmeal, and two corn chips) had elevated levels of DON. The DON levels in these 23

samples were evaluated and appropriate follow-up actions were initiated that reflected the magnitude of the human health concern.

5. References

[1] Codex Alimentarius Commission. *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zearalenone, Fumonisins and Tricothecenes*. [online]. Published 2003 (CAC/RCP 51-2003). Accessed February 23, 2012. www.codexalimentarius.net/download/standards/406/CXC_051e.pdf

[2] Birzele, B., Prange, A., Krämer, J. Deoxynivalenol and ochratoxin A in German wheat and changes of level in relation to storage parameters. *Food Additives & Contaminants: Part A*. Volume 17, Issue 12 (2000): 1027 -1035.

[3] Murphy, P.A., Hendrich, S., Landgren, C., Bryant, C. Food Mycotoxins: An Update. *Journal of Food Science*. Volume 71, Issue 5 (2006): R51-R65.

[4] International Agency for Research on Cancer. Ochratoxin A. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. IARC Scientific Publications No. 56. IARC (1991): 489–521.

[5] Kuiper-Goodman, T.; Hilts, C., Billiard, S. M., Kiparissis, Y.; Richard, I. D. K.; Hayward, S. Health risk assessment of ochratoxin A for all age-sex strata in a market economy. *Food Additives & Contaminants: Part A.* Volume 27, Issue 2 (2010): 212-240.

[6] Campbell, H., Choo, T.M., Viger, B., Underhill, L. Comparison of mycotoxin profiles among cereal samples from Eastern Canada. *Canadian Journal of Botany*. Volume 80 (2002): 526-532.

[7] Pestka; J.J., Smolinski, A.T. Deoxynivalenol: Toxicology and potential effects on humans. *Journal of Toxicology and Environmental Health, Part B: Critical Reviews*. Volume 8 (2004): 39 – 69.

[8] Health Canada, Bureau of Chemical Safety. Health Products and Food Branch. *Information Document on Health Canada's Proposed Maximum Limits (Standards) for the Presence of the Mycotoxin Ochratoxin A in Foods.* [online]. Published February 2009. Accessed February 23, 2012. http://www.hc-sc.gc.ca/fn-an/consult/limits-max-seuils/myco_consult_ochra-eng.php

[9] Health Canada, Bureau of Chemical Safety. Health Products and Food Branch. *Canadian Standards (Maximum Levels) for Various Chemical Contaminants in Foods.* [online]. Modified August 2011. Accessed February 23, 2012. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/contaminants-guidelines-directives-eng.php

[10] United States Food and Drug Administration. *Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed*. [online]. Modified July 7, 2010. Accessed February 23, 2012. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/NaturalToxins/ucm120184.htm

[11] European Union. Commission *Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs*. [online]. Published December 2006. Accessed February 23, 2012. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1881:EN:NOT

[12] Joint FAO/WHO Food Standards Programme Codex Committee on Contaminants in Foods, Fifth session. *Working Document for Information and Use in Discussions Related to Contaminants and Toxins in the GSCTFF*. [online]. Published March 2011. Accessed February 23, 2012. http://www.cclac.org/documentos/CCCF/2011/3%20Documentos/Documentos%20Ingles/cf05_INF.pdf

[13] Canadian Food Inspection Agency. *Ochratoxin A and Deoxynivalenol in Selected Foods*. [online]. Published 2011. Consulted January 23, 2012. http://www.inspection.gc.ca/english/fssa/microchem/resid/2009-2010/otadone.shtml

[14] Canadian Food Inspection Agency and Health Canada. *Risk Ranking Forms in support of the Food Science Committee Report.* Hardcopy. 2008.

[15]Skaug, Marit Aralt. Analysis of Norwegian milk and infant formulas for ochratoxin A. *Food Additives & Contaminants: Part A*. Volume 16, Issue 2 (1999): 75-78.

[16] Shundo, L., de Almeida, A.P., Alaburda, J., Ruvieri, V., Navas, S.A., Lamardo, L.C.A., Sabino, M. Ochratoxin A in wines and grape juices commercialized in the city of São Paulo, Brazil. *Brazilian Journal of Microbiology*. Volume 37 (2006): 533-537.

[17] Ng, W., Mankotia, M., Pantazopoulos, P., Neil, R.J., Scott, P.M. Ochratoxin A in wine and grape juice sold in Canada**.** *Food Additives & Contaminants*. Volume 21 (2004): 971-981.

[18] Scott, P.M., Kanhere, S.R. Determination of Ochratoxin A in beer. *Food Additives & Contaminants*. Volume 12 (1995): 31-34.

[19] Lombaert, G.A., Pellaers, P., Neumann, G., Huzel, V., Trelka, R., Kotello, S., Scott, P.M. Ochratoxin A in dried vine fruits on the Canadian retail market. *Food Additives and Contaminants*. Volume 21 (2004): 578-585.

[20] Lombaert, G.A., Pellaers, P., Roscoe, V., Mankotia, M, Neil, R, Scott, P.M. Mycotoxins in infant cereal foods from the Canadian retail market. *Food Additives and Contaminants*. Volume 20 (2003): 494-504.

[21]Roscoe, V., Lombaert, G.A., Huzel, V., Neumann, G., Melietio, J. , Kitchen, D., Kotello, S., Krakalovicha, T., Trelka, R. & Scott, P. M. Mycotoxins in breakfast cereals from the Canadian retail market: A 3-year survey. *Food Additives & Contaminants: Part A: Chemistry, Analysis, Control, Exposure & Risk Assessment.* Volume 25 (2008): 347-355.

[22] Papadopoulou-Bouraoui, A., Vrabcheva, T., Valzacchi, S., Stroka, J., Anklam, E. Screening survey of deoxynivalenol in beer from the European market by an enzyme-linked immunosorbent assay. *Food Additives and Contaminants*. Volume 21 (2004): 607-617.